NBSIR 81-2212

Evaluation of Methods of Characterizing the Porosity of Porous Polymeric Implant Materials: A Review of the Current Status of Porosity Measurements

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U.S. DEPARTMENT OF COMMERCE, Malcolm Baldrige, *Secretary*
NATIONAL BUREAU OF STANDARDS, Ernest Ambler, *Director*

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ABSTRACT

A search of the published literature pertaining to porous polymeric implant materials has been made. The two porous materials currently dominant in implant surgery, namely, porous high density polyethylene and a porous composite of polytetrafluoroethylene and carbon, have been reviewed with respect to the following criteria pertinent to their medical applications: (1) information supplied by the manufacturers about their methods of characterizing the porosity of their materials, (2) recommendations of the ASTM for quantitative porosity characterization of these materials, and (3) clinical studies of the materials as replacement prostheses in middle ear surgery. A computer search for new quantitative methods of measuring pore size revealed nothing appropriate to these materials. However, disputes in the current literature suggest that current protocols for porosity characterization are inadequate for proper inter-laboratory comparison of experimental data.

NOTICE

Certain commercial materials are identified in this report in order to adequately specify experimental procedures. In no case does such identification imply recommendation or endorsement by the National Bureau of Standards nor does it imply that the identified materials are the best available.

BACKGROUND

The history of polymeric implant materials for bone ingrowth begins around 1955, according to Klawitter and Hulbert[1]. In the early experiments, polyvinyl sponges were implanted in dogs[2], where they were found to be well tolerated. After about 4 weeks, vascular connective tissue and incipient bone ingrowth were observed in the pores of the sponges. Unfortunately, no description of the pore size or void volume of these materials was reported. These early studies were mostly concerned with load bearing skeletal replacement, and the porous polymers, lacking structural strength, were soon abandoned in favor of porous ceramic and metal implant materials.

Early work on the ingrowth of various types of tissues into porous ceramic implants led to the following conclusions:[1]

"(1) Mineralized bone growth into porous calcium aluminate skeletal implants required a minimum interconnection pore size of 100 μm.

(2) The minimum interconnection pore size showing the potential for mineralized bone ingrowths, as indicated by the ingrowth of osteoid tissue, was found to lie between 40 and 100 μm.

(3) The minimum interconnection pore size necessary for fibrous tissue ingrowth was found to lie between 5 and 15 μm."

This appears to be the first systematic study to determine a correlation between pore size and the type of ingrown tissue. More recent work[3] has suggested that 40 - 50 μm is required for organized fibrous tissue ingrowth, and at less than 40 μm infiltration consists predominately of fibro-histiocytic elements. However, it is clear from studies

such as those discussed below that the rate and perhaps even the type of tissue ingrowth depend not only on pore size but also upon the physico-chemical properties of the porous material. Thus, one must be cautious about referring to an "optimum" pore size except in connection with a specific material.

During the past decade, porous polymeric implant materials have been developed for various implant applications. One of these, a porous composite of polytetrafluoroethylene and carbon fibers, has been patented[4], and is currently available from at least one commercial supplier[5]. Another porous polymer which, like the composite, has undergone rather extensive clinical trials and experimentation is porous high density polyethylene. There are at least two commercial suppliers of this material who have developed proprietary processes for producing porous polyethylene of specified pore sizes and pore volumes[6,7]. Other polymers currently under investigation as candidate porous implant materials include porous polysulfone[8,9], medical grade Bioelectric Polyurethane[10], and Silicone Rubber[11]. According to White et al.[12], the latter two ".....have shown independent effects of pore size and biomaterial on incorporation of prosthetic segments[13]."

Unfortunately, it is difficult to compare the results of different workers in their clinical studies of porous implant materials, due to the lack of a commonly accepted system of porosity characterization. Where standard methods such as ASTM Standard Recommended Practices are available, they are often avoided in favor of other

methods which are believed to be more appropriate for a particular material. Clearly, two objectives should be sought in attempting to devise a rational scheme for characterizing the porosity of implant materials. First, insofar as possible, methods should be selected which are applicable to all porous polymeric materials, since this procedure greatly facilitates inter-laboratory comparison of experimental data. Second, in cases where it is absolutely necessary to use different methods for different materials to measure the same parameter, the relationship between the methods (accuracy, reproducibility, systematic errors, etc.) should be well understood. Whenever possible, two or more methods of measuring the same parameter should be used, because there will inevitably be uncertainties associated with each method. It is the purpose of this project to provide a critical evaluation of current methods of porosity characterization and, where necessary, to suggest additional methods to improve the accuracy and reliability of porosity measurements.

POROSITY INFORMATION SUPPLIED BY MANUFACTURERS

PTFE - Carbon Composite

The PTFE - Carbon Composite porous implant material is an invention of Dr. C. A. Homsy[4]. It is manufactured in thin sheets ($\sim$1 mm) by heat and pressure treatment of a 4-component system containing PTFE fibers and pellets, carbon fibers, and NaCl pellets. The salt is extracted from the fused sheet, leaving a porous material which physically resembles gray felt. Homsy's own "characterization" of the porosity of his material relies heavily on indirect evidence. For example, in a recent publication[14], he states that

".....three parameters have been routinely used to assay the nature of the porosity of the material: (a) the volume and weight percentages of the four initial ingredients, PTFE resin, PTFE fiber, graphite fiber, and sodium chloride (NaCl) crystal; (b) the grain size distribution of the NaCl crystal; and (c) the apparent density of the final product."

For quantitative data, he has relied on an independent testing laboratory (address given) which confirmed

"a pore volume of 80 ± 5 volume percent and a pore size range as indicated on the product label. Direct optical measurement of pore size using the SEM indicates a maximum of approximately 400 micra and a percentage porosity by line intercept techniques to be approximately 57%."

Homsy then states that "the independent laboratory....noted that their values were low because of limitations intrinsic to the technique." There follows a discussion of mercury intrusion porosimetry, in which the well-known limitations of the Washburn equation are quoted, together with an opinion by Professor G. D. Armeniades of the Department of Chemical Engineering, Rice University, Houston, TX, that "the deformability of the matrix of the material leads to substantial distortion of pore structure...which, of course, confounds the results." Nevertheless, the pore volume was estimated using the mercury technique by another independent laboratory (address given) for Dr. Homsy. They found

a pore volume of 65% which, according to Homsy, is a "good confirmation of the product literature value range of 70 - 90%, considering the bulk compression during the test." Further comments on the mercury porosimetry technique appear in a letter from Dr. Homsy to Dr. Cassel (Appendix I).

