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/Retrieval and analysis of orthopaedic I
QC100 .U57 NO. 472, 1977 C.1 NBS-PUB-R 1

NBS SPECIAL PUBLICATION 472

NBS
Publi-
cations

U.S. DEPARTMENT OF COMMERCE / National Bureau of Standards

Retrieval and Analysis of Orthopaedic Implants

QC
100
.U57
No. 472
1977

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APR 27 1977

Retrieval and Analysis of Orthopaedic Implants

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QC
100
.457
no. 472
1977

special publication no. 472

**Proceedings of a Symposium
held at the National Bureau of Standards
Gaithersburg, Maryland, March 5, 1976**

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**Sponsored by
National Bureau of Standards
Food and Drug Administration
American Society for Testing and Materials
American Academy of Orthopaedic Surgeons
Orthopaedic Surgical Manufacturers Association
Society for Biomaterials**



**U.S. DEPARTMENT OF COMMERCE, Juanita M. Kreps, Secretary
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Issued April 1977

Library of Congress Cataloging in Publication Data

Main entry under title:

Retrieval and analysis of orthopaedic implants.

(NBS special publication ; 472)

Supt. of Docs. no.: C 13.10:472

1. Orthopaedic implants--Congresses. 2. Orthopaedic implants--Complications and sequelae--Congresses. 3. Metals in surgery--Congresses. I. Weinstein, Allan. II. Horowitz, Emanuel. III. Ruff, Arthur W. IV. United States. National Bureau of Standards. V. Series: United States. National Bureau of Standards special publication ; 472. QC100.U57 no. 472 [RD755.5] 602'1s [617'.0028] 77-608031

National Bureau of Standards Special Publication 472

Nat. Bur. Stand. (U.S.), Spec. Publ. 472 130 pages (Apr. 1977)

CODEN: XNBSAV

**U.S. GOVERNMENT PRINTING OFFICE
WASHINGTON: 1977**

For sale by the Superintendent of Documents, U.S. Government Printing Office
Washington, D.C. 20402 - Price \$2

Stock No. 003-003-01767-1

FOREWORD

The Symposium on Retrieval and Analysis of Orthopaedic Implants was held March 5, 1976, at the National Bureau of Standards in Gaithersburg, Maryland. The symposium was sponsored by the National Bureau of Standards, Food and Drug Administration, American Society for Testing and Materials, American Academy of Orthopaedic Surgeons, Orthopaedic Surgical Manufacturers Association, and Society for Biomaterials. Allan Weinstein, Tulane University, served as Symposium Chairperson, assisted by Emanuel Horowitz and A. W. Ruff as Cochairpersons.

J. D. Hoffman
Director
Institute for Materials Research

Preface

This publication is the formal report of the proceedings of the symposium on the Retrieval and Analysis of Orthopaedic Implants, sponsored by the U.S. National Bureau of Standards (NBS), the Food and Drug Administration (FDA), the American Society for Testing and Materials (ASTM), the American Academy of Orthopaedic Surgeons, the Orthopaedic Surgical Manufacturers Association, and the Society for Biomaterials. The meeting, held at the National Bureau of Standards, March 5, 1976, was designed to bring together manufacturers, orthopedic surgeons, engineers, and others interested in enhancing the performance of orthopedic implants. The purpose was to exchange ideas and results reflecting the current status of the performance of orthopedic implants and to recommend further action. The format of the meeting consisted of lectures providing the state-of-the-art information base about implant characteristics related to performance and a panel discussion, "Implant Retrieval: Problems and Opportunities." Those attending the discussion offered opinions and recommendations regarding the problems associated with, and the information generated from, implant retrieval analyses. Both the lectures and the discussion are included in this report. Approximately 30 recognized experts working in small task groups and addressing problems in their particular areas of expertise attended a workshop, "What Is the National Need?" The conclusions reached are included in these proceedings as individual reports.

The symposium was organized by a steering committee consisting of Allan Weinstein, Tulane University, Chairman; William Allen, University of Missouri; Jonathan Black, University of Pennsylvania; Ricardo Heros, Richards Manufacturing Company; Emanuel Horowitz, National Bureau of Standards; Emmett Lunceford, Moore Clinic; and A. W. Ruff, National Bureau of Standards. We gratefully acknowledge the assistance of the staff of the National Bureau of Standards for its capable handling of the symposium facilities and related activities.

Allan Weinstein, Chairperson
Emanuel Horowitz and A. W. Ruff, Cochairpersons

Abstract

This book is the formal report of a symposium on Retrieval and Analysis of Orthopaedic Implants. This volume contains the invited lectures that provide a state-of-the-art information base about implant characteristics related to performance; the discussions of a panel addressed to the problems associated with, and the information generated from, implant retrieval analyses; and the reports resulting from a workshop on "What Is The National Need?"

Key words: Analysis; implants; metallic; orthopaedic; retrieval.

WELCOME

Welcome to the National Bureau of Standards (NBS) and to the symposium on Retrieval and Analysis of Orthopaedic Implants. We at NBS are pleased to cosponsor this symposium with the Food and Drug Administration, the American Society for Testing and Materials, the American Academy of Orthopaedic Surgeons, the Orthopaedic Surgical Manufacturers Association, and the Society for Biomaterials. The list of organizations is long and impressive, to be sure. I believe, however, that this multiple sponsorship attests to both the importance of the subject and the fact that a wide variety of competences and interests must be brought together if we are to reach our common goal of improving the performance of orthopedic implants.

I personally am pleased to appear before you to launch this symposium aimed at achieving this goal. I have felt for many years that NBS could make unique contributions by helping to provide standards, test methods, and data that would enable manufacturers, surgeons, and agencies of Government to operate from common bases. My deputy, Dr. Emanuel Horowitz, and I have sought to build a program to meet the needs of the user community. Dr. Horowitz has been directly involved in many aspects of orthopedic implant development and has worked toward accelerating the development of much needed standards. Our conviction that NBS could make a unique contribution in this area is based upon a number of factors: our long tradition for work in failure analysis; our long association with the American Dental Association; and our multidisciplinary laboratory built around competences in chemistry and physics and focused on the properties of metals, ceramics, and polymers.

Though we believe that our competence base could be effectively utilized in improving the performance of implant materials, we are very mindful of the fact that standards and measurements are only a *part* of the problem. For this reason we have sought from the very first to operate through such groups and agencies as those represented here today.

During this past year we appointed Dr. James Cassel, Head of the NBS Dental and Medical Materials Section, to take on the additional responsibility of heading our synthetic implants program. We reprogrammed about \$200,000 to him to expand the implants effort. Jim has done a fine job in developing the program, but we are far below a critical mass in this area. We would be pleased to receive comments from you on how we may make most effective use of our resources to develop standards and test methods needed to assure the reliability and durability of surgical implants. The durability issue, of course, is of growing importance since patients live longer and since these devices are used increasingly on younger patients.

This symposium addresses a most important aspect of the whole problem of surgical implant development--the analysis of retrieved devices. We are keenly aware of the sensitivity of this issue. We also are aware, however, that the evaluation of retrieved devices provides information not available by any other method. The program put together by the steering committee covering failure modes, corrosion, tissue response, biomechanical consideration, femoral stem performance, retrieval analysis, and the legal aspects of device retrieval is well thought out and, in my view, represents a milestone toward the goal of the development of improved materials and devices. I wish to compliment the steering committee and its chairperson, Dr. Allan Weinstein of Tulane University, for organizing this symposium and bringing together the distinguished practitioners in this field. Once again, NBS is proud to serve as participant and host for this most important symposium. I am personally interested in keeping abreast of the developments at this symposium.

Have a good meeting.

John D. Hoffman
Director
Institute for Materials Research
National Bureau of Standards

March 5, 1976

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OPENING REMARKS

Patrick G. Laing, M.D.

Clinical Professor of Orthopedic Surgery
University of Pittsburgh Medical School
Pittsburgh, Pennsylvania

The subject of this symposium is very near and dear to my heart since I have been an orthopedic surgeon working the area of analysis of retrieved implants and the adjacent tissues since 1946. In the past, surgical implants were only retrieved when for some reason they had failed or because the patient died and the implant could be obtained on postmortem examination. However, very little was done in the way of meaningful examination of the removed implants or the tissue adjacent and distant from the implants. While working as a registrar or orthopedic surgeon in training in England in 1946, I read some outstanding work by Professor Bowden from the Laboratory of Physics and Chemistry of Surfaces of Cambridge, England; and I started to look into this matter. Under the guidance of Professor Bowden and also of Professor Evans of corrosion fame, I began my study of corrosion and of the biocompatibility of retrieved implants and tissue.

During the course of the last 30 years, various problems have arisen, not the least of which is the legal problem associated with patients' rights and the fact that they do own the implant. I hope that this meeting will be able to deal with this legal aspect of implant retrieval and the ways to protect both the surgeon's and the patient's rights.

We can learn much from the retrieved implants, including information concerning problems associated with the behavior of the material and the mechanical behavior associated with design problems. The American Academy of Orthopaedic Surgeons is vitally interested in developing an association with the National Bureau of Standards to develop an ongoing program in this field.

Since 1956, we have been collecting all the implants that the orthopedic surgeons in western Pennsylvania could obtain and have been examining the tissue adjacent to the implants at the Orthopedic Laboratory of the University of Pittsburgh Medical School. We have accumulated implants and tissues over the course of these years from well over a thousand patients, and the tissue reactions studied will be presented later in the symposium.

One of the main problems has been obtaining people with requisite expertise to examine the materials aspect of the implants. The biological aspects are much less difficult. Both light and electron microscopic studies could be made, and other more sophisticated studies of the living tissues could be carried out.

There are many examples of the premature use of a material for implants before its biological inertness had been proven. At the end of World War II the Judet brothers, orthopedic surgeons in Paris, began inserting the beautifully transparent, diamond-like femoral head prosthesis. Several thousand of these were inserted in patients in Europe. However, many of these fractured and were biologically far from inert. Compounding this lack of inertness was the tissue reaction to wear products and fragments of methylmethacrylate.

This symposium will have to address itself to the total question of compatibility of the implant, not only its mechanical properties and behavior, but also its biological behavior and response of the body implant to the products of its wear and the products of implant degradation, corrosion, or depolymerization.

It is not enough that we just examine the physical properties and the behavior of an implant; we must also realize it is being placed in a human being and this human being is a complicated chemical factory in which we have yet to assess the effects of released metal ions or enzymes or breakdown products on the enzyme systems. I look forward to listening to a very interesting symposium.

OVERVIEW: PERFORMANCE FEEDBACK VIA
DEVICE RETRIEVAL AND ANALYSIS

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Tulane University
New Orleans, Louisiana

The benefits to be derived by performance evaluation of retrieved implants have been succinctly stated by Dr. Victor Frankel [1]¹, "The more reliable implant appliances can be made, the greater security and safety the patient will experience." However, the present status of orthopedic implant standards is as indicated in the following quote from Dr. Frankel, "As far as the devices themselves are concerned, we have been writing standards for design, dimensions, and tests, but have avoided developing performance standards for the devices implanted in the body, since there is such great variability in the way the device is inserted, the type of fracture that may have occurred, and most importantly, the patient's activities after surgery." If we are, in fact, to improve upon device reliability, we must try to overcome the variability of product end use and write performance standards.

As an example of the process of evolving a set of rules for specific devices, it is interesting to look at the development of the "Boiler Code" [2]. With the advent of steam power at the beginning of the industrial revolution in the early 1800's, the fabrication of pressurized steam boilers was pushed to an even more demanding performance, requiring, for instance, higher temperatures, higher pressures, and longer service life. As a result, boiler failures began to occur with increasing frequency and disastrous consequences. In reaction to this problem, the Congress awarded the first research development contract to the Franklin Institute in Philadelphia to study the problem, look for causes or predisposing factors, and recommend remedies. Subsequently, this study and others that followed it, combined with a growing body of practical field experience, were synthesized into a list of "do's" and "don'ts" which, in its updated version today, we call the "Boiler Code." Because of adherence to the "Boiler Code," pressure vessel failures are now a rarity.

The parallel--for example, in total hip arthroplasty--is readily apparent. Now that prosthetic hip joints are being implanted in younger, more active patients, mechanical failure of the femoral stem components is beginning to manifest itself as a problem. The lesson to be learned from the above anecdote is that the "Boiler Code" is essentially empirical. It is basically a set of rules developed from practical field experience that summarized what worked and what did not work. As far as possible, the code is supported by a fundamental understanding of the phenomena involved and by scientific investigation of the basic physical processes. These considerations were not the origins of the code, however. For the most part, basic research followed the establishment of accepted operating procedures. It was a case of "This works, so let's try to understand how and why."

Since the history of conventional engineering specifications has been evolutionary, most likely it is unrealistic to expect that a full understanding of the basic phenomena is going to become available to guide us in the development of specifications of surgical implants where phenomena are certainly no less formidable than in more conventional engineering applications. If we must wait for such a complete understanding before we start to formally standardize surgical implants, the present confusion is going to persist for a long time and many patients will receive something less than the very best health care of which we are capable.

¹Figures in brackets indicate the literature references at the end of this paper.

In summary, the historical precedent indicates that specifications for surgical implants at the present time should and can be developed based on practical experience, without waiting for a full scientific delineation of the basic underlying phenomena involved. The development of specifications is, in fact, currently in progress within ASTM F4; however, very little attention is being paid to performance; i.e., what works and what doesn't.

The literature is replete with investigations dealing mainly with the problems of what does not work. It is essential, however, to examine the other side of the coin as well; namely, what does work, and how do the two differ. Definitive results can only be demonstrated through a comprehensive program of implant device retrieval and analysis.

The essential components of such a program are as outlined below:

- I. Implantation
 - A. Case history
 - B. Roetgenogram review
 - C. Culture implantation area
 - D. Record of implant
- II. Recovery of implant
 - A. Case history review
 - B. Roetgenogram review
 - C. Tissue sample adjacent to implant
 - D. Culture adjacent to implant
 - E. Photographic record of implant
- III. Examination of implant
 - A. Macroscopic
 - B. Microscopic
 - C. Properties
 - D. Chemistry
- IV. Examination of tissue
 - A. Histology
 - B. Identification of culturable organisms, if any
 - D. Quantitative determination of foreign bodies, if present
- V. Correlation
 - A. Reason for removal
 - B. Implant performance
 1. Clinical
 2. Engineering
 - C. Operative procedure
 1. Implant choice
 2. Technique
 - D. Diagnosis
 - E. Histology
 - F. Radiographic changes

Presently we are working within ASTM F4 to develop a standard recommended practice for the retrieval and analysis of orthopedic implants. Such a practice will include a protocol to be followed and suggested tests to be performed. Sample forms are being developed for standardized data accumulation (see Exhibits I and II following this paper). These forms are currently in use in a device retrieval and analysis program being conducted in our laboratories.

It should be pointed out that the information would be best obtained in a prospective implant performance evaluation; however, it is essential that all implants be evaluated if, indeed, we are to develop performance standards.

I would like to illustrate the importance of analyzing implants which have been removed for cause with those that have been removed routinely with several examples.

The first example concerns what may be termed as the crevice corrosion paradox. In a study [3] of 135 (assorted) removed orthopedic devices, it was observed that in all but one instance crevice corrosion was found to occur in stainless steel screw-plate type internal fixation devices. When each case having crevice corrosion was reviewed, the results were typified as illustrated by the following case history:

A 45-year-old man had a hip arthrodesis and subsequent osteotomy with internal fixation with a Blount spline when he was 22 years old. The arthrodesis was painless until 6 months prior to admission when he began to note a dull ache in the operative site. At surgery "green pea" purulent-like material, which was culture negative, was obtained. Metallic debris was found in the tissues adjacent to several of the screw hole sites.

Certainly the implication, which becomes even more probable when one considers that the condition was relieved after implant removal, is apparent: The crevice corrosion is responsible for the problem with the implant. However, if one examines the clinical findings for all removed implants and compares these with those exhibiting crevice corrosion (table 1), the clinical significance of the crevice corrosion is doubtful. The higher percentage of cases exhibiting bursal fluid was more likely due to the mechanical prominence of the internal fixation devices. At least three questions then are unanswered.

- 1) Is crevice corrosion clinically significant?
- 2) Is the implant a failure?
- 3) Would the problem have been avoided if the implant were removed routinely after serving its function?

Table 1. Comparison of clinical findings of all removed implants with those exhibiting crevice corrosion.

<u>Clinical finding</u>	<u>Overall(%)</u>	<u>Crevice corrosion(%)</u>
Pain and/or stiffness	79	80
Infection	30	25
Foreign body	21	35
Granulation tissue	32	30
Scar tissue	46	40
Pus	19	25
Bursal fluid	36	50

The second example is a patient who had a Moore straight stem I-beam prosthesis inserted in June 1965. At that time she was 53 years of age, 5 feet, 11 inches in height, and weighed 160 pounds. After 2 years she was ambulatory without crutch support. She continued to function effectively until June 1974, when she twisted her hip and felt something snap. X-rays (fig. 1) revealed a fracture of the stem of the prosthesis. This case naturally attracts attention, and a failure analysis is performed; however, unless a comparison is made with devices that have not failed, the information obtained is incomplete with regard to potentially improving the implant.

The final illustration involves two 180° spline plates, both stainless steel and both produced by the same manufacturer. One implant exhibited a fatigue failure; the other performed successfully. The microstructure of both implants is shown in figure 2. These microstructures will result in devices having markedly different mechanical properties. The surgeon must be supplied with a product that he can rely upon with regard to either a minimum set of mechanical properties or consistency in mechanical properties from batch to batch. It should be pointed out, however, that differences in the clinical histories may have been contributory to the observance of a fatigue fracture in one plate and not in the other.

These illustrations serve to demonstrate the need for comparing routinely removed devices with devices removed for cause in order to establish a feedback loop. The benefits to be derived from implant device retrieval and analysis are numerous [4]; the most notable benefit is that a more reliable implant will result.



Figure 1. Roentgenogram showing fractured Moore type hemiarthroplasty prosthesis. This implant has functioned satisfactorily for 9 years.



Figure 2. Microstructure of two identical 180° stainless steel spline plates. Note the highly cold worked structure of one plate (a) in contrast to the annealed and cold finished structure of the other (b). The plate whose microstructure is shown in (b) failed via a fatigue mode.

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- [2] Cooke, F. W., Personal communications.
- [3] Weinstein, A., Amstutz, H., Paron, G., and Franceschini, V., Orthopedic implants - a clinical and metallurgical analysis, *J. Biomed. Mater. Res. Symp.* 4, 297 (1973).
- [4] Black, J., Development of standards for surgical implants, *ASTM Standardization News* 3, (June 1975).

Exhibit I

Recovery of Implant
Case History Review Case

1. Date Inserted _____
2. Date Removed _____
3. Implant Type _____
4. Patient Sex _____
5. Patient Date of Birth _____
6. Patient Weight _____
7. Implant Location _____
8. Patient Activity or Occupation _____
9. History of foreign body sensitivity _____
- 10a. Diagnosis at Insertion _____
- 10b. Trauma--simple or comminuted; open or closed _____
- 10c. Contributory conditions (eg., alcoholism, senility) _____
11. Operation at Insertion _____
12. Antibiotics at insertion, if YES, answer the following:
 - a) Reasons for antibiotics
 - i) _____
 - ii) _____
 - iii) _____
 - b) Type _____
 - c) Dosage _____
 - d) Duration _____
13. Functional level of the patient attained between insertion and removal
ambulatory, ambulatory with aids, non ambulatory
Comment on relevant physical activity or event for this treatment _____
14. Roetgenogram review (Indicate YES, NO, DOUBT, or NOT APPLICABLE)
 - _____ a) bony change in relation to implant
 - _____ b) absorption or rarefaction
 - _____ c) increased density (sclerosis - compaction)
 - _____ d) non-union
 - _____ e) bone fragments held apart
 - _____ f) migration of implant
 - _____ g) malalignment
 - _____ h) fracture of bone
 - _____ i) penetration of implant across joint space
 - _____ j) penetration of implant through bone
 - _____ k) other
 - _____ l) other
15. Reason(s) for removal (Indicate YES or NO - mark primary reason with an asterisk)

_____ a) Routine	_____ b) early infection (< 6 months)
_____ c) Late infection (> 6 months)	_____ d) breakage or deformation of implant
_____ e) pain in the vicinity of implant	_____ f) stiffness of joint in vicinity of implant
_____ g) prominence of bursae	_____ h) instability
_____ i) unsatisfactory position of implant	_____ j) non-union
_____ k) allergic or hyper-sensitive reaction	_____ l) reasons not known
_____ m) other (specify)	

16. Findings at surgery (Indicate YES, NO, DOUBT, or NOT APPLICABLE)
- | | |
|-----------------------------------|--|
| _____ a) pus | _____ b) scar tissue |
| _____ c) granulation tissue | _____ d) foreign body (debris or stained tissue) |
| _____ e) bursal fluid | _____ f) implant easily removed |
| _____ g) fractured grouting agent | _____ h) caseation |
| _____ i) boney reaction | |
17. Swab from implant site (YES or NO)
- _____ a) sterile, if NO, indicate type
18. Examination of tissue

Exhibit II

Recovery of Implant
Metallurgical Examination Case #

(This report for component # _____ of _____ total components)

- 1. Implant _____ Type _____
- 2. Number of components _____
- 3. Macroscopic examination (YES, NO, DOUBT, or NOT APPLICABLE)

	Location	Estimate Degree
_____ a) wear or burnishing	_____	_____
_____ b) galling	_____	_____
_____ c) scratching	_____	_____
_____ d) change of shape	_____	_____
_____ e) mechanical damage	_____	_____
_____ f) macro porosity	_____	_____

- 4. Microscopic examination (Indicate location and orientation of sample)
 - a) Inclusion content (ASTM E45)
 - b) Grain size (ASTM E112)
 - c) Grain boundary constituents
 - d) Microporosity
 - e) Other distinguishing features (ex. cast stainless steel-delta ferrite)
 - i _____
 - ii _____
 - iii _____

- 5. Type of material (indicate method of determination)

- a) chemical composition
- 6. Corrosion (if YES, identify)
 - a) general corrosion
 - b) pitting corrosion
 - c) crevice corrosion
 - d) galvanic corrosion

- 7. Mechanical failure (if YES, identify mode)

- a) fatigue
- b) torsion
- c) impact
- d) stress-corrosion
- e) static-overstress beyond yield strength
- f) corrosion-fatigue
- g) combination of above (identify)
- h) other (specify)

- 8. Device flaws (if YES, identify type and origin)

- i _____
- ii _____
- iii _____

- 9. Mechanical properties (indicate N/A if not available).

Samples should be taken from areas representative of the original material.

- a) sample size and orientation _____
- b) hardness (indicate type) _____
- c) .2% offset yield stress _____
- d) ultimate tensile strength _____
- e) % elongation in _____ in. _____
- f) reduction in area _____
- g) other ASTM recommended tests as applicable (ex. transverse bend tests). _____

- 10. Dimensions of implant _____

- 11. Conclusion _____



A REVIEW OF METALLURGICAL FAILURE MODES IN ORTHOPEDIC IMPLANTS

David F. Williams, Ph.D.

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School of Dental Surgery
University of Liverpool
Liverpool, England

1. Introduction

The concept of failure in orthopedic implants has been discussed on many occasions, but it is necessary to review it briefly here in order to identify the significance of metallurgical failures in implants. Implant failure must be viewed clinically; and from this perspective, numerous causes can be observed. Failure of the implantation procedure could be due to surgical error; infection; or the original pathological condition, its recurrence or possibly an unrelated pathological condition. In addition, failure could be mechanical due to wear, mechanical failure of associated hard tissue, or an interaction between the implant and the tissues leading to adverse local or systemic effects, including acute and chronic inflammation, foreign body granuloma, necrosis, and hypersensitivity effects. The manifestation of such failure modes may be malfunction of the implant, its loosening, pain, or a combination of these.

In all but a few of these modes, either the chemistry, structural metallurgy, or engineering design of the implant can be cited as a sole, major, or contributing factor in failure. In cases of mechanical failure of the implant and corrosion-induced, foreign-body response of the tissue, this fact will be obvious, even if the exact failure mechanism is not. In other cases, the effect is not so obvious. Material and design may conceivably influence infection rates; loosening of prostheses has been shown to be associated with hypersensitivity related to the metal in some cases; mechanical failure of the associated bone may be related to the biomechanical difference between prosthesis and tissue.

A metallurgical failure may therefore be defined as a failure of the implantation procedure to produce optimal satisfactory results where this failure is, in whole or in part, due to some characteristic of the metal used. It should be appreciated that while this paper is concerned with metallurgical failures, an equivalent situation arises in the case of polymeric materials used in orthopedics.

2. Potential Failure Modes

As indicated in table 1, the three types of failure mode are purely mechanical, purely environmental, and joint mechanical-environmental. Some features in this list are of interest. First, a few of these phenomena might not normally be considered as failures. The diffusion of metal through an intact oxide film without breakdown, with possible simultaneous dissolution of the oxide film, might take place at such slow rates in highly corrosion resistant passivable materials that the effects would not normally be noticed. However, the release of minute quantities of material into the body could conceivably have clinical significance. Second, it is often difficult for these modes to be identified unequivocally as the single operative mode. This point is reflected by the inclusion of joint modes, but in many cases one failure mode can lead to another without involving a

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Table 1. Potential metallurgical failure modes.

<u>Mechanical</u>	<u>Environmental</u>
Direct overloading	Galvanic corrosion
Impact	Localized corrosion
Fatigue	Pitting corrosion
Adhesive wear	Crevice corrosion
Abrasive wear	Diffusion through
Fatigue wear	passive oxide layer
 <u>Conjoint effects</u> 	
	Stress corrosion cracking
	Corrosion fatigue
	Corrosive wear
	Fretting corrosion

conjoint mechanism. For example, fracture of an implant may take place subsequent to localized or pitting corrosion without actually being an example of stress corrosion, cracking, or corrosion fatigue. Moreover, it may be difficult in such cases to be sure that corrosion was, in fact, instrumental in producing the fracture; and similarly it might be very difficult deciding whether an obvious fatigue failure should really be classed as corrosion fatigue. Metallurgical failure analysis techniques are not always so refined as to make these subtle distinctions, which, nevertheless, may be of considerable importance.

3. Mechanical Failures

From those phenomena listed in table 1, direct overload, including impact, and wear will be discussed in this section. Fatigue will be discussed later in connection with corrosion fatigue.

3.1 Direct overload and impact

Failure here may involve either the occurrence of significant plastic deformation or fracture. It may occur on insertion of the implant, during use, or possibly at removal. At insertion or removal, probably the most important phenomenon is the torsional fracture of bone screws. Although the function of a bone screw is to develop a tensile stress between its head and the plate so that the bone and plate are clamped together, much of the applied torque is used to cut threads and overcome thread friction and friction at the countersink interface. Hughes and Jordan [1]² have estimated that as low as 5 percent of the applied torque is used to apply the tension. Thus the torsional stresses may be high; commercially pure titanium bone screws were subject to this failure mechanism before the introduction of the Ti-6Al-4V alloy.

Although the loads transmitted through the musculoskeletal system are high, direct overloading should not be a problem with surgical implants. The nominal stresses themselves within a suitably designed implant should not be too high, and all the metallic materials available are capable of withstanding these stresses under normal conditions in most devices. Certainly deformation and fracture occur. However, in the majority of these cases we may deduce that either the stress has been raised in the vicinity of the affected area, usually through design features or surgical error, or the material fails at stresses lower than the yield point, that is, in fatigue. Designs that are conducive to mechanical failure have been described by Williams and Roaf [2] and Cahoon and Paxton [3]. The principal fault is the provision of inherent stress concentrators at points of highest bending moment.

²Figures in brackets indicate the literature references at the end of this paper.

A sudden load applied to an implant *in vivo*--for example, when a patient falls--may produce deformation or fracture. This failure might either be construed as a direct overload, since the stress may be higher than that normally applied, or as an impact failure since the strain rate may be very high. Hughes and Jordan [4] have described failure under impact conditions in the stem of a titanium femoral head prosthesis, where it is interesting to note that the crack nucleation site was the spark-etched marking on the stem.

Although differences exist in the mechanical properties of the various metallic materials used in orthopedics, there is no evidence that any of them is significantly prone to mechanical failure of these types.

3.2 Wear

Failures of total joint replacement procedures are largely due to technical error, infection, implant loosening, or, to a lesser extent, fracture of the prosthesis. A further possible cause of failure, which has yet to become manifest clinically to any significant extent, is wear of the prosthetic components, resulting in either the destruction of the component or a clinically significant response by the adjacent tissue. Although plastic components in prostheses can and do wear out, it is highly improbable that this could occur with metal components. However, it is well known that significant tissue reactions may be provoked by both plastic and metallic wear particles (for example, see Winter [5] and Willert and Semlitsch [6]), so this process must be considered as a potential metallurgical failure mode.

Four types of mechanism may be implicated in the wear of metal components of joint prostheses. These types are the abrasive, adhesive, fatigue, and corrosive modes. It would be expected that adhesive wear would be the most prominent in the metal-to-metal combinations [7]. However, some abrasive wear may take place, and Walker [8] has described this mechanism in the all cobalt-chromium alloy McKee-Farrar hip joint prosthesis, probably taking place during the "running-in" phase. The socket of these prostheses also showed evidence of considerable adhesive wear while fatigue wear was noted on one component [9]. Whether corrosive wear takes place is a matter of speculation. Galante and Rostoker [10] quite plausibly suggest that the greater wear rate of stainless steel against ultrahigh molecular weight (UHMW) polyethylene compared to cobalt-chromium alloy against UHMW polyethylene may be related to this corrosion-wear mechanism.

The most important question in this context concerns the choice of material combinations to give the lowest wear rates coupled with the greatest host tolerance to the wear particles. In considering the current clinical option of metal-to-plastic or metal-to-metal, there is, as yet, no definite evidence to favor one or the other. Generally the metal-to-plastic system will exhibit a lower coefficient of friction but a higher volumetric wear rate. However, there is evidence that cobalt-chromium particles may be more harmful than those of polyethylene [5,6]. As already noted, the volumetric wear of stainless steel-polyethylene combinations is greater than cobalt-chromium-polyethylene systems. To date, few metal-to-plastic systems use titanium or titanium alloys for a bearing surface, and Galante and Rostoker have demonstrated high wear rates in such an experimental system [10]. However, Dumbleton and colleagues have shown comparable wear rates of Ti-6Al-4V alloy with polyethylene compared to stainless steel and cobalt-chromium alloy with polyethylene [11]. The only combination used extensively in the metal-to-metal systems is cobalt-chromium to cobalt-chromium. Neither stainless steel against itself nor titanium against itself should provide a low-wear rate, low-friction system because of their tendency to gall and seize. Indeed, the relatively successful use of the cast cobalt-chromium alloy has been attributed to the efficient lubrication provided by plasma proteins [10]. It is interesting to note that the composition of the wear particles is different from that of the parent alloy [6], so that compositional variations in the cast structure may be important. In hemiarthroplasty, there is no clear indication of the most suitable material. Titanium is frequently used in these cases, although it is not immune to wear, as illustrated in figure 1.



Figure 1. Wear on the surface of a titanium tibial plateau prosthesis.

4. Corrosion Failures

Reactions between a metal and the physiological environment may lead to clinical failure of the implant if the released reaction products influence the surrounding (or possibly remote) tissue, if they adversely affect the function of the implant, or if the excessive release of this material seriously weakens the implant so that it then fails mechanically.

4.1 Theoretical considerations

As reviewed by Williams [12], the predictions of *in vivo* corrosion resistance of the metallic materials currently used in orthopedics show that titanium and its dilute alloys should not undergo passive film breakdown under physiological conditions, while cobalt-chromium alloys may do so under exceptional conditions and stainless steel may do so under a wide range of conditions. These observations are largely based on the anodic polarization and potential-time experiments of Hoar and Mears [13] whose basic conclusions have been confirmed by many other workers. The principal features of titanium are that its breakdown potential is not only significantly more positive than the maximum isolated potential reached under physiological conditions, but is also more positive than the oxygen reduction reversible potential. With 316 stainless steel, on the other hand, the breakdown potential is lower than the oxygen reduction reversible potential but within the range that the isolated potential can reach.

4.2 Galvanic corrosion

It has long been appreciated that the indiscriminate use of dissimilar metals in the same implanted device is unwise because of the possibility of galvanic corrosion. In recent years it has become apparent, however, that the coupling of dissimilar metals does not necessarily lead to corrosion if certain conditions are satisfied. Mears [14] has discussed this reaction in relation to orthopedic implants and suggests that titanium may be used with a number of less passive metals without fear of increased corrosion. While this factor would almost certainly be true for titanium and cobalt-chromium alloy combinations, as witnessed by the successful clinical use of such systems by Jackson-Burrows, Wilson, and Scales [15], it is unlikely that the coupling of titanium with 316 stainless steel would be successful. Rostoker, Pretzel, and Galante [16] have concluded that stainless steel is not suitable for coupling to any metal in the body, and Gruen and Amstutz [17] have reported the failure of a stainless steel-cobalt-chromium alloy total hip replacement prosthesis where

galvanic corrosion may have had a deleterious effect on the wear resistance. Williams and Roaf [2] have found significant corrosion whenever stainless steel has been inadvertently coupled to titanium.

It is not necessary to have significantly different materials coupled together to give galvanic corrosion. Cohen and Wulff [18] have noted corrosion at the interface between cast and wrought cobalt-chromium alloy, although it is difficult to distinguish between galvanic and crevice corrosion in these cases. It is also possible that galvanic corrosion could contribute to the interfacial corrosion in stainless steel implants, especially at the interface between bone screws and fracture plates [2]. In these cases, it may be either slight compositional differences or structural differences (i.e., between an austenitic plate and a partially-martensitic screw) that are responsible for the galvanic couple.

4.3 Crevice corrosion

Crevice corrosion is undoubtedly the mechanism involved in the majority of cases of *in vivo* corrosion [4,19-22]. Although such corrosion predominately occurs at the screw-plate interface, any interface is susceptible [2] (fig. 2). Crevice corrosion is traditionally associated with differential aeration cells where the oxygen within the crevice is depleted over a period of time. However, the galvanic corrosion, already discussed, and fretting

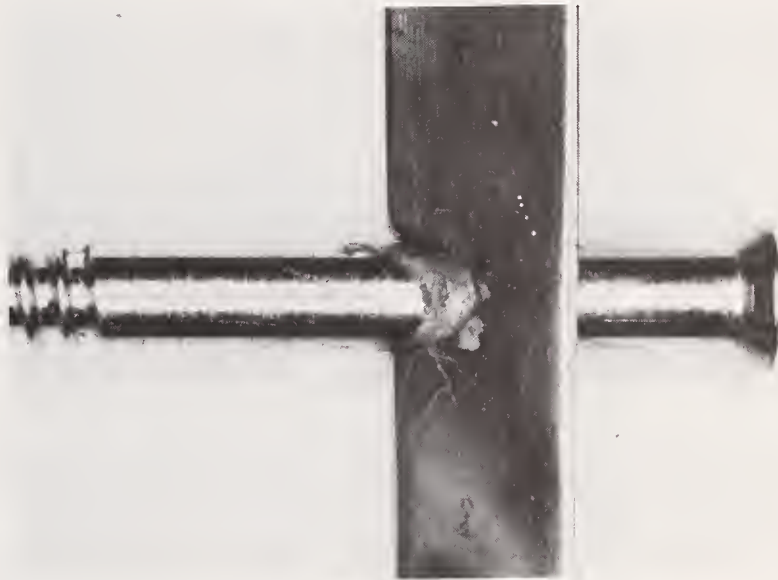


Figure 2. Interfacial corrosion of a stainless steel osteotomy plate.

corrosion, where the passive oxide layer is continuously abraded by relative movement at the interface, may also contribute to the corrosion. Crevice corrosion is possible in cobalt-chromium alloys, especially in the cast material where surface porosity may influence the corrosion behavior.

4.4 Pitting corrosion

The susceptibility of austenitic stainless steel to pitting corrosion is well known. It is equally well established that the resistance to pitting in saline environments can be increased by utilizing a molybdenum alloying addition (as in the use of 316 stainless steel) and keeping the inclusion content to a minimum. Whenever these two principles are violated, corrosion in the physiological environment is highly probable. Williams and Roaf [2], Cahoon and Paxton [22], and Pugh, Jaffee, and Jaffee [23] have all drawn attention to the fate of low molybdenum stainless steel implants in this respect.

4.5 Corrosion due to structural heterogeneities

Although any structural heterogeneity may promote corrosion, intergranular corrosion in stainless steel is by far the most serious type relevant to implantable materials and, indeed, is the cause of the most serious cases of corrosion in these materials. The subject has been discussed at some length by Williams and Roaf [2] and Tennese and Cahoon [24]. The frequently found sensitized condition of stainless steel is a cause for some concern in view of the rapid progress of the corrosion along the chromium-depleted grain boundary zones. The methods of avoidance, especially heat treatment, are well-established metallurgical procedures.

4.6 Diffusion through passive oxide films

The observation of significant levels of titanium in the tissue surrounding titanium implants [25] (fig. 3) is, at first, a little difficult to correlate with the corrosion

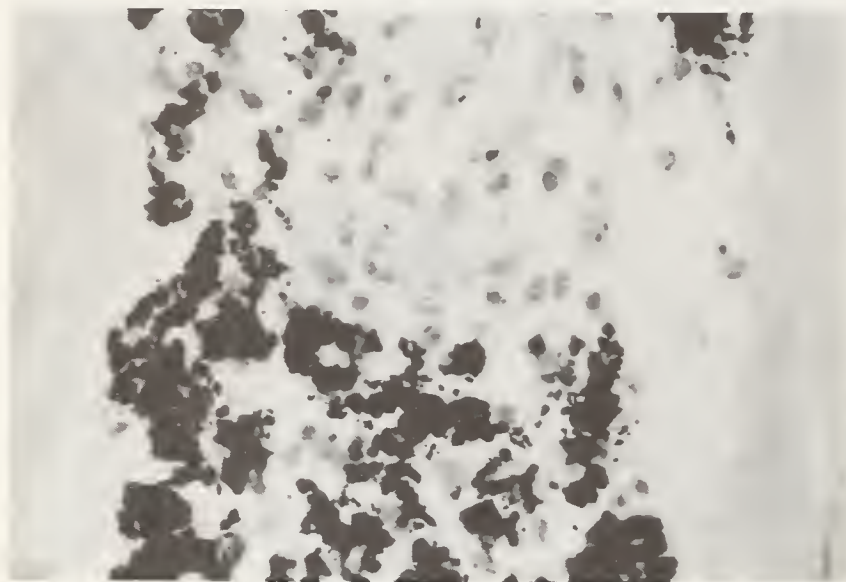


Figure 3. High density of titanium-bearing particulate matter in tissue surrounding a titanium implant. Hematoxylin and eosin.

resistance of the metal. Since this action occurs in the apparent absence of wear (although abrasion of titanium cannot unequivocally be ruled out), it seems likely that this metal transfer occurs by diffusion of the titanium through the oxide layer, as originally suggested by Hoar and Mears [13], or possibly by the very slow dissolution of the oxide layer. Whatever the mechanism, it is important to note that this phenomenon is not confined to titanium and indeed that the discoloration frequently found in the tissue around titanium implants may be misleading as an indicator of the extent of this phenomenon. Experiments have shown that metal will be released from any metallic implant; and it may be a unique combination of circumstances, such as the formation of a dark-colored organic complex that is bound locally, that leads to the clinical observation in titanium but not in the other alloys.

4.7 Conjoint mechanical-environmental effects

Corrosive wear and fretting corrosion have already been discussed. Here the mechanisms of stress corrosion cracking and corrosion fatigue are considered.

4.7.1 Stress corrosion cracking

It is necessary at the outset to define this term. Stress corrosion cracking is the spontaneous cracking that may result from the combined effects of stress and corrosion. As

discussed by Harwood [26], it is very important to differentiate clearly between stress corrosion cracking and stress accelerated corrosion. In this latter case, corrosion will occur in the absence of stress and the principal effect of stress is to rupture the corrosion-weakened material. This phenomenon may, for example, occur as a sequel to the intergranular corrosion of stainless steel implants as illustrated in figure 4. Stress corrosion cracking

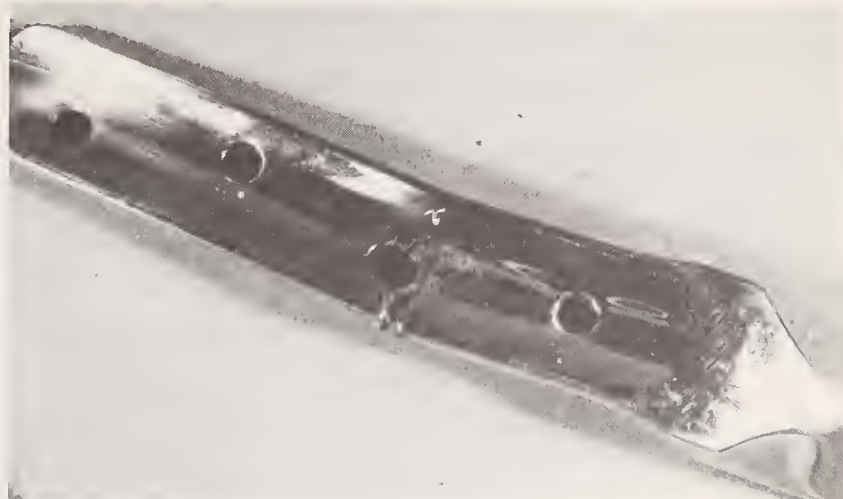


Figure 4. Cracking of stainless steel osteotomy plate subsequent to intergranular corrosion.

is a term limited to cases where no significant corrosion damage occurs in the absence of stress, and in the absence of the corrosive environment, the material exhibits normal mechanical behavior.

