NBSIR 73-262 Some Cutting Experiments on Human Skin and Synthetic Materials

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Consumer Product Systems Section Measurement Engineering Division Institute for Applied Technology

October 1973

Interim Report for Period February -- August 1973

Prepared for Consumer Product Safety Commission Bethesda, Maryland 20016

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This is a progress report. The work is incomplete and continuing. Conclusions are not necessarily those that will be included in a final report.

Prepared for Consumer Product Safety Commission Bethesda, Maryland 20016



U. S. DEPARTMENT OF COMMERCE, Frederick B. Dent, Secretary NATIONAL BUREAU OF STANDARDS, Richard W. Roberts, Director

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I. DISCUSSION OF THE PROBLEM

A. Introduction

Under the sponsorship of the Consumer Product Safety Commission the NBS Measurement Engineering Division is continuing to investigate hazards associated with certain mechanical features of toys (e.g. points, edges, and projections). The two main objectives of this investigation are: 1) to provide quantative data which can be used to establish and support toy safety regulations; and 2) to develop test methods or devices which can distinguish between hazardous and non-hazardous features of toys. The investigations conducted to date under this program have not attempted to characterize those toy configurations which might be considered hazardous under high impact or fall-on conditions. Instead, the studies thus far have been concerned primarily with points, edges and projections which might be potentially dangerous under "casual handling" conditions.

Three prior progress reports have been submitted on this project. The first of these, by Moore $\underline{1}/$ discussed the results of subjective evaluations of sharp points, and described the design of a test device for measuring the sharpness and rigidity of points. The second report, by McGuire and Moore $\underline{2}/$, included a review of published data, and gave the results of experimental puncture tests on pigskin and human skin. That report also gave results of subjective evaluations of point sharpness by physicians. The most recent report, by McGuire et al. $\underline{3}/$, provided additional data on the puncture resistance of human skin, data on the measurements of children's hand velocities, and the results of cutting tests on pigskin with sheared steel edges at various velocities. This present progress report discusses the results of experimental cutting tests conducted on excised specimens of human skin with a variety of typical edges and within a limited range of controlled conditions. This report also describes a method using synthetic materials as cut indicators to differentiate between hazardous and non-hazardous edges.

B. Background Discussion

The establishment of criteria and test methods for categorizing the hazard potential of exposed edges on toys is a complex problem, for which there can probably be no simple and universal solution. Certain edges, such as a broken glass edge or a soft rubber edge, would probably be judged hazardous and non-hazardous respectively by any criteria. Between these extremes, however, there may be an infinite number of possible edge configurations which could occur in real life. Furthermore, in a real play environment, the hazard potential of a given edge depends not only upon the physical characteristics of the edge, but also upon many other factors which are involved in the child-toy interaction. For example, on one toy, a given edge might be perfectly safe if the toy has very low mass, the edge is supported by compliant material, or the use of the toy is limited. On another toy, where these factors might be different, the same edge could be sufficiently hazardous to make it unacceptable for child use. In addition, many edges which might be considered safe under casual handling conditions could, if thrown or fallen on, inflict serious injury to a child due to higher forces which result from impact. During impact, the force which is developed between the child's body and an edge may be several orders of magnitude greater than that experienced during normal handling or casual play.

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In addition to those factors which are primarily related to the physical characteristics of the toy and its use, many factors concerning the physical attributes of the child must also be considered. Physical strength of the child, mass and velocities of body parts, and resistance of the child's body to injury are all significant in determining the injury potential of toy configurations. This adds greatly to the complexity of the problem since these factors vary considerably with age, individual, and body part.

Another complicating aspect of the problem is the complex nature of skin itself. Human skin is a multi-layered, inhomogeneous, nonuniform material with characteristics ranging widely among different persons and body sites. The major layers of skin are schematically illustrated in Figure 1. This is a grossly simplified sketch since skin is also rich in nerves, pores, hair follicles, etc. "Skin consists of the relatively thin, cellular epidermis and two dermal layers comprised predominantly of collagenous and, to a lesser extent, of elastic fibers. Of these two layers, the deeper one is composed of particularly dense networks of coarse fibers, from which it gets the name reticular layer." <u>4</u>/

The papillary layer of the dermis is the first layer below the skin surface which contains any blood vessels - i.e. small capillaries. Typical thicknesses of the epidermis and dermis are shown in Figure 1, the larger values occuring on hands and finger tips. 4/-6/ According to Deck's data, the thickness of the reticular layer represents about 80 to 90 percent of the total skin thickness (i.e. epidermis plus dermis). The subdermis, a relatively thick fatty tissue containing larger blood vessels and nerve bundles, is not usually considered to be a skin component 2/ and 4/.

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A search of the literature reveals very little information about low level laceration injuries to human skin. A few studies of skin trauma have been made in connection with automotive safety programs. Gadd et al. <u>7</u>/ conducted a series of tests on unembalmed cadavers wherein metal and glass edges were impacted against several areas of the body, and measurements were made of the resulting impact forces and lacerations. Force levels of 90 to 405 pounds were measured during impacts that produced total penetration of scalp tissue.

In connection with studies of automotive glass performance, Rieser and Chabal <u>8</u>/ used standard surgical blades to make comparative cutting tests on human skin, pigskin, chamois skin, and a variety of synthetic compositions. From these tests, a synthetic skin simulant was developed and used on headforms to evaluate the performance of automotive glass during impact. While these studies are probably valuable to the field of automotive safety, they do not appear to be directly applicable to injuries associated with child-toy interactions under casual handling conditions.

C. Scope of this Study

At the start of this investigation, it was emphasized by the sponsor's representatives that test criteria and procedures applicable to safety standards for edges on children's toys are urgently needed. Because of this urgency, this initial study does not undertake the systematic and theoretical analysis of all possible factors and conditions involved in laceration injuries to children. Instead, this investigation is based essentially on empirical methods, and is directed primarily at developing practical procedures for evaluating the sharpness of edges on bys, under limited conditions of play. In this report "sharpness" refers to the ability of an edge to cut human skin.

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In this study, only casual play conditions have been considered. As used here, the term "casual play" is intended to include the type of activity usually involved in unpacking, handling, operating and playing with the toy. The term is also meant to include activities associated with reasonable misuse of the toy, but not situations where the toy is fallen on, thrown, or swung, at high velocities. The above definition of activity level is admittedly imprecise. However, at present, no quantitative data are available on the full range of force, momentum or energy that can result from typical child-toy interactions.

The general approach that is used in this study is based on the premise that practical methods for judging the sharpness of edges can be developed without necessarily determining the complex relationship of all parameters involved in cutting human skin. More specifically, this premise suggests that for casual play conditions, edge safety criteria can be adequately defined in terms of two basic parameters: 1) the force, F, developed between the skin and the edge in the casual handling mode; and 2) permissible levels of injury, I, to be tolerated*. Specifications of these two parameters will define a safety criterion, S.C. = (F,I). In choosing such a safety criterion, the tolerable injury may depend on the force. Functionally this is written S.C. = (F,I(F)). Operationally, this means that while only low level injuries (e.g. no break in epidermis) may be tolerated for force levels in normal use (of a toy), higher level injuries may be allowed for reasonably forseeable abuse, and still higher level injuries for abnormal, or unforseen, abuse.

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^{*}Initially it was thought that the relative velocity between the edge and skin might also be an important parameter. However, preliminary tests, in which other variables were held constant and the velocity was varied, showed no appreciable or definite velocity effect (see section III.A).