The "product literature values" of porosity referred to by Homsy appear identically in four different package inserts which we have seen, for the PTFE-carbon composite. The four inserts apply to the implant material in the form of 1) Sheeting, 2) Block, 3) Total Ridge and Posterior Ridge, and 4) Temporomandibular Joint Condylar Prosthesis. In each case, it is stated that

> "The pore size distribution for standard Proplast is 100 to 500 μm with dendritic pore interconnections greater than 200 μm. The pore volume of Proplast comprises 70 to 90% of the total material volume."

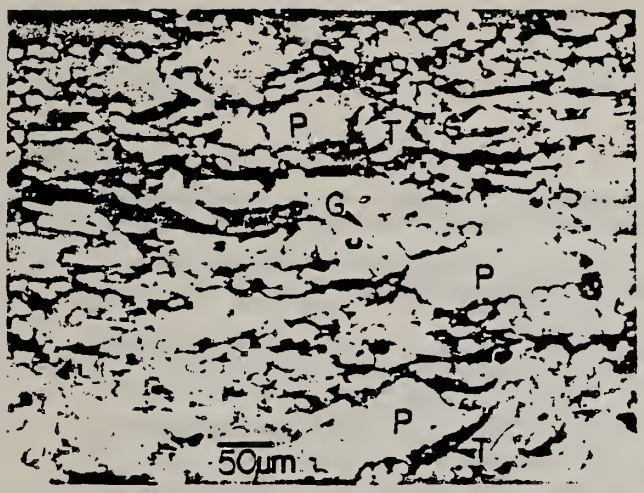
In some cases, it is also noted that the pore size can be varied to meet special requirements.

While this is the only quantitative information provided specifically about the porosity of the material, there is a rather detailed description given in the product literature about the procedures and precautions to be observed by the surgeon when handling, shaping, and cutting the material. Indications and contraindications for surgical use of the material are given, together with a caveat about potential long-term hazards of implantation, because of the relatively short time that the material has been in use. A catalog of implant products was obtained from the marketing company for the PTFE - carbon composite, and the appropriate pages are reproduced in Appendix II.

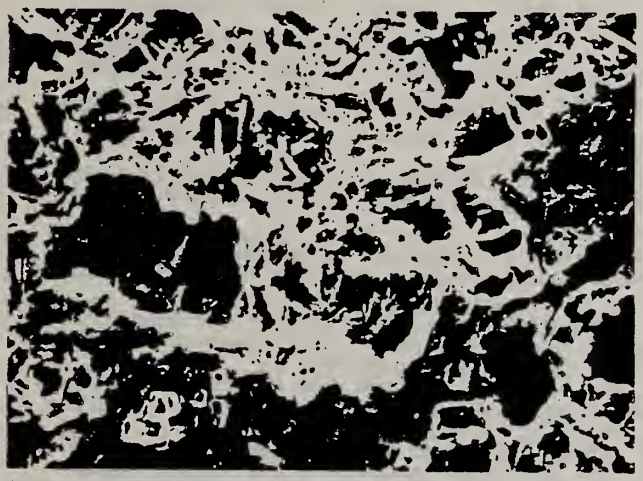
In a letter to Dr. Homsy from Dr. Dehl (Appendix III) opinions were solicited about the critical parameters of porosity. Dr. Homsy's reply (Appendix IV), and in particular the concluding paragraphs, provide an interesting if at times controversial discussion of the relationship of porosity and other physical properties of the material, to successful implantation. In another letter to Dr. Cassel (Appendix V), Dr. Homsy states his beliefs about the best methods by which the user can verify the porosity of his material. As stated above, he relies upon indirect methods (i.e., apparent density and tensile strength measurement) rather than direct observation of porosity to determine whether his product "is conforming to manufacturing specifications with respect to pore characteristics".

Figure 1 illustrates the morphology of the PTFE-carbon composite. The top photograph is reproduced from Ref. 15. It is a light photomicrograph which clearly shows the 3 phases present, as well as the elongation of the pores, due to the rolling of the compact sheet during manufacture. The middle photograph is an SEM reproduced from literature provided by the manufacturer, which shows a lacy network of fibers with a wide range of pore sizes. The bottom photographs, taken from ref. 16, are similar to the SEM above and are said to illustrate the effect of trimming off the top surface, leaving a more open network.

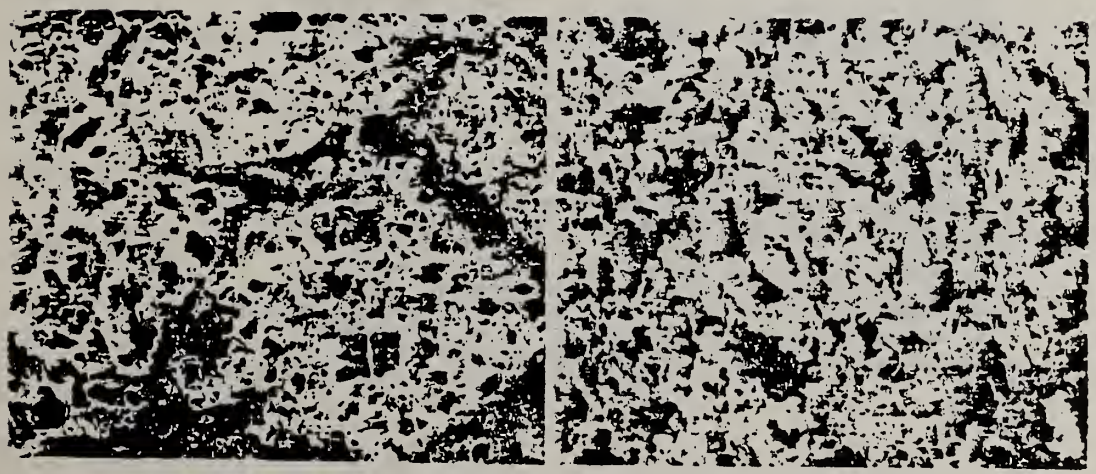
Figure 1. Light micrograph and scanning electron micrographs of PTFE - carbon composite implant material



Incident beam light micrograph of a polished section of plastic embedded Proplast. G: graphite fiber; T: polytetrafluoroethylene; P: pore.