The question has often arisen as to whether stress corrosion cracking can take place *in vivo*. In the case of stainless steel, although Gray [27] has reported an example of the classical stress corrosion cracking appearance in a stainless steel screw removed from the body, it is unlikely that this failure mechanism is of any real significance [2,28]. The reason is that the stress corrosion cracking mechanism is not normally operative at the ambient temperature of the body. Hoar and Hines [29] have shown a very significant increase in the time to fracture of 18-8 stainless steel when the temperature is decreased from 154 °C to 125 °C. Kirk and coworkers [30] demonstrated a minimum temperature of about 120 °C for stress corrosion cracking in 316 stainless steel at 10,000 lb/in² in 875 ppm sodium chloride solution. The occasional occurrence of stress corrosion cracking in 316 stainless steel has been reported, Sharfstein and Brindley [3] suggesting that it can occur at 75 °C under very specific conditions. A report of ASTM [32] also contained evidence of some low temperature stress corrosion cracking in 316. However, these occurrences are so rare that we must conclude that it is an unlikely event in surgical implants.

While stress corrosion cracking is a phenomenon that is not usually observed in pure metals and, hence, pure titanium would appear to be immune, some titanium alloys are relatively susceptible; and it is known that this mechanism may be operative at room temperature in saline environments [33-35]. The occurrence of stress corrosion cracking depends on both the composition of the alloy and the microstructure; and it is clear that increasing the aluminum content does increase susceptibility, especially if it exceeds 6 percent. Although the presence of vanadium may decrease this susceptibility, the Ti-6Al-4V alloy is clearly not immune from corrosion in saline at room temperature [36]. Thus, although no reports have appeared as yet of *in vivo* stress corrosion cracking in titanium alloys, this reaction must be a distinct possibility.

4.7.2 Fatigue and corrosion fatigue

As indicated earlier, it is likely that the majority of mechanical failures occurring in orthopedic implants during use are fatigue failures and that it is equally probable that

the saline environment influences this fatigue behavior. Corrosion fatigue involves the acceleration of the fatigue cracking process by the presence of a corrosive environment. It differs from stress corrosion cracking not only by specifically involving repetitive loadings, but also because the corrosive environment assists an already established mechanism; i.e., fatigue will occur without the corrosion, although at a slower rate. It is also important to define the term fatigue which is the failure of a material under the influence of repeated applications of a stress; in strict metallurgical terminology, it is not the time-dependent failure of a material, and the term static fatigue should not be used to describe this process.

The fatigue failures of fracture fixation devices have been discussed on many occasions [2,4,21,22], and the typical fatigue striations are frequently found on the fracture surfaces. Often fatigue crack nucleation sites are at design-induced stress concentrations or structural defects such as inclusions. Also, it is likely that many of these failures occur when there has been no consolidation of the fracture so that the device sustains the repeated loads without any considerable help from the bone.

In the case of joint prostheses, the metal has to transmit load unaided by bone; and so the occurrence of fatigue failures is far more serious. After several years of widespread clinical use of total hip replacement prostheses, few, if any, mechanical failures of the prostheses had been reported. However, the situation has recently changed, with Charnley [37], Galante et al. [38], and Ducheyne et al. [39] all discussing the fatigue fractures of femoral stems. The conditions under which these failures occur are not clear. Although Ducheyne et al. described eight cases where every one involved a prosthesis in a valgus position, Charnley's failures arose more in varus and neutral positions. Failures have been reported in both stainless steel and cobalt-chromium alloy. Obviously, both stress level and time should be important. Charnley has shown a mechanical failure rate, to date, of those prostheses inserted in 1970 of 0.09 percent for all patients while the figure for males over 196 lb is 6 percent. Support by the cement is extremely important in lowering general stress levels, and 7 of Charnley's 17 failures were attributed to imperfect behavior of the cement. Some fractures have occurred within 2 years; others have taken longer.

Both Galante et al. and Ducheyne et al. place considerable emphasis on the qualities of the metals used and implicate casting porosity, varying grain sizes, and carbide precipitates as contributory factors in fatigue crack nucleation. The extent of the influence of the corrosive environment on the fatigue process is not known at this stage. As Galante et al. point out, it is known that saline solutions significantly degrade fatigue strengths, but the relevant data for these materials are not available. While Charnley has speculated that corrosion is not involved in this phenomenon, both Colangelo [40] and Wheeler and James [41] have shown that fatigue crack growth rates are faster in saline solutions than in air for 316 stainless steel so that this mechanism is likely to be important.

5. Conclusion

This review has emphasized the varied nature of the potential metallurgical failure modes in orthopedic implants. It is important to consider these mechanisms both in the context of the established metallurgical theories of failure and in the light of the special criteria of failure that apply in the surgical implant situation. Clearly these potential mechanisms are applicable across the range of available materials so that there is no one outstanding material.

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Discussion of Paper:

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Analysis of retrieved implants must begin with characterization of the material(s) the implant is made of and the role these materials play in the success or failure of the implant. Dr. Williams' fine presentation provided an excellent overview of the major modes by which metallic implant materials contribute to implant failures. The purpose of this discussion is to briefly reiterate and reinforce the main points of his talk.

Mechanical effects will be considered at a later point in this symposium and therefore will not be covered here. The strength of any device is finite, and surfaces rubbing against each other do wear; but these facts are sometimes ignored.

Corrosion of the implant per se is not necessarily harmful unless it leads to adverse tissue reactions or compromises the strength of the implant. Galvanic corrosion is generally due to dissimilar metals being used together, while susceptibility to crevice or pitting corrosion is inherent in the material structure, as is a tendency to corrosion at structural heterogeneities such as grain boundaries. All of these mechanisms may release undesirable ions into the surrounding tissues, and the latter two contribute significantly to reduction of strength. Furthermore, diffusion of ions through passive oxide layers may also lead to clinically observable tissue changes.

The most complex and most interesting modes, however, are the conjoint modes, where materials science and mechanics meet. Stress corrosion cracking is basically a corrosion process promoted by the presence of a stress. Conversely, a material may exhibit enhanced fatigue crack growth in a corrosive environment.

A case follows that illustrates the need for metallurgical expertise in addition to obvious biomechanical considerations to explain in detail what went wrong:

A 63-year-old female was treated for a painful left hip with marked flattening of the femoral head by excision of the femoral head and a subtrochanteric osteotomy with abduction angulation. The osteotomy was fixed with a six-hole bone plate which was bent at one of the central screw holes. Five months later the plate was removed when it fractured across that screw hole.

Discoloration of the surrounding tissues suggests the presence of corrosion products; crevice corrosion at the countersinks was clearly evident. The most striking thing to me, however, was the altered appearance of the metal near the break--it had become dull, contrasting with the polished finish of the rest of the plate. The material structure, strength, and characteristics were altered by cold working leading to a heterogeneity that contributed to both mechanical and corrosive damage. The surface had been roughened, encouraging the formation of fatigue cracks, and the rearrangement of the crystal structure enhanced the crack growth due to galvanic effects. Many events were taking place simultaneously, and it is insufficient to merely say, "Well, that plate shouldn't have been bent." In-depth studies of such failures by material scientists and others, and transmittal of this information to the surgeons in a form intelligible to them, will lead to a greater understanding of important failure mechanisms, a more rational application of implants, and better treatment of orthopedic problems.



MODELS FOR SYSTEMIC EFFECTS OF METALLIC IMPLANTS¹

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Discussions of the possible systemic roles of metallic corrosion products should properly begin with a brief review of the phenomena that are collectively termed corrosion. Corrosion is the chemical reaction that results in reducing the electronegativity of metals. The most common form of reaction is that of a metal with oxygen to form an oxide. In the presence of water, the reaction may lead to the formation of an hydroxide. In water, under other conditions, this reaction may be displaced by another that leads to the formation of negative ions. The oxides and hydroxides may have different solubilities, depending upon the metals and the conditions of reaction. The ions may form complexes with other ions. In any case, the reactions as a group result in lower electronegativity, removal of metal from the object undergoing corrosion, and introduction of new chemical species into the environment.

All metals have a finite corrosion rate *in vivo*. Questions about the rate of formation and accumulation of corrosion products must then center upon the conditions affecting corrosion. In general, corrosion rates depend upon composition of the metal undergoing corrosion, variables in its manufacture and surface treatment, handling during storage and insertion, and finally the anatomical location in which it is implanted. The anatomical location determines the pH, pO_2 , and mechanical stresses encountered by the implant. We are familiar with the gross evidence of corrosion seen in water pipes, on ships' hulls, etc. Corrosion *in vivo*, particularly uniform attack, may be far more subtle and escape cursory notice.

The distribution of corrosion products depends upon many factors in addition to the corrosion rate. The high water content of the body, constituting a large "pool" with which corrosion processes must come to equilibrium, is little appreciated. The body is 70% water, an extracellular volume of 14 liters and an intracellular volume of 28 liters. Intake and excretion of water, which may reach 2.5 liters every 24 hours, result in an implant being placed in contact with an effective pool of 1000 liters a year.

Let us consider what this means in terms of concentrations. The normal quantity of chromium in the body, expressed as a concentration distributed uniformly throughout the body water, is 0.2 ppm or 6.25×10^{-6} M. A corrosion rate of 1 mg a day of chromium from an implant, if distributed evenly over all body water and excretion products, would raise this concentration to 6.85×10^{-5} M. Thus, the release of just over one-third of a gram of chromium from an implant per year has the potential of raising the concentration of chromium throughout the body by more than tenfold.

This calculation neglects the effects of concentration of ions upon excretion rates. In general, as ionic levels rise, so do excretion rates. Taylor [1]², using available *in vitro* corrosion rates and data on excretion rates, has made estimates of equilibrium concentrations that can possibly be expected in patients who receive implants. The calculations are based upon a 70 kg patient body weight and a 200 cm² implant surface area, similar to that of a total hip joint replacement. He suggests that, for cobalt-chromium

¹Support provided by the National Institutes of Health through Veterinary Medical Scientist Training Program GM02051 and Graduate Training in Bone and Cartilage Grant AM05698.

²Figures in brackets indicate the literature references at the end of this paper.

implants, the concentration of cobalt might rise eighteenfold while that of chromium might increase over 200-fold. In the case of stainless steel (SS) of the 316L type, similar increases are predicted for nickel and chromium with a proportionally smaller increase of free or nonheme iron. This latter point is very significant and will be returned to later.

Is there any evidence that increased concentrations of metallic ions result from implantation? A recent investigation by Coleman [2] on patients before and after receiving McKee-Farrar type metal on metal cobalt-chromium total hip replacements has shown significant increases in cobalt concentrations in both blood and urine. These data suggest that the equilibrium discussed by Taylor is being approached. The rate and level of product accumulation in the tissues of these patients is unknown. Recent work in our laboratory, using 316L implants in rabbits, suggests that blood ion level increases also occur with this alloy.

The *in vivo* corrosion resistance of the two most commonly used surgical implant alloys, 316L stainless steel and cobalt-chromium, is at best precarious, as supported by both thermodynamic and electrochemical theory [3-6]. In practice, Ferguson, Laing, and Hodge [7] have presented evidence from a 4-month rabbit study that ionization or solubilization occurs around all currently used implant metals regardless of their supposed corrosion resistance. Implanting various prosthetic metals into the back muscles of rabbits, they clearly demonstrated spectrographically a higher constituent ion concentration in the tissue surrounding the implant than in the control muscle. These findings prompted subsequent research by Akahoshi et al. [8] to explore the fate of metal ions and corrosion complexes released from embedded implants of commonly used alloys. The study revealed several general patterns, the most noteworthy being that cobalt and nickel from cobalt-chromium alloys and iron and nickel from stainless steel were found to accumulate in the spleen and to a lesser extent in the lung, liver, and kidney. Not surprisingly, constituent metal ions were found in increased concentrations in the muscle surrounding their respective implant alloys.

Although the biomaterials and surgical literature frequently contain research articles or clinical surveys [9-16] either analytically or grossly attesting to *in situ* evidence of implant corrosion, very little research exists (other than that already cited) which specifically addresses the question of possible systemic effects secondary to metallic implantation.

1. Systemic Effects of Implant Corrosion

"There probably does not exist a single enzyme-catalyzed reaction in which either substrate, product, enzyme, or some combination within the triad is not influenced in a very direct and highly specific manner by the precise nature of inorganic ions which surround or modify it" [17]. In recent years with advances in biochemical and physiological research, increasing emphasis is being placed on the importance of trace elements and their roles in normal and disease states. Numerous metal ions at physiological levels (extremely minute concentrations, 10^{-6} to 10^{-12} g/g wet wt tissue) are known to play a significant role in normal metabolic processes. Increases beyond physiological limits in these levels often upset the precise biochemical balance with consequent toxicity. The inherent toxicity of the metal involved, the amount absorbed, and the rate at which the body detoxifies or excretes it determine whether toxic levels of metal ions will result. In general, the systemic effects of implant corrosion (either in theory or practice) can be grouped into four main categories: carcinogenic, metabolic, immunologic, and bacteriologic.

1.1 Carcinogenic effects

Hueper [18-20] by parenteral administration in rats, rabbits, and guinea pigs has implicated nickel as a carcinogen producing sarcomas of bone, connective tissue, nerve tissue, and muscle in rats and rabbits and benign and malignant lung tumors in guinea pigs and rats. Heath et al. [21-23] have demonstrated the carcinogenicity of pure metallic cobalt, cadmium, and nickel when suspended in serum and injected into rat skeletal muscle. Malignant metastasizing tumors including fibrosarcomas, rhabdomyosarcomas, and cellular sarcomas developed rapidly (within 3 months) with an incidence of 50% to 75%. Doll [24] has pointed out the carcinogenic hazards and higher soft tissue tumor incidences in humans

directly involved in nickel industries. Bech et al. [25] suspect cobalt as a possible industrial carcinogen. Metallic chromium has thus far exhibited no carcinogenic tendencies for either rats or humans [26]. Oppenheimer et al. [27], using cobalt-chromium and stainless steel foils implanted subcutaneously, have induced fibrosarcomas in rats. More recently, Heath, Freeman, and Swanson [28] have shown that wear particles from cobalt-chromium alloy total joint replacements, when suspended in serum and injected into the thigh muscle of female rats, have elicited tumor formation as early as 4-1/2 months postinjection with an incidence of 19 percent at the time of publication. They have incriminated cobalt more so than chromium as the primary carcinogenic agent.

1.2 Metabolic effects

Since many of the constituents of stainless steel and cobalt-chromium alloys are also essential biological trace elements, a subsequent systemic alteration in the normal physiological level of an element may manifest itself as a corresponding change in that metabolic process which is so intimately dependent upon precise trace element concentration and balance. Underwood [29] has thoroughly discussed the nutritional aspects of diet-induced trace element deficiency or excess. Similar consideration, however, should be implicit when evaluating any form of trace element entry into the physiological system, particularly by those modes of entry that would bypass normal physiological regulatory mechanisms, e.g., corrosion products from metallic surgical implants, pollutants in the air absorbed either through the lungs or through the skin, or trace element aberrations resulting from extensive kidney dialysis. Taylor's calculations indicate the real possibilities of trace element accumulation with time. The obvious question remains--what is the long-term metabolic effect of chronically elevated essential trace elements?

1.3 Immunologic effects

Several investigators [30, 31], in evaluating local implant acceptance in the musculoskeletal system, have alluded to the possibility that metal ions or corrosion products in combination with complex host chemistry could become antigenic and thus precipitate some form of immunological response. Foussereau and Laugier [32] have cited four case reports of patients having eczematous-type skin reactions attributable to implanted SS 316L or cobalt-chrome alloys. Nickel was implicated as the primary sensitizer, though cobalt and chromium were thought to be equally as antigenic. McKenzie et al. [33] reported the clinical case of a 65-year-old woman having a chronic (10-month) generalized urticaria subsequent to a Smith-Peterson cobalt-chromium nail insertion for a femoral neck fracture. The woman exhibited nickel sensitivity by patch and scratch testing. Removal of the cobalt-chrome device resulted in spontaneous resolution of the urticaria within 24 hours. Barranco and Soloman [34] reported a case of nickel-induced allergic eczematous dermatitis attributable to nickel exposure from a stainless steel screw in the patella. More recently, Evans et al. [35] have shown that of 14 patients having loose cobalt-chromium prostheses, 8 were sensitive to cobalt, 1 to chromium, and 1 to nickel upon epicutaneous skin testing. In contrast, of 24 patients having stable bone/prosthesis fixation, none was metal sensitive. A causal association between metal sensitivity and bone necrosis with subsequent prosthetic loosening is suggested.

1.4 Bacteriologic effects

For three decades, it has been recognized that a host's response to bacterial invasion includes a reduction in the serum or nonheme iron content of the blood [35]. Recently, the mechanism of this reduction has been identified as a suppression of intestinal assimilation of iron concurrent with an increased storage of iron in the liver, the net effect being to make growth-essential nonheme iron less available to microbial invaders and thus manifest a so-called "nutritional immunity" for the host. To illustrate the strength of this argument, patients having infection and inflammation are often unable to mobilize iron from cell depots, often to the extent that iron-deficient erythropoiesis may develop irrespective of a normal total-body-iron content [38]. This phenomenon suggests that the physiological system would rather endure a short period of iron deficiency anemia than risk a systemic microbial invasion. Weinberg [39] in a survey of pathogen-host interrelationships has concluded that

"in the contest between the establishment of a bacterial or mycotic disease and the successful suppression of the disease by animal hosts, iron is the metal whose concentration in host fluids appears to be most important." Recognizing that 316L stainless steel contains approximately 65% iron, that implant corrosion undoubtedly occurs, and that the physiological system has no responsive mechanism to systematically excrete excess endogenous iron, we may well ask what effect does this added iron have upon the disease resistance of the recipient of a stainless steel implant?

Before concluding this discussion, it is wise to sound a note of caution in these considerations. McKee [40], in criticizing the work of Heath, Freeman, and Swanson [28] demonstrating the carcinogenic potential of metallic wear particles, said: "In assessing the importance of this (work), it should be realized that the results apply . . . to rats." The majority of evidence to date on the systemic effects of corrosion products depends upon the use of nonhuman experimental models, utilizing animals and cell lines of various types. Clearly, important systemic physiological differences are in evidence between men and rabbits. However, at the cellular and subcellular level, biological processes are more similar than different. Considerations of differences and similarities must be kept in mind both in designing experiments and in interpreting their results.

Furthermore, it may be argued that the long clinical history of the use of metallic implants, both stainless steel and cobalt-chromium alloys, belies the considerations presented in this paper. However, in the patient population that has received over 100 million temporary and permanent implants to date, it is clear that all of these effects can be found. What is in question is the origin of these effects; more precisely, is there a differentially increased rate of incidence of carcinogenic, metabolic, immunologic, and infectious disorders in groups of patients with implants when compared to groups without implants?

2. Conclusion

Indications from research and isolated clinical observations seem to be sufficient to warrant serious study of potential systemic problems in human clinical populations. Careful, prospective protocols comparing patients who receive chronic implants with matched controls are now required. Such studies can document the real occurrence rates of the effects discussed here and lead to improvement of implant performance.

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DISCUSSION OF PAPER:

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In discussing this paper, I shall follow the outline presented by the authors--namely, (1) Systemic Effects of Implant Corrosion; (2) Carcinogenic Effects; (3) Metabolic Effects; and (4) Immunologic/Bacteriologic Effects--as these subjects relate basically to metallic implants.

1. Systemic Effects of Implant Corrosion

The authors, through a referenced article by Taylor, have suggested that a high corrosion rate of 6 mg/200 cm²/day exists for metallic implants made of stainless steel or cobalt-chromium base alloys. Taylor arbitrarily chose "a rather high corrosion rate, R" without comparison to the actual corrosion rate which is observed *in vivo*. The value of Taylor referred to by Drs. Smith and Black represents a corrosion rate of 0.54 MPY which is approximately 50 times greater than that observed for cobalt-chromium base alloys *in vivo*. *A material with such a high rate of corrosion would hardly be satisfactory for many industrial applications, let alone for implantation.*

Doctors Jones and Green [1]¹ stated in 1966 that for surgical implants "it is usually necessary to employ materials possessing corrosion rates of 0.1 to 0.001 MPY or less."

One of the prime requisites for a metallic implant material is corrosion resistance. It is recognized that all metals exposed to a saline environment, such as exists in the

¹Figures in brackets indicate the literature references at the end of this paper.

human body, will have a tendency toward corrosion (ionization). By polarization, which is the production of counter-emf by products formed or by concentration changes resulting from passage of current through an electrolytic cell, corrosion can be reduced considerably. This phenomenon is well known and has been observed on metal implants in the body.

It is important to mention again that the high rate of corrosion chosen in the example cited *is not realistic* and can result in an erroneous impression. It is necessary to ascertain the actual corrosion rate of the metals or alloys presently being used *under in vivo conditions* and then to correlate the quantity of metal ions formed with the subsequently observed effects within the human system.

2. Carcinogenic Effects

The authors have cited certain references relating to experiments conducted in rodents wherein selected metallic elements were tested both in the form of metal particles and as injected metal salts. These experiments showed tumor formation at the implant site. There is no question regarding the reported results in rodents, but there is a question about the extrapolation of such results to human beings.

With regard to metal ions, the mode of introduction and the dosage can be significant. At observed actual dissolution rates of implanted metals, the quantity of released metal ions is recognized to be so low as to be insignificant and well within the capability of disposal by normal metabolic routes.

As the authors mentioned, over 100 million implants made of metal and metal alloys have been implanted in human beings over the past 35 years. If what the authors are suggesting relative to the potential carcinogenic effects of metal ions in the human body is true, then it should follow that many reports would be in the literature indicating such a trend or tendency if it actually existed.

However, in a recent survey which we and others made of the literature in preparation for an answer on this same subject brought up at the House Hearings on Medical Devices Legislation, only two examples could be found of reported cases of cancer in humans in which the implant was suspected. In both cases, the material was stainless steel, and the authors were not certain that the tumors originated as a result of the implant but were of the opinion that a relation of some sort existed [2,3].

No article was found in the literature relating to carcinogenic tendencies in human beings as a result of implantation of *cast* cobalt-chromium-molybdenum or *wrought* cobalt-chromium-tungsten-nickel alloys.

3. Metabolic Effects

As indicated by Ward et al. (1975), metal salts can affect the metabolism of various cell types by inhibition of protein synthesis at concentrations of 10^{-4} M which normally are not encountered *in vivo*. It would be useful to obtain long-term information as to the actual level of metal attained, both locally and systemically.

4. Immune Effects

High levels of iron hyperferemia do play some role in bacterial infection, as indicated by Weinberg (1974); but as he points out, other salts including phosphate can be implicated. Ward indicates that some metals do in fact inhibit the process by which neutrophils are attracted and move toward a wound site, in addition to inhibiting protein synthesis; but again these effects occur at very high metal concentration of 10^{-4} to 10^{-3} M.

Available data indicate that certain metals at *high concentration* may inhibit cellular metabolic processes and immune mechanisms. However, at observed solution rates, the quantity of metal released is *so low* as to be insignificant and thus easily handled by the normal metabolic route.

5. Summary

A number of interesting points have been raised by Drs. Smith and Black. Detailed cooperative work in developing appropriate animal models and obtaining long-term clinical information in which patients and retrieved implants can be examined would be extremely valuable in supporting the progress of successful implantation of metals in human beings.

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TISSUE REACTION TO BIOMATERIALS

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This paper presenting results of 20 years' study of tissue reaction to implanted materials includes animal experimentation previously reported [4,7]¹ and much of the work presented in a recent review article [6]. It also includes the results of examination of tissue retrieved from patients during the removal of surgical implants for various reasons excluding infection. The numbers of animals involved exceed 600 rabbits, and the number of patients approaches 1,000. It is convenient to present the results in two groups; namely, tissue reaction to metallic implants, and tissue reaction to nonmetallic implants.

As soon as an implant has been placed in a biological environment, a mutual interaction occurs in which the cells adjacent to the implant at first respond to its presence. Later, those distant from the implant may suffer changes consequent to the presence of corrosion products. The tissue reaction to implants is a time-related phenomenon. The severity is related to many factors including the geometry of the implant, any friction or motion, the character of the corrosion products, and the biological activity of these products. The internal environment, of course, is injured and changed by the insertion of the foreign body. Hematomas collect and influence the surface conditions at the tissue implant interface. Some soft tissue and bone may be killed with additional changes in the interface conditions. The pH is also important, and several conditions may occur following the surgery. The pH (fig. 1) of 7.4 will drop sharply after surgery during the reaction of injury, CO₂ collects locally, and a pH of 5 or 4 may be approached. Restoration of normal conditions may take a few days or may not occur if the local collection of blood or serum does not allow free circulation and exchange of gases and chemicals. The superimposition of infection may swing the pH to the alkaline side of the scale with additional consequences to the implant.

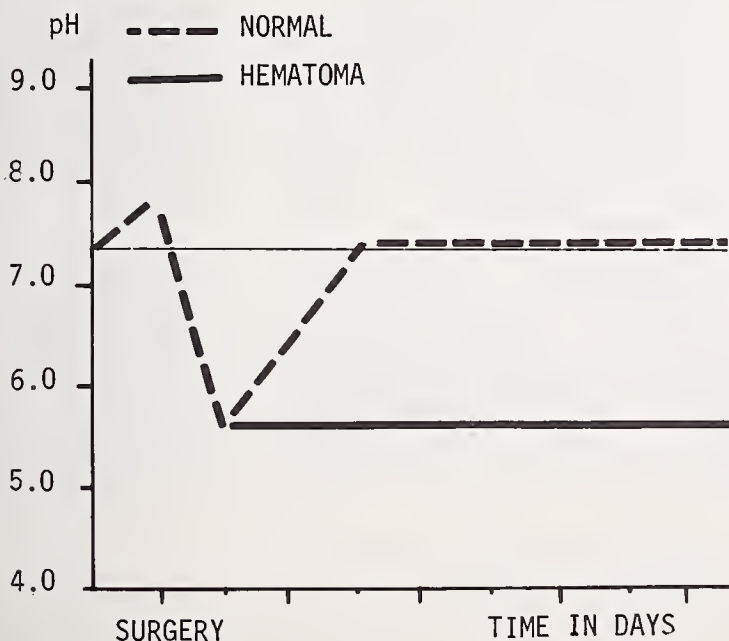


Figure 1. Diagrammatic presentation of possible pH changes in a wound following insertion of an implant.

¹Figures in brackets indicate the literature references at the end of this paper.

1. Tissue Reaction to Metallic Implants

Following the substance of the reaction to injury, the reaction of repair starts. This reaction merges imperceptibly with the first, one with the other. Healing occurs along the implant with the formation of fibrous tissue; at first it is disoriented and later becomes oriented and organized, even being used as a functional part of, for instance, a cup arthroplasty. New bone is formed and will invade and replace dead and injured bone.

Clump active fibroblasts and macrophages of various sizes gather around the implant, and the adjacent tissues are invaded with many new capillaries (fig. 2). As the process dies down, the cells adjacent to the metal become flat and begin to resemble mature fibroblasts. Scar tissue will become less evident, vascularity will decrease, and a steady state may appear to exist.

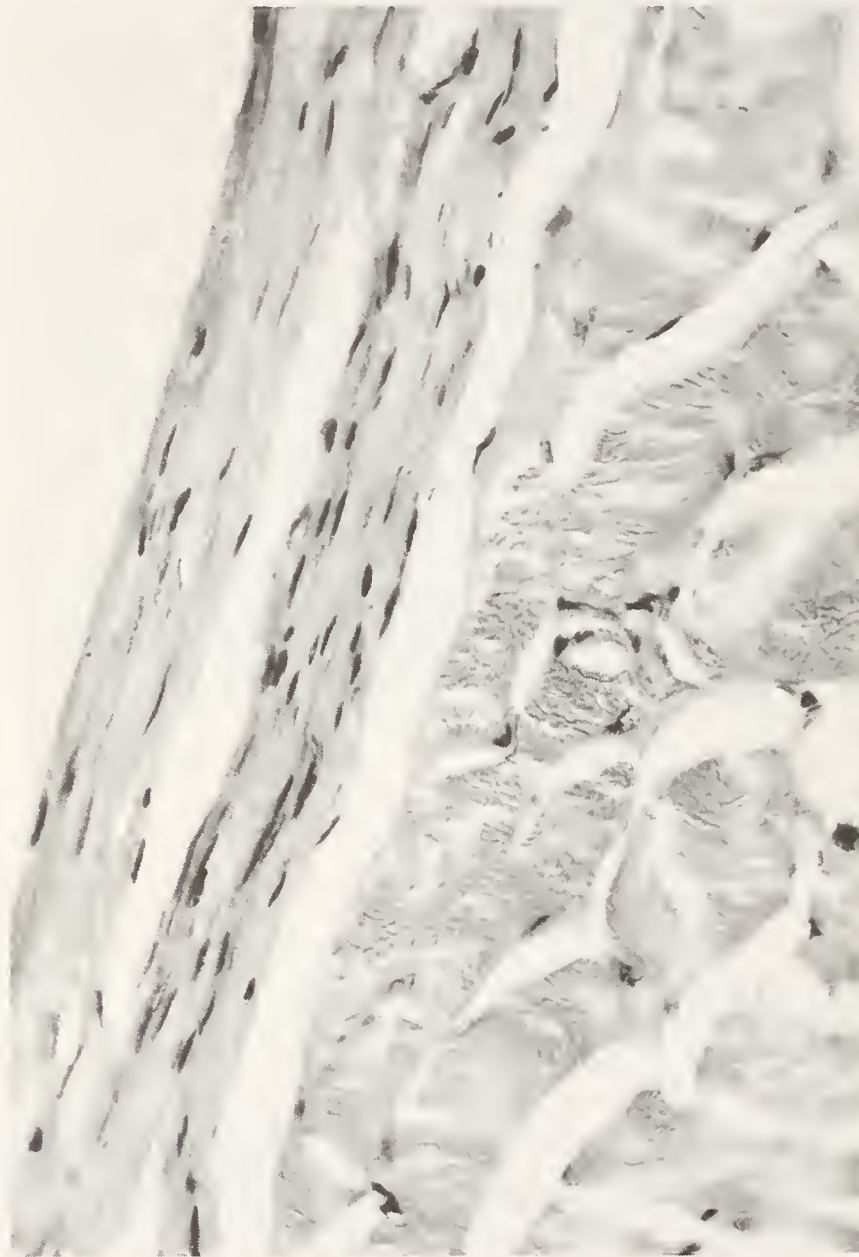


Figure 2. Histological preparation showing early tissue reaction to an inert implant.

1.1. Reaction to Corrosion

In the event that the implant is inert and remains passive and relatively free of corrosion, the situation described may be the end of the story. However, analysis of tissues near and far from the implant will reveal that the constituent elements are leaving it [4]. The lack of a severe tissue reaction may be traced to the lack of biological activity of the products of corrosion. Different metal ions have different effects on enzyme systems. Some act as catalysts, and some as inhibitors. Some, such as cobalt and nickel, are mutagenic in cell cultures while others are inert.

The tissue response to metallic corrosion has been described by many authors [7,8]. It has been called electrolytic inflammation to imply a sterile inflammatory process caused by an electrochemical reaction. It has been graded in rabbits, so that metals can be compared in living tissue in much the same way as their corrosiveness is compared in sea water [1].

The minimal reaction in animals and humans consists of the formation of a few layers of relatively avascular fibrous tissue between the implant and either normal bone or soft tissue. Little if any round cell infiltration should occur, and the only fibrous tissue formed should be that of the healed surgical scar. Marrow elements should be unaffected.

As we move into instances in which corrosion is more obvious, either generally all around the implant or in crevices and cracks, we see an increase in the thickness of the fibrous tissue barrier. Its cells become plump and active, and many phagocytes appear; small particles of metallic salts may be seen in their cytoplasm. Vascularity increases; and fibrous tissue starts to thicken and replaces adjacent normal muscle, binding down fascial planes. In some cases, especially with nonmetallic implants, eosinophilic cells may be found.

Bone reacts in two ways to corrosion. Severe corrosion causes osteolysis and osteoclasts to occur until the implant is floating freely. New inflammatory bone forms over it, and chemical osteomyelitis is present. Less severe corrosion may cause either of two reactions. The first is a minor version of the severe one just described. The implant becomes loosened and can easily be removed. Sometimes an involucrum of bone forms over the implant. In the second form of bone reaction, slightly sclerotic bone is formed, encasing the implant and looking much like the sclerosing type of osteomyelitis.

1.2. Reaction to Metallic Particles

The corrosion process is speeded up by increasing the surface area available for the attack to occur. This increase can be achieved by grinding the metal up into small pieces. Other metals corrode rapidly and cause a proportionately greater tissue reaction than their parent implant. Small metal particles that accumulate in a joint are phagocytosed and entrapped in the synovium whence they can be removed to lymph glands and other organs.

1.3. Long-Term Tissue Reaction

The severity of the process, determined by the various factors considered, may reach an equilibrium, establishing a compatible relationship. The implant may be held adequately and firmly to perform its function with only enough fibrous tissue formed to provide a new joint capsule and not enough to strangle the joint and destroy its function. A giant cell reaction of either the foreign body or the tuberculous type is not seen in tissue reaction to corroding metals.

1.4. Tissue Reaction to AISI 316 Stainless Steel

In most of the 700 cases of removed stainless steel implants examined by the author, some visible signs of corrosion could be seen. The tissue reaction around these implants was moderate with invariable loosening after 10 to 20 days. An involucrum of bone was often found covering part of the device. Frank brown to black discoloration of tissues was

frequently seen, especially around screws to plate interfaces. The types of cells were variable but included few, if any, multinucleated cells. The membrane was variably vascular, depending on the activity in the adjacent metal.

1.5. Tissue Reaction to Cobalt-Chromium-Molybdenum

The tissue reaction to the long-term implantation of this alloy is minimal. However, some reactions do occur, and instances of rather severe reaction have been reported. The pH of the wound is important, and low pH can remove the protection of the surface chromium oxides. Corrosion may also be initiated by infection, which may raise or lower the pH, depending on the organism. The tissue reaction to small ground-up particles of cobalt-chromium-molybdenum is more marked than that to the parent metal.

The tissue around the implants when studied at over 3 months following insertion is free of excessive fibrous tissue, and cellular action generally is slightly less around stainless steel implants unless corrosion has occurred [3]. Small black particles may be seen in sections from tissue adjacent to cobalt-chrome-molybdenum implants. These particles were found to be contained within macrophages and presumably are corrosion byproducts.

1.6. Tissue Reaction to Titanium

Tissue reaction to titanium both in animals and in humans is minimal in the absence of wear. This finding applies to the alloys we have examined in the laboratory and also to titanium-aluminum-vanadium implants used in human beings over the last decade.

1.7. Tissue Reaction to Titanium Particles

Tissue reaction to metallic particles has been studied extensively by Cohen and Wulff [3]. Particle size is important in the type of cellular reaction that occurs. Giant cell reaction is, however, rare. Particles are phagocytosed by the macrophages and removed from the site. Others remain locally isolated.

1.8. Toxicity of Metallic Ions

Previous work from our laboratory and from others has shown that spectrochemical and neutron activation analysis can demonstrate the presence of all the constituents of a metal alloy in the adjacent tissues and many in the distant tissues.

It is interesting that titanium may be present in large amounts around a titanium implant and yet the tissue reaction may be minimal. It is tempting to think that the toxicity of the released metallic ions is the important factor in this reaction. In other words, the biologic activity of the released salt will be the important thing in determining the biologic reaction; and using this knowledge, one might well be able to design a tailor-made alloy with minimal tissue toxicity.

1.9. Future Work

In order to understand the fundamental tissue reactions to metallic implants, it is important to understand the toxicological effects, both inhibitory and accelerant, of metallic ions on enzyme systems and also the mechanism of their toxicity, if any. It would seem unlikely at this juncture that hypersensitivity sensitization allergic reactions would be as important here as they may be with the nonmetallic materials.

2. Tissue Reaction to Polymeric Materials

In the interest of brevity, my remarks will be confined to experiments and clinical cases involving the two commonly used polymers in orthopedic surgery, i.e., polymethylmethacrylate and ultrahigh molecular weight polyethylene and not make mention of any work on the elastomers.

2.1. Implant Size

In the case of polymeric materials, it has been known for some time experimentally and clinically that the size of the implant is related to the type of tissue reaction seen. One may summarize the situation by saying that the reaction to bulk material is usually equivalent to that seen to bulk metallic materials, i.e., at best, a minimal reaction. In the case of fragments of polymers, the size becomes very important. If the particles are very small, they may well be ingested by phagocytes and removed from the scene of the interface. They may have an interaction with the phagocyte resulting in its death as was seen in the Teflonomas of Charnley, which will be dealt with later. Slightly larger particles may produce a foreign body reaction without a necrotizing reaction.

2.2. Tissue Reaction to Polymethylmethacrylate

Tissue reaction to this material is a response to a complicated implant containing many chemicals, both known and unknown. In addition, the heat generated at the interface causing a temperature increase to approximately 60 °C or more has a pasteurizing effect on the local cells leading to coagulation necrosis to a variable extent around the implant (fig. 3). In the clinical case, the histologic picture is further complicated by the reaction to wear particles of both metal and polymers. Additional elements in the reaction not previously recognized in metallic implant studies, but with a possible antigenic response to the macromolecule, deserve further study.



Figure 3. Histological demonstration of the coagulated muscle fibers around a recently implanted polymethylmethacrylate implant. Surface temperature estimated at 60 °C.

Study of muscle tissue reaction at 3 days demonstrates what appears to be dead, but still undigested, muscle fibers adjacent to the implant and extending two to four fiber thicknesses. This picture is presumably a result of a combination of burning and reaction to monomer leaching out of the implant. At 1 and 2 weeks, the boundary between living and

dead muscle becomes infiltrated with round cells. A pseudomembrane of fibroblasts and macrophages then forms and slowly thickens as time passes. At 6 months the picture has appeared to stabilize. Compared to the tissue reaction to known inert materials, such as titanium and tungsten, we see a more active cellular pattern.

Changes in the femora of the animals parallel that in the soft tissues but appear more slowly. In the first few days, minimal changes are seen because the bone cells around the implant presumably have been coagulated (fig. 4). Later, the cells undergo the changes typical of autolysis and disappear, leaving empty lacunae. A cellular reaction is occurring at the same time, and at 2 weeks the picture shows the beginning of new bone formation both externally and internally. Later still, fibrous tissue accumulates at the polymer tissue interface. The picture is characterized by a cellularity at 6 months that is not seen around metal implants, and some giant cells may be found (fig. 5).

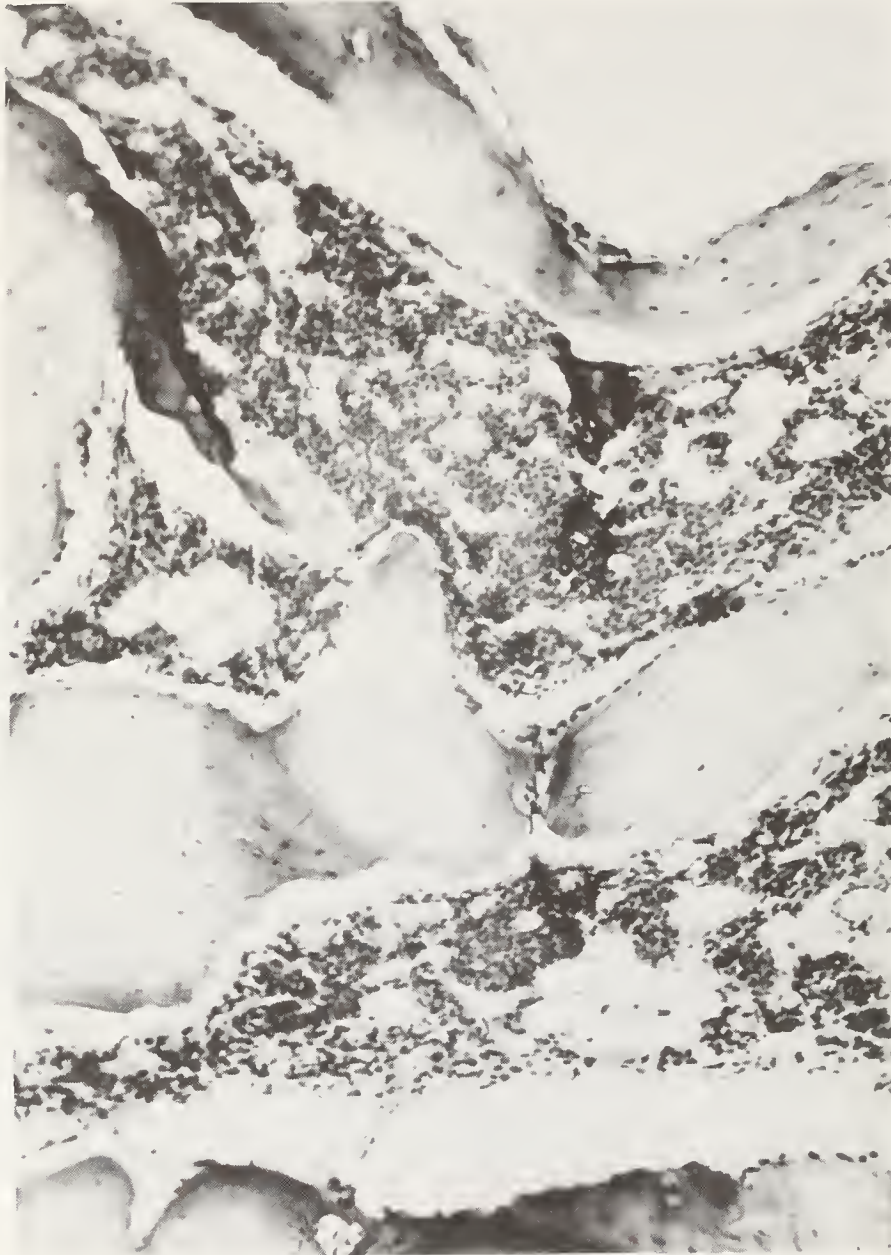


Figure 4. Histology of the femur of a rabbit after implantation of a polymethylmethacrylate plug showing cell death adjacent to the implant.