The present work seeks to cover a reasonable range of force levels in the casual handling mode. In the point sharpness study by McGuire and Moore 2/ it was assumed that the maximum grip strength of pre-school children defines a reasonable upper limit of casual handling forces. Based on this assumption, and data from a study by Krogman and McCown 9/, a force of 7.5 kg (16.5 pounds, 74 newtons) was used in evaluating point sharpness. In a more recent study by Brown et al. 10/, it was found that pre-school (5-year old) females and males exert average maximum grip forces of 19.1 and 20.4 pounds, respectively (85 and 91 newtons). Thus the present work covers a force range from 0 to 20 pounds (89 newtons).

Also needed is a means of characterizing the injury which would result from a sharp edge. In this work, it will be assumed that the depth of cut (or percent depth of cut, D*, see section III.A) is an adequate measure. Of course, pure laceration is not the only type of injury which might result from an edge; at high forces, and for sufficiently dull edges, one may expect to find a significant amount of tissue crushing, whether or not laceration is present. Such crushing leaves a measurable groove in autopsy specimens (section II.D) and thus a depth measurement is actually some combination of cutting and crushing. Thus it is hoped that a depth measurement will be a realistic injury indicator even though part of the injury may be due to crushing. The safety criterion would then be rewritten:

S.C. = (F, D*(F))

It should be emphasized that many difficulties exist in choosing the proper force and injury levels that constitute the safety criterion. As seen above, only maximum child strength data are available

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in the literature. However, if these maximum forces are rarely approached, it seems unrealistic base safety criteria on them. Also there seems to be little or no agreement as to what constitutes a tolerable depth of cut. Mothers may prefer that their children never bleed (epidermis not be broken). Yet in a limited, informal survey of pediatric and plastic surgeons in Maryland, Virginia and D.C., the unanimous opinion was that the dermis must be completely penetrated before the cut would be considered serious.

Once a safety criterion is established, and edges can be classified as hazardous or non-hazardous, it remains to devise an inspection procedure to classify unknown edges. As a final objective of this report, we explore the use of artificial materials as cut indicators to distinguish between safe and dangerous edges. It should be noted that this concept is not new or unique. At least two independent testing laboratories and one major manufacturer are known to be using their own versions of this concept to test the sharpness of edges. Apparently, however, those test procedures and criteria are based essentially on subjective judgement rather than experimental measurement and would therefore be unsuitable for regulatory standards. The test procedures and experimental data presented in this report should be useful in establishing and supporting such standards.

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A. Source and Preparation of Skin Specimens

Human skin specimens, excised during autopsy, were supplied by several local morgues and hospitals. In the interest of keeping independent variables to a minimum, it was decided to keep body site constant throughout the experiment (in section III.B it will be seen that the variability of the data is quite large without introducing this additional variable). Skin from the abdomen was chosen because of its availability (it was the policy of most autopsy rooms not to excise large enough specimens from other body sites).

In all cases, the specimens were removed before the body was embalmed, and were kept moist and refrigerated until the cutting tests were performed. In many cases the specimens were tested within 24 hours after death, although the average delay was approximately 2 1/2 days. Most of the specimens were quite small (approximately 1" X 2") and provided space for no more than five or six test cuts. Several, however, were large enough to accommodate thirty to forty test cuts. General data on all specimens used in the tests are summarized in Figure 2.

When received for testing, all of the skin specimens still had most of the sub-dermal tissue intact. Generally, this tissue was mostly fat, and varied in thickness from one-quarter to three-quarters of an inch. In preparing the specimens for test, all of this sub-dermal tissue was carefully removed with a sharp knife. The remaining thickness, consisting of only the dermis and epidermis, was then mounted on the cutting apparatus.

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B. Test Method and Apparatus for Cutting Skin

The basic method used in all of the skin cutting tests is illustrated schematically in Figure 3. As shown in the illustration, each skin specimen was mounted directly on a semi-circular, hardwood mandrel, with the epidermis to the outside. The specimen was secured in position with several individual loops of fine wire which were wrapped around the outside of the specimen and tightened by twisting the ends of the loop. The mandrel could be revolved at controlled velocities. With the skin in motion at a known velocity, a test edge having a specific geometrical shape, was brought into contact with the skin during a single revolution of the mandrel. The force exerted by the edge, normal to the surface of the skin, was controlled by means of a calibrated spring.

To minimize any inertial loading effects between the test edge and the skin specimen, two precautions were taken. First, the leading and trailing edges of the semi-circular mandrel were rounded off so that the initial contact and final separation between the skin and edge occurred gradually. Secondly, for each test cut, the release of the edge was synchronized with the rotary motion of the mandrel so that the edge always assumed its forward stop position during the non-cutting part of the mandrel rotation (flat side of the mandrel facing the edge). The cutting action then occurred as the curved surface of the mandrel rotated past the spring loaded edge. In all tests, the forward stop position of the edge was adjusted so that the edge was capable of cutting slightly into the mandrel surface, if all other factors permitted.

A photograph of the actual apparatus is shown in Figure 4. As shown in the photograph, the hardwood mandrel was held in the chuck of a small, metal-turning lathe. The drive system for the lathe thus

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provided a convenient means of controlling the mandrel speed. Details of the edge holder and spring assembly can also be seen from the photograph. As shown, the test edge was held in one end of a pivoted lever arm. An adjustable tension spring, attached to the opposite end of the lever arm, provided a means for setting the desired test force. This complete assembly was rigidly mounted to the lathe carriage, and the manual controls for the carriage provided a convenient means of adjusting the test edges relative to the mandrel surface, and for locating adjacent cuts on a given skin specimen. During calibration and operation of the apparatus, a small set of electrical contacts was used to sense the motion of the lever arm and to indicate its calibrated position.

No claim is made as to the ability of the loading mechanism, used in this experiment, to simulate an actual child-toy interaction. In an actual situation, the reaction time of the body should be an approximate measure of the cutting time of an edge. That is, in a non-impact injury situation, one would sense pain and pull away from an edge after 0.27 seconds (a typical reaction time of the body to a pressure stimulus accompanied by pain, as reported by Woodworth and Schlosberg 11/), and the edge would not penetrate further. In the experiment, this time should be compared to half the total time that a given element of skin is in contact with the edge; i.e. the time it takes to cut that skin element to the maximum depth. We have estimated this time to be on the order of 0.2 seconds, which is the same order of magnitude as the reaction time. Thus, it may not be entirely invalid to apply the results of this investigation to injuries associated with other non-impact loading mechanisms.

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C. Test Edges

Throughout the cutting tests, two basic types of test edges were used. One type was made from 1/8" thick hardened tool steel and had smooth cutting edges that were ground to specific dimensions. Edges of this type, having edge angles of from 15° to 105° and edge radii of from .000" to .008" were used in the tests. The second type of test edge was made from .059" thick sheet steel and had cutting edges that were sheared on a good quality, power shear. These edges had an effective edge angle of 90° but the cutting side of each edge was left with a rough, irregular burr that is sometimes called a "wire edge" and is characteristic of most sheared metal edges.

Although a more extensive family of edges was made and used in the preliminary testing, the final tests were conducted with a selected group of eleven edges, which are identified and described in more detail in Figure 5. As indicated, the edges in the final test set were not selected according to a specific pattern of graduated edge angles or edge radii. This was not considered necessary, since we were not attempting to establish safety criteria or testing procedures that are based strictly on edge geometry. For the purpose of these experiments, it was considered more important that the test edges have reasonably typical geometries, and that they range from "sharp" to "dull" in their ability to cut human skin.