Scanning electron micrograph (100x) shows the highly porous structure of Proplast. This open pore configuration allows for thorough tissue ingrowth.



Scanning electron micrographs of *(left)* the rolled "closed" surface and *(right)* a razor-cut "open" surface of the sponge. Note the flattening and the compression of the porosity in the part subjected to the lamination process. (×50)

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Porous High Density Polyethylene (PHDPE)

We have identified 2 suppliers of porous polyethylene which claim to have material for implant usage. Samples of porous polyethylene were obtained from Glasrock Corporation[6] in a variety of shapes, some labeled "large pore size", and others "small pore size". The physical appearance and other properties of this material are clearly very different from the composite. The literature accompanying the samples refers to the "proprietary technology" used to prepare them. It is stated that the ".....permeable material has omnidirectional, interconnecting pores, the size of which can be accurately controlled between 10 and 500 μm, depending on the polymer used". (The company also prepared porous polymers other than PHDPE.) From the appearance of the samples given to us, the material appears to be sintered from rather uniform pellets of the polymer resin. In comparison with the soft, felt-like composite, this material is relatively hard and inflexible. It is not clear to us whether the Glasrock material is actually being marketed for surgical implant use. The literature states a number of uses for their materials, including "biomedical filters, blood serum filters, catheter vents, and prosthetic devices". (Emphasis ours.)

Quantitative information about pore sizes in this material has also been hard to find, and we have found only two references to experimental work in which it is clear that the Glasrock material is being used. Spector et al.[15] in their animal implant studies of porous polyethylene state that they obtained the material from Glasrock and that the pore size was "about 400 μm". Another group[17] studying the strength of the

bone-porous polyethylene interface in implant studies of dogs, reported that their material was from Glasrock and had an average pore size of "about 250 microns with a highly interconnected porous structure". They also reported a bulk density of 0.32 to 0.36 g/cm^3 and about 65% (open) porosity. They do not report how these numbers were obtained .

Another manufacturing company[7] advertises ossicular prostheses made of porous polyethylene, but it is not clear who the manufacturer of the porous polymer is. We recently received 5 technical publications and catalogs from this company[18-22]. There are 16 varieties of ossicular replacement prostheses listed and illustrated in their catalogs which are made wholly or partly of PHDPE. Fig. 2 is a collection of pertinent data selected from this literature. The 300X SEM photograph of PHDPE clearly shows a very different morphology from the composite. One can easily see the smooth sintered particles, separated by open channels. An SEM picture of one of the total ossicular replacement prostheses ("TORP") is also shown.

The method used by this manufacturer to characterize the pore size distribution is mercury intrusion porosimetry, and a typical plot of pore size vs.volume is shown in Fig. 2. As noted by the authors,[18] ".....the majority of pores are between 18 and 35 microns". In the same publication, the authors state that the porosity (pore volume) of this material is "approximately 35%".

Figure 2. Pore size measurements and SEM photographs of porous high density polyethylene implant material

POROUS POLYETHYLENE

Method of Manufacture

Polyethylene particles are bonded by a special process which controls the temperature, pressure, atmosphere, and time. Final machining and finishing operations do not add any detectable amounts of foreign material to the starting material. Porous polyethylene devices can be produced in a variety of shapes. Molds can be used to produce parts that require little or no finishing. Rods and sheets can also be machined to produce devices.

Percent Porosity and Average Pore Size

The percent porosity is the ratio of the volume of pores to the volume of the material. This factor, along with the average pore size (the diameter of the pores most abundant in the material), can be qualified by a mercury intrusion porosimeter, which is a laboratory instrument. Figure 6 was plotted from data obtained when a sample of porous polyethylene was analyzed. Quantitative optical microscopy can also be used to characterize the material.

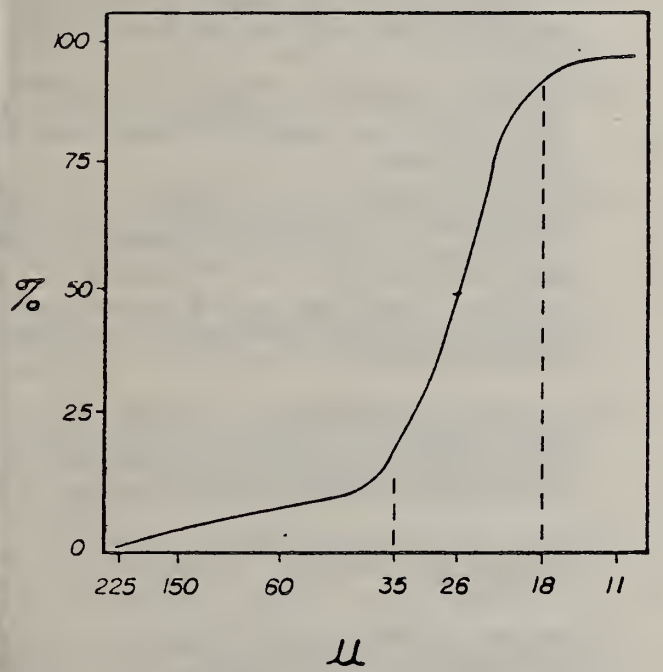
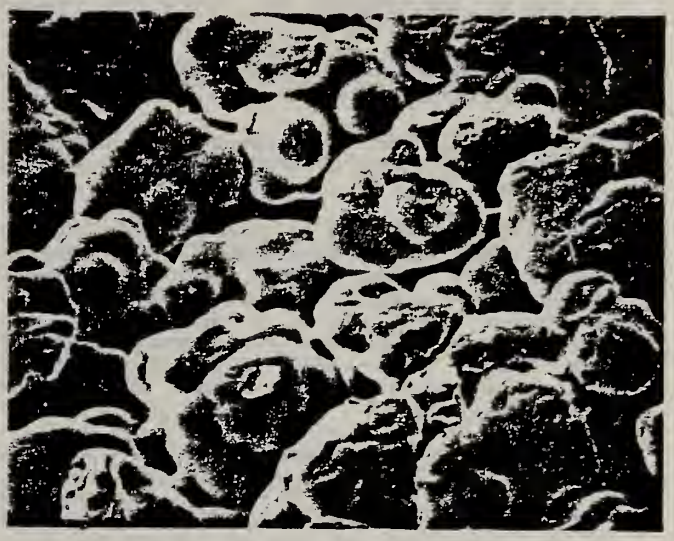


Figure 6. Plot obtained from analysis of a sample of porous polyethylene using a mercury intrusion porosimeter. Note that the majority of pores are between 18 micron and 35 micron.