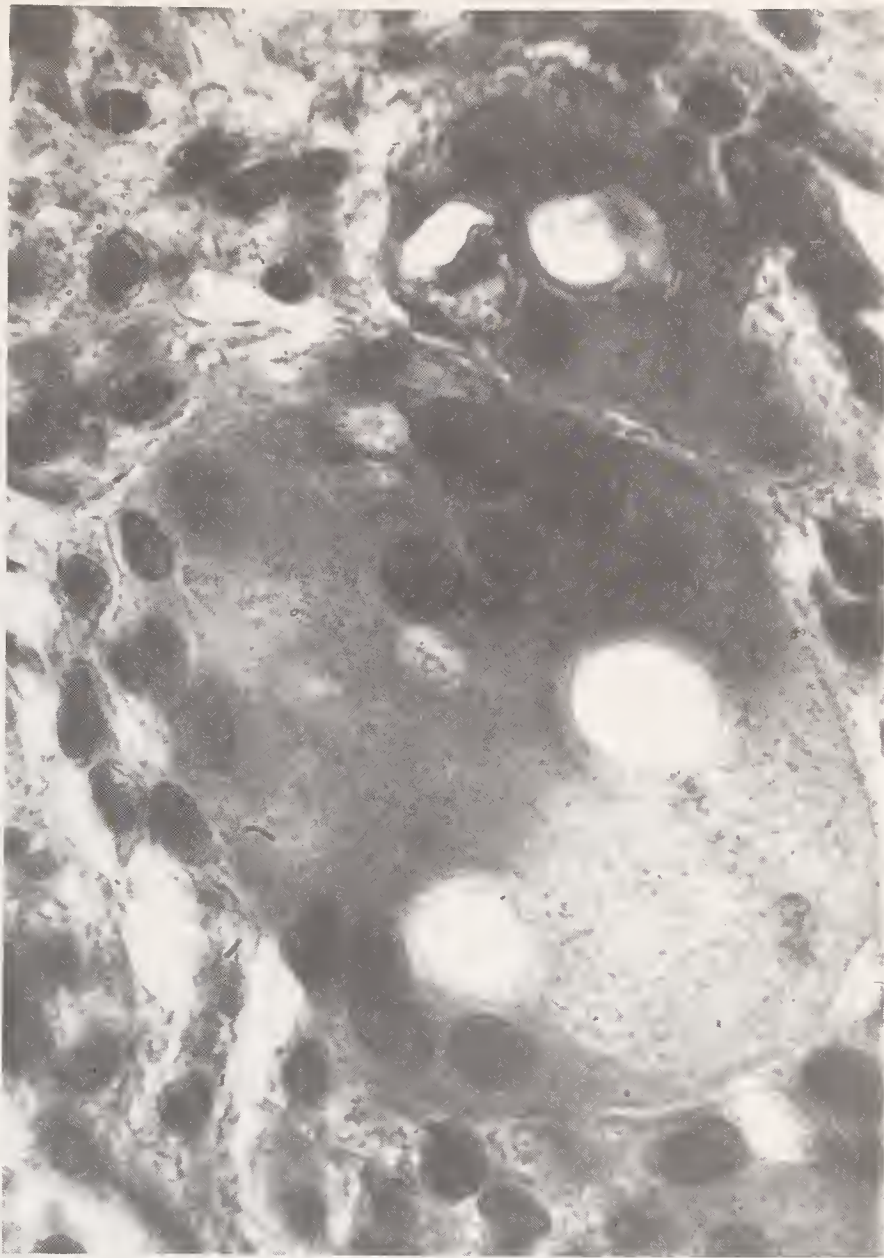


Figure 5. A giant cell containing what appears to be two balls of polymethylmethacrylate and showing what may well be caseation.

2.3. Tissue Reaction to Ultrahigh Molecular Weight Polyethylene

There is a paucity of published work regarding the tissue reaction to ultrahigh molecular weight polyethylene in either the solid or particulate form. Previous studies have been concerned with high pressure, low density polyethylene with branched molecules shorter than those of the one with which we are dealing. These studies have shown little tissue reaction to block polyethylene but more marked reactions to particles. This type of reaction to particulate polyethylene has been shown by Stinson.

The reaction around 12 ultrahigh molecular weight polyethylene cylinders placed in the back muscles of four New Zealand rabbits has been studied in our laboratories. These specimens, 1 x 1/8 inch, were sterilized in ethylene oxide gas and thoroughly degassed. Specimens taken at intervals up to 6 months showed apparent change in the implants. The tissue reaction was minimal and consisted of the formation of a fibrous tissue pseudo-membrane, which was moderately cellular and vascular.

2.4. Carcinogenesis of Polymers

No case of polymer-induced carcinogenesis in man has been reported that we are aware of. Tumors have been reported in rats, hamsters, and mice when metal foil and polymer film have been implanted. Stainless steel, vitallium, polyethylene, and polymethylmethacrylate were all to some extent carcinogenic. There is general agreement that a critical size and shape of an implant is required to produce tumors in susceptible rodent species. Tumor formation in such species in no way suggests that this will occur in humans. The experience with the metals that can be carcinogenic in the laboratory further underlines this fact.

2.5. Tissue Reaction in Humans to Polymethylmethacrylate

Charnley has described the histologic aspects of the tissue reaction in 23 human specimens 17 days to 7 years after implantation. At 17 days, he found cellular damage up to 500 microns from the interface. At 1 year, Charnley claims to have shown a change from fibrous tissue from fibrocartilage adjacent to the cement. He also describes dead bone, presumably killed by thermal trauma, being replaced by new bone and persisting 3 to 5 years later. Foreign body giant cells are also described but no granulomatous or caseation reaction. The evidence that the tissue implant interface is being shown is weak, however. Separation of the cement from the soft tissue is difficult, and the boundary layers may to some extent adhere to the polymer.

Biopsies taken when removing loosened total joint replacements reveal tissue reactions, including the presence of tuberculous-like giant cells and areas of focal necrosis. More such biopsies are required before we can fully characterize the tissue reaction to particles of polymers.

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Discussion of Paper:

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Dr. Laing presents a very good overview of the different mechanisms by which tissue can respond to the surgical implant. His paper can be considered an excellent approach to the overall question of the biological system reacting to a material surgically inserted to a local area. Dr. Laing follows through the problem both from a chronological and biological point of view.

He establishes some chronological milestones that are significant to consider. His analysis of wound pH following surgery is very good. It clearly establishes that in the presence of hematomas the wound pH level may drop to as low as 4, while in the case of infections the opposite may occur and the pH may become as high as 9. Therefore, corrosion resistance of implant materials will have to be considered in this range.

Dr. Laing establishes the sequence of events at the implant tissue interface. He clearly recognizes that the body's reaction to injury and the repair mechanism and the associated observations should not be confused with a response to the implant itself. To a certain extent, phagocytosis macrophage reaction and fibrous tissue formation are normal responses to the trauma and repair cycle. The reaction to the implant itself is observed locally as random fibrous tissue that later becomes oriented with the formation of mature fibroblasts with varying amounts of collagen tissue between them. Later, vascularity becomes less, and a steady state is reached between the implant and the surrounding tissue. Dr. Laing became widely known in 1959 with the publication of his studies on the thickness of the pseudomembrane around various metallic implants in the back of muscles of white rabbits. He classified material into three groups with titanium and similar materials having the thinnest pseudomembrane, while the least biocompatible materials in group 3 have a relatively thick pseudomembrane and an "angry response" (as he calls it) of the surrounding tissue to the material.

I believe his paper is timely and the forum appropriate. The sponsors include the NBS, FDA, and ASTM among other standard- and regulation-generating organizations, where it is of utmost importance to understand the biological phenomena surrounding implants prior to generating standards, legislating devices, criticizing removed implants, preparing package inserts, or in general, evaluating surgical implant devices. Not knowing what is a normal response common to all implants and what is a less desirable response would lead to poor standards and wrong regulations.

The material Dr. Laing has presented in his paper is good and worth listening to.



CLINICAL BIOMECHANICS

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1. Introduction

Tissues, implants, limbs, and bodies all obey certain basic laws which can be described by mathematical expressions of the relationships between forces and motions. Application of these descriptions of the real world are primarily within the purview of the physical scientist and the engineer. Thus, the training of these individuals uniquely equips them to contribute substantially to the analysis of retrieved implant devices for the purpose of assessing the causes for failure. The application of the concepts of mechanics to the medical field has been lumped under the heading "biomechanics"; I am not very comfortable with this term, since it implies that what I do in studying things in the body is basically different from what I do in studying the failure of a bearing cap of an internal combustion engine.

Now that I have alienated all of my friends who are "bioengineers," let me hasten to point out that in looking inside the body we are dealing with an irregular geometry, non-linear materials, ill-defined loading patterns, and a few other factors that make analysis of the forces, displacements, stresses, and strains experienced by the implant very difficult. The principles are the same as those propounded in basic engineering courses, but the mathematics can become almost nightmarish.

2. The Philosophy of Biomechanics Analysis

The principles involved in "biomechanical analysis" of implants are easily outlined, as in figure 1, but generally very difficult to implement. In general, one begins with a free-body analysis, isolating the object of interest from its environment and identifying all interactions (forces, fluid flows, deflections, etc.) between the object and its environment. Force and moment equilibrium conditions are applied to establish relationships between known and unknown forces, and if we are lucky these will suffice to allow us to find the unknown forces. For statistically indeterminate cases, however, the equilibrium conditions are not sufficient to lead us to a complete description of the state of the object, and we must invoke the concept of compatibility of deformations. Finally, constitutive relations are introduced to relate loads and deformations. The resulting mathematical description of the object under study may be quite complex, but solutions of these equations will yield the desired data on loads and deformations experienced by the object.

In the above overview, it was tacitly assumed that the object is in static equilibrium and that the forces are constant in both magnitude and orientation. These conditions are, however, not true for many significant cases; and ignoring these time variations of forces and velocities may lead to substantial errors. If the inertial forces are not insignificant or if the force vectors vary with time, the above analysis must be applied repeatedly, and solutions for each instant of time must be obtained. Clearly this process leads to lengthy computations.

Once the loads and/or deformations on the implant have been defined, material properties are involved to establish the stresses, or force intensities, at every point of interest in the device as suggested by figure 2. Computing the stresses at selected points of

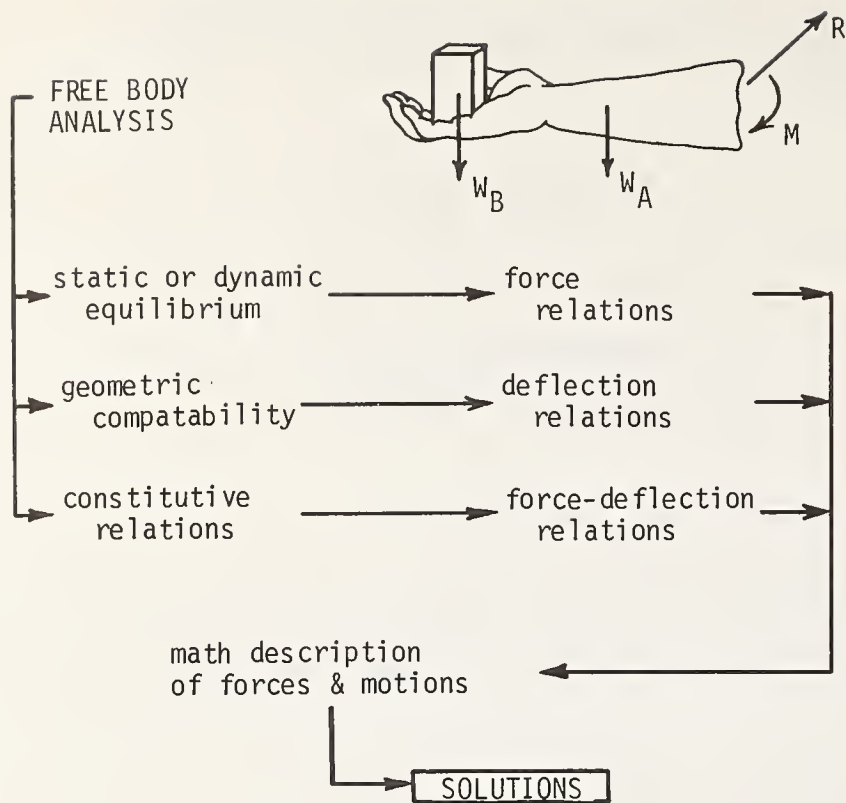


Figure 1. All biomechanical analysis approaches make use of equilibrium conditions, geometric compatibility, and/or constitutive relations to deal with the object of interest, as defined by the "free body," and to attain solutions to biomechanical problems.

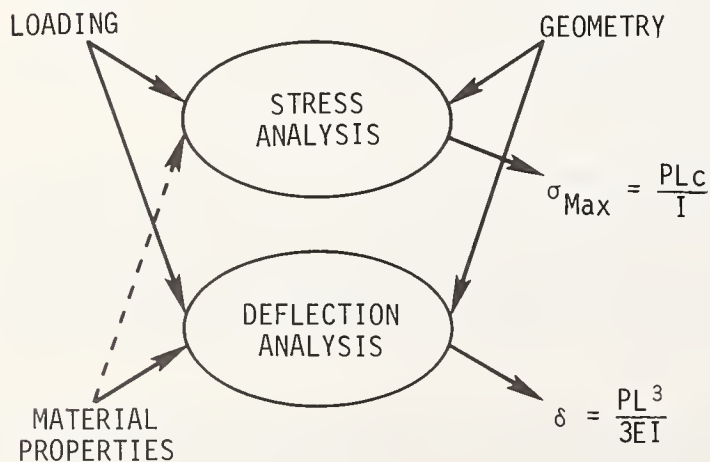
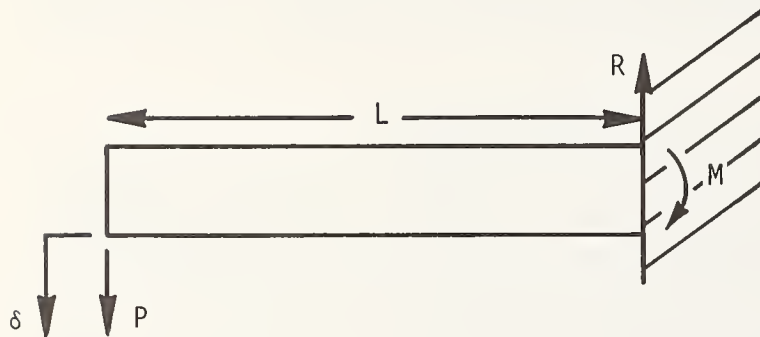


Figure 2. The analysis of stresses and deflections requires that the loading, obtained as shown in figure 1, and the material properties be combined with the description of the object's configuration.

interest, however, frequently implies calculating stresses everywhere in the object. It is at this point that the fields of materials science and mechanics merge, since both deformations and stresses are determined by the applied loading, the geometry of the device, and its material properties.

It is important here to differentiate formally between the terms "applied load" and "strength." The former term refers to the force conditions the device is subjected to, while the latter term describes how much load the device can sustain before bad things happen to it. The applied load is established through the procedure outlined above and differs for every analysis, while the strength depends on the properties of the material and geometry of the implant. One must also distinguish between various strengths, as defined by the various mechanical modes of failure so well described earlier by Dr. Williams.

I will present two case histories that illustrate how an analysis of the mechanics of the implant involved contributed to or even changed the conclusions regarding the cause of failure and briefly highlight some of the many varied and complex techniques used.

2.1 Case I

A 16-year-old white male involved in an automobile accident sustained a fracture of the right femur in the vicinity of the junction of the proximal and middle thirds. The fracture was treated with a 9 mm cloverleaf intramedullary nail. About 3 weeks later, the youth experienced sharp severe pain in his right thigh while putting on his pants (standing up) and felt the nail bend. X-rays (fig. 3) confirmed the bend, and a closed partial straightening was performed. The nail was bent again at 24 weeks postoperatively in a fall, removed, and replaced by a new 9 mm cloverleaf nail. The fracture proceeded to heal uneventfully, and the second nail was removed routinely 15 months after the original fracture.



Figure 3. This tracing of an x-ray shows the bend suffered by a 9 mm cloverleaf nail when the patient put on his pants while standing up at 3 weeks post-operatively.

A metallurgical study of the bent nail produced no evidence of surface defects or anomalous microstructure. X-ray spectrographic results indicated that the composition was "very likely" type 316 stainless steel. A yield strength of 470 MPa (68,000 pounds per

square inch, psi) and a hardness of 25 HRC were measured and deemed to be reasonable. Thus, since no material defects or deficiencies were noted, a biomechanical design analysis was recommended to determine the loads.

In order to assess the loads at the fracture site during the critical maneuver of putting on one's pants, several motion picture sequences were made of a subject of similar weight and stature as the patient. One frame of the film (fig. 4), judged to be the most critical, was traced onto a large sheet of paper. Anthropomorphic data published by Drillis et al. [1]¹ were used to locate and weigh the centers of mass of each of 15 body segments on the two views of the subject. The locations of the center of mass of the entire body, the right lower extremity below the fracture site, and remainder of the body were then calculated. The maneuver was assumed to be quasistatic, and inertial forces were neglected. Since the center of mass of the entire body was found to be located directly above the right foot, which was the single support for the entire body, a reasonable amount of confidence in the appropriateness of the analysis was acquired.

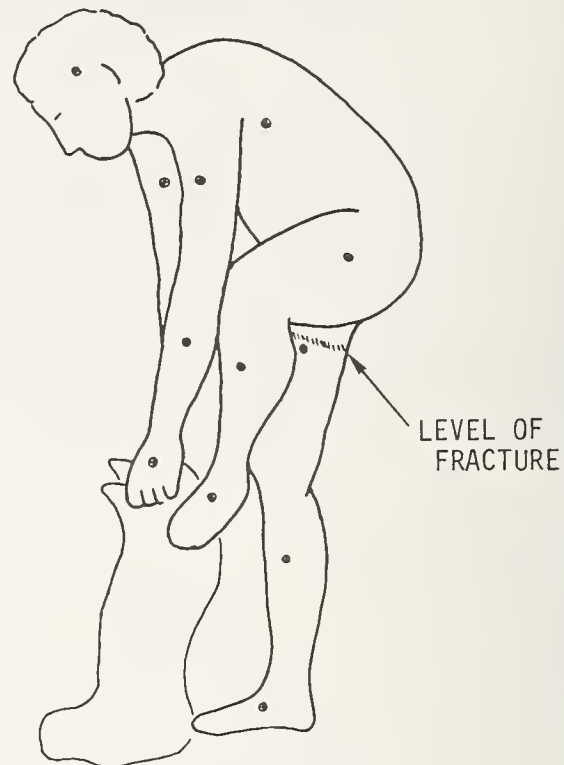


Figure 4. Configuration of a subject filmed in the act of dressing himself. Note the position of the upper body is far in front of the fracture site.

A free-body analysis of the body proximal to the fracture site showed that a new compressive load of 547 N (123 pound-force, lbf) and a bending moment of 92.1 N·m (newton-meter) (815 in-lb) had to be transmitted across the cross section of the thigh at the fracture site. Furthermore, this bending moment tended to bend the thigh in an antero-medial direction.

The compressive load is manifested in a compressive stress across the fracture site. This stress is quite tolerable and, in fact, thought by some to be essential for bone healing. The bending load, however, has two factors involved. A major portion of it is resisted by the bending of the nail itself, while the balance originates from the fact that the hamstrings act at some distance away from the center of the femur. These two components of the bending load at that cross section are difficult to separate rigorously. However, some very interesting comparisons may be made, as depicted in figure 5. The yield moment of a 9 mm cloverleaf nail, based on a yield strength of 690 MPa (100,000 psi) for cold worked stainless steel was calculated to be about 22.6 N·m (200 in-lb) (at this point yielding just began at the points furthest away from the neutral axis). A solid "nail" of the same outer diameter would exhibit a yield moment of about 49.1 N·m (435 in-lb). Both of these calculated values are well below the applied bending load.

¹Figures in brackets indicate the literature references at the end of this paper.

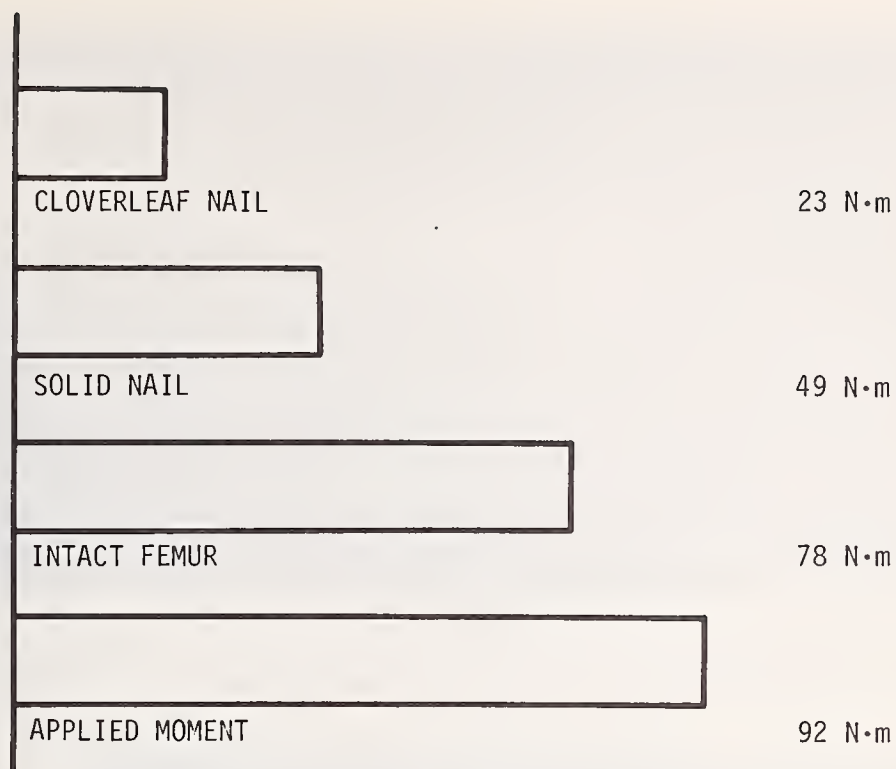


Figure 5. Comparison of the strengths of the cloverleaf nail, a solid rod of stainless steel, an intact femur, and the bending moment applied to the thigh at the fracture site.

Clearly, the hamstrings must, in fact, be tensed. Acting at a distance of about 75 mm, they would have to exert a force of about 925 N (210 lbf) to protect the nail. While these muscles can exert such forces quite readily, they would also act to flex the knee, an action that is undesirable since the knee is already slightly flexed. Thus, to keep the leg in the configuration required to support the body, the hamstrings and quadriceps must maintain a substantial force differential. However, the nail can only withstand a small portion of these forces exerted within the thigh. Furthermore, the body has little feedback information to tell it that the nail is getting bent. The nail thus is easily bent during this extremely strenuous behavior, and the implant "fails." One must conclude that the bending of the intramedullary nail was a consequence of the large load applied through the patient's actions and would not have been prevented by the use of a different nail design or different material.

An interesting and very significant postscript is that the physician could not see any reason for the nail to bend. That he was under the impression that the nail would withstand full early weight bearing points out acutely the fact that the physician needs to be advised, in a routine and standard manner, of the implant's finite strength. To facilitate the receipt of this information, the manufacturer must give the physician precise data regarding what forces a given implant can or cannot sustain.

2.2 Case II

A 61-year-old white male had had generalized arthritis for many years. Persistent pain in his left knee led to an attempt to fuse the joint. A Hansen-Street nail was driven through the length of the femur and half the length of the tibia. The nail blocked motion, but some of the pain persisted. About 3 years postoperatively, the patient felt a sharp snap in his left knee when he stepped off a curb. Swelling and increased motion ensued.

The intramedullary nail was seen on x-ray (fig. 6) to be fractured. Upon the removal of the implant, the fracture surface presented an appearance characteristic of fatigue failure as depicted in figure 7. The flat areas show where the fatigue cracks grew under



Figure 6. X-ray of a Hansen-Street nail, intended to fuse the knee, which failed abruptly about 3 years after implantation.

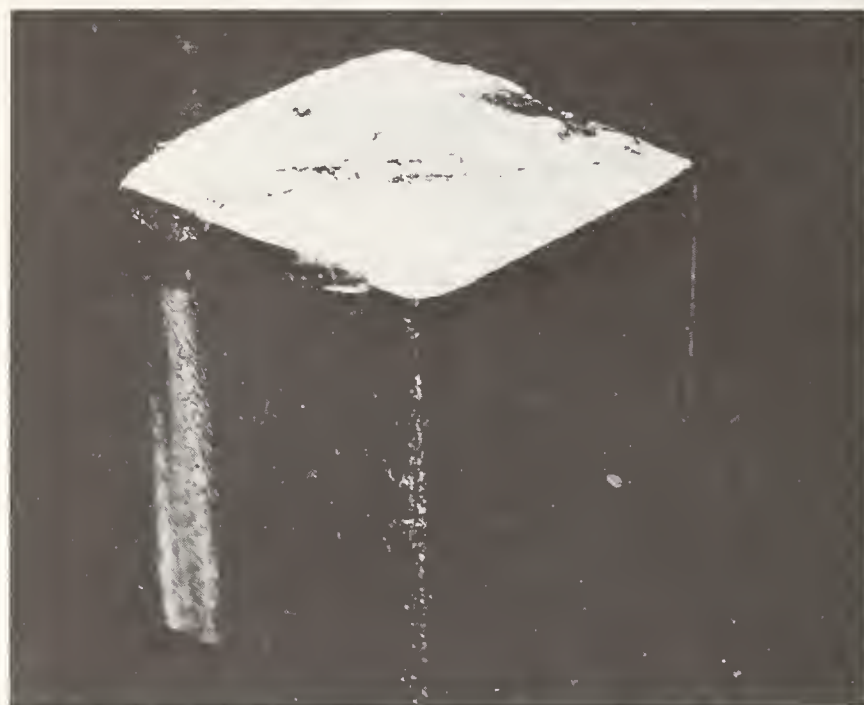


Figure 7. The fracture surface of the implant shown in figure 6 presents an appearance typical of a fatigue failure in reversed bending. The central ridge running horizontally across the diamond-shaped cross section was the last part to fail.

the cyclic loading, leaving only the central ridge to snap off for the final failure. The gouge marks visible on the implant apparently were created during the removal of the implant. Unfortunately, the marks obscure the question of whether any stress concentrators, due to either manufacturing defects or technical errors by the surgeon, were present prior to the fracture and acted to facilitate the failure.

As before, a free-body diagram of the implant (fig. 8) is illustrative of the type of load seen by the nail. The muscles of the leg continue as a reflex action to try to flex and extend the knee despite the presence of the nail. While the magnitude of the forces cannot be obtained without much work, the morphology of the loading on the nail can be established without difficulty. The bending moment experienced by the nail in the vicinity



Figure 8. Free-body analysis of the implant shown in figure 6 prior to its failure shows that the bending moment experienced by the nail is quite constant across the joint space.

of the knee can then readily be plotted in a qualitative fashion. The crucial feature of this moment diagram is that the bending moment is largest in the joint space between the femur and the tibia, and this moment is reasonably constant across that space. Closer examination of the implant (fig. 9) showed that another fatigue crack existed about 5 mm distal to the break in the anterior surface of the nail. A matching crack, although not as well developed, was found on the posterior side. The original surfaces of the implant were still visible in the vicinity of this crack, and no surface defects were evident under 40 X visual observation. A metallographic section through the incomplete cracks also

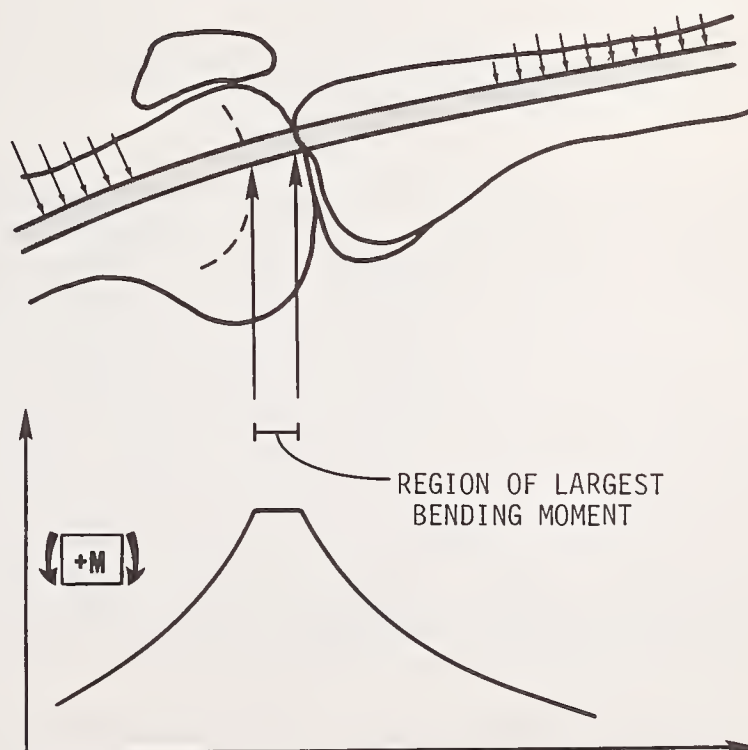


Figure 9. Another view of the fracture surface of the nail shows another fatigue crack about 5 mm distal to the fracture surface.

revealed no abnormalities. Thus, the incomplete fatigue crack did not originate at an overt defect. Since both cracks occurred under identical conditions of loading (i.e., both cross sections were subjected to the same bending moment), one can safely conclude that formation of the failure crack was also not enhanced by any surface defects and the nail was placed in a situation where it was overloaded in cyclic bending.

Without the consideration of the (bio)mechanics of the nail's failure, the integrity of the nail's surface would have remained in question. The nail itself was not defective, but its application for this situation was erroneous. Again, I would raise the question as to whether such misapplication could be avoided if the surgeon was provided with data outlining the mechanical characteristics of the nail.

3. Summary

The principles of mechanics, applied to a clinical situation, can be used to define or describe the forces and stresses acting on an implant. These data must be combined with the metallurgical analysis to describe, in a comprehensive fashion, what led to the failure of an implant. When only one or the other of the analyses is performed, incorrect conclusions may be easily drawn, leading to erroneous corrective actions or charges. Only when the expertise of both fields is applied to the retrieved implant will a consistently correct assessment of its success or failure be made.

Reference

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Discussion of Paper:

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Memphis, Tennessee

First of all, I would like to commend Dr. Piotrowski for presenting such a interesting and well thought-out paper. It is most significant that in both cases presented, the conclusion from the available evidence was changed after a biomechanical evaluation of the factors involved. This point is often overlooked in many situations. Based on my experience as a part of industry for the last 8 years, I would have to say that this point is very little understood. In preparation for this meeting, I conducted a minor survey of doctors in our area. I contacted five orthopedic surgeons and asked them a simple question, "Doctor, if you had a case of an intramedullary rod on a femoral fracture, would you see anything wrong with the patient putting on or taking off a pair of pants?" Without any question, the first reaction was to say, "Absolutely not, there should be no problems whatsoever." In one particular case, a doctor did call me back after a great deal of time and explained to me that the more he thought about it, the more he realized that it would be absolutely not the right thing to do. I am not trying to bring up this point to illustrate any deficiencies in the training of orthopedic surgeons in this country but rather to establish the fact that the biomechanical considerations in the field of orthopedic devices are not only very complicated, but also rather misunderstood.

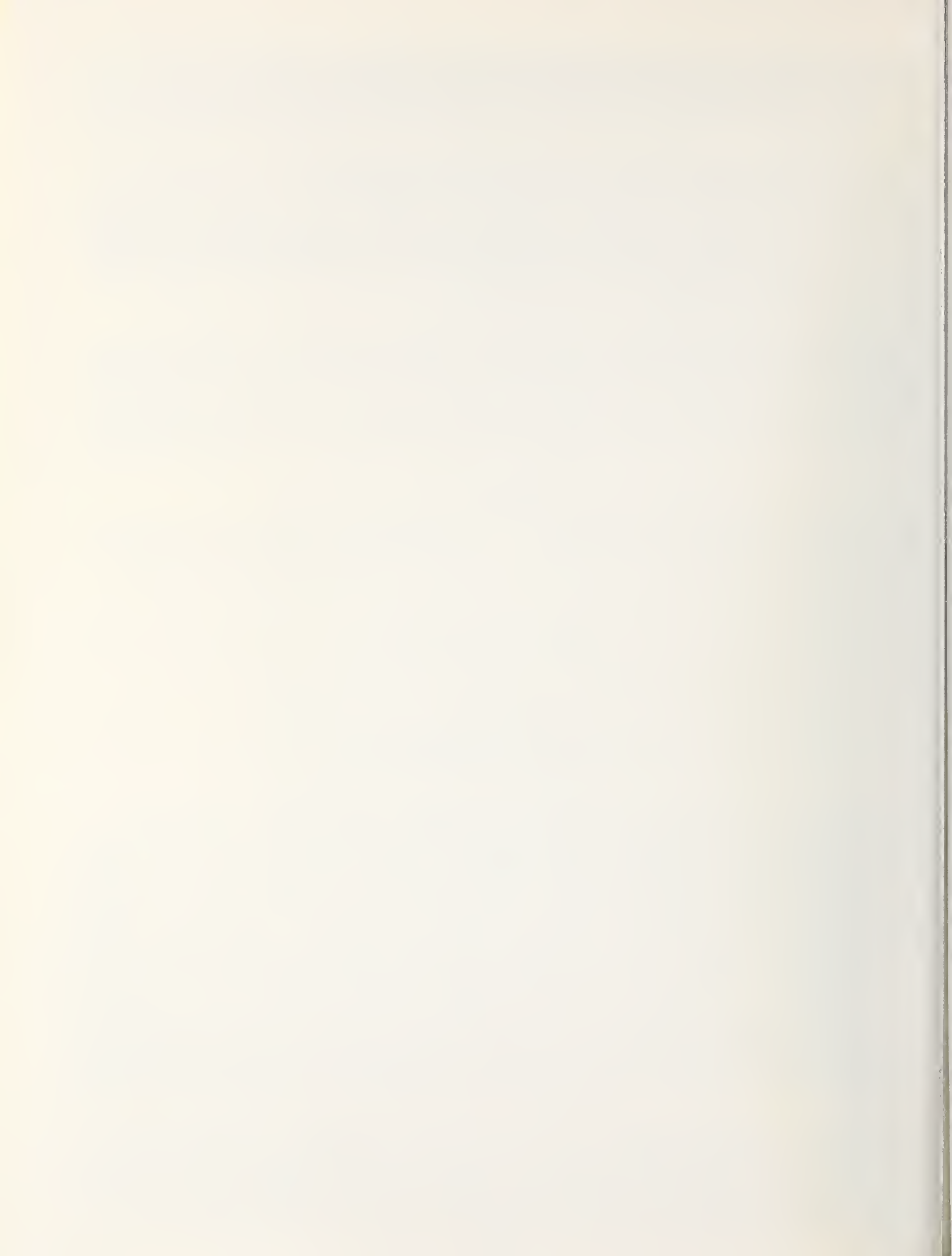
We as manufacturers are faced with having to offer an opinion on whether a particular device offered by us is defective or not because it failed under a clinical situation. This puts us in the very unfortunate situation of trying to analyze just a part of the device rather than fitting it into the complete schedule which includes biomechanical, clinical, physical, and all of the other considerations that we are here to discuss. I

hope that the two examples presented here by Dr. Piotrowski will illustrate how a bio-mechanical evaluation could completely reverse certain conclusions.

As an interested party, I would like to present the following two questions to Dr. Piotrowski:

1. Based on the information presented here, have you been able to develop any bio-mechanical guidelines by which to consider implants?
2. In both of your cases you indicate that if industry had provided more information to the surgeons, failures could have been averted. Would you please elaborate on what kind of information this would be and how it should be communicated to the surgeon, since some of these attempts have been shown to be rather futile exercises in the past?

I appreciate the opportunity to review this paper.



FEMORAL STEM PERFORMANCE

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1. Introduction

The purpose of a prosthesis fixation stem is to position the artificial joint surface with respect to the bone and to transmit loads from the joint to the bone. Currently, the most common means of fixing the stem is with cement so that the resulting bone-implant system consists of a three-material, bone-cement-stem composite. If the materials used are compatible with the biological environment and if the wear of the joint surfaces is acceptable, then the performance of the composite depends upon its mechanical integrity and the problem becomes one of mechanical analysis and design.

Failure of the system may occur in the bone [6]¹, the cement [13], or the stem [5]. In most cases, failure of one of the components leads to failure of the system. A single overload can result in catastrophic failure, or normal loads can lead to failure in a relatively short period of time if the prosthesis is implanted improperly or if there are significant defects in materials. Repeated loads of magnitudes much less than that required to destroy the system in a single application can result in failure after a long period of time. Fatigue failures of this type have been identified for femoral stems [5]. In any case, it is necessary to determine the stresses in the components of the composite structure in order to estimate the expected life of the bone-prosthesis system.

The stresses in the structure can be determined if the geometry and material properties of the components and the external loads on the system are known. However, it is important to understand that it is not possible to determine stresses in system components in isolation from the system. For example, the stresses in an implanted fixation stem cannot be determined by considering the stem alone. The geometry and material properties of the bone and the cement will affect the stresses in the stem, and the characteristics of the stem will affect the stresses in the bone and cement. Therefore, the emphasis here will be to consider the bone-cement-prosthesis composite as an integral system. In other words, the structure under consideration is the bone-implant system before *any* failure has occurred in any component of the system.

Several levels of analysis can be employed to calculate stresses. The simplest is beam theory (BT) which can be used to determine nominal stresses in simple structures. The methods of the theory of elasticity can be used to obtain more detailed information about stresses, and closed form solutions can be obtained for relatively simple geometries. When the geometry and material properties of systems become more complex, numerical methods must be employed to obtain solutions. One of the most common techniques employed today is the Finite Element Method (FEM).

¹Figures in brackets indicate the literature references at the end of this paper.

The stresses obtained from these methods can be used to evaluate various design concepts. The design variables that can be specified for a bone-cement-stem system are the geometry of the stem (cross-sectional shape and length), the geometry of the cavity, and the material properties of the stem and the cement. In general, these variables should be chosen to decrease the stresses in the cement and stem, but in the bone the situation is not so clear. Resorption of bone can occur for both too much and too little stress. To say the least, the problem is complex, and in all probability the objectives are competing; that is, improving the situation in one component of the system may create a worse situation in the other components. Consequently, the results of parametric studies must be considered carefully and applied with caution, but they are valuable in that they indicate the probable effects of changes in geometry and material properties on the performance life of the system.