D. Cut Measurement Method

In order to evaluate the results of these experiments, it was necessary to develop a method for measuring the depth of each test cut, relative to the thickness of the skin specimen. Optical techniques were tried but were judged to be unsuitable because of the time required to

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make each measurement. A more convenient method was devised using the apparatus shown in Figure 6.

As shown, the basic measuring device consisted of a mechanical dial comparator with a special probe tip. The wedge-shaped tip was approximately one-half an inch long and had an edge angle of 15° and an edge radius of 8 mils. This particular geometry was chosen to facilitate the insertion of the probe into the test cuts and to minimize the pressure exerted by the probe during measurements. This tip was attached to the shaft of the dial indicator with its "sharp" edge downward. A piece of 1/2" thick aluminum plate served as a movable specimen block and as a reference surface for the probe. To further minimize the pressure exerted on the specimen by the probe, the return spring was removed from the dial indicator mechanism. The lamp shown in the photograph was used to illuminate the test specimen and facilitate the positioning of the probe for the measurements.

For each test cut, two measurements were made: T1, the total skin thickness immediately adjacent to the cut; and T2, the thickness of tissue at the bottom of the cut. From these two measurements, the depth of cut, D, and the percent depth of cut, D*, were later calculated. $(D = T1 - T2 \text{ and } D^* = D/T1 \times 100)$. This measuring technique was used because total skin thickness varied from specimen to specimen and within individual specimens as well.

The general procedure used in making the measurements was as follows. Immediately after cutting, each specimen was placed on the specimen block, with the epidermis side up, and spread out to its approximate original size and shape. The probe was then lowered onto

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the skin, adjacent to the first cut and allowed to reach equilibrium before the dial reading (T1) was recorded. The specimen block was then repositioned and the probe was lowered into the first cut. Since the average length of cut was approximately 1 1/4" and the length of the probe tip was 1/2", it was relatively easy to locate the probe in the center of the cut where the depth was most constant and least affected by any inertial loading effects. To make certain that the probe was actually "bottomed" in the cut, the position of the specimen block was critically adjusted to obtain a minimum reading on the dial indicator. This reading was then recorded as T2 for that particular cut. The above procedure was repeated for each cut on the specimen.

In many cases it was found that the duller test edges crushed the skin rather cutting it. In these instances, the test produced a permanent groove in the specimen but did not cause a break in the epidermis. When this occurred, the groove was measured in the same way as a cut, but special note was made that a true cut was not produced.

III. RESULTS AND APPLICATION OF EXPERIMENT

A. Presentation and Discussion of Results

A preliminary experiment was run on a particularly large skin specimen (from a thigh) to determine if there was any appreciable velocity effect. At each of several force and edge combinations, the tangential velocity was varied in the range of one to ten inches per second, and the depth of cut recorded. No appreciable or definite velocity effect on depth of cut was noted. On the basis of these observations, all subsequent tests were conducted at a fixed velocity of one inch per second (the slowest speed was chosen for the ease in synchronizing the release of the edge).

The results of the experimental investigation are shown in Figures 7 to 17. For each edge, the percentage depth of cut, D* (i.e. the depth of cut non-dimensionalized with respect to the skin thickness adjacent to the cut) is plotted as a function of the normal force on the edge. The specimen number is recorded beside each data point. Generally, the lower numbered specimens were cut first.

Qualitatively, the effect of normal force on the percentage depth of cut is similar for each edge. At some force the edge begins to cut and the percentage depth of cut increases with force. The rate of increase of D* appears to decrease with force until the specimen has been cut all the way through. This observation seems consistent with the fact that both the density of collagen fibers and the size of individual fibers increase with depth into the dermis 4/, i.e. as an edge cuts increasingly deeper, it becomes increasingly more difficult to cut the skin.

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[†]D* was chosen as the dependent variable because it exhibited less variability than the absolute depth of cut, D.

In the appendix, John Mandel describes a technique he used to extract information about the general shape of the D* vs. F curves. The nature of the data precluded the use of least squares methods to fit the data for each edge. Due to the extreme variability in the data, such a curve would not be very useful in setting safety criteria anyway. It was found that if a given skin specimen is cut by a given edge, the data could be fit to equations of the type:

 $D^* = \alpha + \gamma (1 - e^{-\beta F})$

where β is independent of edge and skin specimen. Thus it appears that this exponential behavior may be related to the physical nature of the cutting phenomena itself. The coefficients α and γ depend upon both edge and skin specimen. For a given edge, changing the coefficient α serves to raise or lower the entire curve; thus α may be related to the overall strength of a given skin specimen. The values of the γ coefficient may be related to how the strength of skin specimens vary with depth. Values for α , β , and γ are given in the appendix.

Some of these curves have been plotted in Figures 7 to 17 to illustrate the general shape of these D* vs. F curves. Each case is for a single skin specimen, which is labelled on the curve. Since specimens 16 and 18 were quite large, it was possible to cut them through the full force range with many edges. Thus Figures 7, 9, 10 and 13 all contain curves for both specimens. Recall that each curve was fit to the data for a given specimen and edge. Thus there seems to be a remarkable consistency (through these figures) in the relative' shapes of the curves for these two specimens. This observation adds to the credibility of the mathematical model. It is very difficult to quantitatively assess how edge angle and edge radius influence cutting. Generally, the smaller the angle and radius, the deeper the cut (assuming that all other variables are held fixed). However, in several instances, the above generalization did not appear to hold. For example, in Figures 11 and 12 edge E (105°, no radius) cut deeper than edge F (90°, no radius).

Also the two 90° edges, B and F, had drastically different cutting capabilities (Figures 8 and 12). A profilimeter was used to trace the geometry of these two edges. It was found that edge F had a significant edge radius (on the order of .001 inches) in some spots. The photograph in Figure 18 seems to confirm this point. This evidence indicates that the microscopic features of an edge may have a very significant effect on its ability to cut human skin.

Some other qualitative phenomena should be noted. Often, an edge would leave a permanent measurable groove in the skin, even though the epidermis was not broken (such data points are indicated by a filled in circle in Figures 7 to 17). This was more pronounced with the duller edges. Thus we must suspect that our measurements are a combination of cutting and crushing of tissue, though we expect that for the sharper edges, the amount of crush is negligible. For some of the deeper cuts, it was noticed that the dermis was completely penetrated in spots, although values of $D^* = 100\%$ were not measured. This phenomenon occurred at about the level $D^* = 80\%$ and is attributed to the hill and valley structure of the bottom of the dermis (see Figure 1).

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B. Some Limitations of the Experiment

Perhaps the most obvious difficulty in evaluating the experimental evidence is the extreme variability in the results from cutting specimens from different bodies. In order to estimate this variability, measurements were taken on many specimens at 8 lbs. on edge E (Figure 11), and at 4 and 8 lbs. on edge C (Figure 9). While a clear indication of the distribution is not available in any of these cases, estimates for the standard deviations of these points are 14.6, 10.7, and 14.1 percent, respectively. In order to estimate how much of this variability is attributed to experimental error, repeated cuts were made on the same specimen with edge and force held constant. This procedure was in turn repeated on other specimens and for other edges and forces. It was thus determined that experimental errors are no greater than 5%.