Plasti-Pore® Porous Polyethylene 300X

Tilt-Top™ TORP® Prosthesis, All Plasti-Pore® Material, 14X

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QUANTITATIVE METHODS FOR POROSITY CHARACTERIZATION

ASTM Standard Specifications for Porous Surgical Implants

It is interesting to compare the recommended procedures for characterization of pore volume and pore size contained in the current ASTM draft Standard Specifications for the PTFE-carbon composite and for porous polyethylene. The pertinent paragraphs are excerpted below.

(1) Standard Specification for Porous Polyethylene for Use in Surgical Implants. Draft #10 F-4.20.01.07 (3/80).

> 2.3 This specification is applicable to all device standards in which porous polyethylene is used.....It is expected that the pore size, pore volume, and the mechanical properties will be specified in the particular device standard.

3. Applicable Documents

3.9 ASTM D2873. Standard Method of Test for Interior Porosity of Poly(vinyl chloride) (PVC) Resins by Mercury Intrusion Porosimetry.

3.10 ANSI/ASTM E562. Determining Volume Fraction by Systematic Manual Point Count.

3.11 ASTM F316-70. Pore Size Characterization of Membrane Filters for Use with Aerospace Fluids.

6. Test Methods

6.3 Average pore diameters shall be established.

6.3.1 Pore size can be measured in accordance with ASTM F316-70.

6.3.2 Pore size can be measured by Mercury Intrusion Porosimetry. (ASTM D2873 is an acceptable method.)

6.4 Average pore volume shall be estimated by one of the following methods:

6.4.1 Pore volume can be measured by Mercury Intrusion Porosimetry. (ASTM D2873 is an acceptable method.)

6.4.2 Pore volume can be approximated by measurement by weight of a saturant of known specific gravity and relating its volume to the matrix volume.

6.4.3 Pore volume can be estimated by Optical Microscopy as described in ANSI/ASTM E562.

(2) Standard Specifications for Porous Composites of Polytetrafluoroethylene and Carbon for Surgical Implant Use. Task Force F4.20.04.05.

4.4 Porosity Characterization

4.4.1 Volume Pores. Specimens of composite with apparent density within the limits indicated under paragraph 4.2.4 will exhibit pore volume between 70 and 85%. This range of pore volume can be conveniently corroborated by confined pressurization at greater than 1000 Kg/cm^2 ($9.8 \cdot 10^7 N \cdot m^{-2}$) and computation of the ratio of post-pressurization dimension to pre-pressurization dimension measured in the direction of pressurization. It has been determined that direct measurement of pore volume using mercury intrusion technique is not appropriate for composites which are subject to this standard specification.

4.4.2 Pore Size Range. Direct optical examination of scanning electron photomicrographs of the composite surface prepared by sharp (i.e., fresh scalpel) dissection of a specimen of composite is recommended for determination of pore size range. The intrinsic softness of the composite requires care in specimen preparation such that cutting procedure does not distort and occlude some

of the pores. Inspect before cutting to determine plane of fibrous orientation. Cut in a direction parallel to this plane. Such determination should indicate a pore size range between approximately 80 microns and 400 microns and inter-pore connections of the order of 100 microns.

Comments on ASTM Standard Specifications

It should be emphasized that both of the above documents are presently in draft form, and there may be changes in them before they become final. However, certain contrasts between their approaches to porosity characterization are interesting to note. For the porous composite, no mention is made of any of the ASTM test methods related to porosity characterization, whereas the porous polyethylene specification relies heavily on existing ASTM methods. For the porous composites it is stated that the mercury intrusion technique is "not appropriate". As we have discussed above, previous statements by Homsy indicated his belief that the composite material is too soft and compressible for mercury intrusion, even at the very low pressures required to measure pore sizes of 80 - 400 μm. No mention is made of ANSI/ASTM E562-76, "Determining Volume Fraction by Systematic Manual Point Counting". Paragraph 1.5 of that document states that "In case of dispute involving other manual approaches or techniques for estimating volume fraction of a second phase or constituent [e.g., the void volume in a porous solid] the point counting practice described herein shall be the reference method". The "confined pressurization" method mentioned above for measuring void volume in

the composite is not well defined, but neither is the void volume (70-85%) very precisely specified, so that the method is perhaps appropriate to the desired precision. Similarly, the broad range of pore sizes given for the composite seems to imply that the authors feel that the pore sizes are not critical to surgical implant applications. It is very difficult to understand how these paragraphs for the composite can be considered part of a Standard Specification because no attempt is made to relate specified pore size to any particular implant application. By contrast, for the porous polyethylene the ASTM methods suggested for characterizing both pore size and pore volume are carefully written with respect to the recommended procedures, apparatus, and statistical analysis of error. Also, the authors of the latter document recognize that the pore size must be specified for each particular device, and that simply stating a wide range of "acceptable" pore sizes does not specify anything.

Porosity Measurements Described in Published Literature

A computer search of existing literature was performed to determine (1) whether new methods of determining porosity are being developed which could be applicable to the porous polymer implant materials, and (2) to what extent the current porous implant materials are being monitored either by the users or by independent testing laboratories, with respect to their porosity characteristics.

(1) Current Research in Porosity Measurement

A computer search of chemical and physical abstracts for the years 1972-present using the key words "Porosity Measurement", evoked 42 references. There were no specific references to implant materials, and none that seem to offer promise of improving the accuracy of measurements of pore size or pore volume relative to current methods. The term "porosity" is applied to such industrially important properties as the integrity of film coatings and the flow properties of packed beds consisting of metal ores, ion exchange resins, coal, cement, etc. As a group, these references are concerned with operational definitions of porosity suitable to industrial processing or quality control, rather than to quantitative pore size or volume measurements. It is apparent that for quantitative porosity characterization of the implant materials we will have to rely upon established techniques such as ASTM methods, or invent new methods which are suitable for each particular material.

(2) Published References to Porosity Characterization

In the early studies of porous ceramic implants, relating pore size to the type of tissue ingrowth[1], three types of measurements were used to characterize the porosity. The void volume was measured by "Archimedes density", which is presumably equivalent to apparent density, and by the "Point Count" method, which is not further described but presumably refers to the Optical Point Count method as described, for example, in ANSI/ASTM E562-76. The pore size distribution was determined by mercury intrusion porosimetry. These methods of characterization are also being used by some workers to measure pore size and

volume in polymeric materials, even though some of the methods which work well for hard materials may be less than ideal when applied to relatively soft and flexible polymers.