2. Analysis of Stresses--Beam Theory

In beam theory, it is assumed that plane sections before deformation remain plane after deformation. This assumption leads to the following expression for normal stresses due to a compressive load P :

$$\sigma_i = \frac{E_i P}{E_b A_b + E_c A_c + E_p A_p} \quad (1)$$

and to:

$$\sigma_i = \frac{E_i t_i M}{E_b I_b + E_c I_c + E_p I_p} \quad (2)$$

for bending moment M . In the above equations, b , c , and p denote the bone, cement, and prosthesis, respectively; E , A , and I are the elastic modulus, cross-sectional area, and second moment of area, respectively; and t_i is the distance from the neutral axis to the point of interest in component i . The results obtained are in good agreement with more detailed analyses at sections away from abrupt changes in load or geometry. In fact, for simple geometries such as systems consisting of concentric circular cross sections, it can be shown that eqs. (1) and (2) give the exact solution for normal stresses as determined by the theory of elasticity [8]. As a result, these equations are extremely useful for the

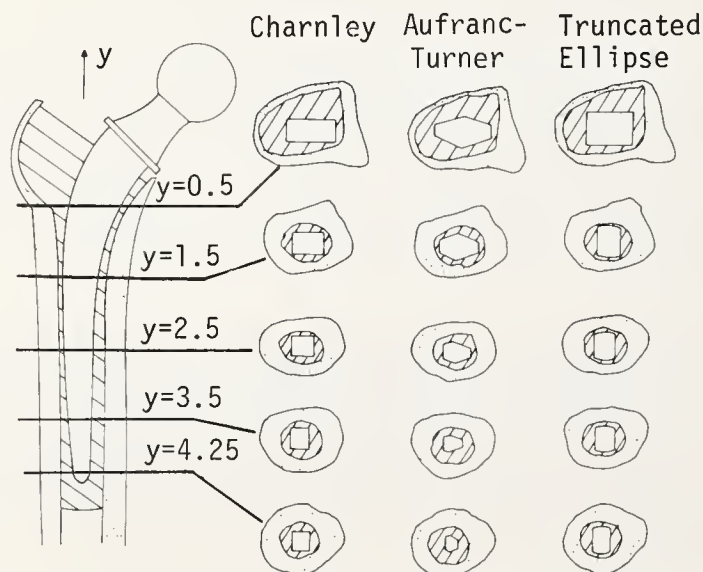


Figure 1. Cross-sectional geometry for three types of fixation stems.

design of prosthesis stems, and much can be learned about bone-prosthesis systems by applying them. Figure 1 shows sections of a femur for three types of fixation stems. The nominal stresses due to bending can be determined using beam theory, and these have been plotted in figure 2. In this case, stems of different cross-sectional shapes have been compared, but the same relationships can be used to evaluate the effects of changing material properties, stem orientation in the medullary cavity, and shape and size of the cavity.

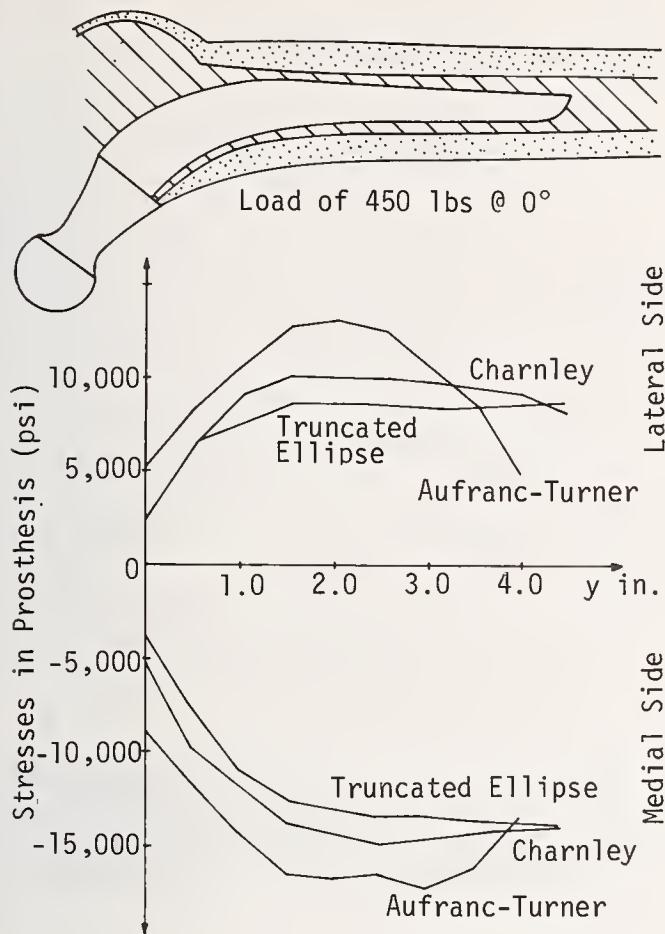


Figure 2. Nominal normal stresses due to bending and axial loads for the stem shapes shown in figure 1. The stresses were computered using beam theory.

3. Analysis of Stresses--Finite Element Method

The Finite Element Method (FEM) has been developed to determine stresses in complex structures [3]. It is particularly well suited for the analysis of structures with abrupt changes in geometry or material properties such as bone-prosthesis composites. As a result, a number of investigators have applied the FEM to analyze bone-implant systems [1, 2, 7, 9-12]. The general features of the method are illustrated in figure 3, where an idealized bone-cement-stem model consisting of concentric circular cylinders is shown. The model is approximated by an assemblage of three-dimensional finite elements.

Bone-implant problems are clearly three-dimensional, and it is therefore desirable to use three-dimensional methods to analyze them. Three-dimensional FEM studies are expensive to execute on the computer and require a large amount of time for data input and for interpretation of results. Consequently, most investigators have used two-dimensional methods to approximate the three-dimensional problem by reducing it to an axisymmetric or a plane stress problem. When analyzing the results of such studies, it is important to thoroughly understand how the two-dimensional approximate was determined so that the results can be interpreted properly.

The results presented here have been obtained from three-dimensional analysis. Relatively few elements (62) are needed to model the system, since mesh refinement studies have shown that additional elements change the results only slightly. Furthermore, it can

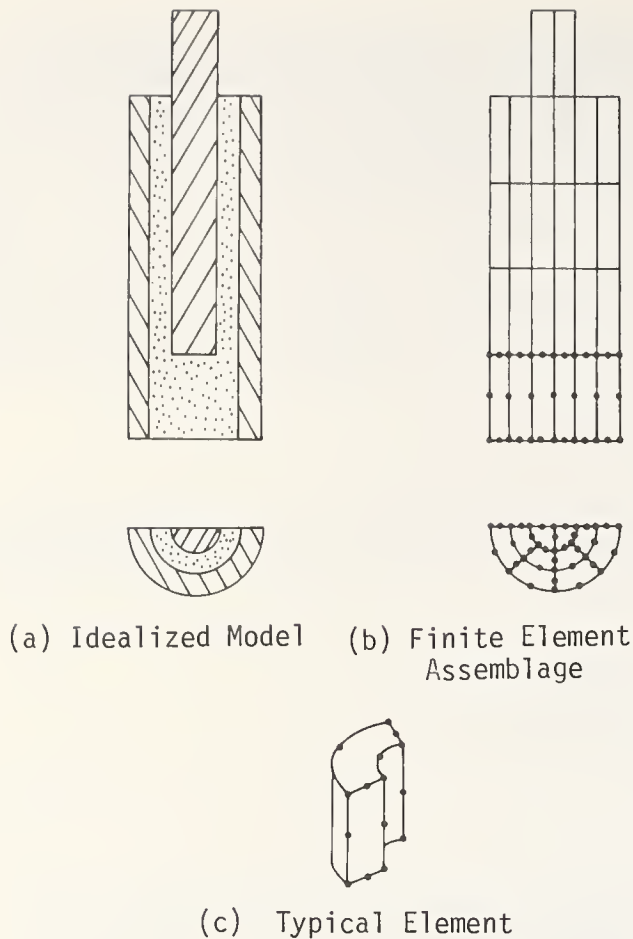


Figure 3. Finite elements are assembled to approximate the geometry and material properties of composite systems. Here an assemblage is created to analyze stresses in a representative, but idealized, bone-implanted system.

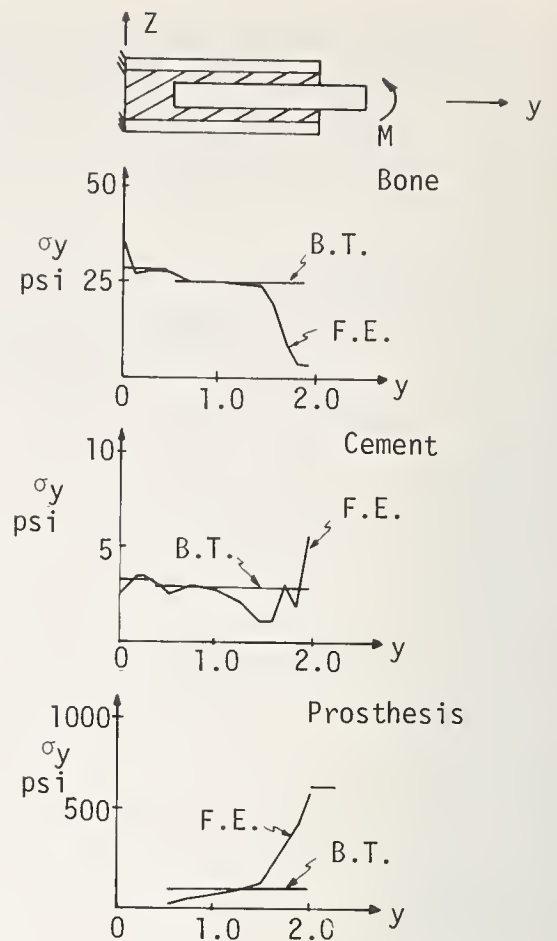


Figure 4. Normal stresses in bone, cement, and stem due to a unit-bending moment. The stresses were computed using the three-dimensional finite element model shown in figure 3.

be shown that the FEM results agree closely with the theory of elasticity solution for the problem at points away from abrupt change in geometry and loading. Consequently, good approximations of the stresses can be obtained even though a relatively small number of elements are employed.

Figure 4 shows the normal stresses in the Y direction along the extreme lateral fiber of each material due to a unit bending moment. These stresses are the dominant stresses in the bone and stem. Stresses from the beam-theory solution are superimposed on the finite-element (FE) results. Since the BT results are adequate away from changes in geometry and load, the primary value of the FEM results is to point out the areas where stresses differ greatly from nominal values. In the bone, stresses near the proximal free surface are low since little of the load has been transferred from the stem. Stress concentrations occur in the cement where the stem enters the bone and near the tip of the stem due to pinching of the cement between the stem and bone. In the stem, stresses decrease towards the tip of the stem, and the load is transferred to the bone over a relatively short distance.

Shear stresses due to transverse bending loads are small with respect to normal stresses in the bone and stem. But in the cement, they are of the same order of magnitude as the normal stresses and therefore must be considered in any detailed analysis. This point is illustrated in figure 5 where the effects of cross-sectional shape on stresses in the cement are shown. The large stresses seen near the tip are due to the large shear stresses that occur in this region [4]. It should be noted at this point that two-dimensional analyses, properly structured, give good results for normal stresses in the bone and the

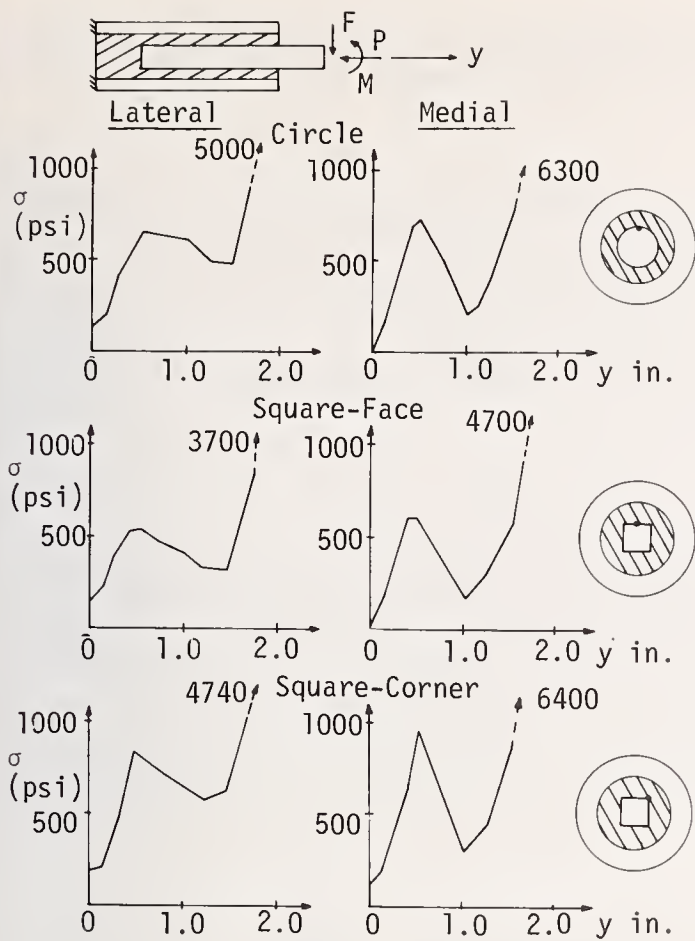


Figure 5. Normal stresses in the cement for square and circular stems. Stresses were computed for a combined load having components similar to those in the human hip.

stem, but three-dimensional analyses are required to determine the shear stresses. It should also be emphasized that the FEM is not limited to the idealized models shown here, which have been developed for generalized parameter studies but can be used for detailed analyses of specific bone-implant systems.

4. Performance--Fatigue Life

Since an implant system is subjected to many cycles of fluctuating load, the fatigue strength of the components of the system must be considered in evaluating system performance. Little quantitative information exists concerning the combined effects of corrosion and cyclic loading on the life of implant materials; and as a result, the endurance limit of the implant can only be approximated. Endurance limits of 38 ksi for Type 316 stainless steel and 35-40 ksi for cast cobalt-chromium alloys have been reported for tests conducted in air. The results from these standard tests must be modified to account for such factors as surface finish, size, and reliability. These factors have been applied to the data for rotating-beam specimens [4]; and the endurance limit for a Charnley stem, made from a cast cobalt-chromium alloy, is estimated to be approximately 23 ksi. This value is probably conservative since it does not include the effects of corrosion.

Some simplifying assumptions are necessary to obtain a design load on which to base an evaluation since actual load cycles are complex and vary from patient to patient. A load of 0° with respect to the bone axis was used as a worst case, and it was also assumed that the load varies from zero to six times body weight. Therefore, the mean and alternating load components are both equal to three times body weight. Referring to figure 2, where stresses are shown for a 150 lb patient, the alternating and mean components of stress on the tensile side of a Charnley stem are approximately 10 ksi.

Fatigue life, as a function of mean and alternating stress, can be represented using a Goodman diagram; and this procedure has been used to estimate factors of safety for various situations [4]. For a Charnley stem in a neutral orientation in a 150 lb patient, the

factor of safety is estimated to be 1.85 for infinite life. For the Aufranc-Turner stem, where the peak tensile stresses are about 13 ksi, the factor of safety on the tensile side is about 1.42. For a neutrally oriented Charnley stem in a 200 lb patient, the factor of safety is 1.39; and for varus orientation in a 200 lb patient, the factor of safety is about 1.1.

These rough estimates, based on beam-theory considerations and loading in the medial-lateral plane only, suggest that some existing hip implant systems may be operating at the limit of their strength. Furthermore, the effects of larger peak loads, due to greater activity in younger patients, and the effects of corrosion will further reduce the factor of safety of the device. Consequently, it is possible that fatigue failure of bone-implant systems may not be a rare occurrence when these devices are used in younger, more active patients. At the very least, the question of fatigue strength should be one of continuing concern as better information becomes available.

5. Performance--Stem Cross Sections

Since the beam-theory solution gives acceptable results in the midsection of the stem where fatigue failures have been observed, it can be used to investigate general design concepts for the stem. Figure 6 shows the nominal maximum bending stresses in the stem as a function of cross-sectional prosthesis height (Z_p) and the moment of inertia of the stem normalized with respect to the moment of inertia of the medullary cavity (I_p/I_m).

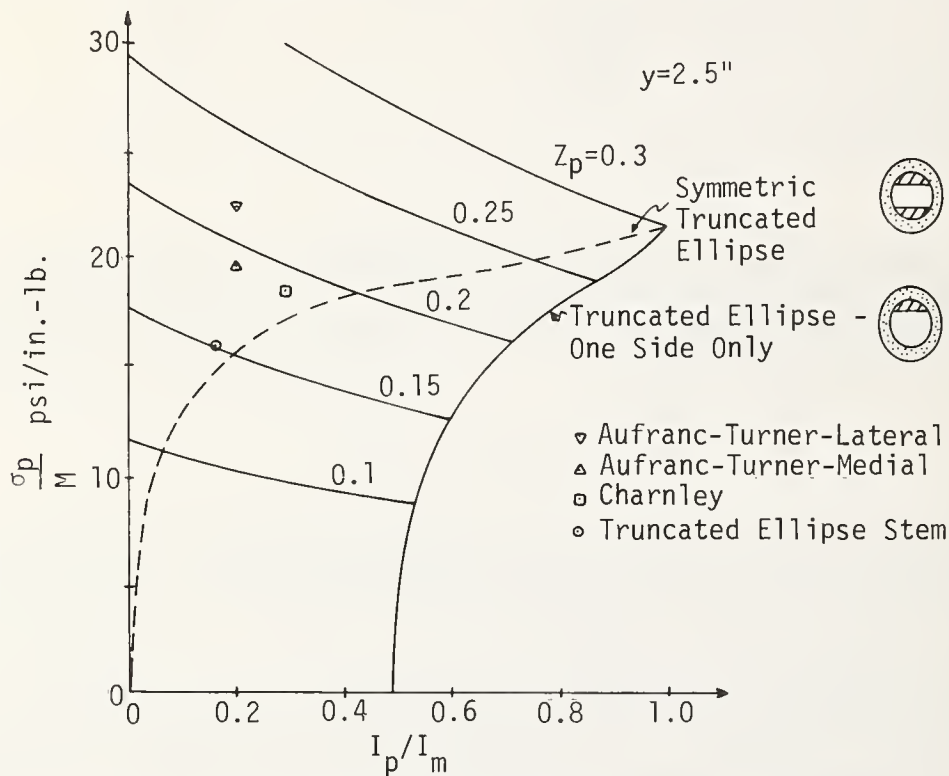


Figure 6. A comparison of bending stresses in stems having the cross-sectional shapes shown in figure 1.

Stresses in the stem are lowest when the moment of inertia and stem height are small, but this geometry also produces large stresses in the cement. Large bending stresses in the prosthesis occur when the stem height is large and the relative moment of inertia of the stem is small, corresponding to a tall, thin cross section. For a given moment of inertia of the stem, bending stresses in the prosthesis are minimized by reducing the stem height. Assuming an elliptical cavity, the resulting shape is a truncated ellipse, filling the cavity in the anterior-posterior direction (see fig. 1). If the stem is truncated symmetrically about the centroidal axis of the bone, then the bending stresses at the medial and lateral extremes of the stem are the same in magnitude but opposite in sign, so the dashed curve in figure 6 gives the stress magnitude at both aspects of the stem. The

lowest stresses in the stem occur on the truncated side of the ellipse when only one side is truncated. This section is not symmetrical, and the lower stress level on the truncated side is produced at the expense of larger stresses on the side not truncated.

A beam-theory analysis of the Charnley and Aufranc-Turner stem designs (see fig. 2) was performed to determine nominal stresses in these stems. To isolate the effects of stem cross-sectional shape, it was assumed that the moment arm of the load with respect to the axis of the bone is the same for each stem. Assuming an elliptically shaped bone and cavity, the maximum bending stresses in the stem at $Y = 2.5$ inches were determined and are shown in figure 6. For bending alone, the largest stresses occur on the lateral side of the Aufranc-Turner stem since it is a relatively tall, thin section. The Charnley stem has lower stresses since it is nearly an inscribed rectangle and lies in a region near the symmetric truncated ellipses. Stresses in the stems are shown in figure 2. Note that the peak tensile stresses in the Charnley and Aufranc-Turner designs occur in the same region where stems are observed to fail. The lowest stresses occur in the truncated elliptical stem with peak values about 15 percent lower than in the Charnley stem. Based on FE studies, it is expected that stresses in the actual system would be somewhat lower near the tip and somewhat higher in the proximal region. Also, since the truncated ellipse has a broader, flat surface over which to transfer the load to the cement, the distortion of the cement at the cement-stem interface should be lower than for the Charnley stem.

The results of this study show that the cross-sectional shape of the stem has a significant effect on stresses in the system. In particular, cross sections that are tall in the medial-lateral direction and narrow in the anterior-posterior direction should be avoided if bending stresses in stems in intact systems are to be reduced. Finally, the study of the truncated elliptical cross section indicates that it may be possible to improve designs by reducing these bending stresses.

6. Discussion

The preceding descriptions and examples lead to the following general observations. First, stress analysis methods exist that can be used to determine reliable values for stresses in implant systems. Second, existing femoral stems are probably operating near their strength limits when implanted in active patients; and finally, the design of the stem does have a significant effect on system stresses and consequently on the expected life of the implant.

Stem design reduces to a problem of determining optimal geometry if the material properties are known. But what should the design objective be? At this point, the answer is not clear. If the goal is to reduce bending stresses in the stem, then the approximate I-sections proposed recently by some are not optimum since the stresses can be further reduced by adding additional material to increase the section modulus. But this procedure will reduce the amount of cement in the cavity, and the question then becomes one of determining the effects of cement thickness on stresses in the cement. Further parametric studies are needed to document these effects and to identify appropriate design objectives which can, in turn, provide the basis for routine design procedures and standards. It also should be noted here that the geometry of the system depends upon surgical procedures since the shape of the cavity and the position of the stem within the cavity are determined at surgery. Here, consistency should be the goal; and devices, procedures, and instrumentation should be developed to insure a predictable position of the implant with respect to the bone.

In order to determine whether or not stresses in particular implant systems are dangerous, one must be able to determine the expected life of the composite. In principle, this determination can be made; but uncertainties exist in values for the fatigue life of the materials, in the magnitudes of loads applied at the joints, and in the effects of boundary and interface conditions. The problem is further complicated because the properties of the system change with time due to bone remodeling and because the activities of patients vary considerably. Fortunately, considerable research effort is being directed toward these problems; and as more reliable information becomes available, better estimates of expected implant life will be possible.

Design evaluations and expected life estimates depend upon the availability of realistic values for the stresses in the components of bone-implant systems. The capability exists, but it must be applied carefully. Particular attention must be given to modeling and interpretation when significant simplifying assumptions are involved such as in beam-theory and two-dimensional FE analyses. In this regard, experiments should be encouraged to corroborate theoretical results and to provide additional measures of system life and performance. Furthermore, the presentation of the results of theoretical and experimental analyses must include a clear description of boundary conditions and assumptions used in modeling so that results from different investigations can be compared and evaluated.

To date, the stress-analysis capabilities have been used to analyze specific designs or to do parametric studies on idealized bone-implant systems. Such investigations should continue and should be directed toward understanding the basic mechanics of the bone-implant composite. Additionally, new designs should be supported and evaluated by detailed stress analyses of the system as a whole and should include estimates of the stresses developed in the bone and the cement as well as those in the implant itself. In the future, these capabilities may also be used to provide additional information. For example, until sufficient data become available for material properties and subsequent calculation of acceptable factors of safety, it may be possible to establish safe stress levels and *in vivo* fatigue strengths by retrospective studies of successful and failed joint replacements.

In conclusion, the mechanical analysis and design of bone-implant systems have become an important component in the development of improved prostheses. Much has already been learned, but there is still much that needs to be known. The performance of femoral stems has proven adequate in many applications; but as the increased number of reports of failures indicates, performance will have to be improved if these devices are to be successfully implanted in more active patients.

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Discussion of Paper:

E. M. Lunceford, Jr., M.D.

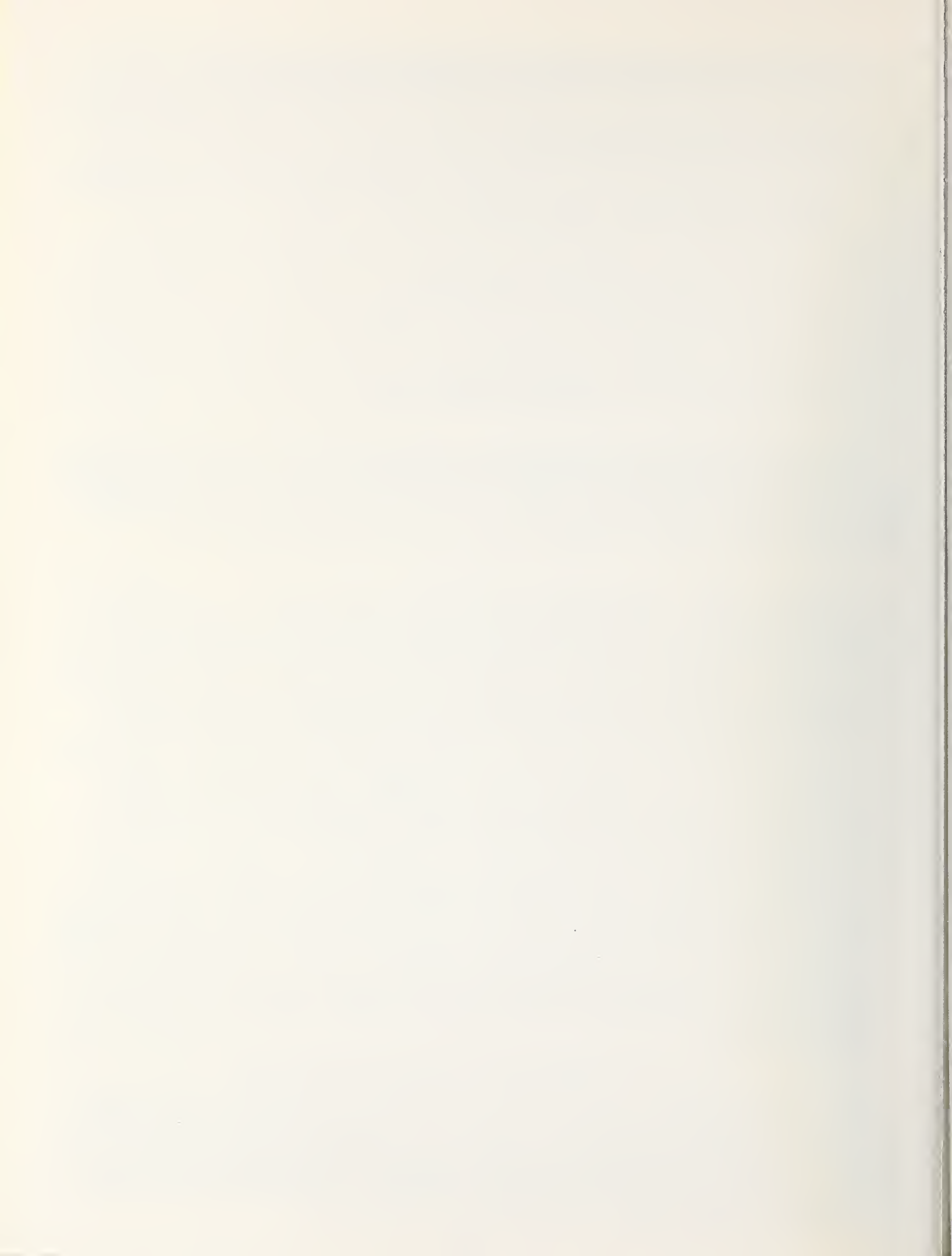
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Dr. Bartel has presented an excellent paper on the analysis of *Femoral Stem Performance*. He has identified the reasons for evaluating performance *in vitro* and *in vivo* or the femoral stems in use and those potentially available. The factors that lead to failure of one of the components may be the result of a single overload or the result of fatigue stress combined with corrosion. One of the factors which he alludes to, but does not stress very effectively, is the problem of polymethylmethacrylate in the entire implant system.

The Finite Element Method of evaluating the implant systems enables us to predict with some degree of certainty the performance of the various implant systems. This method provides us with more information than we heretofore have had available for a critical pre-implantation assessment of various prosthetic components. Dr. Bartel rightfully states that stress-analysis methods exist that can be used to determine reliable values for stresses in implant systems. Many femoral stems are probably operating near their strength limits when implanted in active patients, and it is probably correct that the design of the stem does have a significant effect on the system stresses and consequently on the expected life of the implant. The question as to what the design objectives should be is posed, but the answer is obviously not clearly available. Ideally, an implant system needs to be devised that is more nearly like the bone in which it is implanted; that is, properties should exist that simulate the modulus of elasticity of bone, cartilage, and soft tissue for adequate performance *in vivo*. Since we do not have this information available and this type of material readily accessible, it will be necessary for us to continue utilizing materials that are acceptable and will function under the limitations which we impose. Dr. Bartel gives us further insight into the problems that are present and will enable us to better understand the forces that are at work in this very complex system. He states that fortunately considerable research effort is being directed toward these problems; and as more reliable information becomes available, better estimates of expected implant life will be possible. I would like to commend him for his excellent presentation and further ask if he could propose a femoral stem implant design that will more readily satisfy the requirements imposed by the body in the utilization of these implants. Further, is one particular type of metal alloy better suited to this type of performance than another from a mechanical standpoint? Finally, is corrosion of the implant a significant factor in the failure mode or modes that exist?

Dr. Bartel's Response to Dr. Lunceford's Discussion

Dr. Lunceford's first question points out the fact that there is no single optimum design for all possible applications. The point of the paper is that certain aspects of particular designs can be evaluated and that some improvements can be made in existing designs. As more information becomes available in the future, it may be possible to optimize certain designs for limited classes of applications. The second and third questions are answered in greater detail in other papers in this symposium.



ORTHOPEDIC IMPLANT RETRIEVAL ANALYSIS

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1. Introduction

Our laboratory has recently participated in a project to establish and operate a system for orthopedic implant retrieval and performance analysis. The main purpose of the overall project was to "provide specific and detailed recommendations for upgrading of existing standards for safety and efficacy in the field of metallic orthopedic implants" [1]¹. The data gathered had to be related, where possible, to existing standards (e.g., those by ASTM Committee F4); and the efforts had to be restricted principally to metallic components of implants.

Further, it was required that approximately 100 implants be retrieved and analyzed and that all project activities be completed within 13 months. The performance of other tasks was required before retrieval and analysis so the establishment and operation of the retrieval and analysis system was restricted to the period from fall 1974 to spring 1975.

It was required that all retrieved implants be classified as either "failed" or "successful" whether or not other terms were also used to describe their performance. Lastly, it was required that unused implants that duplicated the retrievals be obtained and subjected to similar laboratory analyses as a means of comparison and of possible identification of implants with atypical or changed properties.

2. Retrieval System

2.1 Solicitation

Procurement of clinically removed orthopedic implants was accomplished on a "good will" basis through the cooperation of the orthopedic community in the Salt Lake Valley and professionally associated orthopedists from surrounding communities. The required number of implants were successfully procured for analysis. The keys to success proved to be the existence of an area-wide resident program covering seven hospitals and the assignment of a first-year orthopedic resident to the project with particular responsibility for implant procurement and collection of pertinent clinical data.

¹Figures in brackets indicate the literature references at the end of this paper.

2.2 Retrieval

An attempt was made at first to identify prospective implant removals prior to surgery to help promote uniform removal and handling procedures, but prior notification usually was not received. The method that evolved most commonly was to have the responsible resident informed of removals by other residents and operating-room personnel after they had occurred. Implants were received from 12 different hospitals.

In addition to some minor variations in removal and postoperative handling procedures due to the number of surgical teams involved, three other problems were encountered. First, since implants were obtained on a "good will" basis from a large number of physicians in a dozen different hospitals, it proved to be impossible to obtain all the removed implants. The principal reason is that other people including the patients, attending physicians, residents, pathologists, and orthopedic manufacturers' representatives often wish to keep the implants, especially if they have failed mechanically or are otherwise unusual. This "competition" for implants was minimized in our study through the involvement of the interhospital residency program but still posed a problem.

In addition, one class of used implants was seldom retrievable for study. These implants are joint replacement prostheses or other semipermanent devices that cause no clinical problems and happen to remain with the patient until he or she dies. Chances for retrieval are small if the patient does not enter the hospital system and is not seen for postmortem examination. Even then retrieval is difficult since requests for permission would often be considered inappropriate or would be poorly received under the circumstances. Retrievals of this type might be accomplished best through prearrangements similar to those used by organ banks.

Finally, there is the problem of implant ownership and confidentiality. We did not become involved in the surgeon-patient relationship with respect to the implants and expected each physician to make whatever arrangements he felt were appropriate. It was considered essential that the identities of the physicians and patients associated with each implant not be made available to anyone outside the project team.

2.3 Handling

When the retrieved implants were picked up, it proved convenient, in most cases, to wrap them in small, cloth, surgical towels to prevent scratching or other damage. Upon delivery to our laboratory, the implants were gently cleaned to remove extraneous blood and tissue using distilled water and, if necessary, a soft brush and a mild low-residue detergent. Care was taken not to disturb areas of corrosion or fracture surfaces.

The cleaned implants were given an identification number and were tagged with a plastic band or adhesive sticker. A master file was created for each implant to serve as the repository of all data. In addition, a log book was kept to show progress in obtaining clinical information and performing laboratory tests for each implant.

2.4 Unused implants

Unused implants were purchased over the course of the study to match as accurately as possible the used implants that had been obtained. The implants were ordered through normal clinical channels at the University of Utah Medical Center with funds transferred from the project to the Medical Center Purchasing Department. To the best of our knowledge, the implants thus obtained had received no special preparation, inspection, or handling and were typical of those received for operating room use at the Medical Center.

3. Analysis System

Both clinical data and implant data are, of course, required as a basis from which to analyze implant performance. The types of information gathered are described as follows.

3.1 Clinical data

The types of clinical data gathered are shown in table 1. Within such categories as "implant application," "clinical reasons for removal," and "surgical findings at removal," the raw data obtained from charts and interviews were expressed as much as possible by using sets of uniform terminology which were arrived at through discussion and experience. Either original roentgenograms or 35 mm copies were obtained.

Table 1. Items of basic clinical data obtained with each removed implant.

Patient age, sex, weight, general condition
Implant type
Implant application (original diagnosis)
Dates of implantation and removal
Clinical reasons for removal
Surgical findings at removal
Roentgenograms (preimplant, postimplant, preremoval)
Bacteriologic culture from removal site
Histologic specimen from removal site

It was not always possible to obtain a complete data set. This situation was particularly true in regard to bacteriologic cultures and histologic specimens. Not all participating surgical teams remembered to take cultures in all cases, and some elected to take them only when there was clinical evidence of infection. It was requested that specimens for histologic examination be taken from the synovial, capsular, or pseudocapsular tissue surrounding the implants. Surgical teams provided specimens for about half of the implants studied.

Standard paraffin sections were prepared from the tissue specimens and stained. They were evaluated for inflammatory response and tissue debris using a technique and classification scheme developed by Mirra et al. [2].

3.2 Implant data

Three general types of implant data were obtained: initial documentation; nondestructive test data; and destructive test data.

3.2.1 Initial documentation

The purpose of the initial documentation procedure was to identify the implant as to its origin and to record its gross condition as received. Most of the larger implants could be identified unequivocally by the manufacturer's trademark and serial number.

Each implant was checked with micrometers and calipers to determine if the implant met the *dimensions* listed for it in the manufacturer's literature. Where applicable, these dimensions were also checked against dimensional specifications and tolerances listed in the various ASTM surgical implant standards. In most cases, this dimensional check was not exhaustive, and only dimensions that appeared critical to implant function were recorded. In all cases, whether or not sufficient dimensional information was available, bends or other geometric irregularities were recorded. They were detected by comparison with catalog photos and unused implants.

Each implant received a thorough visual check for any *surface abnormalities* such as cracks, wear on articulating surfaces, burnishing or polishing of surfaces from moving contact with bone, crevice or fretting corrosion, and scratching or gouging of surfaces other than those which appeared to have occurred at removal. Since the implants would eventually be cut up, each was fully *documented photographically* to record its general appearance and to accurately locate any noted abnormalities.

3.2.2 Nondestructive testing

Each implant was tested for the presence of internal flaws (e.g., casting flaws, voids, irregularities in internal dimensions) and for surface flaws (e.g., cracks, pitting) by the following techniques.

Each implant in the study was examined by *high intensity, high resolution x-ray radiography*. Implants with complex shapes were x-rayed at two or more orientations. The resolution obtained in radiograms of this type is such that a variation in thickness or density of only 2 percent is detectable (e.g., serial numbers stamped on many implants to a depth of only 0.15 mm were readily visible). Because each implant was not of constant cross section in the x-ray exposure direction, it was necessary to record multiple exposures in order to obtain sufficient detail and resolution.

Implants were tested for the presence of surface flaws by a *liquid fluorescent dye penetration* technique. Because of difficulties inherent in controlling both excess dye removal and the uniformity of application of the developing powder for a large variety of specimens, the technique was used only to indicate the presence of surface irregularities, and no reliable measurement of their actual extent was possible. However, reproducible qualitative results were obtained for specimens of a given type such as femoral head prostheses.

3.2.3 Destructive testing

The implants were eventually cut into pieces and subjected to chemical analysis, metallurgical examination, and mechanical tests. Before these procedures took place, the clinical information, initial documentation, and nondestructive test data were reviewed. A decision was made at that time as to which portions of the implant would be most appropriate to subject to destructive tests.

The ASTM and orthopedic implant materials standards [3] specify chemical compositions. It was not possible within the scope of our project to measure all the specified chemical parameters on all of the implants collected (105 used and 73 new implants). However, it seemed appropriate to perform some key *chemical analyses* on as many implants as possible to see if the general range of values corresponded to ASTM standards and to serve as a possible explanation for any unusual amounts of corrosion which we might encounter. The analyses also held some intrinsic interest, since the ASTM orthopedic materials standards do not directly specify or refer to methods of analysis.

All but a few of the retrieved implants proved to be stainless steel or cast cobalt alloy. It was decided originally to measure key metallic alloying elements (e.g., Cr, Ni, Mo, and Mn in stainless steel) and carbon content on as many of these implants as possible. Initially, atomic absorption spectroscopy was selected for metallic element analysis because of the ease of sample preparation and the ability to measure overall (rather than local) composition provided by putting materials into solution. The method worked well for stainless steel but proved impractical for cast cobalt alloy due to difficulties in completely dissolving the material. An alternative, a limited number of cobalt alloy analyses by spark emission spectroscopy were obtained at an outside laboratory. The data appeared somewhat scattered, perhaps because of localized inhomogeneities detected in the single spot analyses. A small number of carbon analyses were also obtained and did not prove to be reproducible enough to assess a general correspondence to ASTM specifications.

Sections of most implants were subjected to *metallographic evaluations* including grain size, inclusion content, and porosity (for cast materials). For stainless steels, standard ASTM methods were used for grain size (ASTM E112-63) and inclusion content (ASTM E43-63 Method D). For cast cobalt alloy, no standard semiquantitative method is available for measuring inclusion content or porosity; therefore relative, qualitative observations were made. Cast cobalt alloy grain size (much larger than for wrought stainless) was evaluated using a modification of ASTM E112-63.

The fracture surfaces of implants that fractured while implanted were analyzed for failure mode using optical microscopy, scanning electron microscopy, and carbon replica transmission electron microscopy.

Three different types of *mechanical tests* were performed. Knoop microhardness measurements were made near the surface and at the interior of the metallographic specimens. Also, tensile specimens were machined and tested from the larger implants. Because of dimensional restrictions, it was necessary to use specimens smaller than those specified by any applicable ASTM standards. Lastly, a number of intact devices (bone plates, intramedullary rods, and hip nail plate devices) were subjected to bend tests according to methods described by ASTM (F382-73, F383-73, and F384-73).

3.3 Performance analysis

As the project progressed, it became evident that it was necessary to review the clinical information, initial documentation, and nondestructive test data on each implant so that a decision could be reached on the manner in which subsequent evaluations should be made.

After presentation of the information on each implant and an ensuing discussion, summary notes were dictated for the implant file. Initial impressions of implant performance were also recorded; and a decision was made as to how to cut the implant up for chemical, metallurgical, and mechanical tests.

It was as a result of these discussions that the project team eventually developed what is considered to be a workable scheme for analyzing and classifying implant performance. The scheme is based on recognition of the conditions of implant removal and the causes of adverse clinical conditions leading to required removals.

The relationships which we believe exist among conditions of removal, implant success or failure, and overall clinical success or failure of the surgical treatment involving the implant are shown in table 2. The following definitions may be derived from this table:

Table 2. The relationship of implant success or failure to conditions of removal and clinical performance.

<u>Conditions of removal</u>		<u>Implant success or failure</u>	<u>Clinical success or failure</u>
Incidental (after unrelated death, during other surgery)		Success	Success
Routine (fulfilled function)		Success	Success
Required (adverse clinical conditions exist)			
misapplication	Clinically related	Success	Depends on degree and duration of anatomic correction achieved
suboptimal surgical technique			
physiological limitations			
unforeseen patient condition			
patient abuse			
Causes			
mechanical design deficiency	Implant related	Failure	
materials degradation, incompatibility			
mechanical or materials manufacturing error			

A successful implant is one that has been removed incidentally (after unrelated death or during other surgery), routinely (having fulfilled its function and being removed for precautionary purposes), or because of adverse clinical conditions not principally caused by the implant itself.

A *failed implant* is one that has been removed because of adverse clinical conditions principally caused by the implant. The general types of implant-related causes are mechanical design deficiency, materials degradation or incompatibility, and mechanical or materials manufacturing errors.

It is apparent that there is often no clear-cut line between implant success and failure. Adverse clinical conditions may have both clinically related and implant related causes. Also, since clinical implantations are not controlled laboratory experiments, the data collected are seldom complete enough to identify unequivocally the causes of adverse clinical conditions.