A closer scrutiny of the data at 8 lbs. for edge E reveals another difficulty. These values were plotted in the order in which the specimens were cut; i.e. as D^* vs. N, where N = 1 (the first specimen cut), 2 (the second specimen cut), etc. When a straight line was fitted to these data by the method of least squares, the slope of the line was negative and significantly different from zero (using a 5% level of significance). This finding lends support to the conclusion that the edge is dulling from continued use.

This observation points out an inherent difficulty with any cutting experiment; namely, that the cutting process is likely to dull, and thus microscopically change the surface geometry of an edge. One method

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of avoiding edge dulling might be the use of many edges all ground to the same specifications. However, to obtain reproducible results, these edges would have to be macroscopically and microscopically identical.

There are some reasons to suspect that in an actual child-toy interaction, a given edge would not cut as deeply as it did in the experiment. In the experiment, the specimen was mounted on a hardwood backing with all subdermal tissue removed. Presumably this is a worstcase situation since a softer backing would distribute the force and increase the resistance to cutting. (However, there are several areas of the body where skin is backed by bone with little subdermal tissue knees, shins, knuckles, forehead, etc.) Also there is some evidence that live skin is more difficult to cut than the excised autopsy specimens used in the experiment: in preliminary testing, at forces for which an edge clearly cut the excised specimens, the epidermis of the authors' skin was not broken. Also, in a penetration experiment Deck 12/ tested the same skin specimen in vivo and in vitro and found that considerably less force was required to penetrate the specimen after it was excised. Thus in the absence of any other influences, the use of the experimental results in supporting safety criteria would be conservative.

However, there are several factors which might lead one to draw opposite conclusions. For example, the evidence that the edges are dulling means that an edge may not be cutting as deeply as it would in the absence of such effects. Another non-conservative factor is that our contact time estimate (section II.B) was made for a cut of maximum penetration ($D^* = 100\%$). This time estimate would decrease with D^* .

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Recall that this time was compared with what was assumed to be the cutting time in an actual child-toy interaction; i.e. the reaction time of the body. Since many cuts were less than 100%, many contact times in the experiment were less than this reaction time. Thus in many instances the edges used in the experiment were not in contact with the skin as long as they would be in a real situation; and presumably, they would not cut as deeply.

It is, of course, very difficult to quantitatively assess how the above factors would affect a safety criterion based on the experimental data. To some extent, the conservative factors will be balanced by the non-conservative ones, though at this time the net effect cannot be deduced. In addition, two other factors should be expected to influence the applicability of the experiment: 1) the difference in resistance to cutting between abdomen and other more vulnerable body sites, and 2) the effect of age - the average age of the specimens used was 55 years, much greater than the typical child. However, insufficient data are available to ascertain whether these effects are conservative or non-conservative. (McGuire and Moore 2/ summarize some investigations which bear on this question.)

C. Discriminating Between Safe and Hazardous Edges

For convenience, the data in Figures 7 to 17 has been replotted as D* vs. edge for a given force. This is shown in Figures 19 to 23 for the forces 4, 8, 12, 16 and 20 lbs., respectively. The position of the edges on the abcissa has been arbitarily selected, though, generally they are in the order of decreasing sharpness.

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Horizontal lines have been drawn at three representative values of D*: 80%, 50% and 30%. The D* = 80% level is where serious injuries may begin to occur (since this is where holes were observed in the bottom of the dermis). The D* = 50% level is representative of an injury which damages the reticular layer of the dermis. The D* = 30% level was chosen as an example of a cut which has just entered the reticular layer. In addition, another injury level representing no break in the epidermis is discernible in these figures (filled-in circles). We call this later injury level the "no blood" level, since bleeding does not occur until the epidermis is totally penetrated. These injury levels (no blood, 30%, 50%, and 80%) are examples of injury levels 1, 2, 3 and 4, respectively, as described by Mahajan 13/.

The following convention will be used in determining if an edge is safe or dangerous at a given force level and for a chosen D* to be tolerated: if none of the specimens tested for that edge cut as deeply as the prescribed injury level, the edge is designated "safe"; if only one specimen cut that deep, we call the edge "possibly safe"; more than one - "hazardous." Of course the limited number of specimens tested and the extreme variability in the data will make the labelling of edges somewhat suspect. It is for this reason that for an edge to be called safe, no specimens were allowed to cut beyond the prescribed injury level (as opposed to allowing a certain percentage of weak specimens to exceed the injury level).

In Figure 24a, the safe and possibly safe edges are summarized for the four injury levels described, and for the five force levels presented. The Roman numerals in each box refer to discrimination points

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between edges, which are summarized in Figure 24b. For each of the discrimination points illustrated, those edges above the line are hazardous. The discrimination points used in the boxes of Figure 24a were chosen such as to minimize the total number of discriminations that need to be made. Thus a possibly safe edge may be left in or taken out for convenience.

As an example, discrimination point II, for which only edges J and K are considered non-hazardous, will be appropriate for several safety criteria (defined in section I.C): (8 lb., no blood), (12 lb, 30%), (16 lb, 50%); see Figure 24a. Thus it is possible to satisfy multiple safety criteria (as would be needed if the tolerable injury were chosen to depend on the force level) with a single discrimination. Therefore, the three safety criteria satisfied by discrimination point II may correspond to levels of normal use, reasonably forseeable abuse, and abnormal abuse. IV. DISCRIMINATION TECHNIQUES USING SYNTHETIC MATERIALS

A. Inspection Procedure for Unknown Edges

Once a safety criterion has been proposed, it remains to devise a procedure which will discriminate between safe and dangerous edges on toys. Unfortunately a simple requirement on edge angle and edge radius is not adequate; as seen before, microscopic irregularities may affect an edge's cutting capability. Thus it was decided to seek out a synthetic material which at some given force would be cut completely though by only those edges, in our family, deemed hazardous by the safety criterion. Hopefully, at the same force, those edges deemed non-hazardous would not completely penetrate the material. The idea is that a field inspector would place a strip of the material on some constant force device, run it across an edge associated with a toy, and decide if the edge is safe or hazardous (depending upon whether or not the material was cut all the way through).

For a given safety criterion, we can order our family of edges from sharp to dull (depending on their ability to cut skin). We can also perform a sharp-to-dull ordering of the edges for each synthetic material (depending on the force required to cut through the material). An ideal test material would be one for which these two orders are identical. Even so, we can never be sure that an untested edge will occupy the same position, relative to the members of our family, for both skin and the synthetic. However, drastic shifts in position are not expected. Thus, while there always exists the possibility of wrongly classifying a given edge, the choice of a more conservative safety criterion should serve to overcome such problems.

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B. Testing of Synthetic Materials

For testing the synthetic materials, the apparatus shown in Figure 25 was used. As shown in the photograph, the force system and apparatus for holding the test edges was the same as that used in the skin experiments. The arrangement for holding the test specimens was modified, however, in order to obtain linear rather than rotary motion of the specimen, relative to the test edge. This change was made in order to simulate a proposed field test procedure wherein the test material would be mounted on a simple, hand-held device and rubbed along the unknown edge to test its sharpness.

To obtain the required linear motion, the lathe chuck was removed, and an old, but functional, microtome was mounted on the lathe ways. The assembly which normally holds the microtome blade was removed, and a special aluminum mandrel was made and attached to the microtome head. With this arrangement, one turn of the microtome handle caused the mandrel to reciprocate over a vertical distance of approximately 2 inches.