As previously mentioned, Dr. Homsy is convinced that mercury porosimetry cannot be used to measure pore size distributions in the PTFE-carbon composite, because of possible pressure distortion of the pores. In a recent published exchange, Homsy[14] is critical of Spector et al.[15] for using both mercury porosimetry and optical techniques to characterize the porosity of the composite material, and he quotes two "authorities" to prove his case. Spector's reply[23] defends his own use of "conventional" techniques and also defends his own experimental results, which disagree with Homsy's "independent laboratory". The discrepancy between the interconnecting pore sizes claimed by the two authors is quite large (50 μm vs. a minimum of 200 μm)and it is difficult at first to understand how two laboratories using the same techniques could disagree so much. Yet, examination of Fig. 1 could lead one to wonder whether the very definition of a "pore" in such a complex matrix may be subject to debate. This point must be resolved before meaningful pore size measurements can be made.

We have examined many papers describing clinical trials of porous polymeric implants, but we have not as yet discovered any other studies of these materials in which the authors attempt either to measure the pore size or to correlate pore size with in vivo performance. Most authors, if they mention porosity at all, simply state the porosity information provided by the manufacturers. This is perhaps not surprising, because surgical clinicians who use the materials are not

likely to be expert in the use of physical methods of porosity characterization. It would seem that the clinicians are heavily dependent on the manufacturers to provide materials suitable for their intended implant applications.

CLINICAL STUDIES OF OSSICULAR REPLACEMENT PROSTHESES

PTFE - Carbon Composite

The first published reference to the use of the PTFE-carbon composite in middle ear surgery appeared in 1974[24]. Dr. Shea, a co-author of this paper, is a surgeon who has also designed and worked with PHDPE ossicular prostheses, as discussed below. Reference 24 describes the use of a total ossicular replacement prosthesis in humans and states that animal studies "are now underway to determine the effect on the inner ear of a Proplast as an oval window seal". The results of this latter study, which were encouraging, appeared in 1977.[25] Pictures are shown in reference 24 of the ossicular prosthesis, which consists of a rod of solid PTFE with a small pad of the composite attached at each end for tissue ingrowth. As of the date of the publication, none of the first 23 such prosthesis implanted had been extruded (rejected) which, according to the authors, "is not true of any other artificial columella prostheses". In a later publication,[26] Janeke and Shea report that of 33 patients receiving this ossicular replacement none had been extruded over a 24 month period, ".....by which time most implants would have been extruded if they had been

Teflon or Silastic....". Clearly, the initial results were encouraging, but the authors caution that more time for postoperative followup was needed to properly assess the material.

Despite the encouraging outlook for the composite prostheses, we have not found many further references to the use of the composite material in middle ear surgery. Recent references, as described in the following section, appear to be mostly concerned with the PHDPE prostheses.

Porous High Density Polyethylene

As discussed previously in this report, we have received catalogs and extensive references to clinical uses of PHDPE ossicular implants. This bibliography (pp.12-14) includes many references which we have not, as of this writing, had the chance to examine. One which has just been received[27] is a good review article about the use of many kinds of biomaterials in head and neck surgery. We will continue our study of this literature in hope of obtaining more information about PHDPE prostheses, and we will be especially watchful for any studies which may specifically relate the porosity of the material to the eventual success or failure of the implants.

Comments of Dr. Shea excerpted from two of the references provided by the manufacturer of PHDPE prostheses (refs. 58 and 60, p.13) provide a brief glimpse at his experiences with this material. In ref 58, he states that ".....the Plasti-Pore Total Ossicular Replacement Prosthesis [is] superior to the total ossicular replacement made of Proplast and Teflon previously reported and all other natural or synthetic columellas."

In ref. 60 he goes on to state that the PHDPE prosthesis ".....has the advantage of being slightly flexible and compressible compared to the rigid Teflon strut used in combination with Proplast."

Other authors have commented that the PHDPE material, due to its small pore size (Fig.2), does not allow as much tissue ingrowth as might be desirable. Clearly, the problem is complex and involves a great deal more than consideration of pore size and pore volume alone. A very important first step in understanding the behavior of these materials, however, will be to establish a meaningful system of pore characterization.

SUMMARY

Although our search of existing literature is not complete, we have examined a large number of representative examples of recent literature pertaining to porous polymeric implant materials. Certain generalizations may be drawn from this study, which will be helpful in guiding our future efforts, namely:

(1) The success or failure of a tissue-inviting porous implant is, as expected, apparently dependent on many factors other than the "porosity" of the material.

(2) Although porosity is certainly an important property of these materials it is impossible at the present time to relate the success or failure of a porous implant to the dimensions of the pores. This is because there is no general agreement about how to measure the pore dimensions. Not only do different methods probably give different results, but there is no assurance at present that different workers are getting the same results using the same method.

(3) Surgical clinicians do not, as a general rule, bother to check the porosity or other physical properties of their materials. They are thus totally dependent on the manufacturer for information about the materials and their suitability for implant applications.

(4) The morphologies of the porous polymer materials, in particular the PTFE - carbon composite, suggest that it will be difficult to devise a rational working definition of a "pore" which will be necessary for applying some of the quantitative measurement techniques currently in use (e.g., optical line intercept).

In conclusion, there is clearly a need to devise a rational protocol for quantitative comparison of the porosity of porous implant materials.

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APPENDIX I

Letter from Dr. C. A. Homsy to Dr. J. M. Cassel concerning Mercury Intrusion Porosimetry.

THE METHODIST HOSPITAL TEXAS MEDICAL CENTER
6516 BERTNER • HOUSTON, TEXAS 77030 • (713) 790-3311 • CABLE: METHHOSP

7 January 1980

James M. Cassel, Chief
Dental and Medical Materials
Polymer Science and Standards Division
U.S. Department of Commerce
National Bureau of Standards
Washington, D.C. 20234

Dear Mr. Cassel:

Thank you for your letter of December 27th. I am sure that the Dow Corning Corporation who market Proplast® implant material can provide you with a block specimen. The 40 mm x 60 mm x 8 mm dimensions which you mention, is, in fact, a commercially available size. Incidentally, because of the way in which the material is manufactured, the 40 mm x 60 mm faces of such a block have a somewhat reduced surface porosity. Since the blocks are intended to be carved into finished shapes by the surgeon, this characteristic is not clinically significant but may bear on possible porosity measurement of an uncarved block.