Inevitably, therefore, the identification of principal causes and subsequent identification of failed implants involve subjective judgment and depend on the background and orientation of those doing the judging. The team responsible for analyzing the performance of these implants consisted of orthopedists and independent test laboratory scientists and engineers involved full time in medical device and materials test and evaluation. Our analyses represent a consensus judgment for each implant based on multiple individual and group reviews of the available data. It can be expected that a different project team might analyze the performance of any given implant somewhat differently.

4. Results of Performance Analysis

4.1 Overall

A total of 106 removed implants were obtained and analyzed as has been described. The distribution of devices studied by implant type is shown in table 3. According to the definitions established, we encountered 2 incidental removals, 48 routine removals, and 56 required removals. Nine of the required removals were further classified as failed implants as shown in table 4.

Table 3. Distribution by implant type of devices received and analyzed.

<u>General use category</u>	<u>Implant type</u>	<u>No. received and analyzed</u>
Partial and total hip replacement devices	Hip cups	9
	Femoral head prostheses	11
	Total hip prosthesis	11
Partial and total knee replacement devices	Tibial plateaus	1
	Total knee prostheses	6
Large fixation devices	Bone plates	20
	Hip nails and nail/plate devices	25
	Intramedullary rods	6
	Spinal distraction devices	2
Small fixation devices	Pins and wires	7
	Bolts	2
	Bone screws	3
	Staples	3
	Total	106

Table 4. Failed implants.

<u>UBTL No.</u>	<u>Type implant</u>	<u>Type failure</u>	<u>Failure location</u>	<u>Possible principal cause</u>
129	Cast cobalt all metal total hip	Single overload fracture	Femoral stem	Materials manufacturing error
028	Cast cobalt all metal total hip	Incompatibility	General	Material selection
132	Cast cobalt-PE total hip	Fatigue fracture	Femoral stem	Materials selection and/or manufacturing error
144	Neufeld femoral nail plate	Fatigue fracture	Proximal screw hole	Mechanical design
142	Stainless steel Jewett nail	Fatigue fracture	Proximal screw hole	Materials manufacturing error
133	Stainless steel Dyerle hip fixation device	Materials degradation	Pins	Mechanical design
125	Stainless steel Hansen-Street IM rod	Overload bending	Mid-rod	Materials manufacturing error
017	Stainless steel Steinmann pin	Single overload fracture	Mid-pin	Unknown

We do not know the statistical relationship between the number and types of devices *received* for study and the numbers and types actually *retrieved* by the surgeons participating, since the implants were collected under a voluntary system involving a large number of surgeons and hospitals as previously described. For similar reasons, we do not know if the ratio of failed to successful implants is representative of clinical experience. If anything, we would expect that the surgeons tended to present us with more "unusual" implants (e.g., joint replacement prostheses and implants that had become altered mechanically during service) and perhaps neglected to pass on all routinely removed fixation implants (e.g., bone plates).

With these factors in mind, it can be noted with caution that four of the nine implants classified as failed were total hip prostheses, and seven of nine were either total hips or hip fixation devices (see table 4). Roughly one-third of the 106 devices retrieved and analyzed were of these two types. This retrieval and performance pattern suggests both the high interest that orthopedists have in these devices and the difficulties inherent in designing and fabricating devices to repair the body's principal joints.

4.2 Specific examples

Descriptions of performance analyses for each of the implant categories in table 3 have been reported elsewhere [4]. For purposes of illustration, performance analyses for two types of implants are discussed below.

Femoral head prostheses offer a good example of some of the difficulties of retrieved implant performance analysis, especially when implant success or failure must be specified. Eleven of these devices were retrieved and analyzed. The period of implantation for 10 ranged from 1-1/2 to 18 years. The remaining device was removed after 6 months because of the presence of infection. This device was classified as a required removal, and the infection was deemed ascribable to surgical technique. In accordance with table 2, the *implant* was therefore "successful" even though the *procedure* clearly offered little *clinical* success.

Categorizing the performance of the remaining 10 implants posed problems. They might have all been classified as clinically required removals since adverse clinical conditions typically were present (e.g., pain, deterioration of articular cartilage, loosening of the femoral stem). Furthermore, these conditions might be attributed to implant design factors, particularly the high stiffness (compared to bone) of the femoral stem. Some case could be made, therefore, for classifying the implants as failed. No evidence was found, however, of significant manufacturing errors, materials degradation, or chemically induced tissue incompatibility from the laboratory data.

After considerable thought, we decided that these implants were actually routine removals and, consequently, successful because, in our opinion, the removal of these devices was an anticipated event at the time of surgery. The prostheses are not usually cemented in place, and loosening can be expected to occur in some cases. Similarly, the high stiffness of these devices compared to bone contributes to loosening but is accepted because of no available alternate material.

In retrospect, the implants might also have been classified as required removals by adding a new item to the list of clinically related causes of adverse conditions: known limitations of the surgical technique. The implants would still be described as successful in that case.

One *total hip prosthesis* that was studied represents what we believe is a relatively clear case of a failed *implant*. This device had a conventional polyethylene acetabular component but a *cast* stainless steel femoral component. The femoral stem failed in cyclic fatigue followed by single overload fracture after 1-1/2 years of service as shown in figure 1. In our opinion, there were no major contributing clinical causes of the failure. Cementation was not optimal but appeared adequate.

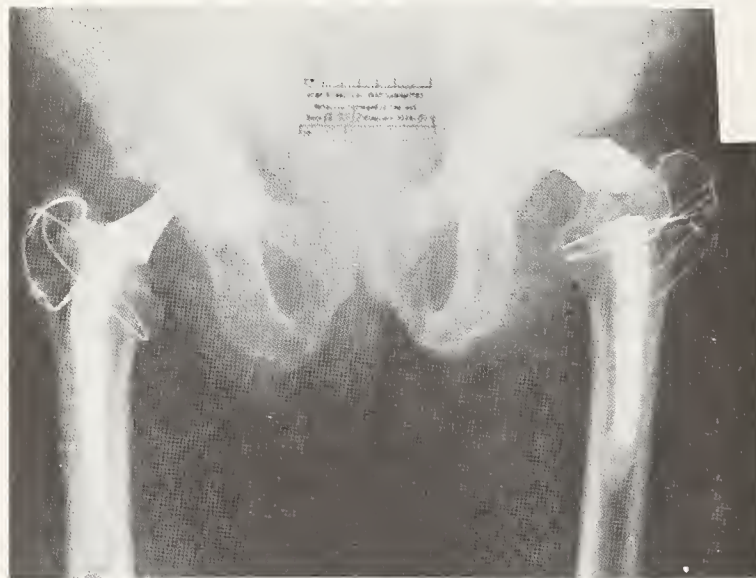


Figure 1. Roentgenogram of cast stainless steel femoral component which fractured 1-1/2 years after implantation.

On the other hand, there was considerable evidence of what we regarded to be materials and mechanical manufacturing errors in the context of this relatively critical application. First of all, cast stainless steel proved to be generally the least strong and softest of the metallic implant materials tested. Three cast stainless steel femoral components (one used and two new) had an average tensile strength of 5016 kg/mm² and a surface Knoop Hardness Number (KHN) of 205. By comparison, 30 conventional cast cobalt alloy femoral prostheses and components had an average tensile strength of 74.4 kg/mm² and a surface KHN of 363.

The strength and hardness of the cast stainless did approach the values for annealed wrought stainless steel (typically used for hip nails), but the cast material does not offer any of the advantages in fatigue life and toughness generally ascribed to the finer grained (by a factor of about 100) and less porous wrought material. We found that the low

hardness, besides indicating lower strength, meant that the cast stainless prostheses were easy to scratch during handling. Scratches on the stem during installation could serve as sites for the initiation of fatigue cracks or stress corrosion cracking. In short, we believe that the cast stainless steel material is an intrinsically poorer choice than cast cobalt alloys or wrought stainless steel in this application.

In addition to the inferior mechanical properties of the basic material, we found evidence of less than optimal manufacturing procedures. The inclusion content appeared to be generally higher than that observed for wrought stainless steel and markedly higher than that observed in cast cobalt alloys. Finally, the two new cast stainless prostheses purchased for comparison showed surface irregularities on the femoral stem in the same area that the failure occurred on the used prosthesis. These irregularities were visible to the naked eye and also produced a positive response in dye penetrant tests.

5. Conclusion

1. A retrieval system that can provide relatively large numbers of orthopedic implants for study with appropriate clinical data can be based on implants voluntarily relinquished by interested surgeons. The communication channels available in a multihospital residency program augment such a system.
2. Not all implants removed will be available for study in a large volunteer system due to "competition" for the implants from other interested parties. Also, implants are not generally available from patients who expire from unrelated causes.
3. A working method for analyzing the performance of retrieved orthopedic implants can be based on recognizing the circumstances of removal and identifying as well as possible the principal causes of any adverse clinical conditions leading to removal. This procedure is accomplished through the review of clinical data and laboratory examination and analysis of the implant.
4. Performance analysis becomes somewhat more complicated conceptually if the implants must be classified as successful or failed.
5. Since clinical implantations and removals are not controlled laboratory experiments, the data are seldom complete enough to identify the causes of adverse conditions with total certainty. Therefore, subjective judgment that reflects the background and orientation of the evaluating team must be recognized as a significant factor in analyses of this type.
6. Many of the failed implants encountered in this study were hip replacement or fixation devices. Such failures are thought to reflect the difficulties inherent in designing and fabricating devices to repair the body's principal joint. Possible causes of failures included prosthetic materials biocompatibility, mechanical design, and materials manufacturing errors.

This work was performed as one of several tasks required under FDA Contract 223-74-5252, "Research Evaluation of Performance Requirements for Metallic Orthopedic Implants."

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Discussion of Paper:

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Anyone who has undertaken the task of retrieval and analysis of orthopedic implants is aware of the many problems that must be overcome in order to obtain not only the implants but all of the supporting information. I should like to commend the present authors on their attempts to overcome these problems.

I should like also to comment on several specific areas of this research. The first area concerns the necessity of classifying implants with regard to "success" or "failure." While the authors have established their own criteria for determining failure, as they themselves point out, it is still basically a judgment situation and open to interpretation. Different groups analyzing the same data and using the same criteria for classification into "success" or "failure" will ultimately establish different numbers for these two categories. It is interesting to note that only 9 of 106, approximately 8-1/2 percent, of the implants analyzed in this study were termed "failures." The authors imply that this number is probably not representative because they were prone to receive the more "unusual" implants and not necessarily all routinely removed devices. Assuming this to be true and noting that by their definition a routinely removed implant is a success, then the percentage of failed implants can be expected to be somewhat less than the 8-1/2 percent reported in this study. Taking into account a certain number of implants that have performed successfully and are never retrieved, the percentage is reduced even further. If we simply focus our attention on "failed" implants, we are going to spend an enormous amount of time, energy, and money on a very few implants; in fact, the implication in my mind is that very few implants "fail." I do not believe this to be the case, and I also do not mean to imply that I agree with the classification system of "failure" or "success." One cannot simply rule out all of the clinically related causes for implant removal and state these to be defined as successful implants. Obviously, on the other hand, we cannot classify them as implant failures. We must avoid this misnomer if we are to use the information generated in device retrieval studies to improve upon implants.

My second comments are associated with the conclusions, based primarily on the analysis of one fatigue failure, regarding cast stainless steel. First, I would question the cement fixation because of the radiolucent seam between the cement and bone on the medial aspect. Note the lack of this seam on the contralateral side. However, it is interesting to note that the cast stainless steel is least desirable from a mechanical property point of view. Perhaps more research should be performed before a condemnation of the material is forthcoming.

My third comment is with regard to the failure reported to be incompatibility of a cast cobalt, all metal, total hip prosthesis. I find this to be particularly startling in light of the fact that ASTM F4 has issued its first standard of compatibility testing based on a comparison with the cast cobalt-chromium alloy.

I would like further to point out that 47 percent of the author's implants were removed routinely. Several years ago I reported a study of 133 consecutive implant removals in

which an analysis revealed that of 100, only 16 percent were removed routinely, and that of the total 133 (including all percutaneous pins and wires which are always removed routinely and none of which are included in the present study) at least 37 percent were removed routinely. If these percentages are further normalized to account for the fact that only internal fixation devices are routinely removed, then in the present study, 81 percent were routinely removed as compared to 20 percent, a fourfold difference. I wonder whether or not orthopedic surgeons have changed their attitudes with regard to removal of internal fixation devices in the last 7 to 8 years.

In summary, I would like to suggest to the authors that they rethink their data in terms of a comparison of implant design and properties for implants removed for cause, be the cause clinically related or implant related with implants removed routinely.



LEGAL ASPECTS OF DEVICE RETRIEVAL

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Our firm represents Zimmer-USA, Inc., one of the major orthopedic implant manufacturers in the United States. Included in this representation is the primary responsibility for the defense of all their product liability claims. As a result of the experiences we have had in the defense of these claims, we have been able to observe many recurring problems in the manufacture and utilization of orthopedic implants. These observations include problems involving the retrieval of failed implants. My remarks primarily are stated from the viewpoint of a trial attorney and concern the problems that would be encountered in the preparation and trial of a lawsuit; however, many points that I will discuss also could be used in an effort to avoid claims and ultimate litigation. Several areas of particular relevance to the symposium theme are:

- (a) a general background regarding the nature of product liability litigation;
- (b) the retrieval of fractured implants, including ownership and proper documentation and handling of the fractured device;
- (c) legal considerations and investigative reports;
- (d) trial-related problems and testing methods; and
- (e) an overview of effects of regulatory and industry standards.

From a legal and nonlegal viewpoint regarding implant retrieval, the primary concern is with those implants that have in some way failed while in use. Before a specific discussion of legal problems relating solely to implant retrieval, it would be worthwhile digressing to consider the law of "Products Liability" generally and the related area of medical malpractice. An ever-increasing number of legal actions are instituted as a result of implants that have failed in use. This number is not limited to the orthopedic field, but also involves all other types of medical implants such as pacemakers, heart valves, blood vessel replacements, and other artificial organs. In order to fully understand the total ramifications of the retrieval of orthopedic implants, it is vital and important that all those concerned with the development of such devices, including those persons retrieving devices for use in the evaluation of better methods of manufacturing, have an understanding of the problems and trends in product liability litigation at the present time.

In the first instance, it must be remembered that while orthopedic implants have been in use since the early 1900's, only recently has their full potential been utilized on a large scale by the medical community. Implantation is a young science in the area of medicine, and it is realized by all concerned that we are probably a long way from developing the perfect implant.

Also, products liability is a relatively new concept in the law of litigation. Basically, civil litigation is seen as being for the purpose of proving restitution for injuries that have occurred to either persons or to their property and for the purpose of deterrence to other persons from committing negligent, careless, and harmful acts. For example, one of the reasons that we have developed the law of negligence with regard to the operation of automobiles is not only to provide compensation to those persons injured in an accident, but also to serve notice upon the public in general that speeding, running a stop sign, or committing other traffic violations are not to be encouraged; and when such activities involve injury to another person, then a person is held accountable for his actions.

Products liability, on the other hand, involves the payment for injuries arising to a person even though there is no discernable fault. In other words, if there is a defect in a product manufactured by a producer of any consumer item, including the ones that we are discussing here today, and even though a defect could not be discovered by reasonable methods of quality control or assurance, liability is still imposed upon a manufacturer if it is shown that a defect in the product caused an injury to the consumer. Accordingly, in defending manufacturers, we continually are faced with the problem that even though there is no fault on the part of the manufacturer, liability may still exist. It is essential that we take into consideration when arriving at standards and methods for retrieving orthopedic implants, the total consequences of all of the reports and standards that are developed and imposed upon the manufacturers of such devices.

As I indicated, we are at the very beginning of a new science that is designed to provide improved medical care for the public. No science is developed overnight and without some trial and error. While the basic concepts of product liability litigation provide exceptions and recognize the development of scientifically useful products which may not be perfect at any given stage of development, as a practical matter these exceptions are not regularly followed by the courts. As a result, we find liability imposed even though it is generally acknowledged in an industry or a science that no other reasonable alternatives were available at the time the product was developed. Further, it should be recognized from the outset that in the area of product liability litigation, we are continuing to find an ever-increasing number of expert witnesses who will testify that defects exist whether or not in fact they can be substantiated in truth. While it is somewhat alarming to me as a litigator, it must be recognized that an expert exists somewhere who will find a defect in any product that has failed. It must be assumed by the attorney defending a products liability case that the other side will, in fact, produce someone who will find some fault with the product and thus allow the case to be submitted to a jury where factors other than the technical aspects of the case will be taken into consideration.

I personally do not feel that the ultimate goals for the creation of product liability litigation have been achieved. The ultimate achievement was hopefully the reduction of defective products that are received and used by the consumer. Rather, I think we have created an albatross that finds more and more reasons for imposing liability upon manufacturers for conditions which cannot be substantially changed by them and make the manufacturers actually absolute insurers of anything that goes wrong with their products. Further, to complicate this matter, we are finding ourselves in an era of increased governmental controls and standards set by persons not directly involved with the manufacturing process, and we find standards developed for entire industries even though various products within a given industry may have totally different characteristics and problems associated with them. We find arbitrary standards being applicable to all. It would indeed be foolhardy for independent organizations, manufacturers, and the Government to ignore the increasing rate of private civil litigation when establishing new rules and regulations and publishing reports and findings on how products should be improved. No single product is on the market today that could not be improved in some respect, and this fact alone has unfortunately led to some very unjust results in the area of product liability litigation. Accordingly, with this background in mind, I would like to turn to some of the particular problems that we are faced with in the area of product liability litigation as it applies to orthopedic implants.

The first problem that is encountered in the retrieval of orthopedic implants is the right of the hospital, attending physician, or other person to obtain the implant after it has been removed from the body of the patient. The ownership of the device undoubtedly belongs to the patient; and in the litigious society in which we now live, it is not unusual to find that the patient has consulted an attorney prior to the operation for the removal of the broken device. Accordingly, the orthopedic device, like any other piece of merchandise that can be bought on the open market, belongs to the patient and not to the doctor, the hospital, manufacturer, or other interested party. The tendency heretofore has been that broken devices are either thrown away or discarded or, in the cases where litigation has been anticipated, are retained by the hospital; and often hospitals refuse to return the same to the patient. Certainly, such retention works as an advantage to the potential defendants; however, it would certainly run contrary to existing law concerning the ownership of property. Accordingly, in any case in which the device is requested by the patient, it is an obligation of the hospital or the physician to retain the same for the patient. If any of the interested parties or potential defendants were to take the device over the

objection of the patient and subject the same to any type of testing or evaluation, there could be liability for the refusal to deliver the property to the patient. Therefore, thought should be given to the preparation of some type of release to be signed by the patient, either immediately prior to or after surgery for the removal of such devices, allowing the hospital, physician, or other investigating body to retain the ownership of the device. Unauthorized control over such devices could subject parties to not only criticism, but possibly even ultimate liability. Accordingly, thought must be given to obtaining possession of the devices as well as considering how they are to be retrieved.

Next, we must take into consideration the retrieval of the implants themselves. Again, it would be greatly beneficial for those engaged in the actual removal of the broken devices, when removing such devices, to consider litigation that may be pending or forthcoming. We must anticipate the possibility that litigation will be involved in a large number of cases, and the time the device is removed from the patient is the one occasion when a great deal of evidentiary information can be obtained for such litigation. Unfortunately, in most of the cases in which I have become involved, litigation is either not taken into consideration or it is completely ignored. Most medical records involving failed orthopedic devices contain little information useful to the potential parties to a lawsuit.

More concern and attention should be directed to the patient's immediate activities prior to his admission to the hospital. Unfortunately, the initial conference between the doctor and patient upon the discovery of the broken implant has led to more misunderstanding and probably caused more lawsuits than any single factor. While it is exceedingly well known in the orthopedic field that most of the orthopedic devices are merely fixation devices and not designed to replace bone or bone tissue and therefore not designed to withstand unsupported stresses of weight bearing over any extended period of time, it is amazing how many physicians on initially discovering the broken device put up their hands in horror and say, "Oh, my God, there must be something wrong with the metal," or "I've never seen anything like this happen before," or "I don't know what could be wrong," or "It must be the fault of the manufacturers." Thereafter, the doctor is often contacted by an attorney who says, "Doctor, we want to assure you that we have nothing against you. We're only against the manufacturer of this terrible device; please cooperate, and we will not sue you because we think you're the greatest." However, as is often the case, the doctor is shortly thereafter disturbed by the sheriff knocking on the door and to his amazement finds he has been named as a defendant in the case after all; at this point he realizes he can trust no one. Unfortunately, the damage has been done, and attention to the truly relevant facts may have been ignored. Accordingly, if I were to suggest any one thing to physicians who discover or find themselves in the position of treating a patient with a broken implant, it would be to obtain a very careful and exact history of the patient's activities since the implantation of the implant itself. Moreover, he should carefully review all of his instructions to the patient and review the x-rays and other relevant records that he has made over the course of treatment.

The single greatest factor in the failure of the temporary fixation implants that I have observed to date is the repeated abuse of these devices by the patient either as a result of ignoring physician's instructions or the physician's failing to give the proper instruction. Also involved is the unfortunate, but not unusual, circumstance that the clinical observations of the patient by the doctor together with x-rays, which are sometimes inconclusive with regard to healing, result in a situation where the patient is permitted to become weight bearing before union is complete. I would say that in the vast majority of all the cases involving fixation devices that have proceeded to litigation, the fracture of the device in question occurred at the point near or at the fracture site of the bone itself. It is amazing how many defects just by chance seem to exist at the place of the original fracture of the bone itself. It would be hard to calculate the probability of this happening in almost every case. In any event, it is extremely important that before the removal is attempted, a very careful and detailed history be obtained regarding all relevant information. However, it should be noted that if the patient has already seen a lawyer or is put on the defensive by a doctor, the answers that are obtained from the patient will not always be entirely reliable; and as a matter of fact, you can count on the patient's saying that he always followed the doctor's instructions and never varied one iota. Therefore, efforts must be made to go beyond information supplied by the patient himself.

It is important to note that from a legal viewpoint we are most concerned with evidentiary matters which will be preserved for presentation to a court if a suit is filed. Accordingly, after collection of the initial information concerning the failure of the implant, attention is directed to its actual removal.

Since nonunions and delayed unions are present in the vast majority of all cases involved in the failure of implants used for temporary fixation, these terms should be understood and defined. Unfortunately, both terms have been susceptible to many definitions by different physicians. A nonunion is classically defined as a total lack of healing that will not develop into healing. Often it is referred to as fibrous union. Most physicians agree that once a nonunion has occurred, it will require a subsequent operative procedure and bone grafting to achieve final healing. The problem that arises is determining when a nonunion has, in fact, occurred. The disagreement appears to be on the time factor; and while some doctors will testify that a nonunion can occur as soon as 3 months after initial surgery, others say it takes 6 to 9 months or even 12 months before they can definitely diagnose that a nonunion exists.

A delayed union is more easily defined. It is a union that has not healed as fast as one would ordinarily expect and could develop into either union or nonunion. Again, there seems to be disagreement as to when a delayed union occurs. Most physicians seem to indicate that healing begins to occur in a fractured femur almost immediately after reduction has occurred and that the normal healing or substantially normal healing period will be between 2 and 4 months depending upon the age of the patient and the location of the fracture; but it must be understood that during the entire healing process, less and less stress is placed upon a metallic implant as a result of the healing and more stresses are absorbed by the bone. In either, the delayed or nonunion situation, healing is not occurring at any substantial rate; and during the period of either nonunion or delayed union, excessive stresses are placed upon the implant, thereby increasing the chances for failure of the device itself. Thus, when a physician first observes the fracture site, careful records should be kept as to the exact findings with regard to the fracture site itself. One of the most important hospital records that is often missing or nonexistent in these cases is the lack of a pathology report as to the condition of the bone at that site. This one record, showing evidence of fibrous tissues or nonunion or delayed union would probably do more to help all of the potential defendants than any one other single factor. Also, the physician should carefully document what he observes when he goes into the fracture site. If he sees nonunion or delayed union, he should carefully document this information in order that all of those who review the records and become involved in the potential litigation are fully aware of the circumstances at the operative site. The physician who goes in to remove the device will have the best opportunity of making a judgment as to the condition of the bone fragments.

Furthermore, a detailed inspection should be made of the device itself before any attempt is made to remove it. Most orthopedic manufacturers highly recommend that all metallic devices not be bent, scratched, marred, or in any way damaged prior to insertion. Most manufacturers also highly recommend that noncompatible metals not be used for the insertion of any device. Unfortunately, it is not always possible to avoid bending a device or scratching or otherwise marring the surface of an implant. At the present time, we are greatly limited in the size of the implants that are used, the design of the implant, and the types of metals that are used. We must use those metals that are compatible with the body tissues and are not susceptible to high rates of corrosion. Because God made the original bone, we are limited by the size and shape of the bone as created; and we have to design implants with these limitations in mind. Sometimes the best engineering concepts are not available to the manufacturers of orthopedic implants. Further, depending on the severity of the type of the injury that the physician faces when he proceeds into the operative site, he must on occasion bend or scratch the device in order to make it fit properly. I would highly recommend that where a device is bent, it should be noted in the original operative report that it was necessary to bend the device for proper insertion. The patient should then be warned of this additional problem.

In any event, before a device is removed, observation should be made as to all highly visible markings that are on the device. This procedure will give some idea as to what additional marks, scratches, or problems resulted to the device during the removal process. In the case of medullary rods, it is not unusual that the fracture surfaces have been rubbing against each other for a period of time following the fracture of the rod and that the

fracture surfaces have become destroyed or greatly damaged. This damage should be noted in the original report involving the removal of the device. Also, with litigation in mind, care should be taken to avoid making unwarranted or speculative remarks in the operative report. For example, tissue or blood deposits are very often confused by the nontrained observer as corrosion or metallic problems. Only after careful cleaning is it discovered that what was thought to be evidence of corrosion was nothing more than dried blood or other body tissues that were on the implant itself. In addition, unwarranted speculation as to the reason or cause of failure should be avoided in the operative report. It is unbelievable how many physicians record statements such as, "We took out the defective rod." This kind of remark can cause all kinds of grief to everyone involved at a later date. Further, after the removal of the implant itself, a great deal of care and consideration should be given to the packing of the device and the handling before its examination by either the patient or some other person investigating the reasons for the implant's failure.

Naturally, one of the ultimate goals for the study of retrieved implants is the hope that we will be able to improve the methods of manufacturing the devices, to discover new metals able to be used in implants, and to improve design. However, a great deal of caution should be exercised in the accumulation of the data obtained from the analysis of the broken implant, and still further consideration should be given to the publication of standards or reports for improvement. Considering the vast number of implants available today and the various uses to which they can be put, the failure rate is extremely low and one which everyone can be proud of. Unfortunately, this pride does not keep companies from being sued and does not mean that study for improvement should not continue. Nevertheless, any study with the idea of improving existing methods must keep in mind the dangers that are likely to flow from the suggesting of radical improvements and the condemning of past practices. For example, I have recently reviewed the Utah report, some of which appears in these proceedings. This report sets forth various considerations that were felt very important in the analysis and retrieval of broken implants and drew conclusions regarding those implants that failed the purpose for which they were intended. The most obvious oversight, however, was the fact that the investigators did not have available to them adequate reports of the actual usage to which the implants have been put by the patients themselves. This single factor must make the report suspect in terms of ultimate implant failure. We must keep in mind what the devices were originally intended to do and how they actually performed under clinical conditions. This factor is the single most important one in the investigation of the reason for the failure of orthopedic implants. Accordingly, I think any published results must be very careful to note whether or not they contain all of the information that is relevant to them before the publication.

The next fact to be taken into consideration is the actual metallurgical examination of the devices themselves. This area has led to a great deal of misunderstanding in litigation. Unfortunately, there are as many testing methods as there are metallurgists to perform such examinations. It is true that there are some very commonly accepted methods of testing such as microscopic examination of the surfaces of the material, chemical analysis, spectrographic analysis, electron microscopic analysis, and hardness tests. However, standards as to how such tests are conducted do not appear to be consistent. Further, because the metals used in most orthopedic implants are highly refined and not commonly found in ordinary manufacturing processes, many of the experts who have the opportunity to examine the devices are not fully familiar with the techniques involved in the manufacture of implants, their material content, or the reason for some of their unusual designs. Therefore, we very often see experts finding fault with such devices when they are not actually aware of the total circumstances or the problems involved in the manufacture or use of the device. We also find many different experts looking at the same conditions, the same fracture surfaces, or the same specimens and defining them differently. Two of the most commonly confused results or conditions are stress corrosion cracking and fatigue failure. It is obvious that they must have extremely similar characteristics as the two conditions are invariably found in a large number of the cases of failed implants. I am not certain what methods or studies should be undertaken to clarify this situation; however, it is obvious, whether the condition is referred to as stress corrosion cracking or fatigue, that it is one of these conditions that occurs with some degree of regularity in the cases of early weight bearing or extended weight bearing in a nonunited situation. Accordingly, I would urge attention be given to the defining of the various conditions that are found by investigators and that some effort be given to reconcile the different results found by different experts with regard to the same problem.

Naturally, as I previously stated, as a result of all of the findings, certain standards and possibly even laws or regulations will be enacted by independent bodies such as ASTM or through regulations enacted by Congress. One of the greatest dangers we have in this area and one that you should be aware of is the legal result of the imposition of standards which cannot be reasonably met or followed or are arbitrary to an industry as a whole and apply to devices for which the standards really do not apply. One result of this imposition of standards would not necessarily be the improvement of existing or new products, but rather the creation of a new type of liability for doctors, physicians, hospitals, and orthopedic device manufacturers. We have in our civil law a doctrine of negligence per se. Basically, negligence per se refers to those situations for which there is a statute, and the violation of the statute results in some type of injury. For an example, one of the obvious types of negligence per se is when somebody runs a stoplight and collides with an automobile that is using the intersection properly. It is not necessary to prove that the driver was not paying attention or was negligent in looking out for other traffic. You only have to prove that there was a statute that put the stoplight there and that the person ran the light. You then have proven your case, and you are entitled to go to a jury or to have a jury determine that the man was negligent. No further proof is needed other than the fact that the statute existed, that the person ran the light, and that the person who was injured was one of the class of people who would be protected by that statute.

When we create a standard setting forth that certain steps will be followed in the manufacture of an implant and if a plaintiff is able to show that any single step was not followed, regardless of whether or not the failure to follow that standard had any material effect on the implant itself, liability could be imposed. Further, we can adopt standards for the types of material or the exact chemical contents; and even though there may be some minor variations in the chemical content of each individual batch of material, if the chemical content differed from that prescribed by the law, you would have negligence per se. You then would have a case going to the jury even more easily than under the rules of products liability. It becomes very disconcerting that when we pass regulations for controls in consumer areas, we fail to recognize the total effects of such regulations in the area of litigation. Everyone is aware that the FDA is currently considering the enactment of standards with regard to medical devices. Unfortunately, there is a large variation of medical devices controlled by the proposed law, and I personally feel that it is impossible to enact one set of regulations that can apply to each type of device. Further, each type of device has different internal standards by which failure is judged. One of the interesting aspects of the proposed regulations is that every time a failure is reported to a company, it must be reported to the FDA within a certain time limitation. If this is not done, criminal liabilities can be imposed on the chief executive officer of the company. This failure to report also could, under certain circumstances, impose civil liability and afford a patient a "cheap shot" at recovering against the manufacturer. The problem exists that within the orthopedic industry the mere breaking of the metallic device is not necessarily considered a failure. As a matter of fact, in a huge number of cases, the breaking is not considered a failure at all and is related to the misuse of the product by the patient. The requirement that all breakages be reported not only is going to create or have the tendency to create more litigation, but will oblige companies to recognize something as a failure which heretofore they have not considered a failure at all. This situation is somewhat analogous to requiring Ford Motor Company to report every automobile accident on the basis that it might involve a failure of the automobiles manufactured by it.

It is my feeling as a trial attorney that we must be very careful as we move forward in the entire area of retrieval and analysis of orthopedic implants. Certainly it is important that we do not move backward, and it is important and vital that strides forward are made on a reasonable basis. We must take into consideration, however, that we have come a long way and essentially most orthopedic devices that have been developed to date are successful in their use. Most of the retrieval and most of the analyses have been done on the fixation types of devices. However, we are going to be encountering on an ever-increasing scale the larger prosthetic devices, designed to be permanent replacement of the bone tissues. Unfortunately again, the first or early uses for the metallic prosthetic devices were in the cases of older persons who lost the function of the hip. We have now greatly expanded this use to areas of arthritis and other crippling diseases that affect younger persons. The problem which occurs is that our original experiences dealt with the utilization of the prosthetic devices by older persons who had shorter life expectancies and were not as active as the younger people. Accordingly, as we gain experience over time in the uses of such

devices with more activity on the part of the younger patients, greater failure is bound to occur. We should not be surprised, therefore, to find that these devices, intended to be somewhat permanent, are not permanent at all and that hips and other joints may have to be replaced every 10 to 15 years. Nothing we have devised is as strong as the bone that God created for us. The bone in our bodies continually rejuvenates itself, and dead cells are replaced by new living tissue. Once any device made of metal, plastic, or other substance is put in the body and weakened in any area, it never regains its original strength. Accordingly, failure will continue to appear on a larger scale.

We are now moving into an area with the total ankle, the total knee, the total hip, the total everything, the "Six Million Dollar Man," and "Bionic Woman." As we are making tremendous strides in medical science, we cannot be certain at any stage that every design and every device will succeed. As a matter of fact, I think we should consider that they are not going to succeed and yet the ultimate benefit to the patient is worth all of the efforts that we are making. But, as we move forward, we can never forget that in our country litigation is a very important aspect of everything we do. This freedom that we enjoy is important, but it cannot and should not be ignored as we proceed with our analysis in the retrieval of implants.

Discussion of Paper:

R. T. Rylee, II

Wright Manufacturing Company
Arlington, Tennessee

Mr. Lemon's paper presents an excellent background regarding the nature and the development of product liability litigation, particularly as it involves human implants which failed in service. It is particularly important for us to remember that today manufacturers are held to strict liability for their products whereas in prior years they were held accountable only for negligence that had been proved against them. There has been a bit of confusion recently concerning the right of various interested parties, including the surgeon, to have failed implants tested. Mr. Lemon correctly identifies the owner of an implant as the patient. It is the patient who paid for and received the implant. The title thus is his. Accordingly, it is the patient who has the right to determine if and what testing will be done. Obviously, the patient may delegate or transfer these rights to other persons. Interested parties will have to be careful to make sure that the control of a retrieved implant be properly authorized.

Following retrieval, all interested parties should avoid hasty conclusions concerning the condition of the implant, both before and after surgery, and must carefully document all relevant clinical data and patient activity. We also need to very carefully develop standard test methods relating to failed implants. This area requires substantially more knowledge than we have available today, and it is of critical importance that we develop the necessary expertise for reliable failure analysis.

Unfortunately, failure of implants is a reality with which we will have to contend. In addition to doing the research for the development of better materials and better designs of implants, we also must develop better understandings of the problems faced by patients, surgeons, and manufacturers so that we do not improperly attach liability.

I want to thank Mr. Lemon for an excellent presentation.



IMPLANT RETRIEVAL: PROBLEMS AND OPPORTUNITIES

Panel Discussion

E. Horowitz, Moderator

Regulatory View	L. Pilot
Legal View	T. R. Lemon
Industry	R. Heros
Basic Science	J. Black
Clinical	E. M. Lunceford, Jr.
Standards	J. M. Cassel

Dr. Horowitz (NBS): Let me make a few remarks about how we would like to conduct the panel discussion. First, we will have the panel assembled, and we will hear from each of the panel members in the designated areas. Then we will have an open period of questions from the audience and answers by the panelists. We look forward to this part of the symposium as one where we can all learn together and where we can get the important issues related to retrieval of surgical implants out on the table. When we come to a point in the proceedings where we have answered essentially all of the questions from the audience for the panel members, I am going to open up a second phase of the question-and-answer period which will permit you to raise questions about the papers that have been delivered. I know that several of you have written down questions but have not had an opportunity during the course of the speakers' presentation to raise them; you will be given that opportunity. I would like to invite the panel members to step forward and take their seats.

Let me start with a few remarks. This panel discussion is entitled "Implant Retrieval--Problems and Opportunities." I think we owe a debt of gratitude to the speakers for really setting these problems and opportunities in a proper context. If I may take just a moment, I would like to at least touch on some of the topics. It costs a considerable amount of money to engage in retrieval and analysis activities. There is also an element of timeliness; that is, the results are required within a specific time frame if they are going to be of value to someone. As Mr. Lemon has mentioned, there is a need for accurate and standardized methods of test and evaluation, not only for the materials themselves, but for the clinical aspects as well. The availability of the material is important. The ownership of the implant, as Bob Rylee has just indicated, is an area that is still unclear and diffuse in many hospitals, and needs to be explained and understood by those involved in implant retrieval. The question of confidentiality with regard to the retrieved implants and the data developed from such materials is a sensitive issue and one that needs to be confronted and resolved. Biocompatibility is an important issue; and definitions, protocols, and guidelines are required. Finally, there is the problem of litigation which has been treated very well by the last two speakers.

What are the opportunities? We can, if we are successful in establishing a data base on retrieved surgical implants, support a feedback-loop to furnish data for the development of improved standards and the design of improved implant materials. The data would also provide facts rather than fiction in cases where implants had failed or had performed inadequately. On the other side of the coin, an implant retrieval activity would provide facts where implants had performed satisfactorily. I would like to just conclude my brief remarks with reference to Bob Rylee's statement. He said that when he obtains a retrieved implant it helps his learning curve. I think that is the essence of what we are trying to do at this symposium today; we are trying to establish a platform for action in the future where the learning curves of all of those who are concerned with orthopedic implants will be rather steep and positive. I would like to turn to our panel and introduce Mr. Larry Pilot of the FDA who will discuss the regulatory view.

Mr. Pilot (FDA): Thank you. I appreciate your covering the subject matter and discussion, Implant Retrieval--Problems and Opportunities, because when I looked at that yesterday and tried to figure out what I would address myself to today, all I could see were a lot of problems and no opportunities. When I discussed that with one of the fellows in the office, he said, "Well, I think there are some opportunities; it just depends on whether or not you are the patient." In light of what we have heard this morning, I think there are some opportunities here certainly for the Federal Government, the FDA in particular, to implement our responsibility under the law. There are opportunities for the industry, the physician, and scientists to learn more about what went wrong with something and why and how to prevent it. Also, it is an opportunity to present papers at a symposium such as this. Finally, there are opportunities for plaintiff attorneys and, as I heard from Mr. Thomas Lemon, defendant attorneys also.

With regard to the responsibility of the FDA and the opportunities that we have, I would like to take just a few minutes to describe to you what our responsibility under the present law is and a little bit about what our responsibility will be under future legislation. As some of you may be painfully aware, the FDA has the responsibility of regulating the interstate shipment of medical devices. Our responsibility under the Food, Drug, and Cosmetic Act comes into focus whenever there is a violation of that Act. Very simply put, if a device is adulterated or misbranded under the Act, then we have the responsibility to apply appropriate penalties. Those penalties can be against the device itself, as in the case of seizure of the device, or against the manufacturer through prosecution; in some cases, we shall make an effort to enjoin the manufacturer or other responsible parties from shipping his device in interstate commerce. In addition, we have an administrative procedure with which some of you may be familiar; this procedure is referred to as "recall." We refer to it as a voluntary procedure since we do not have authority under the legislation to require the manufacturer to recall his product. By and large, we believe that it does represent a voluntary effort on the part of industry and the Government to recognize that a problem exists and that a method can be undertaken to correct the problem. In most cases, it is not necessary for the agency to go beyond this effort and implement or apply those procedures for which we have the authority under the Act. I mentioned those before: seizure, prosecution, or injunction. So much for our present authority.

Congress has for several years been considering the possibility of amending the Federal Food, Drug, and Cosmetic Act and giving us additional authority so that the burden would not always be on the FDA to prove a case. As things stand now and as they have stood since 1938, the burden on "after-the-fact" basis is with the FDA to establish that a product is adulterated or misbranded and then pursue the sanctions under the Act. Under the legislation that is now under consideration, some of this burden will shift to the manufacturer. In some cases, he will be responsible for assuring that his device is safe and effective and for demonstrating to the Government, prior to marketing that device, that it is indeed safe and effective. In other areas, he will be responsible for conforming to performance standards as they are established pursuant to a procedure that is outlined in the Act. In addition, he will be responsible to the Government and be required to perform certain functions that are different from those that now relate to his responsibility under the Act. With regard to the practitioner, I want to make it clear that the FDA does not regulate the practice of medicine or any other activity in the professional area, and under this new legislation there will be no change in that status. Our concern is with the device and with the manner in which that device is manufactured and distributed by the manufacturer or other responsible parties. In summary, I think through meetings of this sort, we have a good opportunity to exchange views, focus on what the problems are, and make some attempts to resolve those issues. I hope that as we proceed during the day today that we can bring some of these to light. Thank you.