The procedure used in testing each material was as follows: A sample of each material was first wrapped tightly around the mandrel and secured with an adhesive tape. Generally, only a single wrap of the material was made, directly on the metal mandrel with no intermediate backing. With the test sample in place, a series of test cuts were then made to determine the force required for each test edge to cut completely through the sample material. Prior to each cut, the tension spring was adjusted to the desired force setting, and the forward stop

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position of the test edge was adjusted, relative to the mandrel surface. The cutting edge was then positioned on the test sample and allowed to bear against the material with the pre-set force. The microtome handwheel was then turned one complete revolution, causing the test sample to rub back and forth (down and up) along a two-inch length of the cutting edge. For some particularly weak materials, only an up or a down stroke was used (single stroke). If the material sample was cut completely through by this action, an electrical circuit was completed between the edge and the mandrel, lighting a small indicator lamp.

For each test cut, the only data recorded were simple "yes" or "no" observations as to whether or not total penetration occurred. For a given test edge, cuts were repeated at various force levels until the force required to produce total penetration of the particular material was clearly determined.

In our search for useful cut indicating materials, more than forty different synthetics have been tested. Approximately half of these materials were commercially manufactured products, and the remainder were special formulations made in our own laboratory. Among the commercial materials tested were various types of paper, PVC foams and sheets , polyethylene foams and sheets, neoprene foams with and without solid exterior films, polytetrafluorethylene (TFE) sheets, and butyl rubber. The special formulations that were tested included several types of plastisol sheets, silicone gel sheets, silicone gels reinforced with rayon fibers, silicone rubber foams, vinyl resin and paraffin films, and various silicone impregnated papers. In many cases, different thicknesses of a given material were also tested.

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Many of the materials proved to be totally unsuitable as cut indicators either because the forces required to cut completely through the material were unreasonably high, or because the difference between partial and total cuts was not visually distinctive (this difference could not be appraised electrically for non-metallic edges).

C. Results of Tests

Some representative synthetic materials are described in Figure 26. The results of tests on these materials are shown in Figures 27 to 29. For any given material and edge, two points were usually plotted. The upper point (open circle) is a force at which the material was completely penetrated and at which all higher forces would also cause complete penetration. The lower point (closed circle) is a force at which penetration was not complete; below this force, the material would not be completely penetrated by the edges. At forces between these two points both "yes" and "no" (see preceding section) readings were recorded. That these two points are not identical is attributed to variablities in the material and to experimental errors in setting forces. This latter source of variability should be nearly constant from one material to the next. Thus the distance between the upper and lower readings may be interpreted as a relative measure of inhomogeneity of the synthetic materials. In a given material, we expect that the variability for any edge is probably as large as for the edge for which the variability was greatest. The fact that the upper and lower points were occasionally recorded quite close to one another is considered fortuitious since only a limited number of cuts were made.

The edges used in the tests on synthetics were the same as in the skin cutting experiment. Thus, we should expect all of the edges to be duller (see section III.B) than in the previous investigation. This

- 25 -

means that, for all edges, forces required to completely penetrate the material will be greater than if the edges had retained their initial sharpness. Thus the force setting at which the material is used by an inspector will be greater, and a given edge would be more likely to completely penetrate the material. So, in this case, the dulling of edges is a conservative feature.

Recall that our interest is in finding a material which will make the discriminations of Figure 24b, i.e. the material would be cut through by only those edges above the discrimination point. For a single material to accomplish this goal, it must order our family of edges (from sharp to dull) in, generally, the same way that they were ordered by skin. This means that if we view the pairs of points (in Figures 27 to 29) as being a "function" of the edges, it would be desirable to have this "function" monotonically increasing. For all of the synthetic materials in Figures 27 to 29, the relative order of sharpness of the edges is quite different than for skin. E.g. on most materials, edge E is duller than edges G and H, while for skin the opposite is true. This difficulty, in using relatively uniform, synthetic materials to order our edges as skin did, is probably due to the complex structure of human skin.

Although none of the materials tested can make all of the discriminations of Figure 24b, some can make one or two. In Figures 27 to 29, a material is said to be capable of making a discrimination if the open circles, for all edges above the discrimination point, are no higher than the filled-in circles for all edges below the discrimination point. This is clearly illustrated in Figure 27 for the SM-2 material.

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At 5.5 lbs. (dashed line) only edges J and K do not completely penetrate the material. This is discrimination II of Figure 24b. Other materials capable of making this same discrimination are SM-5 and SM-8 (Figure 28) at 2.5 and 3.8 lbs., respectively. Many materials (SM-2, SM-3, SM-4, SM-5, SM-6, SM-7, SM-8, and SM-11) can make discrimination VI. Some materials come quite close to making other discriminations: except for edge B, both SM-4 and SM-8 can make discrimination V; also SM-1 and SM-7 are within one edge of making discrimination I. We point out these near misses because slight variations of these materials might be satisfactory, and this may be a starting point for future work.

One other property of these synthetic materials should be noted. Increasing or decreasing the thickness of a given material causes the "function" of the edges to shift up or down, while generally retaining the same shape ("relative maxima" and "relative minima" remain fixed). I.e. the order of the edges, for each material, remains fixed. This is readily seen for SN-2 and SM-3 in Figure 27 and for SM-9 and SM-10 in Figure 29. Also a change in thickness does not seem to affect a material's ability to make a given discrimination. Thus SM-3 can also make discriminations II and VI as did SM-2.

V. CONCLUDING REMARKS

A. Summary and Conclusions

Non-impact cutting tests were conducted on rigidly supported specimens of human skin <u>in vitro</u>. Various forces, velocities, and edge geometries were tested and the depths of the resulting cuts were measured. Also a variety of synthetic materials were evaluated for possible use in edge inspection procedures. Several of the more important points of this study are summarized in the following statements

- Although the loading mechanism used in the skin cutting experiment may not simulate a variety of real-life injury situations, it is believed that the results of the experiment may be applicable to many non-impact injury situations associated with casual play (see section II.B).
- Over a range of one to ten inches per second, relative velocity between the edge and skin did not appear to have any significant effect on the depth of the resulting cut (see section III.A).
- 3. Generally, edges having smaller edge angles and radii produce the deeper cuts. However, the experimental evidence indicates that the microscopic features of an edge may have a very significant effect on its ability to cut skin. Thus it appears that the sharpness of an edge cannot be defined quantitatively in terms of gross features such as edge angle and radius (see section III.A).

- 4. Empirical curves fitted to the data indicate that the effect of normal force on the depth of cut is similar for all edges. The depth of cut increases with force but the rate of increase appears to diminish exponentially. (see section III.A and appendix).
- 5. The wide variations in the experimental data are attributed primarily to natural differences in the skin specimens (see section III.B).
- 6. Based on the skin cutting data, useful methods for discriminating between hazardous and non-hazardous edges can be devised, using permissible level of injury (depth of cut) and force to define safety criteria (see section III.C).
- 7. Since edge sharpness cannot be defined adequately in terms of easily measured features, inspection procedures using synthetic materials as cut indicators were considered (see section IV.A).
- 8. Many synthetic materials were tested but none were found with the capability of making all of the desired edge discriminations. Some of the materials tested appear to be capable of making some of the discriminations with reasonable reliability (see section IV.C).

B. Recommendations for Future Study

In order to establish a safety regulation, which would protect children against dangerous edges associated with toys used under casual handling conditions, it is essential that a safety criterion (section I.C) be chosen. That is, a tolerable injury level (which, in this report, is measured by depth of cut), and a force level, representative of children's capabilities in play situations, must be determined. This latter specification may require studies to determine typical forces that children exert in casual play.