Also, we have, in the past, discussed the potential usefulness of mercury intrusion porosimetry in studying the porosity of a material such as Proplast with American Instrument Company. Mr. Samuel Greenberg of that company wrote to us that the data obtainable using the porosimeter with resilient materials would be suspect since the applied pressure would distort and compress the normal structure of the pores.

In addition, we have discussed the use of mercury porosimeter with Hillar M. Rootare who has written extensively on mercury porosimetry and is now employed by MicroMeritics Instruments Corporation, 5680 Goshen Springs Road, Norcross, Georgia 30093. Dr. Rootare also did not encourage the usefulness of the standard mercury porosimeter for characterizing relatively soft materials such as Proplast implant material. Additional information on this subject is contained in a recent communication to the Journal of Biomedical Materials Research from us, a copy of which is enclosed. Best wishes for the New Year.

Sincerely,

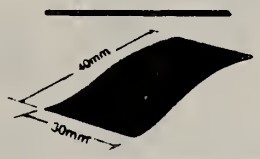
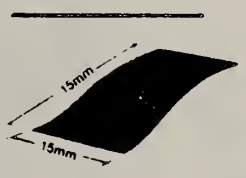
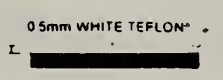
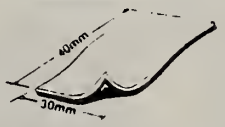
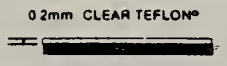
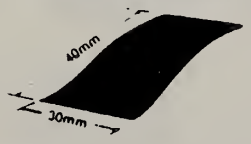
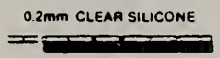
Charles A. Homsy, Sc.D., Director
Prosthesis Research Laboratory
Fondren Orthopedic Center

CAH/klw
Enclosure

APPENDIX II

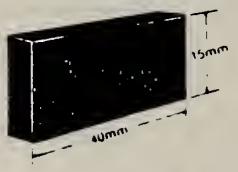
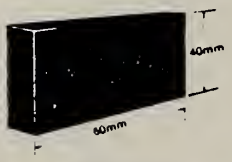
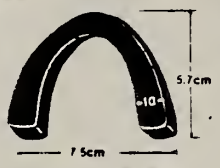
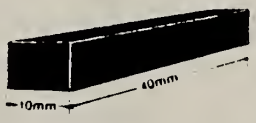
Catalog and Price List of PTFE-Carbon Composite Implant Materials from Dow Corning Wright Corporation.

Proplast® Surgical Implants
Supplied Non-Sterile

Description		Quantity	Size	Cat. No.	Price
Sheeting					
30mm x 40mm (2 Pieces)		1 box	1.0mm	P 911.90	$36.00
30mm x 40mm (2 Pieces)		1 box	2.0mm	P 911.91	$78.00
Thin Sheeting					
15mm x 15mm (10 Ea. Per Box)		1 box	0.35mm	P 911.86	$91.50
15mm x 15mm (10 Ea. Per Box)		1 box	0.65mm	P 911.87	$91.50
15mm x 15mm (10 Ea. Per Box)		1 box	0.80mm	P 911.88	$91.50
15mm x 15mm (10 Ea. Per Box)		1 box	1.00mm	P 911.89	$91.50
Sheeting w/porous Teflon®					
30mm x 40mm, White/Black (2 Pieces)		1 box	1.5mm	P 911.95	$118.00
30mm x 40mm, White/Black (2 Pieces)		1 box	2.5mm	P 911.96	$157.00
30mm x 40mm, White/Black (2 Pieces)		1 box	4.5mm	P 911.97	$234.00
Sheeting w/non-porous Teflon®					
30mm x 40mm (2 Pieces)		1 box	1.2mm	P 911.94	$ 51.00
30mm x 40mm (2 Pieces)		1 box	2.2mm	P 911.92	$ 87.00
30mm x 40mm (2 Pieces)		1 box	3.2mm	P 911.93	$129.00
30mm x 40mm (3 Pieces)		1 set	1.2mm, 2.2mm, & 3.2mm	P 911.99	$133.00
Sheeting w/silicone elastomer					
30mm x 40mm (2 Pieces)		1 box	1.2mm	P 911.98	$51.00

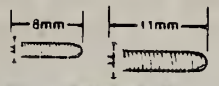
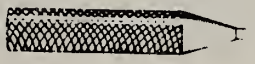
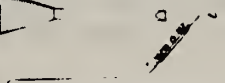
Teflon® is a registered trademark of the DuPont Company.

Proplast® Surgical Implants
Supplied Non-Sterile

Description	Diagrams Are NOT Actual Size	Quantity	Size	Cat. No.	Suggested Price
Proplast® Block, Small Facial					
15mm x 40mm		1 box	6mm*	P 911.26	$58.00
15mm x 40mm		1 box	8mm*	P 911.28	$78.00
15mm x 40mm		1 box	10mm*	P 911.30	$96.00
Proplast® Block, Large Facial					
40mm x 60mm		1 box	6mm*	P 911.46	$216.00
40mm x 60mm		1 box	8mm*	P 911.48	$293.00
40mm x 60mm		1 box	10mm*	P 911.50	$362.00
Proplast® Block, Oval					
15mm x 40mm		1 box	6mm*	P 911.76	$51.00
15mm x 40mm		1 box	8mm*	P 911.78	$67.00
15mm x 40mm		1 box	10mm*	P 911.80	$82.50
Proplast® Ridge, Total					
"U" Shaped		1 box	6mm*	P 911.06	$142.00
"U" Shaped		1 box	8mm*	P 911.08	$180.00
"U" Shaped		1 box	10mm*	P 911.10	$225.50
Proplast® Ridge, Posterior					
10mm x 40mm (2 Pieces)		1 box	6mm*	P 911.05	$ 78.00
10mm x 40mm (2 Pieces)		1 box	8mm*	P 911.07	$103.00
10mm x 40mm (2 Pieces)		1 box	10mm*	P 911.09	$129.00

Actual Thickness
Drawn To Scale

Proplast® Surgical Implants Supplied Non-Sterile

Description	Quantity	Size	Cat. No.	Price
Proplast® Stabilized TMJ Prosthesis/TMC Flat Shank				
Prosthesis/TMC Flat Shank 	1 box	40mm	P 912.22	$172.00
	1 box	47mm	P 912.24	$196.00
Proplast® Stabilized TMJ Prosthesis/TMCK Box Shank				
Prosthesis/TMCK Box Shank 	1 box	40mm	P 912.23	$172.00
	1 box	47mm	P 912.25	$196.00
Bone Screws ACTUAL SIZE (4 ea.) 	1 box	*8.0mm	P 912.26	$30.00
(4 ea.)	1 box	*11.0mm	P 912.28	$36.00
Screw Driver 	1 box		P 912.35	$98.00
TMJ Template (Kent Design) 	1 box		P 912.40	$86.00

*Length measured medially from lateral cortex of mandible.