Dr. Horowitz: Thank you, Larry. I would like to proceed with the other panel members because I think that several of them may, in fact, address some of your questions. Therefore, let us hold the questions for the very end of the panel presentation. Next we hear from Mr. Tom Lemon on the legal views.

Mr. Lemon (Zimmer--USA, Inc.): Thank you. I think that there are some opportunities and certainly some problems. Turning first to the problems. In a real sense, I think that the orthopedic industry, unlike possibly some of the other persons or companies that might come under device legislation of the FDA, has acted responsibly. We are really talking

about a very small problem when we talk about the failure of these various devices. Yet, because of litigation and publicity, we find ourselves, at least manufacturers find themselves, thrown in with a lot of other people who might not have acted as responsibly. I think that several problems are created by legislation that lumps every type of implant, including pacemakers, artificial blood vessels, and all these other devices, into one category. For instance, you have a problem for performance standards; I think we discussed that briefly. There is a statement that these regulations do not regulate the practice of medicine. But, in fact, they certainly have a substantial impact on those who practice medicine and what is available to them to solve any given problem. Also, for example, regulations can cause problems because of definitions and uses of terms. For example, there is a requirement or could be a requirement that manufacturers are going to have to report failures of implants. The problem is that most manufacturers of the implants do not consider it a failure unless the device broke as a result of some defect in the material. So we get in a situation where we are going to have to call things failures that do not deserve to be categorized as failures, possibly with criminal sanction of companies if we do not. This kind of problem needs to be considered. Yet some real benefits can flow from some type of organization's taking responsibility for or, if not regulating, at least organizing and creating standards for dissemination and enlightenment of the general public. I do not think that the problem is all that bad, but most people do not know how to properly go about getting the information that they need and are dependent upon outmoded forms of communication. We are dependent upon the law, I think, which is lagging behind. I am talking about civil law, so there is a great deal to be gained from the flow of information and from interaction of all these agencies. If all concerned keep in mind their relative position in this system I think they can move forward with great strides. If we go helter skelter, we are just going to have a lot more problems.

Dr. Horowitz: Thank you, Tom. I would like to move on now to the industry point of view and Mr. Ricardo Heros.

Mr. Heros (Richards Manufacturing Co., Inc.): A number of people over the last few months have commented to me: "We do not really expect industry to be deeply involved in the future of this area." I emphatically challenge that statement, since it considers industry as an archaic entity that does not face today's realities. As part of industry, I would have to state that this area will prove to be of critical importance to the orthopedic companies that will survive the future.

We are at the beginning of a most crucial period in this area. The era of the consumer has left a deep mark on all of us. Overnight, we are expected to make devices which are foolproof, everlasting, economical, easy to operate, etc. Attorneys are gathering like birds of prey over doctors and manufacturers alike and are waiting for an opportunity to proceed against us. Regulatory agencies are created that tell us whom to employ, how to advertise, how to ship products, how to develop products, etc. Consumer groups criticize everything that we do but fail to speak in practical terms such as benefit-to-risk ratios. They state very emphatically that in the use of a device there should be absolutely no risk. There are patients who, after establishing the fact that a failed implant resulted in their case, blame all of their previous bone failures and clinical history on the implant. I could spend the rest of the day developing the background present in industry today; however, my point in establishing the background is to emphasize my belief in the ability of our industry to meet the future challenges.

The subject under discussion today represents one of the biggest challenges ever issued to our field. This symposium represents the first such opportunity in this area. It should allow us to air our views, to have a meeting of the minds, to argue, to create, etc. It also represents the beginning of a course of action having many dangers. Any false step and we will have angry attorneys, doctors, or regulators at our doorsteps. We must be absolutely clear that steps in this area must be small and careful and at the same time forward and positive.

I firmly believe that industry could do a much better design function if it were able to better evaluate retrieved implants. We all know that any designer who is deprived of a full analysis of his design, such as information on failed or retrieved implants, lacks one of the fundamental design tools. This basic principle covers designers throughout the world; however, the manufacturer is faced with a very slow-responding and unclear feedback

on his own devices. I am sure that a number of the points mentioned here today will undoubtedly help greatly in this area.

I would like to propose that one of the areas of information most lacking in the retrieval and analysis of orthopedic implants is that of placing these implants within proper statistical perspective. Not only designers but everybody interested in this topic could be helped by the establishment of the benefit-to-risk ratio to be used as the baseline for optimal new designs pertaining to each "device procedure." I realize that these designs must be established for each "device procedure" combination with a very large number base. However, once this baseline ratio has been established, new designs will be easier to evaluate in the future. The guidelines within which this system will operate are readily available and workable.

I present this item for discussion and suggest to you that this information can be established and, furthermore, that its value will prove to be as important to the future of this group as any other single item discussed here today.

I would like to thank you very much for allowing me an opportunity to present my views to this group.

Dr. Horowitz: Thank you, Ricardo. The next topic will be basic science by Dr. Jonathan Black.

Dr. Black (University of Pennsylvania): The development of orthopedic implants has been by and large an empirical process. From the initial applications of ivory pegs, soft iron wire, and wood screws in fracture treatment to the use of modern, high strength alloy, total joint replacements, devices have developed from concept to practice under the guiding hand of the treating physician. Safety and performance have been measured against comparative and subjective criteria: Is the patient improved? Is he satisfied with the result?

From modest beginnings, the use of implants in orthopedic surgery has grown to enormous proportions. Several million metallic and polymeric parts are implanted each year; perhaps as many as 100 million parts have been used, and millions remain in patients permanently, either by design or by chance.

A vast experiment has been undertaken. It includes millions of subjects and will last far beyond the lifetime of those who started it. The present situation can only be recognized as experimental since it is widely accepted that there are uncertainties in the performance of present devices and both medical and engineering deficiencies in many. In the normal course of such a widespread application of technology, we would expect a continual feedback from the user to the developer and the manufacturer that would result in evolutionary improvement.

The clinical performance of devices is resulting in changes in some cases, but the vast majority of evidence of performance is being neither obtained nor studied. This situation arises from several conditions.

In the first place, devices attract attention only when they fail to fulfill their intended function. Such failure, either of the device or of the treatment plan or of both, is rare. Accurate data are not available, but practical experience suggests that "failure" rates for most commonly used devices are below 1 percent. Although failures may be recognized, they are not generally studied in depth. Frankly, broken or damaged devices often excite fears of legal action against surgeons, hospitals, and manufacturers. Such devices may simply disappear. Some devices are returned to manufacturers for analysis. The knowledge gained from these is often limited by lack of access to clinical records and failure to understand clinical details of the problem. The knowledge gained from such analysis is rarely shared with the medical and academic community. Some devices are given to the patient, either as a gift or upon demand by the patient's lawyer. And many devices end up, unlabeled and unprotected, in a drawer in the surgical scrub area.

In some ways, the failure to study the other 99 percent of devices is more tragic. We know remarkably little about normal device/body interactions, either local or systemic. We know little about corrosion and wear rates *in vivo*. With the exception of some isolated

experiments with instrumented prostheses, we know almost nothing about the true stresses and strains in functioning devices or the effects of these conditions on repair, remodeling, and growth of tissue in the vicinity of the device. If we were to study, in a systemic way, successful devices, both in patients and upon routine removal, many of these unknowns could be resolved. Knowledge of this sort would lead to better selection of devices for particular patients and to prospective design of improved devices. We would arrive at a greater confidence in the level of performance that can be expected from implanted devices.

In summary, it is fair to say that basic scientists experience considerable frustration in the study of orthopedic devices. A vast number of implants are in use, but few are accessible to systematic study. In the present medical/legal environment, reports of implant performance are restricted to isolated cases and to small, collected series. What is required to open broad vistas of knowledge in this area is recognition across disciplinary boundaries of the desirability of studying implants more closely and the development of retrieval practices that protect the interests of all parties in a fair and equitable manner.

Now I would like to make one additional comment, a thought that came to me today while I was listening to the talks. It is that a great deal of ticklishness that people have about this field arises from ideas that we have about compatibility. Let us say if something does not seem to go right, we conclude that something has been done wrong. The next thing we do is to assign the blame. I would propose to you that the basic scientist has something very important to offer to this situation. If we were to establish the true state of affairs, it would probably be that regardless of the origin of problems related to the performance of implants, such problems represent a very small proportion of the total implants in use, perhaps 1 case in 1,000 or 1 case in 500 or 1 case in 10,000. We would no longer have to be concerned with who had caused the failure. We could simply adopt an American principle of simply insuring against the risk, if the risk were known quantitatively. It is that quantification that I think basic science could add. Thank you.

Dr. Horowitz: Thank you very much, Jonathan. Our next speaker will be Dr. Lunceford of the Moore Clinic who will deal with the clinical aspects of surgical implants.

Dr. Lunceford (Moore Clinic): Thank you, Manny. I want to show you a few pictures of some of the horror stories that were alluded to a little earlier this morning. First, we need to set things into perspective and try to envision some of the reasons for our being here today. In the early days of fracture management, bones were reduced to maintain their proper position by optimizing the bonesetting techniques that were being used by the bone setters in the early stages of the art. The earlier healers gave us a considerable amount of information that enabled us to take care of patients who were suffering. It was not possible to perform procedures for repair and maintenance of position with restoration of anatomical function. The precepts inspired by Lister contained improvements on those earlier techniques. These improvements have enabled physicians to better approach the idea of anatomical realignment of fractured bones. With this increased expertise in technique and the use of implants, the problem of compatibility with metallic implants arose. The metals used for implantation were rather poor quality in those early days and were not accepted by the saline medium of the body without producing rather marked corrosive effects. If we will look at some screws which were implanted in 1948 and remained in the body for more than 20 years, we find evidence of some corrosive effects resulting in the dissolution of metal around the screws. We have learned or profited from some of the experiences that did occur, and specific alloys have evolved that have proved to be more suitable for implantation. This type of outcome has been alluded to earlier, and there was mention of this topic during the discussion of the basic science aspects of implant retrieval. The 316 stainless steel chrome-cobalt alloys and the titanium alloys currently are metals that are accepted for implantation. These do function quite effectively in most instances. Although we have materials that are more physiologically acceptable and more biologically inert, there is still dissolution of ions at the implant-tissue interface. The long-term effect of this has not yet been established, but it does appear that there is no toxic effect from the implanted alloys which were mentioned. Unfortunately, many implants made of these metals undergo perils of one kind or another. One type of problem is that the screws may pull out of the bone because there may not be enough bone substance to hold screws securely in place. The failures that we see may also be attributable to poor implant design, poor choice or selection of materials, poor surgical technique, poor bone structure, and/or adverse metabolic activity or infection. Several of the manufacturers provide instrumentation for surgeons to use in implantation operations.

Today I am not talking about implants of other than metals, but implants other than metals do undergo failure. In implants that have been present in the body, we have seen the discoloration that occurs around the metal at the metal-tissue junction. Dr. Laing has discussed this and given you some of the examples that do occur. Once again, we could have a poor implant design, a poor material selection, poor surgical technique, poor bone structure, or infection. The opportunities that exist for further evaluation of available implants and their improved design so as to prevent failure are intriguing and fertile areas for future development. I think this is the reason for having a preliminary program on retrieval and analysis of orthopedic implants. Hopefully the symposium will provide us with some information that can be used to further enhance our knowledge of the various fractures that contribute to the success and/or failure of orthopedic implants and thereby with a better understanding of the physiological interaction of the implants with the body. Thank you.

Dr. Horowitz: Thank you, Dr. Lunceford. The last speaker of the afternoon panel will be Dr. Jim Cassel of NBS, and he will be talking about "Standards."

Dr. Cassel (NBS): The following remarks might be considered *opportunities* and *problems* that interrelate with implant retrieval and standards development.

1. Opportunities

Examination of removed implants by the clinician, as well as analysis by the laboratory, offer almost the only means for deciding whether specification requirements are really applicable.

Suggestions for different requirements may evolve.

Suggestions for new test methods may originate.

2. Problems

It has been difficult to generate sufficient information on the material as it existed in the preimplanted stage.

It has been difficult to generate quantitative data relating to the implant and surrounding tissue at the precise moment of removal.

There will be variability in the treatment imposed on identical implants by different patients.

There will have been differences in the quality of the technique used in the implant operation, and the status or condition of the removed implant will reflect this.

Any standard, to be worth much, must set forth criteria as well as procedures or methods by which it can be judged that these criteria have been met. These criteria are directed toward two goals: reproducibility of the material or product, and a level of quality commensurate with the performance or function that is to be performed.

The tests or methodology set forth to assess if the criteria have been met are considered *reliable* if various laboratories can repeat them and achieve results in agreement; they are considered *valid* if the testing predicts the behavior of the materials in service.

So, we have criteria and we have testing and we have a chicken-and-egg situation in which it is often difficult to decide which comes first.

3. Parallel With Dental Area

Having dual contact here at NBS with a dental materials program of long standing and a synthetic implant program of shorter duration, I am impressed with certain parallels. Certainly, the long-term goal in the orthopedic standards area should be to produce for the orthopedist a Guide to Orthopedic Materials similar to what has been provided to the dentist on dental materials.

Shown in figure 1 are a number of common dental materials on one side and on the other side a list of properties that may or may not serve as performance criteria. Let me make brief comments about two of these materials.



Figure 1. Relation of properties to clinical performance of dental materials.

Years ago when an effort to develop a specification for dental silicate cement used to fill cavities in anterior teeth was in progress, a questionnaire went from the American Dental Association group at NBS to the dentists to assess their views on the clinical performance of the different brands that were available.

What brand are you using?

Why (mixes soundly, sets rapidly, sets slowly, etc.)?

What complaints do you have about this or other brands?

What properties do you think are most important (crushing strength, fineness of powder, etc.)?

Is your mixing technique reproducible? Define it as to powder/liquid ratio, temperature of slab on which mixing is done, time of mix, etc.

Of the respondees, 80 percent indicated a preference for two brands, which, in the NBS laboratory, had been shown to have similar properties.

Solubility (or more properly disintegration), discoloration, low strength, and shrinkage, were listed in that order as the causes of failure, clinically. These were failure analysis conclusions drawn by the persons who were observing the restorations while they were in service.

To contend in a specification with the mode of failure detected most frequently in the clinical situation, a standard test method for solubility had to be developed and a standard powder/liquid ratio defined. The one selected for test purposes in the specification was not necessarily the best one but was one used by the majority of dentists queried. A procedure was developed and specific requirements agreed upon which assured a means of separating good clinically performing materials from those that were known to be poorer performers. This is the important aim of specifications.

Lest one think dental specifications are set in concrete, I should point out that the first specification to be issued was on dental alloy for amalgam. The dentist, in his constant observation of amalgam restorations, has observed that a main source of failure of this restoration is in marginal fracture. Sufficient experimental evidence has now been obtained to sort out one physical property, namely, dynamic creep, that appears to be most closely related to this mode of failure; and the specification is in the process of being modified accordingly.

4. Current Input to Implant Standards from Retrieval and Analysis

While x-ray techniques are invaluable to the dentist in judging the clinical condition, he is also able to make repeated visible assessments of the clinical status. The orthopedic surgeon, on the other hand, must rely a great deal on x-rays to diagnose the clinical status; and he cannot directly observe the implant until it is removed.

For a long time, the only feedback on the clinical experience with orthopedic devices was to the manufacturer. In more recent years, reports on analysis of removed implants, certainly not all of which have functionally failed, are beginning to appear. Reports such as that of Professor Scales of the Royal National Orthopaedic Hospital at Stanmore, who in 1973 reported on some 1,800 removed metallic implants and tabulated the reasons for removal, are beginning to appear. Other similar reports have been referred to at this symposium. The Utah Biological Test Laboratory report of 1975 is one of the most recent ones. This latter effort used analysis of removed devices as a basis for making comment on present standards and where new and improved ones should be developed.

There is no doubt that clinical assessment of implants as they are removed, coupled with laboratory analysis, provide a major tool for upgrading the level of orthopedic implant standards. Our job in this symposium is to suggest procedures for how that can best be done.

Dr. Horowitz: Thank you, Dr. Cassel. I would like now to open up the panel topics and the speakers to questions from the audience. Before we begin the general questions, however, there have been two requests from the participants to make some formal comments, and I would like to call on Dr. Chao first for his comments.

Dr. Chao (Mayo Clinic): Since late 1972, at my laboratory, I have collected many prostheses--some metal, some polyethylene. I have collected every piece of material, patients' history, surgical history, and slides of the roentgenograms. I have not performed any metallurgical analyses or analyzed the polyethylene samples because at that time I was concerned about who owns them. I feel that this precaution was wise because since then I have had a number of requests asking me to provide a prosthesis because of litigation action. The fracture type of failures that we often find can be observed from the roentgenograms. Many times loosening of the prosthesis occurs, which is a very important problem, especially in the knee prosthesis. Fracturing is not the problem anymore; it is the loosening.

We are currently using three methods to analyze our retrieved prostheses. Actually the second method should not be called metallurgical because the prosthesis is not made from metal; polyethylene and other synthetic materials are often used entirely. I would like to propose that these be subjected to material analysis. Since I do not have facilities for doing this kind of analysis, I send the materials elsewhere to have it performed. We do clinical and biomechanical analyses. I would like to emphasize the biomechanical analysis aspect because if you look at the loosening of the prosthesis, unless you look at the mechanics and all other factors in it, I do not think that you will learn anything.

The collection of the information is very important. I will not dwell on this because many people have already emphasized this point. My hope is that a standardized form can be established so that we may all share the information. In fact, we can even dream about a computer information-sharing system. All you have to do is call a particular group, and all of the cases can be made available. If you are interested in doing statistical analysis or metallurgical analysis, you can call for the materials, you can call for the slides, and you can perform any analysis.

Because I was involved in two litigation cases I have a word of caution to my engineer friends in the audience. If you are involved in the design of any prosthesis, be careful about it unless you are covered by an insurance policy. In one case, a metallurgist developed a material and tried it successfully in an animal. We were ready to put it in a patient when he called us and advised us to not put it in unless we could give him insurance coverage or exclude him from responsibility. I fortunately work in an institution that is primarily clinical and covered under a regular type of insurance.

We have to think about standardization and also the dissemination of information. We have to share our data and information. I have very large clinical sources, amounting to over 150 prostheses, but I have no funds to do analyses. Who should pay for this kind of work? On the legal side, we have questions as to who owns the prosthesis. Then I have another question concerning biopsies. After you have performed the biopsy, who owns the tissue? We store the tissue in our tissue storage facility, but I do not think there is any difference between a prosthesis and a piece of tissue. I think certain centers probably could have a storage place for prostheses; and then the evidence would be in effect like pathology--pathological histories that could be shared by the legal people, by the patient, by the attorney, by everybody. Each laboratory has its own emphasis.

Finally, I think that a professional group like the orthopedic academy or the FDA could provide some kind of regulations for manufacturers. I would like to see some type of restrictions on irrational design. The design of prostheses could be optimized with the information we could obtain through a well-organized retrieval system, and therefore we could really benefit from the engineering technology.

Dr. Horowitz: Thank you, Dr. Chao. I am sure there will be people in the audience who would like to get back to your topic and raise some questions, but I would like to go on and introduce Dr. Lewis who also has some prepared remarks.

Dr. Lewis (Northwestern University): Thank you. I want to share with you our similar experiences on looking at removed prostheses. I would like to go into some detail and offer some suggestions about how coordination could be achieved between retrieval centers in the future.

Our engineering group at Northwestern University works on internal joint replacement. When we first started working 3 years ago, our immediate questions were: "What are the most important problems to work on?" and "What are the problems of existing joints that need to be solved?" Then, as now, there was a great deal of speculation, rumor, and scattered studies with contradictory results. It was not really clear what the most important problem was that needed to be worked on. We undertook two studies to try to clarify this dilemma for ourselves. First, we identified a series of total hips, about 250; and we followed all of them for a period of time. Second, we looked at all removed prostheses to indicate current problems. We are notified when the total joints are going to be removed during surgery. We review the patient's history and x-rays so that we are familiar with the case. An engineer will go into surgery at the time of prosthesis removal. He watches the surgery and notes how much breaking of the methacrylate is done by the surgeon and how much was already broken. Afterwards, we conduct postoperative examination for any mechanical failure. We do only the materials analysis and not the tissue analysis. We have a standardized form on which we put our information. It is a coded sheet so that we can enter it into our data analysis system. Periodically we summarize the results. You can look for correlation of several variables. For example, the degree of loosening of the approximal component correlated with the degree of loosening of the distal component. Here is a series of total hips which we had at this time. We had 12 total hips and 8 total knees. There is one fractured stem. There were no infections that were removed, and I want to emphasize that these are all of the prostheses which were removed at our hospital. This sampling, therefore, is not random and represents all of the problems that were occurring in our center. The primary cause for the removals was the patients' falling and complaining of pain. Evidence of loosening was found and when the prosthesis was removed it was definitely loose; 5 of the 12 were of this type. Invariably there was poor methacrylate around the stem in this group. The main result with the knees was three out of eight infections.

In conclusion, the analyses we perform are much the same as what Dr. Chao and other investigators have described. It is not so much that anyone has to do more than they are currently doing but rather that they should communicate their activities. I think that with the computer system we have developed using a standardized form all reports can be prepared in a matter of hours. Data can be manipulated very simply. The results we have found emphasize the necessity of having several centers contribute their removed prostheses. At the Mayo Clinic, for example, their loosened hip prostheses are usually associated with infection. Different centers have different problems so we need to have several centers presenting their results; otherwise the true problems will not be presented.

Dr. Horowitz: Thank you, Dr. Lewis. I would like to open up the full session now to questions from the audience. Yes, Dr. Martz.

Dr. Martz: May I ask three questions?

Dr. Horowitz: We have an hour remaining, and you may ask your questions! Since this is being recorded, please identify yourself and your organization, and then go on to your questions.

Dr. Martz (American Orthopaedic Association, ASTM): How many of you are members of ASTM, and how many orthopedists are here? May I see a show of hands? Good. My first question is directed to Dr. Cassel. Do you realize that the tremendous program of dental research in reference to their implants is not entirely applicable to our orthopedic problems? You have a captive industry; you have a research assessment on each practitioner; you have problems that do not involve a large number of patients, particularly of the welfare category. For years I have said that the dentists are 10 years ahead of us in surgery, and yet there is a very special difference; those differences must not be forgotten.

Dr. Cassel, my first question is: "Do you realize there is a little difference?" The second question has to do with who really owns the implants. Many years ago, we suggested these implants be sent to the pathologist and be regarded as pathologic data. Today we heard that the implant belongs to the patient. If it belongs to the patient, then he had a choice in his selection. The vendor he went to is responsible for quality assurance, and the total step-by-step sequence of that implant was under his control. I challenge you that the patient did not have any choice of the implant for the most part, or who made it. He had perhaps only a small choice of who put it in. I feel very strongly that Dr. Chao is on the right track and that it is a pathologic specimen--whether it is a hip nail or a cardiovascular mesh or a small staple in the ear. If we take that implant out with its adjacent tissue and send it to the pathologist, from that point on it comes in his domain. I think we are in danger if we allow the implant to be considered the property of the patient. I would like to challenge every lawyer on the panel, so Tom Lemon and Larry Pilot, that is your question. I have a third question about package inserts. I would like to address that to Dr. Black and Dr. Lunceford. Do we want inserts to be a cookbook that tells us step-by-step how to put it in, or do we want a road map that describes the general directions? I would like to ask if you are familiar with learning machines and learning curves. We can flunk a lot of young orthopedists if we ask them cookbook questions, and so we do not ask them anymore. We are asking roadmap questions, and in the whole process of education we are getting away from centering on the student but concentrating on the problem at hand. My fourth and final question is: "Do you realize what a wonderful day this has been? What a fine program we covered today?" Thank you.

Dr. Horowitz: Thank you, Dr. Martz. The first question, dental confrontation. Dr. Cassel.

Dr. Cassel: Dr. Martz, I do not think I would suggest that the restoration procedures involved in filling a cavity in a tooth are nearly as critical to the patient as that of implanting a total knee prosthesis. However, I do think that the very adequate standards program for dental materials developed over the years reached the level of success it has mainly because the American Dental Association saw fit to commit dollars and manpower and establish a program at the National Bureau of Standards that eventually brought the manufacturers into the picture in a cooperative endeavor.

Mr. Pilot: From our standpoint, we have very little interest in ownership of the prosthesis--whether it belongs to the patient or physician. Of course, we have some responsibility in this area. When we uncover a device that we believe is adulterated or misbranded, then we do something called seizure and we pick it up, and then it becomes ours. There has been more than academic discussion of that subject in the past, but in any event we do not take title. We do not own something when we seize it. All we do is facilitate its removal from the marketplace. If any manufacturer or patient or anyone else has an interest in obtaining that device, he can go through an appropriate legal procedure to claim it. If there is a decision in court to give it to some party, then it becomes his. That is my only comment on ownership so far as the agency is concerned. I think, with regard to the commercial transaction, Tom Lemon might have some comments.

Mr. Lemon: The fact is that the patient at the time of a given operation might not have any input into the selection of what device will be put into him because he has put that judgment in the hands of the orthopedic surgeon. For example, you go to your doctor because of a cold, and you get a prescription and take that to the drug store. You buy whatever they give you, and you do not have any choice as to which medicine the doctor prescribes. You do not have any choice as to which company made it because you always go to the same drug store. But you own those pills when you pay for them. I would submit to you, whether it is right or not, that the ownership, if it comes down to a question, is going to go back to the patient. While it has not been contested directly, it will come up indirectly that a hospital will have retained possession; and when a lawsuit is started, a person will go to court asking for an order requiring the delivery of the implant to him and the patient always wins. I am suggesting to you, by way of warning, that I believe, as Mr. Rylee said earlier, in this kind of transaction the courts are going to unanimously find that the patient owns the device. Now, over the years, and prior to a lot of litigation, implants were taken out and thrown away or retained by the physicians. They had their storage chests full of them, and certainly the manufacturers had many returned to them. By and large, all devices that are returned to manufacturers are retained simply because future litigation might occur. If the patient demands that the device be given to him, we are compromised if we say we have destroyed it or lost it. I am really convinced that the ownership does belong and rest with the patient. As a matter of fact, if it came down to it, he probably owns the pathological specimens that have been taken from his body, as he owns the x-rays and as he has the right to disclose who will see the x-rays if he wants to limit their inspection by anybody. The hospital generally keeps them for its own protection; but believe me, when it gets down to it, it is the person who paid for them who has the ultimate right to direct what is going to happen to them.

Dr. Horowitz: Thank you, Tom.

Unidentified Speaker: I just wanted to mention an experience that we had where we were given direct legal advice that any implant that we get in our plant that has any legal implication behind it should not be touched but should be logged and put away in a safe.

Dr. Black: I want to say something about ownership, too, because we have overlooked another factor. By the way, I am very pleased to hear that Blue Cross owns 70 percent of the implants in my state because after all it, not the patient, paid for them. Being associated with an educational institution which has a hospital as a portion of it, we have an academic accreditation procedure, and our hospital recently had its 10-year evaluation. It is very interesting to note the attitude of that accreditation committee. One recommendation contained the original instructions for tissue retention and inspection and the establishment of the tissue committee. Those instructions did not refer to tissue but simply to anything removed from the patient's body. They suggested in very strong terms that implants were indeed removed from the patient's body and that the previous recommendation covering things removed from the patient's body covers them just as well as it did tissue. I think the immediate realistic solution, short of what the legal profession is going to place upon us, will be to treat these devices in the same sort of way that tissue is treated. In my opinion, tests will then be necessary to confirm diagnosis and efficacy of treatment, preservation of physical materials, preservation of confidentiality, and preservation of records.

Now let me get to the question addressed by Dr. Martz about packaging inserts; I think it is a very nice one. For years I suggested that packaging inserts ought to be sterilizable so the attending nurse could hand them to the surgeon and say, "Sir, could you please read this and sign it with your sterile felt tip pen before you proceed?" However, experience suggests that these inserts are going to waste as rapidly as the present paper ones do. I think the approach has to be somewhat different. I will remind Dr. Martz that today the majority of surgeons who install total joint replacements never did it during their residency, and the problem is thus an educational one. Perhaps the approach to be taken is that when a major new system, such as the total knee system, comes on the market, somebody--and I hope it would be the professional association, in this case the American Academy of Orthopaedic Surgeons--takes the lead to provide educational opportunities and additional certification. Since an orthopedic surgeon can be distinguished from a general surgeon, it would be nice to distinguish those among the orthopedic surgeons who have actually received instruction on putting in total knee systems. I think that is probably the course to follow, although the details may be wrong. I can see Dr. Martz shaking his head. I think from the

point of view of education that is the kind of direction I would favor rather than more paperwork, and more packaging, and more things to go into the wastebasket.

Dr. Horowitz: Dr. Lunceford.

Dr. Lunceford: I would concur with Jonathan's thought that this is really an educational process, and I think that the medium for its use is the same as that for total hips. Information was disseminated through a series of symposia that were conducted by the Academy of Orthopaedic Surgeons and other concerned institutions around the country. It did have a response in that a number of orthopedic surgeons did attend these symposia and learned a great deal about how to implant the total hip system. I will tell you one story to try and illustrate the importance of this educational system. I had a phone call about 10 o'clock one night, 10 or 12 years ago, from a surgeon who wanted to know how to put in a hip prosthesis. He wanted me to tell him on the phone how to do this. I do not think that is the way you want to teach somebody how to do something. Thank you.

Dr. Horowitz: Any other questions? Yes, sir.

Unidentified Speaker: I recently ran across an article in the *Journal of Bone and Joint Surgery* which Dr. Lunceford has probably also read. It was authored by a gentleman from Cambridge named Ray. He went into the presence of high levels of cobalt in tissues surrounding certain implants. He seemed to feel that levels of cobalt in the tissues adjacent to these implants possibly had something to do with the delayed infections that we have been seeing from time to time. In other words, as the cobalt concentration builds up in the tissue interface, the cells may become more susceptible to infection. This process explains why the infections are clinically delayed. The other comment is these patients ultimately die. I do not know how legal it is when it comes to the disposal of these implants, but it might be interesting to hear a brief comment on that.

Dr. Horowitz: Does someone on the panel want to answer the first question?

Unidentified Speaker: I do not know whether you heard Dr. Laing's discussion this morning; but in his presentation he did mention the toxicity of the various elements, and some of the other members discussed this. Dr. Williams spoke about the particular ions causing some derangement of the extracellular architecture. Dr. Williams, would you care to answer that?

Dr. Williams (Clemson University): Yes, I would like to make the comment that one possibility is that any metal ion released into the tissue may affect the normal processes.

Dr. Horowitz: I think that it is important while we are talking about the ionic states of these metals to keep in mind that the valence of the metal is extremely important, as is the coordination number, its binding power to organic groups, since we are dealing with enzymes and proteins, I think. I have not heard about that at all today, but I think someone needs to look at that question.

Unidentified Speaker: Dr. Jonathan Black referred in his discussion to the work of Mr. R. F. Colman in England. A statement in the Proceedings and Reports Section in the *Journal of Bone and Joint Surgery* indicated that a raised cobalt level in blood was not necessarily harmful because the body excretes cobalt fairly rapidly.

Dr. Horowitz: Yes, Dr. Daniels.

Dr. Daniels (University of Utah Biomedical Test Laboratory): I would like to make a couple of comments rather than ask questions. Sometimes it is not very constructive to list problems. But I think in this case our listing of problems is useful so that we can perhaps attack some of them in these scheduled task force activities. I was pleased to see that Dr. Horowitz listed a few problems and talked about expense and ownership, confidentiality, biocompatibility, and litigation and other subjects. I wanted to make sure a couple of other topics got added to the problem list, if possible, because I think it would be very constructive for these task forces to consider what we do about these specific problem areas. One that no one has mentioned yet is terminology. A classic example was today when I got up I talked about forces and the kilograms of force and somebody else got up and

talked about psi and somebody else got up and used newtons. I cannot correlate the data fast enough sitting in a meeting, and it is indicative of our problem. Terminology might be something that should be considered very carefully. Another problem that I want to make sure is on the list and that has come up a couple of times regards funding for any kind of activities. Another topic that perhaps could be expressed in a different way is the question of education. I do not view that as a problem but rather an opportunity. You made a list of opportunities also. We found in our experience in Utah that orthopedic implant retrieval analysis is an extremely fine opportunity for education of residents. The residents in many cases do not get much formal exposure to implant design. I am not suggesting that every orthopedic resident has to become an implant design engineer. That is not the point. We found that retrieval analysis is an excellent educational tool and it affords another opportunity.

Dr. Horowitz: Yes, sir.

Mr. Taussig (Taussig Associates, Inc.): I have a partial answer and a comment. The partial answer to Dr. Lewis and Dr. Chao is to join ASTM Committee F4.20.8.1 on Implant Retrieval of which Dr. Weinstein is the Chairman. We have a medium for you to be active in, and we would just love to get all that data. The comment that I have is that whether you know it or not there is close to us what we call "laboratory accreditation." In fact, the Department of Commerce has almost become a regulator which merely says, or which does say, that every laboratory that does testing will have to conform and be certified. As far as I am concerned, that is good and I am in favor of it. I am working for it through our American Council of Independent Laboratories. It is something all of you should be aware of. You will have to become certified as to background, experience, calibration of instrument, procedures, recordkeeping, and all of it down the line. I am just throwing this out as a comment as I believe it is in the Federal Register, too.

Dr. Horowitz: Yes, sir.

Dr. Piehler: I am a Professor of Metallurgy at Carnegie-Mellon and an Adjunct Professor of Law at the Tulane Law School. I think maybe our problem with regard to ownership may be in the process of solution by all people in the ASTM. We have formed a committee of which many of you here are members, E40, Technical Aspects of Product Liability and Litigation. One of the first standards that is being promulgated and is now ready for main committee ballot is a standard that deals with the sequence of tests and the procedures that are to be used in this process. It distinguishes very clearly between destructive and nondestructive testing. I think in that case there is a serious difference with the tissue, as I understand it, because presumably someone else could look at this at a later time and nothing would be destroyed. This procedure is totally unlike many of the tests that are used to evaluate surgical implants. If you decide to do destructive testing prior to that, you must make a reasonable effort to contact all parties who are known or can reasonably be foreseen to have an interest so they can be there to watch it. If you do not do that and proceed anyway, then it is incumbent upon you to be answerable so that the test that you have done plus any other reasonable tests can still be performed on that device. What ASTM is doing in this field and who is writing standards have been kicked around for a long time. We happen to have people like Tom Lemon helping us, and we also have the former President of the American Trial Lawyers Association. We suggest that the people who are working in this field may not have a problem of ownership at all. My personal feeling, based on the reaction of judges, is that they will welcome such a standard and if this practice is followed then there will be no question about ownership.

Dr. Horowitz: Yes, Dr. Brown.

Dr. Brown: My name is Sherman Brown, Professor of Ceramic Engineering at University of Illinois. I have a couple of comments. First of all, when we talk about nondestructive testing, I think anytime you run a test, you are going to perturb the material you are testing. It is very important to ascertain whether a test destroys evidence, even though it is called a nondestructive test. My second point concerns someone's comment that stress corrosion cracking could not happen in the body. That is really strange, because you have both stress and corrosive environments present. Some of these stresses in some places can be substantial. I do not know how we can come to the conclusion that there is no stress corrosion cracking possible in the body.

Dr. Horowitz: Professor Williams, do you want to respond?

Dr. Williams: I think he misunderstood what I said. I defined very clearly what stress corrosion cracking was. It is a specific metallurgical phenomenon. It is highly unlikely for stress, corrosion, and cracking to take place in 316 stainless steel under the conditions in the body. May I take this opportunity to make one comment and then ask one question? The comment is if we were to reconvene this meeting in England, we would have none of these problems on ownership because no one buys implants; it is all in the National Health Program. I would like to ask one question of Dr. Laing and Dr. Black. We talked about biocompatibility, and it seems evident at the moment that so far no one is very clear as to how we can get a quantitative determination of biocompatibility. Everything is qualitative or at best a subjective quantitative assessment. I would like to ask if there is anyone else who has any opinion of how we may quantitate biocompatibility?

Dr. Horowitz: Very good question. Dr. Laing, would you address that please?

Dr. Laing (University of Pittsburgh): I do not really have an answer. As you probably know, we have tried to quantitate the animal experiment, and we had difficulty doing that. I think that quantitation of tissue reaction is rather like trying to quantitate poisonous properties of a chemical. That is, what is the lethal dose? I really do not know how one could set about doing it with the lack of information which exists. My feeling is that until we understand more of why it happens, we are not going to be able to have a really good understanding. I think the answer lies in fields of sophisticated research far beyond anything I have ever tackled.

Dr. Black: Well, I am reminded of the famous joke of one man asking the other man, "How's your wife?" The other man replies, "Compared to what?" Taking that as a starting point, I will reply to Dr. William's comment. I find myself in substantial agreement with Dr. Laing. In the very general sense if one considers biocompatibility, I doubt if quantitation is ever going to be possible. However, having said that I will retract the statement and say that I am quite certain that relative qualitative evaluation will be possible. In the same way we have been able to develop a practical electrochemical series to tell us something about corrosion of metals in a defined environment such as seawater. It will probably, if not eventually, become possible to rank materials in the same way for clinical or animal use. I will make a further point. I think that while we are never going to arrive at a quantitative index for biocompatibility, it probably is going to be quite possible to arrive at individual tests which produce quantitative results. Examples of tests to produce quantitative results, whatever the interpretation may be, are already prevalent in medicine; Lee-White clotting time is an excellent example. One does not know how to interpret the results; but there is, by God, an answer that you get and that you can write down. You can rate things by Lee-White clotting time whatever it means.

Dr. Horowitz: Do you have a question?

Unidentified Speaker: Yes, I do not want to cut this discussion off, but I want to take the prerogative of asking a question that has been bothering me personally. It seems to me that there is a very important point about device retrieval that everybody has overlooked. That is, how can we assure the parties of interest, as one of the previous speakers indicated, that the device that is being presented for discussion is actually the one that came out of the patient? If you consider this a while, I think that it is a very serious question. How are you going to be absolutely certain that the piece of metal that you put in the lawyer's hand, let us say, actually came out of the patient in question?

Dr. Horowitz: Let Tom Lemon comment on that.

Mr. Lemon: I will comment on that, and I would also like to comment on the stress corrosion problem that came up earlier. First of all, I was using that as an example. Differences in terminology come about after people examine the same condition. I agree with Dr. Williams. I have agreed with some of the work that I know is going on with stress corrosion cracking, prestressed materials placed in rabbits, and materials stressed to the yield point. They found very little or no evidence of stress corrosion cracking. It does not mean that it cannot happen. Yet in the field of litigation the incidence of experts' finding stress corrosion cracking is somewhat overwhelming. I will admit that most of the

people who find stress corrosion cracking are plaintiff experts, and the defendants' experts on the other side are calling it fatigue. Now one group is wrong. This kind of problem will occur in any type litigation and is not limited to product liability or implant-type lawsuits.

The continuity of evidence can be an issue in any type of litigation, especially criminal law. It can become an important problem. Therefore, it is not unusual to find in those cases where the patient has contacted an attorney prior to implant removal, that the attorney is present and obtains the implant in the operating room. We have had cases where an attorney was taking pictures when the implant was removed, supposedly showing what tremendous pain the patient was undergoing at this time. If a doctor suspects litigation, it would not be unwise to identify the implants. I certainly would have no objection, even though the patient demands it, that the hospital protect itself by photographs or other means to make sure that what ends up in the courtroom was actually the device taken out. You really run into a problem where the piece has been partially destroyed by destructive testing.

Dr. Weinstein (Tulane University): I have just a couple of comments. One I would like to address is the stress corrosion problem. I happen to agree with Dr. Williams. Stress corrosion cracking is a metallurgical phenomenon that is not very well understood by many metallurgists, and that includes myself. However, in my mind, stress corrosion cracking implies that the materials placed in the environment would fail if placed in the environment without the stress and would not fail if the stress were placed on the device without the presence of the hostile environment. What is being referred to as stress corrosion cracking implies that there is a crack and a corrosive environment present. That in the truest sense of the word is not stress corrosion cracking in terms of its metallurgical definition. I do not know in what respect stress corrosion cracking is being talked about in terms of litigation.

One question I would like to ask any attorneys that are present and particularly Tom Lemon is: Can we use a patient release form, a form of consent in which we obtain the implant and where we specifically state that we are going to perform destructive metallurgical evaluation of the implant? I would like to know from a personal point of view, since I am the one doing the testing, how that would stand up in a court of law with regard to destruction of evidence.

Mr. Lemon: For that question, you will have to call me. I will just repeat that I think there is a definite ownership problem and you could run into the same kind of problem with that release as doctors would run into with a form of consent. The patient signs it, indicating that he was told all the appropriate things when in fact later he forgets everything told to him. "He didn't tell me that was going to happen!" "If I had known that, I would never have signed that thing." You could run into the same problem later with the patient saying, "Heck, I didn't know he was going to destroy that thing so I couldn't use it. I knew that there might be a few tests but he didn't tell me what the results were; and if I had known it was going to be destroyed, especially the fracture surface, and lose my lawsuit, I would have never signed the release."