Once a safety criterion is chosen, the next phase would proceed in a similar manner to the present work. First, more skin cutting experiments would be conducted in relatively narrow ranges surrounding the force and injury levels of the safety criterion. Hopefully the experience gained in the present work would allow us to specify new edges with geometries that produce injuries in the correct range. These edges would be made to stricter tolerances so that "identical" edges could be obtained - thus the edge dulling problem discussed in section III.B would be minimized. Then our experience in cutting synthetic materials should expedite the development of a final inspection procedure.

Recall that the present work was concerned only with injuries suffered in the casual handling mode. A natural extension of this work would be to investigate more general loading mechanisms - specifically impact loading. An apparatus for conducting such studies has been built in the Consumer Product Systems Section, and some preliminary tests have already been made. It is expected that many edges, considered safe under a casual handling regulation, would be judged hazardous under impact conditions.

Because the impact loading mechanism is more general than the casual handling mode, it may be tempting to delay a "casual handling regulation" until impact studies are completed. However, in the

- 30 -

relatively long time it would take to conduct such an investigation, many potential injuries, suffered under casual handling conditions, could be prevented. Besides, one might not exercise the same degree of caution under casual handling conditions as he would when impact conditions are likely. In this sense, the casual handling mode may deserve special attention in formulating regulations.

Several other studies, which should logically follow or support the present work, could be suggested. First, this work has pointed out that insufficient information is available on the nature of the cutting mechanism. Thus some fundamental investigation of the basic cutting phenomena, using materials whose properties are well known, would be very useful. Secondly, there is a need to test the validity of using <u>in vitro</u> studies to approximate an <u>in vivo</u> situation, as regards cutting. <u>In vivo</u> testing of animals should prove to be a valuable tool in obtaining this information. Lastly, arrangements should be made to conduct future studies in conjunction with facilities having access to cadavers or large autopsy specimens. The availability of abundant skin samples would not only reduce the time of the experiment, but would also allow the collection of sufficient data for statistical analyses.

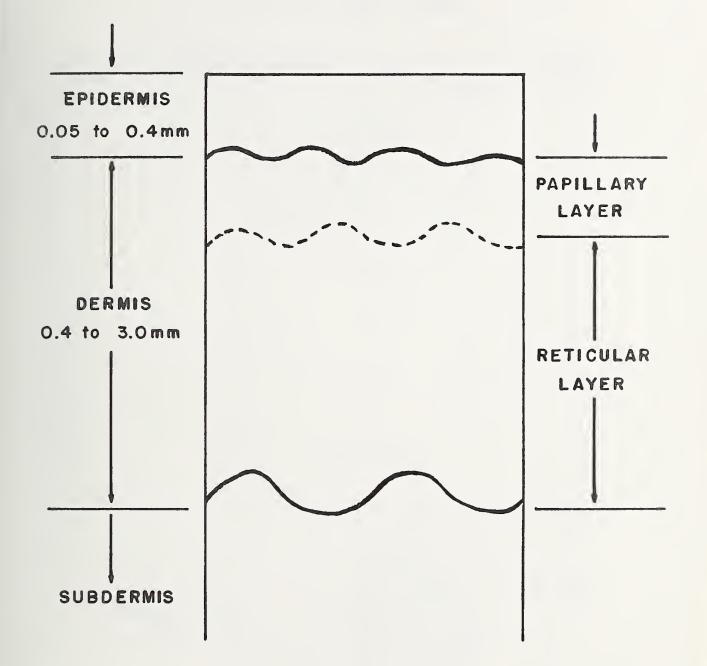
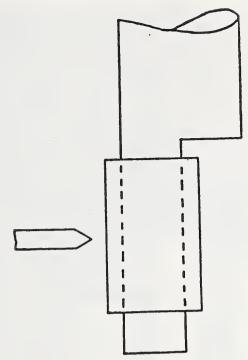


FIGURE I. SCHEMATIC CROSS SECTION OF HUMAN SKIN

FIGURE	2.	SKIN	SPECIMEN	DATA
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Specimen Number	Age	Sex	Average Thickness of Epidermis and Dermis	Test Delay
	(Years)		(mm)	(Days)
1	41	F	1.9	1
3	64	М	1.4	1
4	23	М	1.4	8
5	38	М	1.5	6
6	57	М	1.2	2
7	63	F	1.0	3
8	45	М	0.9	1
9	44	F	1.9	7
10	52	F	2.1	3
11	53	F	1.3	1
12	66	М	1.8	1
13	51	М	1.1	1
14	86	М	1.2	2
15	47	М	1.3	2
16	59	М	1.3	3
18	69	F	1.2	8
19	75	М	1.9	2
20	54	М	1.5	1
21	45	М	1.1	1
22	50	F	1.2	1
23	51	М	1.7	3
24	58	F	0.8	1
26	43	М	1.7	2
27	41	F	1.4	1
28	20	М	2.2	2
29	48	М	0.9	2
30	51	F	1.6	2
31		-	1.6	-
32	62	F	1.1	5
33	-	М	1.1	4







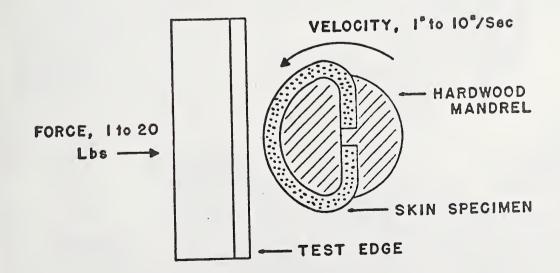
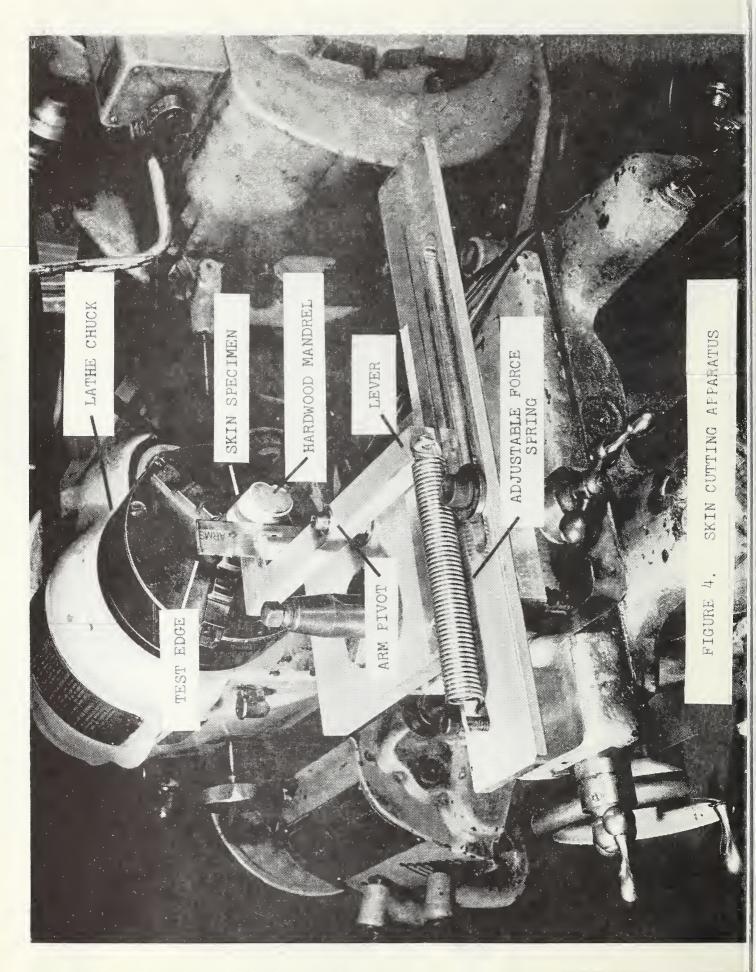
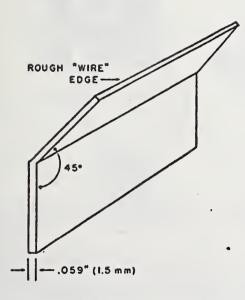