Proplast® Chin
Kent Design
Dimensions (mm)

	A	B
6mm	48	6
8mm	54	8
10mm	60	10

Qty.	Description	Cat. No.	Suggested Resale Price
1 box	6mm	P 911.66	$121.00
1 box	8mm	P 911.68	$130.00
1 box	10mm	P 911.70	$147.00
1 box	sizers H P Silicone set of 3	P 911.65	$ 77.00

Proplast® Malar
Kent Design
Dimensions (mm)

	A	B
6mm	40	6
10mm	40	10

1 box	6mm	P 911.62	$108.00
1 box	10mm	P 911.64	$121.00

APPENDIX III

Letter from Dr. R. E. Dehl to Dr. C. A. Homsy soliciting opinions about Critical Porosity Parameters.

November 9, 1979

Dr. Charles Homsy
Methodist Hospital
Fonderan Orthopedic Center
Houston, Texas 77030

Dear Dr. Homsy:

The Bureau of Medical Devices (FDA) has requested our assistance in developing methods for characterizing and specifying the porosity of porous implant materials. Your name was suggested to us by H. R. Sauberman at the BMD, as one who is quite knowledgeable about the clinical applications of such materials. We have read about some of your work in this area (e.g. Shea and Homsy, Laryngoscope, 1974), and we would very much like to solicit your opinion about the critical parameters of poroxity which need to be specified.

In particular, we are concerned about the following questions:

(1) Is the total void volume useful as a parameter for intercomparison of porous materials?

(2) Is there a "critical" range of pore diameters and lengths for optimum tissue ingrowth?

(3) What role do "thrupores" play in the tissue ingrowth process and would it be desirable to measure their contribution to the total void?

(4) Do you think that surgical procedures currently in use affect the tissue ingrowth process by changing the surface porosity?

(5) Are there any other aspects of porosity characterization which you feel should be specified?

We would appreciate any reprints or other information which you can supply us that have a bearing on this problem. Thank you in advance for any assistance that you can provide.

Sincerely yours,

Ronald E. Dehl
Dental and Medical Materials
Polymer Science and Standards Division
Phone (301) 921-3336

APPENDIX IV

Response of Dr. Homsy to letter from Dr. Dehl.

THE METHODIST HOSPITAL TEXAS MEDICAL CENTER
6516 BERTNER • HOUSTON, TEXAS 77030 • (713) 790-3311 • CABLE: METHHOSP

15 November 1979

Mr. Ronald E. Dehl
Dental and Medical Materials
Polymer Sciences and Standards Division
National Bureau of Standards
Washington, D.C. 20234

Dear Mr. Dehl,

Thank you for your letter of November 9th in which you requested an opinion concerning critical parameters of porosity for porous implant materials. In response to your questions respectively, I can provide the following comments:

(1) The total void volume is useful as a parameter for inter-comparison of porous materials because it is a direct measure of the relationship between ingrown tissue volume and implant volume. Generally, it is desirable to maximize the ratio of ingrown tissue volume to implant volume since this would naturally tend to make more normal the three dimensional tissue structure within the implant material. The usual objective in application of porous implant material is to develop healthy tissue within the pore volume inherent to the implant material; as, for example, in maxillofacial surgery where soft tissue profile restoration is the objective. This is not to say, however, that the useful range of total void volume is narrow. Total void volume greater than about 50% to 60% will probably be effective in entertaining and maintaining tissue ingrowth; however, other things being equal, the larger the total void volume, the better.

(2) The literature generally shows that there is a minimum pore size below which tissue ingrowth is seriously inhibited. This is generally reported to be in the range of 30 to 50 micra. Naturally, the larger the pores and the interpore connections, the easier it is for tissue to develop within the porosity. Practical upper limits to pore diameter and pore volume are usually dictated by the mechanical requirements to be placed on the porous implant material in a given application. Generally, in the development of the PTFE/graphite porous material (Proplast®), here in our Laboratory, we were guided by the belief that the larger the pore volume, pore diameters, and interpore connections, the better. Also, we have maintained that the mechanical characteristics of a porous implant material should more closely approximate soft tissue than hard tissue when some relative motion may be expected between surrounding tissue and the implant. This specification minimizes interfacial stress on ingrowth tissue and also allows physiological physical forces to be sustained by the ingrown tissue.

(3) I do not understand the meaning of "thru pores." If you mean a pore which passes completely through the implant material, then I think if these were large enough in diameter (>100μ), ingrowth rates would be enhanced. However, the ratio of "thru pores" to micro-porosity within the matrix of the material could be quite high and yet tissue ingrowth (and effective coupling between the implant and surrounding tissue) could be less than optimal if the matrix does not effectively entertain tissue ingrowth at the micro level. Therefore, "thru pores" could play a role in the tissue ingrowth process but must not be the predominant factor in the total void volume.

(4) Porous implant materials currently in surgical use are either supplied in the finished shape for implantation or, in the case of the soft varieties such as Proplast implant material, allow carving by the surgeon to facilitate specific anatomical requirements. There are two possible ways that surgical procedures could effect the surface porosity for the latter material: (a) by manual compression of the material or compression during the carving process; (b) by maladroit carving procedures using dull instruments. In the case of Proplast implant material the various surgical procedures for which it is used require attention to appropriate surgical technique, which as described in the product literature for the material. The clinical reports on this material are quite positive and indicate that necessary care in manipulation is not difficult to exercise.

(5) Early in our experimental work which led to development of the PTFE/carbon composite, we conducted extensive animal implantation studies with a variety of candidate porous implant materials. One particularly illuminating set of experiments was a direct comparison between two porous materials of the same pore volume and pore size distribution where one was entirely of PTFE polymer and the other was a composite of PTFE/graphite fiber such that the graphite fiber is disposed on the PTFE matrix. The latter materials was the prototype for what ultimately became available as Proplast implant material.