Dr. Weinstein: I have just one other quick comment. I get the feeling from some of the people who are talking about their retrieval systems that they have to go through some severe procedures to get implants. I have been associated with three medical institutions in which we ran retrieval studies and in each case we had a very sympathetic chief of orthopedic surgery who issued a simple doctrine. The doctrine was that all orthopedic implants will be returned to the orthopedic service. I would like to know if perhaps Dr. Black might want to comment as to whether others have had similar experiences to mine or whether they have had to go through various other routes to get the implants.

Dr. Black: I am glad we came back to this subject because I think it is not nice to sling brickbats at one's peers. I find myself critical of the short reports we had from Dr. Chao and Dr. Lewis. I think that they reflect the darker side, if you will pardon the expression, of device retrieval. The fact of the matter is that it is not an engineering concern; it is not a bioengineering concern; it is a concern of the institution. I think that the decisions that enter into these programs have to be made, as Dr. Weinstein said, by the administration of the institution. If the medical director's office and the chief

surgeon agree, then it will be done as an institutional activity. I think anything short of that falls sufficiently short of the target and is not worth pursuing because there will not be adequate cooperation. Certainly in the institutions that I know of, where this is being done, where it is in fact an institutional activity, the penalty for not participating is simply the loss of admission privileges. There is near 100 percent participation, and I believe that is the way it should be. Then again, despite the differences I indicate to you there is a parallel between this and the treatment tissue. The surgeon who takes a chunk of tissue makes very sure that some of it goes to pathology. He knows that if he takes out tissue and the tissue can later be used in his records and nothing went to pathology, he is going to be in serious difficulties because of the institutional policy decisions. I think that is the only valid approach to the situation.

Dr. Horowitz: Dr. Lunceford has a few remarks.

Dr. Lunceford: The approach that Dr. Black and Dr. Weinstein stated is the approach that we have taken as far as obtaining implants for evaluation. I have talked to some legal counselors about it, and they do not have an answer as yet. I would like to raise a question for the speaker to consider on the legal portion this evening. What is the realistic legal approach to the routine removal of implants and analysis? When I say a realistic approach, I am talking about a prospective study. We have been engaged in a prospective study for some time now. How can you tell an individual in whom you are placing a plate and screws for a fractured extremity that you want to take this out in 1 or 2 years and analyze it? Well, we do this, but I do not know how well it will stand up. The reason I say this is because the patient comes in with a broken arm or broken leg and he is in pain. He has been given medication and if you ask him for permission to do something, you could ask him if you could cut his head off and he would say yes when he is hurting that badly. So I do not know whether this would really be appropriate.

Dr. Horowitz: I would like to call on Dr. Ruff.

Dr. Ruff (NBS): I wanted to ask the panel members if they might consider a slightly different area performance criterion? I get the feeling that the bottom line of the next few years as opposed to standards of materials is going to be standards of performance. I think all the views I have heard today seem rather pessimistic. I think it would be useful, particularly if there is some optimism about this criterion on standards, to discuss it. We have heard a couple of papers on biomechanics, and apparently some promise for looking at the entire system has been offered. A mechanical analysis including some realistic calculations on loading is apparently the missing step with respect to inserting a device and trying to state what performance you can expect of it. So perhaps biomechanics does offer some promise.

Dr. Horowitz: Is there an optimistic panel member?

Dr. Black: I will disagree with you, Bill. I think that performance has always been the bottom line. In fact, I think that people have been very hesitant when talking about failures today to call the failure a failure in performance, and that is really what this is all about. You do not treat a patient theoretically for artistic or static purposes; you treat him to improve the performance of his body to serve him better. I think the only reason that we have been sort of nibbling around the edges, writing materials specific and now even starting to think about design protocols and, as one speaker suggested, to entertain thoughts of outlawing irrational design approaches, is because we do not know how to come to grips with the central kernel. We do not know how to define performance except in a very general philosophical way, and we know very little about inadequate performance, let alone, as I indicated in my introductory remarks, adequate performance and what assures adequate performance. In the very long run when you get all the way downstream, you find out that it is performance that counts. I will give you a parallel that is very interesting. One of the reasons that we have wonderful statistical processes available to us now is because the Government had to face the issue of performance when the fused artillery shell was invented and it could not test an artillery shell to see if it would explode because if it did, you could not use it. They had to do exactly the same thing that we are faced with here. Out of this came some of the vast amount of statistical techniques that we use today. I think that we are going to find the same sort of approach here, that sooner or later after wandering around in the dark we are going to find some indicators of performance. I do not

think we know what they are now. With those indicators, we will begin to derive intelligent performance based specifications.

Dr. Lunceford: I would like to agree with what Dr. Black said and add a little more. I think that what we can perhaps come up with in the next few years is a minimum set of performance standards. I do not know that we can put in anything like a minimum or maximum, but I do think that we can look toward having some minimum performance standards at some time. We can accomplish this based on information that is being collected from various centers. First we had the work from Scandinavia on implanted prostheses. Dr. Harnz has instrumented a prosthesis that will be implanted at some time when he has the right patient and has all the bugs worked out of it. It will give us a little more information on the functional capacity of the hip in relatively normal individuals. I think with information like this we can begin to come back with some performance standards.

Mr. Heros: I just wanted to add that I think the word performance is used too openly at times. There are several ways of assuring the performance characteristics of a device. For example, rather than a performance standard, the ASTM has taken a slightly different approach, which is to specify certain mating characteristics, for example, between a screw and a plate. Certain material combinations and certain geometry in essence give you a level of performance. These are in the standards book now, and they are in effect a performance standard that we would probably not consider to be so in the next few years, but they are a beginning. When we talk about performance, I think it is very important to keep in mind that all we can offer and all we can talk about in the next few years is relative performance on a bench test. For example, ASTM has F382, 383, and 384 going along with a round-robin test and grouping different appliances into groups one, two, and three. No numbers are associated with them, but the types can be very easily established; it is just a matter of whether we want to engage in round-robin testing and first of all whether we have the right test method. I question some of our present test methods in that they are not workable at all. If you do much testing with the three test methods that are already available, you will find that you will have to modify them to make them work. I hope that we can first attack the test methods and that then we can get to the performance.

Unidentified Speaker: I think if you are talking in terms of performance standards (for example, a package insert may read "this nail will support a 180 lb woman for 2 weeks if she walks 10 times or it will support a 120 lb man, etc."), then I think with what we know now it cannot happen. We are stuck with three variables. First of all, you must have metals that are basically compatible with the body and not subject to corrosion. We have established a standard for that, and there are three metals that succeed in that function. Secondly, you are limited to the amount of metal. As Dr. Laing said, I think that any time you put in one of these implants you are causing damage. The more metal you implant, the more damage you cause, especially if you are going to be taking it out (exclusive of total joint replacement). So you are limited; you want to implant the least amount of metal to hold the bones together. The third function is design. Man did not design bone; God did. He came up with a pretty good system but a difficult one for people trying to design within its constraints. With these limitations and until new materials are developed, I think the variables--in terms of body weight, size, muscle, strength, degree of fracture, where the fracture is located, and the amount and ability of the patient to follow instructions--impose a ridiculous burden. Frankly, performance should be spoken of in terms of holding the bone together during a normal healing period.

Dr. Horowitz: Dr. Gibbons, did you have a question?

Dr. Gibbons (Case Western Reserve University): I think that some progress is being made and that semiquantitative histology and biocompatibility are almost with us now, particularly with the energy analysis techniques that we and other people are currently using. My other comment follows what just has been addressed--performance. I personally am very boggled by the position taken by the lawyer concerning the definition of performance. In my opinion, as he described it, "X lb individuals X number of walks" is completely unrealistic. To me performance does not mean that. Performance is closer to that which was almost described by Collard but not quite; namely, you have a bench test for an individual device. There is no level of performance which devices must meet in a bench test. I think this is sad because all the standards are dimensional and all of the material specifications refer to a bar or billet and such that have nothing to do with the final device. I think that

this sense of performance is what we have to approach first, and I prefer to think of performance analysis in those terms. You cannot accomplish one 10 steps ahead until you start with one at a time, and I would suggest that performance analysis or some phrase for testing the device on a bench should be the first approach, as it is more realistic.

Dr. Horowitz: Larry Pilot.

Mr. Pilot: I don't want to belabor the point on discussion of performance standards, but I want to bring to your attention, if you are not already aware, the fact that under proposed device legislation there is an entire section on performance standards; and I am sure if we tried to settle on a definition today, we would not complete the process in this 24-hour period of time. But I direct your attention in any event to the expressed explicit language in the legislation and the intent with regard to performance standards.

Dr. Horowitz: There was a question back there before; is there still one?

Unidentified Speaker: Every standard contains a minimal level of performance. The suggestion was made that we can only give a minimal level of performance based on the incomplete test data that we have. We should point out its limitations and observe its capabilities. In that way, we are really addressing the total performance and indicating what we can do now and what we have to look forward to in the future. I also suggested that if this is done, it might hasten some of the work that people keep saying we cannot do. Perhaps gradually the area of uncertainty will begin to diminish as it is articulated.

Dr. Horowitz: Dr. Daniels.

Dr. Daniels: I would just like to reinforce something that Mr. Heros said with regard to performance analysis. Our original contract with the Bureau of Medical Devices and Diagnostic Products of the FDA was entitled "Research Evaluation of Performance Requirements for Metallic Orthopedic Implants," which we thought was a pretty frightening title. We ended up telling the Bureau that we did not think that any performance requirements were possible at this point, and the approach we took in our report was just what Mr. Heros suggested: that it is way too early in the sequence. The important factor with regard to performance requirements right now is the development of test methods. The next step that can go on in parallel with the development of test methods is dissemination of the data, as we told the Bureau in our report; that is, we would like to see that kind of data become available to the users so they could get accustomed to thinking about implants in terms of which IM rod has the greatest bend strength, which does not, and so forth. I think that I would just like to reinforce the idea that test methods and dissemination of data will lead naturally toward performance requirements.

Mr. Heros: One of the dangers in looking at performance standards is that implants will be classified immediately in group one, two, and three, etc., or weak, medium, and heavy. This classification leads to the idea that the heaviest that can possibly be implanted is the correct choice, as is already developing in prostheses. Personally that petrifies me. I happen to think there is a place, for example, for the stamped Neufeld nail. I think there are some good indications for this implant and there are some good results using this appliance. Some people who are using it get good results. Dr. Martz, I know you don't agree.

Dr. Martz: Let me give my view on that point. The other side of that coin is that you put in as small a piece of metal as possible, and it is done by a man who is not aware of the strength-loading circumstances involved with that small piece of metal. You don't put in a larger piece or you don't put in a smaller piece, but you put in a piece that matches the requirements of performance in some sense. Even if you want to argue about the definition of performance standard, I do not think it serves us too well to say that we can forget something about performance having dimensional standards and material standards.

Unidentified Speaker: I happen to think there are many ways of predicting the performance of a device. One is to give a number according to a test method. Another is to tell you which metal or in which configuration the device should be fabricated. One point we have discussed a number of times has been that our device specifications or standards in ASTM list a number of devices and list a number of materials that the device can be made

from. Obviously, there are different levels of performance associated with each. I am saying that somewhere in the future, if you want to define the geometry of a particular device and you want to define the material it should be made from, then that is a performance standard. I think, in law, a performance standard is something that makes an appliance safe and efficacious.

Unidentified speaker: I want to comment on this issue very briefly, too, for the benefit of those here who have not been party to these sorts of discussions. This is becoming, unfortunately, a bit of end discussion. I want to make quite clear that we are locked into what is called enlarging a vicious circle. Because on the one hand, if we address the issue of performance in the most general sense meaning a device *in vivo*, the reply most generally given is: Well, we don't know how to measure that; let's devise a bench test. We spend a lot of time and we devise a bench test and are told something about the device. What do you think is going to be the reply then? It is the one that closes the logical loop. Well, that is all very well and good for the bench test but does not tell us anything about performance *in vivo*. Now I am afraid the hour is past when this loop can continue to run round and round and round. Consumerism and the legal profession nipping at our heels here suggest that performance as I indicated before is the bottom line, and we're going to have to get there by hook or by crook. It is no longer going to be satisfactory to say "well, they developed test methods and we're going to categorize the stiffness of things, but we're not going to set limits and standards and requirements," and so on. I would suggest if there is any way out of this loop, it is through some kind of comparative testing. I think the key always is going to be comparative rather than absolute testing. I do not see the road out, but I suggest that we have got to find a road out and in very, very short time.

Unidentified speaker: One of the things about writing standards is that our supervisors are very critical about rationale and performance. I can comment that we are well aware that the ASTM standards need good paragraphs on significance. If you have a bend test or a bench test, as you call it, in terms of *in vitro* compared to *in vivo* tests, we will have to write significance tests so we can use that test later on. What does the significance of the tests mean?

Dr. Horowitz: Let's see. We have about 10 minutes, and if there is anyone in the audience who has a question that has been burning in his mind and has not asked a question before, I would like to get to those people. Then we can spend the remainder of the time with those who had a chance to ask a question earlier.

Dr. Chao: I would like to use the last few minutes to correct Dr. Black when he says that what I have presented is a pessimistic view. I do not agree. A point I want to make is that at least one person in the audience commented about the biomechanics aspect. I think it is important that we consider the biomechanics aspect because if you want to do any tests, you want to know what the basic loading should be to put on the device.

Dr. Horowitz: Yes.

Dr. Bardos (Zimmer, USA): I would like to make a few comments on some metallurgy points I heard today which can be potentially misleading. The question of molybdenum content was raised by one of the speakers this morning as being somewhat on the low side in stainless steel. I would just like to say that a molybdenum content of 2.2% is near the optimum value. If you start manipulating the constituents in stainless steel, you offset the balance and find that the material is guaranteed to fail. One of the speakers referred to a microstructure in stainless steel as being overworked and being a positive factor in failure. That microstructure was very clearly not overworked, it was a very reasonable range. One of the other speakers referred to martensite stainless steel, and there is no martensite in 316L stainless steel. I just thought I would mention this for the record. Thank you.

Dr. Horowitz: Dr. Martz.

Dr. Martz: I hope we do not go away from here thinking that a standard is either a promise or a guarantee. In a sense maybe that is one of the traps Dr. Black mentioned that we didn't go into in detail. We are seeking the truth or seeking the lowest common denominator in minimum requirements. When we set up a standard, when we talk about standards,

they are not to be described or defined as promise or guarantee.

Dr. Horowitz: Dr. Brown.

Dr. Brown: It seems to me that one way of getting around ownership at least for research purposes would be to offer to repurchase the device. If the patient owns the device, he can sell it. That comes down to the matter of under what conditions he can sell it and what kinds of reservations he wants to put on it.

On the matter of stress corrosion, there is a large bulk of literature dating back two decades in which some very bright people have written about stress corrosion in such diverse materials as glass, aluminum oxide, and many kinds of materials; and they are not metals at all. It meets the general criterion that the reaction would not occur if the stress were not present; it would not occur if the environment were not present. It is the same kind of phenomenon. Some work, of which many here are very much aware, also is going on where people are advocating ceramics for orthopedic purposes; but there are some drawbacks to these materials at the present time. You find that there are ceramic materials being used in some parts of the world. Whether this use is precipitous or not is for someone else to judge; I mean I have my own opinion. But someday, sooner or later, we may be faced with the matter of judging a ceramic material for these purposes. If we exclude these from the possibility of stress corrosion, we may be doing ourselves a disservice.

Mr. Lemon: You are correct; they could be purchased back from the patients, and I'm involved in several cases where that is exactly what they want us to do in the range of \$25,000 to \$100,000. One of the things I was commenting about is what Dr. Martz said. He said in an interesting statement, and it is true from a practical or scientific standpoint, that a standard is not a promise or a guarantee. But I cautioned in some of my remarks that we want to be very careful when we enact a standard because while we may not intend it to be, by the time it comes out in the ASTM Handbook or wherever, it becomes the standard by which lawsuits are then judged. If you fall below that standard, you may not have promised it or you may not have guaranteed it, but believe me you are buying the implants with that in mind.

Dr. Williams: They clearly know now that 316 L stainless steel will undergo a stress transformation during cold work. Whether this is martensite as clinically defined, I am not saying for certain. It certainly happens and gives a great change in the structure of the steel.

Dr. Horowitz: Yes, sir, Dr. Jaeger.

Dr. Jaeger (M.D., Silver Spring, Maryland): I have one brief question about the medical/legal aspects of these implants that have been removed because of failure. Let's say for the sake of discussion that the patient has an implant, but the implant fractured, and you're going to use this as evidence in a court case. Now if he is going to use this as evidence in a court case, he must have it analyzed and he must prove why this thing failed. He has already paid the cost of having it analyzed. If he has not, the piece is no good as evidence. Once it is analyzed, he has paid the bill for the analysis and the findings are made a matter of public record or can easily be obtained from the attorney presenting the case and put in with findings from other centers. If he does not have it analyzed, if there is no legal case involved, he will gladly give it up. The fractured device can be analyzed years after it is taken out. Or am I wrong again?

Mr. Heros: The situation may be different in university surroundings. Let's say as a manufacturer, a failed implant comes into our plant and there is no indication of a lawsuit; it is retrieved normally; we have been advised to do absolutely nothing to it. Six months from now that same individual changes his mind, comes back, and says "I heard that shouldn't have broken; give me back my appliance." There is no way you can prove beyond any doubt whatsoever that the parts you mounted in a specimen holder to look at in a microscope all belong to the same article. He can claim that you defaced the part. We have been advised not to even touch it, period. Log them; put them away in the safe; and that is it. Well, assuming that the person is an adult at the time it broke, you generally have a 1- to 5-year statute of limitation; most states have 2 years. So I think if the manufacturers have the device over a reasonable period of time, it would be susceptible for testing. However, your

tests are going to be very inconclusive unless you have taken very good clinical information at the time it was removed. This information is what is failing or lacking in almost all of the work performed to date. I notice on the work sheets for Northwestern, the doctor had to recall from memory what the clinical aspects were. Yet this aspect is probably tremendously important. It is as important as your metallurgical examination. You would not necessarily want to depend upon the report you would get from the patient's metallurgists, in preparation of filing a lawsuit, as to what the truth of the matter is.

Dr. Horowitz: We are going to allow two more questions.

Unidentified Speaker: Let me finish this question, please, Manny. I am going to say what Dr. Daniels is about to say; I think I can read his mind. That is, we already know that even in the case of freshly retrieved implants that actually have something physically wrong with them, metallurgically or mechanically, we cannot figure out what is wrong half the time. The more time goes by, the more handling there is, particularly in fractured devices, and the more obliterated the evidence becomes. Furthermore, there is no reason to believe a patient will keep it around. I remember a photograph in *Time* magazine several years ago of a well-known Texan who had a total hip prosthesis, at least the femoral section, mounted as a hood ornament on his car. I surely would hate to analyze that at some later date.

Dr. Horowitz: Tom Murphy.

Dr. Murphy (Veterans Administration): I wonder if I could not use a neutral certified laboratory.

Unidentified Speaker: You can, but while Sayre is willing to subscribe to registration or approval, most of the cases are not going to be taken care of, and neutral laboratories are used very infrequently. Frankly, one side is going to be disappointed with the result, so that the other side is still going to go get somebody else. I think that there is a lot to be said for the procedures that are done prior to the removal and prior to the insertion and that becomes part of the education of total use and limitation of these devices. If patients were more informed as to what to expect in failures and the other complications that are going to occur, we would probably have less lawsuits and less trouble getting hold of these devices.

Dr. Horowitz: I'm going to end this meeting; we have time for just one more question. Yes?

Dr. Lewis: I think we are losing perspective about what you do with the removed piece after it comes out. Out of approximately 25 that we obtained, we have never had a problem of anybody wanting them back. We had all 25 of them sitting in bags. We do not do any destructive testing on them. I think we are talking about the possibility of getting a system operating so we can figure out what the main problems in the design or the function of these prostheses are. It seems as though we can go ahead and we can do all that; and as long as we do not do destructive testing, I do not see where we run into a legal problem. We should not let the litigation problem scare us away from going ahead and making some sort of central collection or coordination among the collecting groups.

Dr. Lunceford: I would like to put things in a little better perspective. Here we are sitting in the Green Auditorium, discussing these subjects in a very idealistic fashion. When we look at the real world, we have to deal with patients coming to the operating room at 2 o'clock in the morning and a first-year and a senior resident operating on those individuals, putting plants and screws in or whatever has to be done. They will not catch up with our idealistic approach for some time. I do think the best way we can achieve good medical care for these patients is to have an idealistic approach such as we are trying to achieve here. But we also must maintain a good doctor/patient relationship, and only in this fashion can we avert many of the lawsuits which we are faced with today. I think this is a somber note on which to terminate the program, but I think that we do need to realize this factor is probably the one that has failed in many cases, and that is the communication between the physician and the patient.

Dr. Horowitz: My final remark has to deal with one of the many problems that was mentioned, and that is the differences of opinion that you have heard here today. I would like to leave you with the suggestion that one of the ways out of this dilemma in respect to terminology, philosophy, differences in engineering concepts, and so on is through a strong program in measurements that leads to the development of test methods, the known accuracy. Through a program in standards, materials can be used to calibrate our test equipment, and this concept of retrieval certainly is part of that. I think then we will have a scientific and technical basis on which to resolve some of these problems that seem so unresolvable.

Dr. Weinstein: I would like to take this opportunity to thank Dr. Horowitz, the panel, all the speakers, and especially the attendees.

"WHAT IS THE NATIONAL NEED?"

Workshop Task Force Reports

A. W. Ruff, Chairman

Dr. Ruff (NBS): Can we come to order, please. We are starting a 2-hour session. We will allot 15 minutes to the presentation of each task force. Each presentation will involve an evaluation and up to three principal recommendations from each group. Finally there will be a 30-minute period for discussion. I hope the speakers will present a summary of the group discussion, a summary of the current situation, and then their recommendations.

Dr. Martz, would you please start and present the clinical findings?

Dr. Martz (American Orthopaedic Association): This is Dr. Martz, an orthopedist from Indianapolis, reflecting the work of the clinical task force.

Historically, implant retrieval has been spontaneous, episodic, and anecdotal, resulting in an inconsistent data base. The test patterns have been diverse, and the analysis systems have been varied. There have been differing motivations and attitudes in the approaches and interpretation with little statistical validity or clinical reference. The current knowledge of performance of implants is incomplete, and hard data are emerging slowly. Some, but not many, relevant conclusions can be drawn because of the anecdotal and commercial flavor of the studies.

The relationship between design and the performance of implants is somewhat primitive at this time, is highly individualized, and has inadequate relevance to the anatomical and physiological models that have been available to us. The need for improved performance of implants suggests that we study the expectant service loadings and the service life and ensure that the design and the materials are compatible with the biological requirements. We need information as to the indication for the choice of the various implants and methods of insertion of the various implants. In a relevant and realistic manner, methods for retrieval should be spelled out so that performance analyses and quality assurance can be provided.

Some of the fundamental information to be used is referenced as "Body Mechanics," which must include bone, muscle, and fascia as well as the neuromuscular patterns and load patterns that human beings employ. All of the activities of daily living must be considered, and the material fatigue problems involved must not be overlooked. The trauma and micro-trauma of ordinary living must be considered as well as the aging processes which bring wear and tear. Unusual trauma might be considered together with the disease process of neoplastic and degenerative nature. Is there a chance for progress in these areas where implants for replacement arthroplasty are becoming ever more numerous?

Individually and as organizations (voluntary, foundation, and Government), we are interested and concerned with the retrieval of devices. In the retrieval of devices, there are barriers which must be removed. These will be considered elsewhere.

Our first recommendation is that a standard protocol be developed. We recommend that the present ASTM F4.2.8 task force draft practice be made compatible with our clinic considerations. There are other standards to be considered as well. Those of ASTM F4 referable to handling and labeling requirements are also relative to this study. The work of many other ASTM committees comes to bear upon this problem; A1, E7, C5, E4, E9, E24, E28, G1, G2, F15, E30, E40, along with others, have relevance to our programs.

The next recommendation is that the work of other centers, such as Northwestern University, Mayo Clinic, and University of Utah, should be considered pertinent to this study. Multiple centers for the study of implant retrieval should be established. It is suggested that universities or medical centers be selected in geographic areas throughout the country. We could name a dozen or more in addition to Veterans Administration centers. Among the possible geographic areas to be represented would be Boston, Pittsburgh, South Carolina, Utah, San Francisco, Los Angeles, Seattle, Houston, El Paso, Chicago, Rochester, Denver, and even possibly, Indianapolis.

The last recommendation is that a central data bank be provided by ASTM in Philadelphia to answer questions of concern. This information would cover both the voluntary sector, including the national, regional, and state orthopedic societies, and the Federal sector, including the National Bureau of Standards, the National Institutes of Health, the Food and Drug Administration, the military establishment, and others. The question of funding, whether voluntary or contract, was left open by the task force.

Dr. Ruff: Thank you, Dr. Martz. There is time for discussion of these recommendations.

Mr. Heros (Richards Manufacturing Co., Inc.): You mentioned a central data bank; yet you mentioned it in relation to ASTM. Are you then considering a voluntary central bank?

Dr. Martz: We suggested the good offices of ASTM as an appropriate central data bank that would be impartial in reference to governmental agencies, the orthopedic industry, and the orthopedic surgeons--presenting the idea of consensus.

Let me now mention the barriers that we encountered and failed to mention; these include industrial reluctance, surgical reluctance, and hospital procedures in the way of purchasing and storing and retrieval methodology. There is some consumer misunderstanding and need for informed consent to ensure long-term cooperation and the avoidance of legal redress. However, the basic barrier seems to be our lack of knowledge (biomechanical, material science, engineering science, manufacturing practice, and surgical procedures) and performance evaluation. Perhaps the uninformed are trying to achieve the impossible.

Dr. Horowitz (NBS): Could you summarize how the data that have been collected and evaluated will feed into the clinical area again?

Dr. Martz: Do you want to talk about feed-in or feedback?

Dr. Horowitz: Well, feedback into the clinical area.

Dr. Martz: A feedback from the central data bank and the study centers could be arranged through either the professional literature, or by bulletins of ASTM and our Academy of Orthopaedic Surgeons, or through our *Journal of Bone and Joint Surgery*. In other words, there is feedback directly through the literature.

Another feedback mechanism could be a consensus bulletin in which the industry would cooperate with the profession and with both the Federal and the volunteer groups. I am thinking here of any publications that might arise in the Federal area or could arise under auspices of ASTM, the American Academy of Orthopaedic Surgeons, and the American College of Surgeons.

We do put out periodic bulletins and newsletters so that feedback could be both through the formal literature and the immediate literature. The Orthopaedic Surgical Manufacturers Association (OSMA) and similar organizations could provide appropriate and impartial representation through their trade representatives to the surgeons and the hospitals. As they sell their wares, perhaps they could deliver our message.

Dr. Ruff: Thank you. We shall now hear from the legal task force.

Mr. Lemon (Zimmer--USA, Inc.): This is Tom Lemon speaking for the legal task force. We had a lot of discussions and, as is typical of most lawyers, very few conclusions. Basically, an overview of where we are with regard to the state of the law as it pertains to product liability and the development of retrieval analysis regulations is just what Bob

Rylee stated. We seem to be going down two different paths. And they are probably not going to join with each other. One of the paths is the need for advancement of medical science generally and the improvement of products to patients. The other path is purely litigation oriented, and it attempts to improve or recover alleged damages sustained by patients who have been or who feel they have been injured by a broken device or device that in some other manner failed and caused pain or some other problem.

Increasingly, the law of product liability is continuing to get out of hand. We are rapidly moving forward to an era that is going to require almost absolute insurance unless there are some reversals in the trend in the courtroom.

In any event, I think that there are problems that must be considered because of existing litigation. But I think that the overriding concern with regard to improvement of products and patient care must be the primary one. And while the matters that we have discussed and brought up in the questions and in the presentations of some of the legal problems are important, I think that they must be considered, but not be the dominant force, that motivates what goes on in the orthopedic world of physicians and manufacturers.

Certainly these are a number of areas that we feel we might be helpful in, and we did make a couple of recommendations. One, that was already brought up, is the development of a uniform retrieval and analysis protocol. It is obvious that the work that has been done to date is probably the only thing that is available to show what we need to do if we are going to have useful materials. We need to operate differently from the way we did in the past. The primary ingredient that is missing is clinical evaluation.

Now, certainly there are going to be some barriers and problems in obtaining relevant clinical material. First of all, you do have the potential invasion of the privacy of the patient; that is, his right to have his case be discussed or known by other people. And certainly there are relevant factors that he might not want known; for instance, whether he is an alcoholic or a diabetic. But yet that information may be relevant to the clinical material that needs to be obtained.

Secondly, if you are going to have really comprehensive clinical material you could be in the situation where the doctor himself must make an admission against his interest where he feels at fault in some regard after an honest evaluation of the patient. You are going to have to be very cautious about making those kinds of admissions in the clinical reports because you are right back into the lawsuit area.

Further, the manufacturers could likely be put in the position of making declarations against their interest in obtaining the entire clinical picture, not only including what the patient did but also the entire management process of the individual case.

The other area in which we have a recommendation is with regard to the issue of ownership. Theoretically, ownership belongs with the patient once the patient has paid for the device. But I think that ownership is a practical problem that has not been all that much of a concern or been encountered in the area of retrieval today. People have talked at length about ownership problems. But it has not seemed a handicap in obtaining the device. I think that anytime ownership comes up, giving the device to the patient is the easiest way to handle it.

Another obligation, however, that relates to patient ownership is that anyone who undertakes to do any type of investigation of a broken implant should be very careful to document his receipt of the implant, to respect the integrity of it, and to carefully document and maintain all specimens and the implant for a reasonable time period. That reasonable term of time must be the existing statute of limitations. Since that is going to vary from jurisdiction to jurisdiction, I think this matter should be developed further.

We also talked briefly about the idea of establishment of a regional collection center for the investigation and analysis of these devices. It was felt at this time that the problems with regard to confidentiality and the problems of getting complete cooperation from all sources probably are going to be the principal impediment. We felt that a primary consideration is that of protocol. But it is obvious many people already are doing investigations on their own. And the important point is that they all attempt to use the same type of protocol procedure. I think that is the more realistic approach in the short run.

Dr. Ruff: Thank you, there are several more minutes to discuss this. I want to ask whether the legal group had considered the ASTM committee on product liability and whether there might be some partial interaction between that group and ours in the way that they recommend things be accomplished and some of the legal problems that might come up.

Mr. Lemon: We did consider briefly the work of E40. The primary area that we considered and that E40 is not considering is the one with regard to testing done by experts. There is a kind of a blanket investigation, and this particular standard requires or would require notification to all known interested parties. This is not that difficult to ascertain. If you are an expert for the plaintiff, you know that the manufacturer and the hospital and the doctor are interested parties. Or, on the other hand, if you are the manufacturer you know that the patient and the same other people are the obvious ones. You would have to notify them prior to the undertaking of any investigative testimony. Now, it was felt that this notification would thereby afford everybody a chance to look at the device before it was destroyed or cut up, regardless of the product.

The problem that arose, that Bob Rylee mentioned--as a matter of fact he said he was going to vote against this standard when it comes out--is that routinely most of the orthopedic companies now are making examinations of devices that are sent back by doctors or hospitals. Most of these do not lead to litigation. That standard would also require notification. It would mean they are going to have to give a notice to the patient of their intent. In many cases patients do not care what is going on with the implant. All of a sudden, "We want your expert or your attorney. You had better get him over here because we are going to cut this device up." That is what you do; you get his attorney and expert, and you have got a lawsuit. It would be potentially harmful to do the exact thing that we are talking about here. All of a sudden if the University of Utah had to give notice to all of the patients before they had done any testing, believe me, much litigation would have come from that.

Mr. Weisman (Howmedica, Inc.): Do you think that E40 could address itself to the items that are specifically involved in litigation rather than all devices? And then would you give the others or the interested parties an opportunity to examine them?

Mr. Lemon: Well, the problem is, as you know, insurance cases end up in litigation.

Mr. Weisman: Well, why not leave it until that time? Do not assume that there is going to be a litigation. Only include those products that are in litigation.

Mr. Lemon: Well, that might be the only way you are going to have a standard that is going to be passed. But if you do, an attorney does not know whether it is going to end up in litigation or not.

Dr. Horowitz: I have a generic question. It has to do with the result of litigation providing a source of income to lawyers. You alluded to this yesterday. Is not there some mechanism, perhaps the no-fault philosophy, that could be introduced into the area of orthopedic surgical implants so that only those cases that need to be tried in a court of law are tried? Perhaps some of the driving force for litigation may be coming from the legal profession itself? I do not know that that is a fact.

Mr. Lemon: Well, to do this, you are going to have to make some basic changes in your whole approach to our legal system. And that question is not really a legal one. It is a policy question. How many times do you have injuries that you want to remove from the litigation process?

Frankly, no-fault with regard to automobiles has not worked effectively because in spite of reducing litigation, it has not worked in the lowering of insurance rates. However, I think that we are going to see some stage of trying no-fault in the malpractice area. I think there is some really serious problem in trying to introduce this. Workmen's compensation was an idea, in fact, no-fault in a way; and it has not really been effective in terms of providing a good answer. But again that problem is not a legal question as much as one for the public as a whole to decide how it wants to be served in this area.

Dr. Ruff: One more question.

Dr. Murphy (Veterans Administration): At the very end of your discussion, we touched on what amounts to the answer to Mr. Weisman's question that possibly one way to overcome some of the barriers would be to delay any suits for 4 years until the statute of limitations would have run out. Therefore, we just keep things sterile and locked up in the vault for that time. However, who in our society wants to have a guaranteed delay of at least 4 years? Is this any progress?

Dr. Ruff: I think that we should probably move on, gentlemen. We can direct questions to the legal task force at the end. We next turn to the report of the industry task force.

Mr. Heros: I am from Richards Manufacturing Company. Now, to start with a little of the background. I think that you know the perspective; what we are looking for is not really a way to make the best use of devices, but to give the best patient care. As such, we recognize that we are talking about a complete system geared towards the gathering of information. We are talking about the complete environment which includes patients, surgeons, hospital behavior, and the manufacturer's behavior towards the presentation of certain products. Hopefully, implant retrieval analysis will be a multibenefit activity.

As we defined it, some of the benefits would be:

1. To provide vital data for improvement of surgical results. This information could be anything as simple as, for example, a recommendation, which could establish surgical trends, not to use a certain product for surgery.
2. To give information about temporary function devices--whether they get removed or are left in.
3. To place an emphasis on getting as many different expert opinions on questions as possible.
4. To clarify some of the legal aspects. By that, we mean that there would be more of an understanding in this area, such as who is the owner of a retrieved implant.
5. To pinpoint problem areas.

I keep going back to concerns rather than specific devices because they are not isolated; they are part of a system. We hopefully will be able to pinpoint problem areas whether they happen to be a particular device, a particular geographic area, a particular type of patient, or whatever. Also, another one of the main points the group discussed is the improvement of the information feedback pattern by shortening the lead time that is necessary. We would then be able to provide more accurate information to everybody concerned and in less time.

Now, we see some major problems prior to achieving progress in these areas. Dr. Daniels covered one point when he said yesterday that any time you condense data you can miss valuable information. I have been involved in litigation. Reviewing the complete records on one device took 1 day for the technical reports and another day for the patient records from the doctors and the hospital. So I think we have to be very cautious with the techniques we are going to use in the gathering of information. The amount of information available is massive, and condensed information loses significance. In our own experience with one case, on the record it appeared that the patient was instructed to "ambulate with care"; but it was not "care," it was "cane." That made a lot of difference in that case. One little word that appeared in the middle of reams of paper in the hospital records really brought out a point that was crucial to the whole issue.

Another big problem is the resolution of all legal questions: ownership, confidentiality, etc. Obviously, the misuse or availability of this information to plaintiff's attorney would be a major matter. Another factor is competitive misuse. We see this as a distinct possibility, maybe healthy or maybe not healthy; but I see it as an area to be concerned about.

We then arrived at our recommendations. First we have to resolve some of the legal questions, possibly by presenting them in writing to a group of attorneys for clarification. Some very pressing legal questions will have to be established before we can really get going.

Second, we think that in any system, we have to begin at the starting line. We see it as beginning at the voluntary consensus approach through the ASTM and through the effort that has been put into existing work. We are concerned that some of the situations that we are talking about in voluntary consensus groups will, in the future, be made mandatory. I think that it is a point of concern to all of us, not just industry but the doctors, for example. To be made to take photographs during the removal process could be absolutely horrendous. So there are many questions that will involve all of us. Obviously the regulatory agency needs to be very, very careful that whenever we approach something from a voluntary consensus standard, it does not necessarily mean that we all prescribe it on a mandatory basis.

Finally, we feel that utilization of the system that is being developed by ASTM F4, at least on a trial basis for a year with certain groups, may give an indication as to whether this system is yielding the results that it should.

A point of concern is the tremendous amount of money that this system is going to represent. Ultimately the money is going to come from patients, consumers, etc. I think we need to weigh the relative gain that we are going to get from the system and the amount of work that is going to go into it. Maybe I am being naive; but to do a complete, proper evaluation would require a tremendous amount of work. That represents a lot of money. I do not know whether we are going to get that much feedback. We should view carefully the costs and establish an "impact value" of the proposed steps.

Dr. Ruff: Are there any questions?

Dr. Black (University of Pennsylvania): I think that I would like to address the last point about cost. Presumably in a routine retrieval system in which one is removing all devices, perhaps 90 out of 100 receive no study because it is not warranted. Perhaps the second group, 8 out of 100, receives some sort of preliminary investigation at relatively low cost. Perhaps the remainder, 2 out of 100, gets full study because there is an associated problem. I think it develops that care must be taken to see that there is this sort of sliding scale. One needs to continually retrieve and preserve implants, but the effort involved in the analysis should be commensurate with the indication of satisfactory or unsatisfactory performance.

Mr. Heros: From a practical standpoint, I would agree that would be the only functional approach, the only sane approach to the question. However, you get the problem that we were talking about yesterday: if we are truly trying to establish a feedback situation, do you analyze only the failures, or do you analyze some of the successful ones also? What would be better: to analyze very roughly all of the implants and establish a benefit-to-revision record, or do we deeply get into two or three? I would tend to lean towards an overall approach. "This device was used, and we had a revision." I do not know about the approach of two or three in-depth analyses--I really would question the validity of the information retrieved. I think that the answer to your question is simply, yes, one must do both. One must consider very broadly satisfactory performance, and one must also study a detailed list of performances. The system has had to be flexible enough to permit both kinds of approach.

Dr. Ruff: Are there any other short questions?

Dr. Martz: These recommendations propose two questions to all other task forces. First, would there be any validity in the clinical data, because the information may not contain, for example, the type of occupation of the patient and reference to any pathological status?

Question two, would the ordinary procedure of surgery and pathology suffice to obtain the data needed on the implant and to permit the discussion of the implant and the adjustable changes? Would this be a sufficient source for further study?

Mr. Heros: With respect to your first question--obviously that would be extremely important. There would be concern over an alcoholic following certain instructions. It is absolutely essential that that type of information be in there somewhere. With regard to the pathologists' system, I am not an expert on how that works. I would venture to say, yes, it would be a workable situation to channel through. But I am just not familiar enough with pathology departments.

Dr. Martz: It is our suggestion that perhaps as much attention should be given to our ordinary procedures as you pay to the basic procedures of pathology, with reference to device process. We would suggest that, with all good humor, perhaps you acquaint yourself with the practice of surgery on which we base those recommendations.

Mr. Weisman: Mr. Lemon already discussed this question earlier and raised the significant point that this might relate to infringing on the privacy of the patient.

Dr. Ruff: All right, we will then unleash the tiger and ask for the presentation of the basic science task force.

Dr. Black: I am going to take 2 minutes at the beginning and answer the two questions that have been posed.

The answer to the first one concerning the desirability of studying retrieved devices is, I think, obviously yes. Further, the more that is known about the clinical condition of the patient before, during, and after the incident that led to removal of the device, the better the chance of determining the basic principles that result in successful or unsuccessful forms of the device.

The second question whether the relationship between surgeons and hospital administrators is adequate to gather data, to retrieve the device, and to further insure that the needs of the various parties can be served can only be answered with a qualified yes.

I think that present system can evolve into a satisfactory one. Some of the elements that are required are recognition that the study of tissue removed from the body ought to become more generally the study of all *things* removed from the body, including tissue and devices, and the necessary introduction of physical scientists to work side by side with their biological and medical confreres in the study of such removed tissue and devices.

Let us now move to the report of the group on basic science. We were faced with considerations spanning the entire breadth of human knowledge so we had to get rather specific and develop a systematic approach to our task. We followed this plan of attack:

First, we defined the areas of investigation in basic science that are related to orthopedic implants.

Second, we developed statements on the present status, problems and opportunities, and near-term objectives and their relationship to device retrieval and analysis programs.

Then, still working on an individual basis, we prepared recommendations for action in each area.

Finally, as a group we discussed all of the above material and attempted to reach a consensus on the various recommendations.