FIGURE 3. SCHEMATIC ILLUSTRATION OF SKIN CUTTING EXPERIMENT

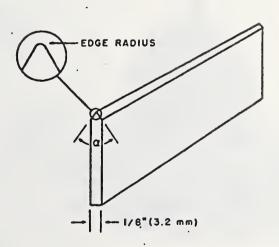


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EDGE	ANGLE (a)	RADIUS	TYPE
A	60*	.000"	GROUND
8	90*	.000	GROUND
C		-	SHEARED
D			SHEARED
ε	105 *	.000"	GROUND
F	90*	.000"	GROUND
G	15*	.002"(.05 mm)	GROUND
н	30*	.002"	GROUND
I	60*	.002"	GROUND
J	15 *	.004"(.10mm)	GROUND
к	90*	.002"	GROUND

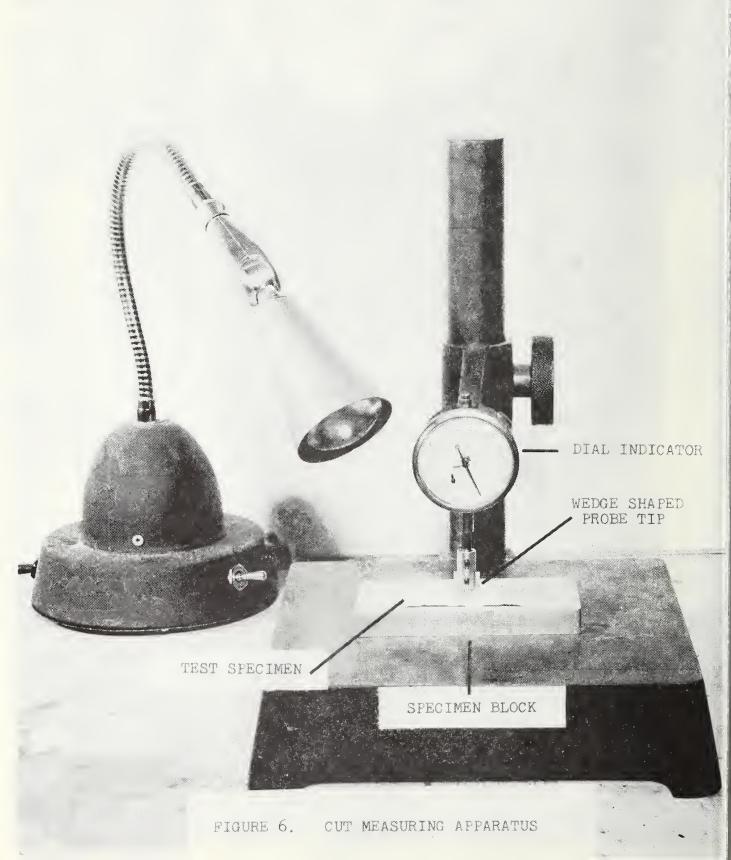


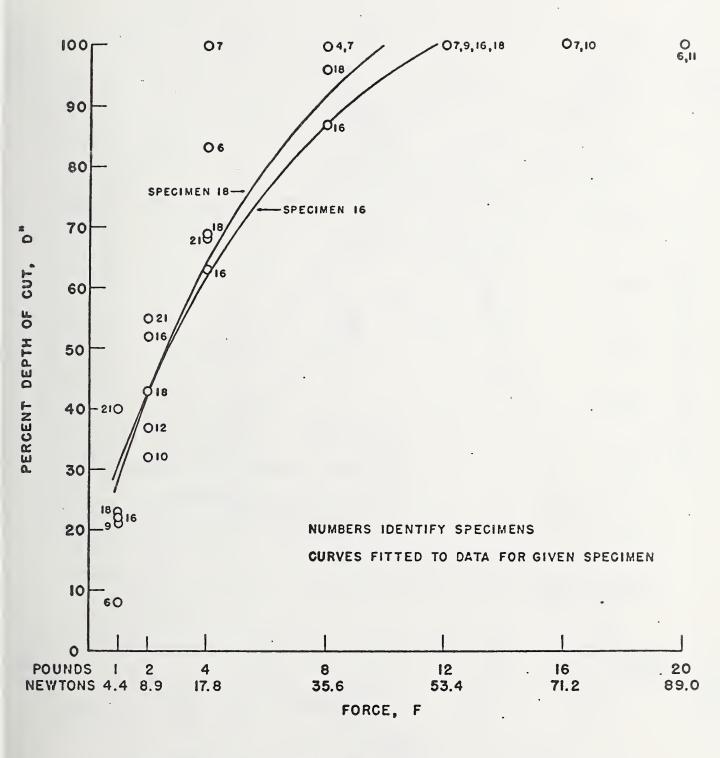
TYPICAL SHEARED EDGE

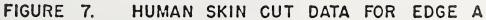