What was interesting about this experiment was the much more rapid tissue ingrowth with the composite as compared to the porous polymer. The enclosed paper published in 1972 describes these findings. We believe there may be two main reasons for the observed difference in ingrowth rate: the one relating to the higher surface-free energy exhibited by the composite which is engendered by the carbon fiber ingredient; the second, the higher specific surface area exhibited by the composite. Both factors can be interpreted as allowing for more effective cellular adhesion to the matrix and movement of the cells within the matrix. The cells, specifically fibroblasts, elaborate the collagen matrix of the ingrowing fibrous tissue.

We have enclosed a selection of reprints which may be helpful in your examination of the matter of porosity in porous implant materials. Please do not hesitate to write or call should you have further questions. We are pleased to be of assistance.

Sincerely,

Charles A. Homsy, Sc.D., Director
Prosthesis Research Laboratory
Fondren Orthopedic Center

CAH/klw
Enclosures

APPENDIX V

Letter from Dr. Homsy to Dr. Cassel concerning pore size and pore volume measurements.

THE METHODIST HOSPITAL TEXAS MEDICAL CENTER
6516 BERTNER • HOUSTON, TEXAS 77030 • (713) 790-3311 • CABLE: METHHOSP

15 November 1979

James M. Cassel, Chief
Dental and Medical Materials
Polymer Sciences and Standards Division
National Bureau of Standards
Washington, D.C. 20234

Dear Mr. Cassel,

Thank you for your letter of November 9th in which you commented on the draft standard on porous composites of polytetrafluoroethylene and carbon for surgical implant use. I am copying your letter to Professor K. Piekarski at the University of Waterloo, Ontario, Canada, who is the Task Force Chairman for porous composites. There was considerable discussion concerning tradename identification of a specific porous composite for which the standard had been drafted. I agree that it would not be appropriate to specify a tradename and will re-present this point of view at the Task Force meeting in Williamsburg later this month.

The matter of performance criteria for pore characteristics has been a vexing one. The Proplast® composite is soft and almost felt-like. Therefore, we found mercury intrusion porosimetry to be inefficient for pore characterization. However, the tensile strength and apparent density parameters in the standard directly reflect pore volume and character. Specific pore size distribution is controlled by the manufacturing process as disclosed in U.S. Patent No. 3,992,725 and the specific methodology is set out in detail in the Manufacturing Product Record for the product as called for under the FDA Good Manufacturing Practice requirements for critical devices.

We have also used direct optical line intercept techniques of SEMs to determine pore volume and pore size distribution; however, this is a tedious and inherently imprecise technique which tends to provide values on the low side. For example, the leachable filler used during the manufacturing process for Proplast material is selected to produce a pore size distribution range of between 60 and 500 micra and a pore volume of 75-85%. The line intercept technique indicates a pore size range of 80 to 400 micra and a pore volume of 57%.

Generally, the larger the average pore size, the larger the pore interconnections and the greater the pore volume, the more rapidly does tissue ingrow into biocompatible porous matrices. Proplast was designed to have a very high pore volume and the largest pore sizes and pore size interconnections compatible with mechanical requirements for the various implant functions for which the material is used. I believe that the end user can readily confirm through apparent density and tensile strength measurement that the product

is conforming to manufacturing specifications with respect to pore characteristics. Of course, underlying the standard specification must be the manufacturing controls which are monitored by FDA for all critical implant devices.

Thank you very much for your interest in this particular standard. As you can see, we were keen on developing a true performance standard including biocompatibility assay with the view that ultimately such performance standards will become de facto regulatory standards and meet the needs of FDA and the public. Any suggestions for improving the standard are welcomed. If you will be at the Williamsburg meeting, perhaps we can get together and talk further.

Sincerely,

Charles A. Homsy, Sc.D., Director
Prosthesis Research Laboratory
Fondren Orthopedic Center

Research Associate Professor
Baylor College of Medicine

CAH/klw

cc: Professor K. Piekarski

NBS-114A REV. 2-8C)

U.S. DEPT. OF COMM. BIBLIOGRAPHIC DATA SHEET (See instructions)	1. PUBLICATION OR REPORT NO. NBSIR 81-2212	2. Performing Organ. Report No.	3. Publication Date

4. TITLE AND SUBTITLE

Evaluation of Methods for Characterizing the Porosity of Porous Polymeric Implant Materials : A Review of the Current Status of Porosity Measurements

5. AUTHOR(S)

R. E. Dehl, W. H. Grant, and J. M. Cassel

6. PERFORMING ORGANIZATION (If joint or other than NBS, see instructions)

NATIONAL BUREAU OF STANDARDS
DEPARTMENT OF COMMERCE
WASHINGTON, D.C. 20234

7. Contract/Grant No.

8. Type of Report & Period Covered

May 22 - Sept. 30/80

9. SPONSORING ORGANIZATION NAME AND COMPLETE ADDRESS (Street, City, State, ZIP)

Bureau of Medical Devices
Food and Drug Administration
Silver Spring, Maryland 20910

10. SUPPLEMENTARY NOTES

☐ Document describes a computer program; SF-185, FIPS Software Summary, is attached.

11. ABSTRACT (A 200-word or less factual summary of most significant information. If document includes a significant bibliography or literature survey, mention it here)

A search of the published literature pertaining to porous polymeric implant materials has been made. The two porous materials currently dominant in implant surgery, namely, porous high density polyethylene and a porous composite of polytetrafluoroethylene and carbon, have been reviewed with respect to the following criteria pertinent to their medical applications: (1) Information supplied by the manufacturers about their methods of characterizing the porosity of their materials, (2) recommendations of the ASTM for quantitative porosity characterization of these materials, and (3) clinical studies of the materials as replacement prostheses in middle ear surgery. A computer search for new quantitative methods of measuring pore size revealed nothing appropriate to these materials. However, disputes in the current literature suggest that current protocols for porosity characterization are inadequate for proper interlaboratory comparison of experimental data.

12. KEY WORDS (Six to twelve entries; alphabetical order; capitalize only proper names; and separate key words by semicolons)

Ossicular prosthesis; porosity measurement; porous biomaterials; porous polyethylene; PTFE-carbon composite; synthetic implants

13. AVAILABILITY

☒ Unlimited

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14. NO. OF PRINTED PAGES

15. Price

USCOMM-DC 6043-P80