The areas of investigation that we defined are: properties of tissues; musculoskeletal mechanics; materials characterization; development of fixation technology; implant design principles; instrument design principles; postremoval assessment and design verification; differential diagnostic techniques; and education in basic science. The result of this process was a report running to some 26 handwritten pages. I am going to verbally summarize some of the recommendations of that report. These recommendations appear in Appendix III. With respect to each recommendation, we attempted to determine whether the institution of a device retrieval and analysis program would have a positive impact. In all cases, we came to the conclusion that device retrieval and analysis programs would aid in the achievement of the goals that we had defined in the basic science area.

The first recommendation is a rather small one: that an optional microbiopsy procedure be provided within the retrieval protocol such that one could obtain tissue not just for biological evaluation but, if you will pardon the loose term, for mechanical evaluation. This procedure would lead to better knowledge of growth, repair, and remodeling mechanisms of tissue within the patient.

The second recommendation is that standard methods be developed for functional evaluation of patients to determine how implants, whether successful or unsuccessful, function in the patients and how they relate to the patients' functional requirements in everyday life. This recommendation is a primary one.

Third, we think it is extremely important that new techniques be developed to provide comparative testing of both materials and device and patient function so that a larger body of information concerning material properties including biocompatibility can be amassed.

The fourth recommendation concerns the need to develop a better understanding of fixation techniques. That is to say, how do current fixation techniques work? How does the tissue function in biological fixation by ingrowth in a porous body? How do screws and plates used in fracture fixation actually function *in vivo*?

The next recommendation is also of primary importance and has been alluded to before. We feel that it is of great importance that the results of analysis of device function and of retrieved devices be available so that they can be used in a timely fashion in design and development of new devices. I would certainly be appalled if legal problems required engineers to wait for 3 or 4 years after devices were retrieved before they could be studied.

The sixth recommendation is rather obvious, and we felt it was of primary importance: that is, that a common analysis form be developed and prepared for use in device retrieval and analysis studies. We are not suggesting that data should be gathered into a central point, such as the F4 committee. The point simply is to assure that as device retrieval and analysis programs begin in a broader distribution than at present, the data developed will be stored in a standard form for future comparisons.

Another area that we feel requires some considerable attention is the development and understanding of indications for selection of specific devices. It seems to us that patient indications for selection of a particular design of a device are very poorly understood and little considered today. Much development is needed in this area.

Finally, we feel that patients and, to a greater extent, surgeons require considerably more education in engineering principles, in materials, and in device performance so that those individuals could understand the implications of designs and the importance of their proper use. We think that in the future such information will help improve the performance of devices that are in use today and that will be developed in the future.

Dr. Ruff: The floor is now open for discussion.

Dr. Martz: Just a question to this basic science task force from the clinical task force. Would the basic science people find any value in such suggestions and indications for implants as embodied in a comparable manner by the original USP, followed by the PDR, followed by hospital formula, and reestablished by SOP standards? Do you see the operative procedure as recommended or suggested by the Joint Commission as a means of implementing the suggestions or improving the education of all of us concerned in this area of implant?

Dr. Black: Dr. Martz, it is hard to say no to questions like that. I think that all of these capabilities will contribute to the implementation of these recommendations.

Dr. Martz: The point, of course, is that all of these things mentioned fall far from basic scientific consideration or even good surgical principles. They are properties, and we worry about this sort of an approach. Could you address that point of my question?

Dr. Black: I think I understand the concern. Frankly, this problem was not discussed within the task force. I can only express my own view that it is really a matter of enhancing the use of present methodologies and that the present practice of participation of basic scientists in training programs and in education programs should be continued. And, in fact, a few of the recommendations we make are simply to do what is currently being done.

Let me bring up one point that I indicated to the members of the task force. We had considerable discussion about the desirability of gathering results from device retrieval and analysis in central locations, that is, beyond the confines of the single institution.

Some feel it is desirable but not possible. Others held that it is both possible and desirable. I think it fairly sums up the discussion to say that in the future it would be both possible and desirable to accumulate data that way. Furthermore, such accumulation will start as soon as the various legal and ethical problems involved can be resolved.

Dr. Ruff: I would like to call next for the regulatory task group report.

Mr. Pilot (FDA): The regulatory task force thanks all of you who spent a great deal of time discussing a number of issues which crossed over into areas of special interest to us. I see that some of the recommendations and issues that others have covered relate to the same kind of thing that we were considering. When we get into the summary of the recommendations, I think we will find agreement as to what is desirable.

In an effort to try and visualize what our thinking should be in the regulatory area, we did discuss the influence of the FDA, the professions, and industry with regard to regulatory issues. Certainly the concern over FDA as a regulatory agency is of particular interest. Present regulatory authority is one issue. Another relates to uncertainty about expected changes in the law which obviously will result in an expansion of FDA's interest and responsibility in this area.

With regard to the inadequacy of useful scientific and technical data, there are a number of difficult issues that can be summarized, including the fact that methods of collecting and evaluating information and data on performance may not be complete, thus making it difficult for a regulatory agency to fairly and equitably monitor and evaluate performance on implants. The lack of a standardized method for testing and analyzing retrieved implants results in continuous confusion. Finally, the absence of a nationally coordinated system is disturbing. While several different groups are active in this area, these groups do not coordinate their activities; and the analytical methods used are not standard or compatible. We had some discussion of that yesterday.

With regard to additional needed information, again, we are trying to be brief and identify other characteristics. Certainly the need to have traceable information, which I have indicated as records and reports, is important and critical. We must be able to refer to epidemiological data with regard to who uses what, how it is used, what environmental or physical characteristics are applied to a given fact situation, and the characteristics of a device in terms of properties and better performance. In this regard, we are concerned about data on biocompatibility. Then finally, with regard to additional needed information, we mention the data necessary to lead FDA or the voluntary sector toward the development of performance standards or standard test methods.

Now, this review gets us into our three basic recommendations. The first relates to the need to establish a voluntary national coordinating system which would be designed to provide us with information that would be useful in analyzing and summarizing data on implants. It is essential to plan and provide for an effective reporting network involving the manufacturers, FDA, and professionals including physicians, biomedical engineers, and other health-related personnel.

In addition, a nationally coordinated system should provide for a mechanism whereby voluntary consensus performance standards could be developed. The second recommendation regards development of protocols to protect confidentiality. I know a number of other people are concerned about the availability of information which is transmitted to third parties and, in particular, the Government. Several years ago Congress enacted the Freedom of Information Act requiring the release of certain information. Under regulation promulgated by FDA, we are also obligated to release certain information. There are some limits as to what we can release, and in that regard we feel that it is appropriate to recognize the need for a protocol to keep certain information confidential so that we can encourage those people who have useful information to communicate this to FDA. Finally, on the issue of regulatory discretion, we believe that it is necessary to develop a protocol to assure that evaluated data on retrieved implants are used by regulatory agencies in a fair and equitable manner as they pursue their efforts to monitor and regulate the manufacture and use of implants.

In addition to these basic recommendations, there are some other ones that the group considered. They included the development of a system to facilitate the monitoring of devices to assure conformance with regulatory standards, the need to have good reference materials, and improvement in the design of implants based on data generated through appropriate systems.

As was pointed out in the beginning, our concern is with the regulatory issues relative to the retrieval of implants. We did not get into the details of the law, particularly the Food, Drug, and Cosmetics Act or new legislation that will be enacted shortly. These factors are all critical and must be taken into account. They do relate to a number of the issues that were discussed here today, including the recommendations relative to performance standards and the responsibility of the profession and the industry to provide FDA with necessary information on a voluntary or mandatory basis.

Dr. Ruff: Thank you. Are there any questions or comments?

Dr. Martz: Two questions are addressed to the regulatory task force by the clinical task force.

In reference to your first recommendation of a national coordinated system, have you studied and are you familiar with such coordinated systems as have been tried in Sweden, France, England, Germany, and Australia? Could we use these systems as models for our further endeavors in this matter?

The other question concerns the possibility of a national health program for orthopedic surgeons, which was rejected by our group, unfortunately, but did have a section referring to implant retrieval analysis.

Mr. Pilot: With regard to the first question, we did not discuss or consider any other programs that are in existence. I am not aware myself of those systems or how successfully they have been implemented.

We did reflect on some of the experience that the agency had acquired over the past 3 years in this area and, in particular, with regard to pacemakers. We have set up a recognized system in the last couple of years designed to provide us with certain information basic to the operation of pacemakers. We have a number of facilities gathering information for us and transmitting it to us. This information involves failures that occurred with pacemakers. Insofar as patient confidentiality is concerned, there is a safeguard to assure that this information is not transmitted freely. In addition, we have set in motion over the past several years a voluntary system for reporting experience with devices, working through various professional and industrial organizations. For example, in the diagnostic products area, we have been working through the organization representing clinical pathologists and medical technologists. We have a system with the operating room nurses whereby we try to obtain additional information. With regard to the role of voluntary organizations, we believe there is a significant opportunity for them to generate much of this on their own, either in response to a request that we make or at their own instigation. Now, could you repeat your second question.

Dr. Martz: What assurance can be given to the profession and our industry of regulatory discretion? We know that in several areas of the country, retrieval analysis already is being performed and that the experience and plans of those groups are worthy of our attention.

Mr. Pilot: I cannot give you a detailed description. What I would like to see us do is work together to develop appropriate procedures and guidelines and agree where we can. The practitioner should feel free to exchange information with us without fear of repercussion. I know what those fears are and ask that you recognize that our interest is with the device. As I have said, it is not the practice of medicine that we regulate, and we do not want to do anything to jeopardize the position of practitioners or industry beyond our own authority to do so.

Dr. Black: The question is with respect to the national retrieval of information. Do you foresee the necessity for a federally based system or would a suitable private system fulfill these requirements?

Mr. Pilot: Well, I believe that a voluntary system can provide the necessary information. I would hope that it would turn out that way. In other words, the objectives would be accomplished without the necessity for the Government, including FDA, to get into it. We have tried to stimulate some action on a voluntary basis, and in some cases we support that activity with appropriate funding. But, just as we talked about performance standards here, the agency will have a responsibility to recognize and, in some cases, develop performance standards by law. Incidentally there is a definition for the phrase "performance standards" in proposed legislation. I hope that most of that, if not all, could be achieved in the voluntary area. A great deal has been done already, and I believe that it has taken a long time. However, I think that certain groups have demonstrated the kind of leadership that other groups should seek to pattern themselves after.

Dr. Ruff: Thank you. The final task group report will concern the report of the task force on standards.

Dr. Cassel (NBS): The status is that there is no national consensus practice for retrieval and analysis of implants. Feedback from retrieval analysis that would be useful for standards development is currently severely limited. Particularly lacking are statistical data. A Device Retrieval and Analysis Section has been formed at ASTM F4. It has formulated a recommended practice for retrieval analysis of orthopedic metallic implants. This recommendation is currently being rebaloted at the subcommittee level. One analysis and retrieval study was undertaken recently, a report has been made available to the public, and input was made to the ASTM F4 meeting in New Orleans (1975). Device retrieval analysis to date has not been an effective force in generating performance-related criteria. For example, there are no ASTM end product standards in the F4 area.

Dr. Martz: What do you mean "end product"?

Dr. Cassel: Performance standards.

Dr. Ruff: We can get into a debate on the term product standard. I personally feel that much of the information that is being developed relates to performance.

Dr. Cassel: The task force recognized that retrieval analysis systems are functioning in other countries and that we were ill-informed about them. The effort in Great Britain, especially, may provide considerable information.

Dr. Martz: Do not forget the others, for instance, Sweden, Germany, Australia, France, and Mexico.

Dr. Cassel: It was also recognized by the task force that ISO TC-150 Implants for Surgery provides a forum for future international standardization activity in this area.

We are optimistic about the chance of progress in development of retrieval analysis protocols. We feel the chances are good for developing feedback to standards, a procedure that has already been initiated in the Utah Biomedical Test Lab Report.

We considered barriers to progress: one is a legal barrier--so much concern for litigation that people would not participate in standard development.

A potential barrier could develop if professional organizations do not provide endorsement of retrieval analysis programs. We were thinking particularly of the American Academy of Orthopaedic Surgeons. Funding to implement retrieval and analysis programs is necessary. There may be a philosophical barrier to performance-related standards. In retrieval analysis, we are looking at the end product, and there may be a reluctance to use the data determined in development of standards.

A final barrier could be action by a regulatory agency that preempts the voluntary standard development process.

We conclude that data obtained by analyses of removed implants are essential for improved standard development. The type of data required must provide a sufficient data base to draw statistically based conclusions. These data will assist in the correlation of properties and the performance of implant materials.

We considered the role of ASTM, concluding that ASTM is on the track in its efforts to develop retrieval and analysis protocol. We feel that ASTM could serve a controlling function in analyzing the total data input in this area. ASTM is an organization that consists of members drawn from the profession and industry, Government, and consumers; and its participation in this manner would avoid analysis by a single interested class. Along that line we feel an NBS-ASTM coordinated effort may be possible.

Finally to our two recommendations:

One is to provide encouragement and support to the ongoing ASTM retrieval analysis-standard related program. It is important to enlarge the participation in this effort, bringing in other ongoing retrieval programs.

Second, a conscious effort must be made to transmit information into improved standards, so that the performance of implants can be improved.

Dr. Ruff: Are there other comments or questions?

Dr. Bartel (Cornell University): When you say "end product" are you talking about the device or the system?

Dr. Cassel: I am talking about the device. In this case we are talking about removal of a device from the system.

Dr. Bartel: I think that anytime you draw conclusions from retrieval implant analysis, it must be recognized that there are implications for the system performance because it is not just the device that can fail.

Dr. Cassel: The device operates in the system, and it was pointed out here by Ricardo Heros that the total system controls the functionality of the device. But we are talking about development of standards for the device that is going to be implanted.

Dr. Bartel: The device considered alone may have entirely different standards than the device as it performs in a system.

Dr. Cassel: That is one reason I have tried to stress that it is critical for the orthopedic surgeon to have more of an input into the data collection at the time the device is removed.

Dr. Black: This problem is unusually difficult. In terms of performance standards, we must address the interface requirements. And this, of course, brings us back to the report of my committee on basic science indicating that one of the present shortcomings is our inability to define that interface adequately.

Dr. Martz: Surgeons are very much interested in this interface and everything that can be brought to bear in this particular area. We are grateful to the task force on basic science for their prestigious work in this matter.

Mr. Weisman: I agree with Dr. Bartel on his suggestion for the wording. It seems that only the implant is involved here, and perhaps it would be better if you would make this second recommendation a conscientious effort to transmit retrieval analysis information and to improve standards so that the safety of the overall implantation process (that would cover the surgical aspects as well as the implant itself) might be improved.

Dr. Cassel: The type of information that is being referred to has to play a critical role in the analysis of that implant and must be incorporated into standards development.

Dr. Ruff: That concludes the report of the task force groups. Let me take this opportunity to invite Peter Brown to make some comments from the position of ASTM.

Mr. Brown (ASTM): At this point, I think it would be premature to have any very large program for retrieval and analysis through ASTM. But I think you are all aware of the fact that we give our full support to the development of ongoing standards and that ASTM is very

encouraged by the fact that this type of activity is going on in the F4 committee. A national consensus standard on this problem will be most acceptable.

Dr. Ruff: We will now have a 15-minute period for open discussion.

Dr. Horowitz: Without committing the ASTM to any particular area, it would be worthwhile to point out that ASTM does support data activities with its own funds and employees. The Crystal Data Center at NBS is an example of the kind of productive activity which should be examined by those interested in retrieval and implant data.

Dr. Weinstein (Tulane University): I would like to say that I am very pleased with the response I have heard here concerning retrieval analysis. However, I was rather disappointed that my colleagues in the basic science group did not discuss who is going to pay for all of this work that we are so eagerly waiting to do.

One possible mechanism was mentioned; namely, contributing through patient payments. I agree that would cover part of the costs involved. My first question, and it is directed mainly to the Government and the industry people here, is whether we can get some feeling from them on the current level of funding in this area. And, second, is there any prospective interest at that level? I firmly believe that somebody has to pay for the work. And unless funds are forthcoming a lot of handwaving, but little work, is going to be done in the future.

Dr. Lewis (Northwestern University): First of all, several centers are doing such work now, and they are paying for it. I know how our group is paying, and I assume that others are doing it their own way. I think that funds are available. The second point depends on how do you do your device retrieval analysis. I think that there are two different ways you can go about it. You have alluded to it several times. You either look at all of the devices that were implanted or just at the ones that failed. Now if you look only at the ones that failed, you have to have some measure of the fraction that represents. I think you can get a good representation if you have enough participation. The difference in cost between looking at all the prostheses or all of the failed implants is very great. In many cases it is sufficient just to look at the failures, and that is why we have gone to that. The information that we have obtained has been more than we would have gotten from looking at the total, in our assessment. There is a lot of information in failed prostheses. That study is much cheaper to do, and it is being paid for now. I think that now we must transmit the information that is already available. That is the first step.

Mr. Heros: I have been trying to place in perspective the points raised at this conference. I would have to say one must crawl first and then begin to walk. I think it would be a significant step to come up with a standard method of obtaining and reporting retrieval information. The gathering of information is very critical. All of the facts that are in our history are very applicable. So I think that when you are talking about funding, you must be talking about the costs of a data center, the analysis, and so forth, and whether they are reasonable.

Dr. Ruff: Is that what you are talking about?

Dr. Weinstein: No, it is not. I am really taking issue with Dr. Lewis on his comment. He is obviously not at the level where he has to worry about costs. I am at the university, and somebody has to pay the bills. And unfortunately or fortunately, I have to worry about paying the bills for our establishment. And while I am very interested in this area and I continue to do work in this area, it becomes increasingly difficult without funding to continue to work unless one has a large pool of resources that one can tap. You cannot just hire personnel to do the work.

My second point is to get away from the use of the term failed implants. We do not know what a failed implant is; we have no definition. Implants as far as I am concerned are removed either for cause or routinely. Until we come up with a consistent definition of a failed implant, we should not call them failed.

Dr. Lewis: There is no trouble defining a failed prosthesis. It is a prosthesis that needs to come out. The patient has to have something done to it, and doctors have chosen to remove it. If it did not come out and the patient does not complain, it is successful. I

think, therefore, it is easy to decide which ones are failures, and those are the kinds that you are trying to get away from. Now, you see, they cannot understand why you want to study a successful prosthesis.

Mr. Heros: It is very simple: to find out what works, you find out what does not work. You compare what works to what does not work.

Dr. Lewis: I would like to finish. I think we need to start gathering this information. Obviously funding is available because reports on retrieved implants are in the literature. Articles are appearing now. So I think the main impact we can have is in establishing a system that any surgeon can use to gather certain information and to report it in a standardized method. Of course, we need to have the legal questions all resolved. So I do not know if we have to face the monetary issue right now, in terms of launching this program. I think that the use of a consistent method will be a big enough step at this time.

Dr. Ruff: Let me make a comment because I am sympathetic to Dr. Weinstein's position. I would ask whether the people interested in retrieval and analysis want that work done by any group? Should not the retrieval work be done by the best group or the most experienced groups, and not just those that are in a position to afford to do it?

Dr. Black: I think we are losing sight of the reasons for retrieval analysis. The only legitimate reason for it is to improve the quality of health care. I think if that is the case, there are several questions. First of all, the protocol is certainly very desirable or we would not have this conference. However, it is simply a tool. I think what we are beginning to discuss are the moralities for the use of that tool.

While I do not want to discuss the issue of funding at length, I would make two suggestions, bearing in mind that the justification for retrieval and analysis is improving the quality of patient health care. The first level of funding involves the health care of a specific individual in much the same way that the histological examination is prearranged and funded.

The second, broader level is one involving the health care of the entire group that has the problem or the course of treatment. At this level, the results of retrieval analysis go into a larger environment--into scientific research and development. And it suggests that the money comes from the industry, private sources, foundation sources, all sources. Because it is for the public good, public funding sources would hopefully contribute. In fact, there are existing national groups, National Institutes of Health, and other agencies, that are supporting retrieval.

Dr. Bartel: I think that there is a parallel in some of the programs in the National Science Foundation (NSF) which are broad enough to include basic science and also industry. The funding brings together these groups. We should encourage such funding that forces us to look at the problem in total.

Dr. Ruff: This is the NSF program on Research Applied to National Needs.

Dr. Martz: Continuing Dr. Black's comment and approving all that he said, the spirit of ASTM is that its members have the expertise, position, time, and facilities to pursue their quest for truth. It is the responsibility of each member, individually or grouped, to consider this funding problem.

Dr. Ruff: I would like to move now into an evaluation exercise. The purpose is for the entire group to look over the principal recommendations of each task force and to rank them (see Appendix I). We can now continue with open discussion of the task force recommendations and other matters.

Dr. Black: I would like to take this opportunity to thank all of the seven cosponsors that made this seminar possible. I think that this amount of cooperation is very beneficial and is a very good omen for the future. However, I would like to draw your attention to the fact that only one organization speaks for the community of orthopedic surgeons. I think all of us recognize that the physician is the central figure in the implantation process. I would like to suggest that the following motion be adopted by this workshop as a consensus

view. "The Workshop on Retrieval and Analysis of Orthopaedic Implants thanks the American Academy of Orthopaedic Surgeons for their generous cosponsorship and transmits to them the workshop report. Further, the members of the workshop recommend that the American Academy of Orthopaedic Surgeons give positive consideration to possible additional responsibilities of the treating surgeons in cases involving device removal."

My purpose in offering this motion is to indicate that in addition to his other professional responsibilities, a surgeon has a responsibility to his patient in furthering the basic science and the medical and clinical sciences of implants.

Dr. Martz: I want to thank Dr. Black for this splendid idea and suggest the American Orthopaedic Association be included. Further, since many orthopedic implants are placed by other than orthopedic surgeons, that is, general surgeons and others, I would like also to carry this resolution to the format committee in the American College of Surgeons which, as many of us know, was a prime motivator of this whole area of study on implants.

Mr. Heros: I would like to move that the Steering Committee correspond with the other cosponsors of this symposium indicating the positive nature of what has occurred here and calling upon them for their assistance in the development of a meaningful retrieval analysis system for surgical implants.

(The motion was seconded and carried.)

Dr. Davis (FDA): I get the impression that the consensus here is that we should have a common form of protocol. What is going to happen next?

Dr. Weinstein: We have been working for approximately a year and a half in ASTM F4, preparing a standard recommended practice for retrieval and analysis. That document has been balloted and is presently being revised to incorporate all of the suggested changes. A new document will be generated and will be balloted again.

Dr. Ruff: In answer to this question, the results of the symposium and this workshop will be published and made available.

Mr. Heros: I do not believe that Dr. Lewis' question was answered. He made reference to the independently operated and university-retrieval activities around the United States. I would like to put on the record a recommendation to Dr. Weinstein that he consider at the next F4 meeting that invitations be sent to the principal investigators at these various centers inviting them to come and sit down with the committee, possibly forming a liaison task force.

Dr. Martz: I second that idea.

Dr. Lewis: I would comment that we are going ahead with our retrieval analysis regardless of ASTM because we are doing it for our own purposes. I know that the University of California at Los Angeles is also doing this. And I think that what is needed from this meeting is a method to get people together.

Dr. Weinstein: Let me answer that I have intended to form a task force to coordinate these activities in F4. What we are trying to do is build it one block at a time. I will guarantee everybody that such a task force will be formed.

Mr. Brown: I think that we must recall that the strength of the ASTM system or any national consensus is that we are pledged to revise the standard in a certain time frame. Thus, this first phase of formulating a protocol will then need input from groups to see how it works and to lead to actual promulgation of a more refined document.

Dr. Lewis: Just one brief point in connection with information from the retrieval centers. I think that standards are not going to dictate the design of implants for some time to come. So the retrieval information should be available to people, primarily manufacturers, who are in the position of designing.

Mr. Brown: ASTM does have a variety of publications that would take the output of interlaboratory tests or analyses and put them out for application.

Dr. Ruff: I am going to turn the meeting back to Allan Weinstein now. But first I want to thank everybody who contributed to the workshop, particularly the group leaders today, who did a very fine job.

Dr. Weinstein: I would also like to thank all of the speakers and participants. In particular, a thank you to Mrs. Reeve who did a tremendous job in the coordination of this meeting.

APPENDICES

Appendix I
FINAL EVALUATION FORM

	Average Ranking by Workshop 1 = MOST IMPORTANT 5 = LEAST IMPORTANT
RECOMMENDATIONS (Task Force)	
Standard protocol (Clinical)	1.5
Multiple centers for collection (Clinical)	2.4
Central data bank (Clinical)	2.5
Develop comparative test methods (Basic)	2.4
Close design--development loop (Basic)	2.4
Common analysis format (Basic)	1.9
Uniform retrieval analysis and protocol--clinical information (Legal)	1.6
Ownership problem (Legal)	3.6
Resolution of legal aspects (Industry)	2.3
Consensus through F4 (Industry)	2.3
Utilize the F4 system on trial basis (Industry)	2.5
Support ongoing ASTM retrieval (Standards)	2.1
Translate retrieval analysis to improved standards (Standards)	3.0
Nationally coordinated system (Regulatory)	2.7
Protect confidentiality (Regulatory)	2.5
Regulatory discretion (Regulatory)	2.9

APPENDIX II

SUMMARY OF OVERALL RECOMMENDATIONS IN ORDER OF PRIORITY

1. Use of a standard, uniform protocol for retrieval and analysis.
2. ASTM F4 coordination; multiple retrieval centers; uniform test methods.
3. Discussion and resolution of ownership and regulatory aspects.

Appendix III

BASIC SCIENCE TASK FORCE REPORT

1. Properties of Tissues

1.1 Present situation

The mechanical behavior of hard and soft tissues has been reasonably well characterized in normal individuals.

1.2 Problems and opportunities

Present measurements are primarily of dead, nonphysiological tissues, and their exact relationship to *in vivo* behavior is suppositional. There is also little information on material properties in abnormal individuals and those with congenital or acquired diseases or anomalies of the musculoskeletal system.

1.3 Objective

An immediate limited objective would be to understand tissue property changes that occur in the vicinity of implants.

1.4 Effect of Device Retrieval and Analysis (DR & A)

DR & A would provide systemic access to device-containing operative sites so that microtissue biopsies could be obtained for mechanical and other property characterization.

1.5 Recommendation

An optional microbiopsy technique should be incorporated into DR & A programs to increase knowledge of growth repair and remodeling processes in the vicinity of implants.

2. Musculoskeletal Mechanics

2.1 Present situation

The information on the point load (plus the fixation requirement) and functional motion is not currently available. This situation is specifically true for patients. There also is a lack of knowledge in the area of functional anatomy, i.e., bony geometry, muscle volume, muscle orientation, functional potential, etc., expressed in quantitative terms and including arthropometric variation.

2.2 Problems and opportunities

There is a need to:

- a. Identify load requirement in every "major joint" under the common conditions of daily activity.

- b. Specify the functional (motion range) requirement of these joints.
- c. Standardize patient evaluation techniques for standard followup study.

2.3 Objective

Establish objective criteria based on patient function and provide the minimum requirements for prosthesis and implant evaluation and testing.

2.4 Effect of DR & A

DR & A is essential to progress in this area.

2.5 Recommendations

Primary: Emphasize patient functional evaluation (quantitative) as a part of implant trial studies.

Secondary: Determine joint load and motion requirements for patients of various age groups and diseases under normal activities of daily living.

3. Materials Characteristics

3.1 Present situation

Materials available generally satisfy most mechanical property requirements, with exception of fatigue and wear characteristics in total joint prostheses. Materials are available which are sufficiently corrosion resistant to give apparently adequate clinical performance in the vast majority of cases.

3.2 Problems and opportunities

Major problems are: (a) inadequate fatigue/corrosion fatigue characteristics in materials for highly stressed prosthetic components; (b) lack of sufficient data on *in vivo* wear properties and influence of wear particles on tissues; (c) lack of good correlation of *in vivo* corrosion/degradation rates with clinically significant effects both locally and systematically; and (d) lack of suitable methods for quantitative estimation of biocompatibility.

Opportunity: vast amount of data "available" in clinical records and DR & A studies for comprehensive evaluation.

3.3 Objectives

a. Establishment and standardization of relevant *in vitro* animal test methods for materials evaluation; e.g., joint simulators, electrochemical corrosion measurements, histochemical and electron-optical methods for tissue analysis.

b. Establish correlation between data from (1) with data from DR & A.

3.4 Effects of DR & A

This subject is of great importance for achievement of objectives. We cannot simulate exactly *in vivo* conditions in laboratory tests and especially cannot evaluate the influence of: (a) surgical techniques, (b) infection, and (c) patient activity on material performance.

3.5 Recommendations

Primary: Prepare specification and/or protocols for comparative test methods outlined in objectives.

Secondary: Voluntarily limit (e.g., through professional organizations) clinical use of new materials until standard test methods have been developed and proved.

4. Development of Fixation Techniques

4.1 Present situation

The development of fixation techniques involves thorough understanding of the mechanics of fixation and empirical studies of fixation systems. In general, more effort has been expended on experimental studies than on mechanical analysis. There is increased interest in the study of the mechanics of fixation and, from this, extrapolation to new design concepts. This work is based largely on techniques of stress analysis such as the finite element method and, consequently, is relatively recent. Ongoing work is concerned with the effects of changes in system parameters such as geometry and materials properties on stresses in the system. Such studies are affecting the design of devices in that new designs and design concepts are being increasingly supported by basic analysis of the system.

4.2 Problems and opportunities

We need detailed three-dimensional analyses of the mechanics of fixation in order to understand load transfer from device to bone.

There is a lack of experimental corroboration and verification of theoretical analyses. Experimental analysis should involve the study of idealized systems as well as specific implant designs. There is also a lack of experimental determination of the mechanics of load transfer from implant to bone. Long-term properties and mechanics of the system are not well known and change due to remodeling of bone in the system.

4.3 Objectives

Primary objective: Develop a thorough understanding of the mechanism of fixation and load transfer.

- a. Theoretical analysis using theory of elasticity and finite element methods.
- b. Experimental analysis of idealized systems.

Studies should be done at both macro (e.g., bone-stem-cement, bone-stem-porous coating) systems and micro (e.g., interface systems) levels.

Secondary objective: Develop methods for estimating expected life and reliability of the system.

4.4 Effects of DR & A

DR & A would provide one aspect of experimental work needed. It would provide some indication of overall behavior of specific fixation systems and, by inference, confirm the basic ideas of the mechanics of fixation. Statistical analysis of the data would indicate problem areas for further study and provide estimates on system properties such as endurance strength.

4.5 Recommendation

Implement studies to achieve objectives.

5. Implant Design Principles (Design Methods and Actual Design)

5.1 Present situation

Effective implementation of the design process requires careful definition of the problem; in the case of implants, this becomes, in part, a statement of not only the geometric constraints but also of the expected loading and permissible deflections. The latter two concepts are only now beginning to be included in a formal fashion in the design process.

5.2 Problems and opportunities

Data on the mechanical environment faced by an implant are, by and large, nonexistent. Also missing is information on load environment of osteosynthesis and the interaction between host tissue and implant in general.

Acquisition of such knowledge is essential for rational design of orthopedic implant devices. As implants are expected to survive longer and failures, for any reasons, become acceptable, the need for such rational design becomes more pronounced.

5.3 Objective

The objective in DR & A should be to feed information from the USG portion of the design process back into the areas of PROBLEM DEFINITION, CONCEPT GENERATION, and DETAIL DESIGN, to complement information gathered in studies of musculoskeletal mechanics.

5.4 Effect of DR & A

DR & A needs to become a routine conclusion of the implantation process because a design process without feedback of information becomes an exercise in futility. Data obtained through DR & A will, perhaps only indirectly, provide much of the missing information needed to define the design problem.

5.5 Recommendation

Since estimates of the loading history experienced by an implant are an essential component of design verifications, such estimates should be included in any analysis of a retrieved device.

6. Surgical Instrument Design Principles

6.1 Present situation

These principles are presently designed empirically, and some are such that it is not known if they are successful (large majority are satisfactory).

6.2 Problems and opportunities

General design approach for certain types of devices is desirable.

6.3 Objectives

The objectives are to determine if inadequate instrumentation is the cause of a particular problem and, therefore, whether or not design changes are needed. A second objective is to determine the relative importance of a particular instrument-related problem--is it worth worrying about?

6.4 Effect of DR & A

DR & A will help achieve the objective in certain circumstances.

6.5 Recommendation

No specific recommendation.

7. Postremoval Analysis

7.1 Present situation

Several centers are now collecting and analyzing removed implants. Little communication between centers exists. Each center is collecting devices of particular interest to it; there is no uniformity of interest in particular devices.

7.2 Problems and opportunities

- a. Centers are not communicating.
- b. It is expensive to analyze removed devices--funds are needed for such analysis.
- c. There is no uniformity of analysis methods.
- d. Results from one center will usually not be typical of all centers.
- e. Design methods and techniques are often not sufficiently advanced to use most of the information. Most designs are not around long enough to use the information once it is gathered.

7.3 Objectives

Establish success of particular designs, indicate problems with existing designs, and indicate relative importance of problems.

7.4 Effect of DR & A

Postremoval analysis requires the institution of a DR & A program to be successful.

7.5 Recommendation

Establish common analysis form for all centers *already* doing retrieval analysis.

8. Differential Diagnostic Techniques

8.1 Present situation

Selection of patients, indications for surgery, and use of specific implants are very subjective at the present time. The overabundant prostheses types cause the practicing surgeon difficulty in selecting the proper one for a particular patient. Therefore, the retrospective study of prosthesis performance is very difficult, unreliable, and misleading.

8.2 Problems and opportunities

- a. Lack of quantitation of functional impairment in biomechanical terms.
- b. Engineer's input to patient and implant selection (type and dimension) is seldom available.
- c. Patient postoperative evaluation (management and rehabilitation) is poorly related to device requirements.

8.3 Objective

To assist surgeon in selecting patient, surgical and rehabilitation timing, and prosthesis (or implant) so that unnecessary failure and poor mechanical performance can be minimized.

8.4 Effect of DR & A

DR & A will assist the understanding of the reason certain cases produce unsuccessful short-term and long-term performance of implant and correlate with preoperative diagnostic criteria.

8.5 Recommendations

Primary: Development and understanding of the relation of the functional and tissue abnormalities and the prosthesis characteristics to aid in proper selection of prosthesis.

Secondary: Establish patient evaluation programs to identify the factors that dictate the need for surgery, postoperative precautions, and functional performance. Identify degree of functional impairment and bone and soft tissue destruction based on disease state (through usual diagnostic techniques) that can be alleviated by specific device types.

9. Education

9.1 Present situation

The basis for many of the current educational problems as they pertain to biomaterials design and application lies in the interdisciplinary nature of the field of bioengineering itself. In the past, surgeons have relied entirely on the expertise of the engineer and manufacturer for direction in application of devices and materials while conversely the bioengineer was called upon to develop a product in accordance with nonexistent or, at best, ill-defined specifications. The opportunity, therefore, in biomechanics/biomaterials/medical education is one of bringing the disciplines closer to a mutual understanding of the common problems of bioengineering application. For the basic science biomechanic or biomaterialist, this understanding entails a more intimate working relationship in the medical/clinical world. Educating the resident and, even more importantly, the practicing senior staff as to rapidly changing device design and application may represent a greater challenge.

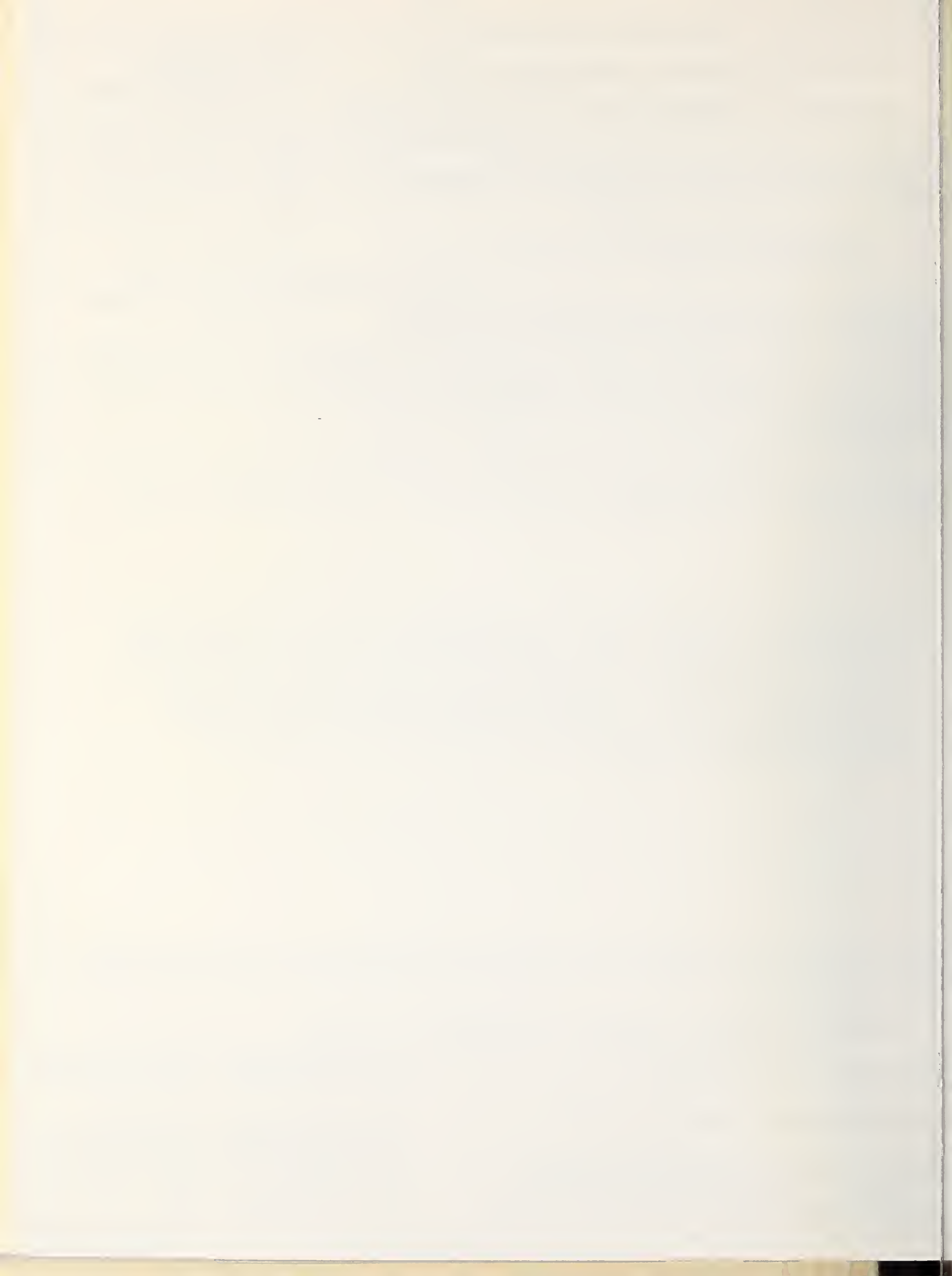
9.2 Recommendations

- a. Educate the physician to educate the patient in the capabilities and limitations of currently used devices.
- b. Include in residency programs, perhaps incorporated in a biomechanics review, the basic science of implant design and applications.
- c. Provide a uniform, rational exposure to bioengineering principles for orthopedic residents.

10. Overall Recommendation

DR & A activities seem highly desirable.

U.S. DEPT. OF COMM. BIBLIOGRAPHIC DATA SHEET		1. PUBLICATION OR REPORT NO. NBS SP 472	2. Gov't Accession No.	3. Recipient's Accession No.
TITLE AND SUBTITLE Retrieval and Analysis of Orthopaedic Implants Proceedings of a Symposium held at the National Bureau of Standards, Gaithersburg, Maryland, March 5, 1976			5. Publication Date April 1977	6. Performing Organization Code
AUTHOR(S) Allan Weinstein, Emanuel Horowitz, A. W. Ruff			8. Performing Organ. Report No.	
PERFORMING ORGANIZATION NAME AND ADDRESS NATIONAL BUREAU OF STANDARDS DEPARTMENT OF COMMERCE WASHINGTON, D.C. 20234			10. Project/Task/Work Unit No.	
Sponsoring Organization Name and Complete Address (Street, City, State, ZIP) National Bureau of Standards; Food & Drug Administration, Washington, D.C. 20910; American Society for Testing & Materials, Philadelphia PA 19103; American Academy of Orthopaedic Surgeons, Chicago, IL 60611; Orthopaedic Surgical Manufacturers, Memphis, 38116; Society for Biomaterials, New Orleans, LA 70112			11. Contract/Grant No.	
			13. Type of Report & Period Covered	
SUPPLEMENTARY NOTES Library of Congress Catalog Card Number: 77-608031			14. Sponsoring Agency Code	
ABSTRACT (A 200-word or less factual summary of most significant information. If document includes a significant bibliography or literature survey, mention it here.) This book is the formal report of a symposium on Retrieval and Analysis of Orthopaedic Implants. This volume contains the invited lectures that provide a state-of-the-art information base about implant characteristics related to performance; the discussions of a panel addressed to the problems associated with, and the information generated from, implant retrieval analyses; and the reports resulting from a workshop on "What Is the National Need?"				
KEY WORDS (six to twelve entries; alphabetical order; capitalize only the first letter of the first key word unless a proper name; separated by semicolons) Analysis; implants; metallic; orthopaedic; retrieval				
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