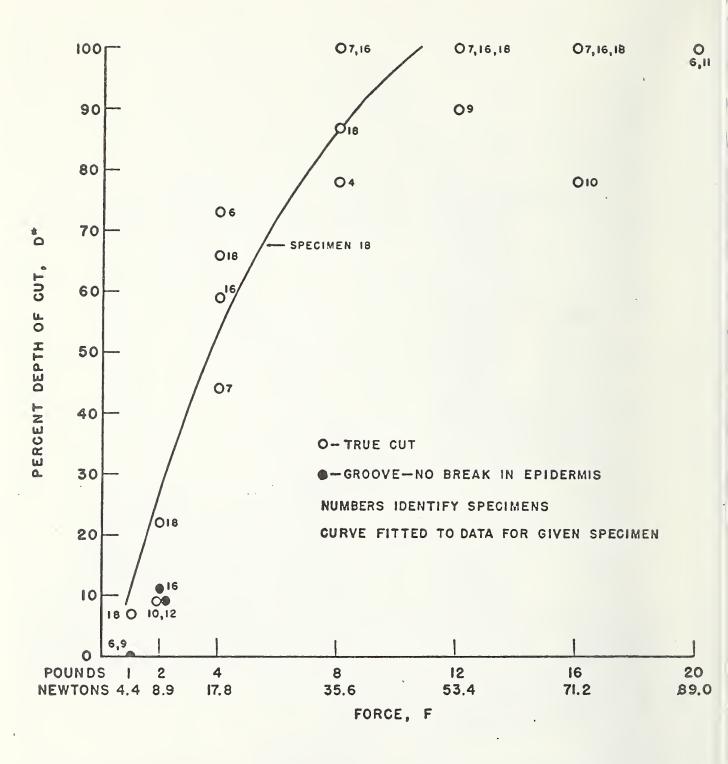
TYPICAL GROUND EDGE

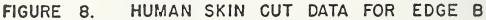
FIGURE 5. DESCRIPTION OF TEST EDGES

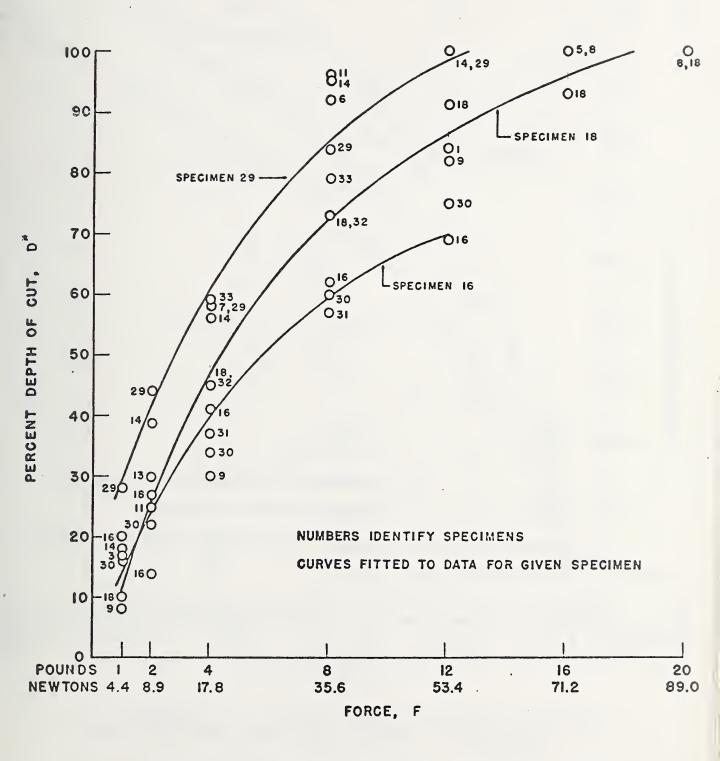






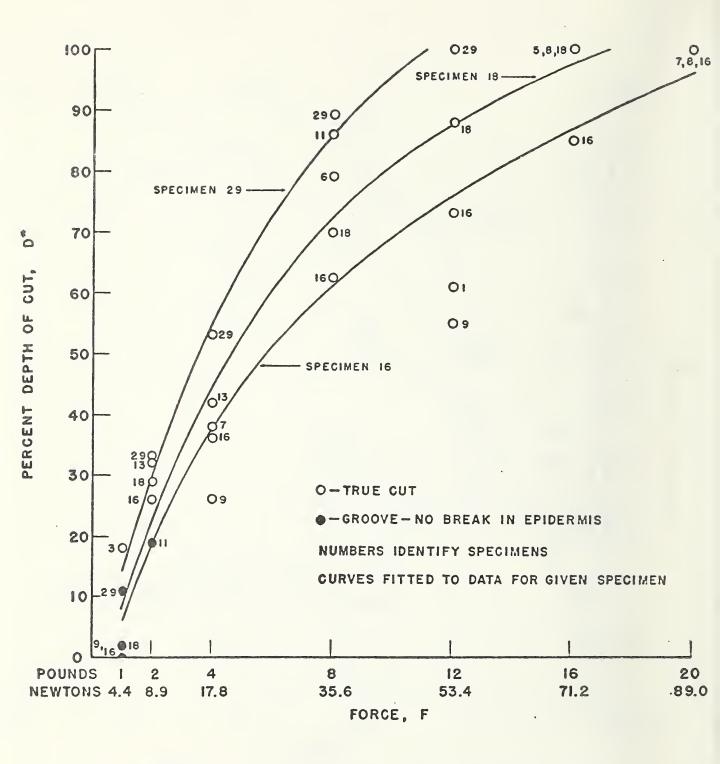


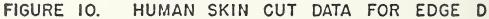




HUMAN SKIN CUT DATA FOR EDGE 9. С

FIGURE





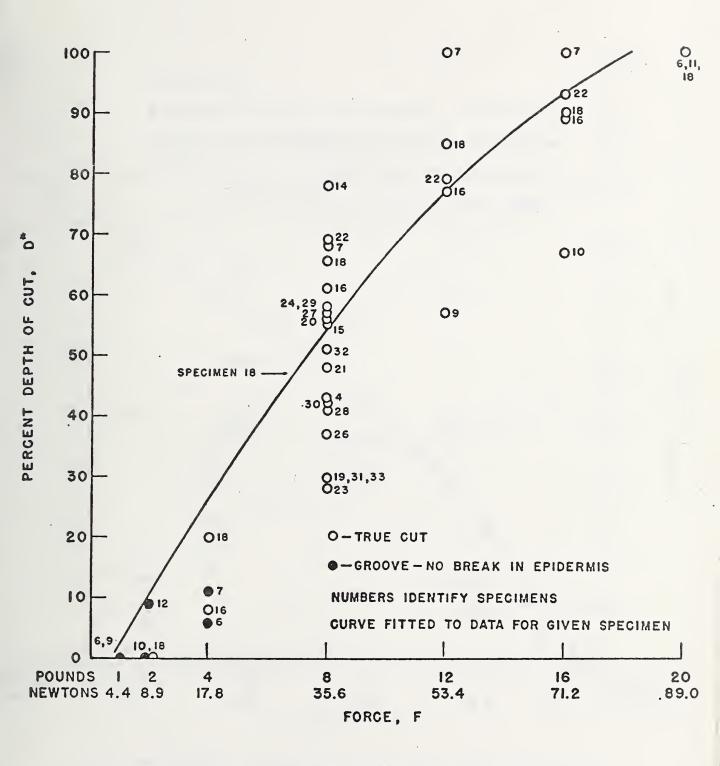
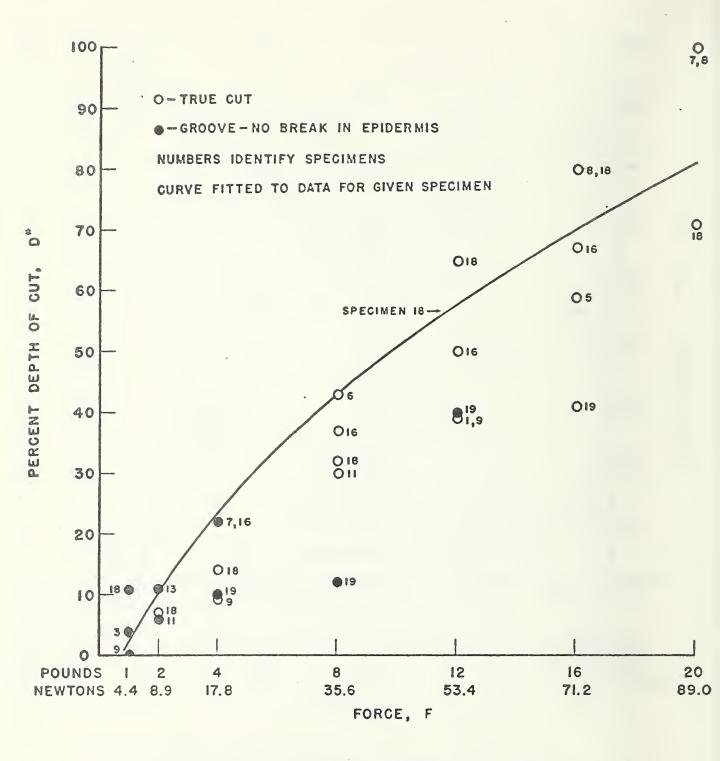
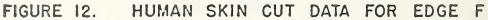


FIGURE II. HUMAN SKIN CUT DATA FOR EDGE E

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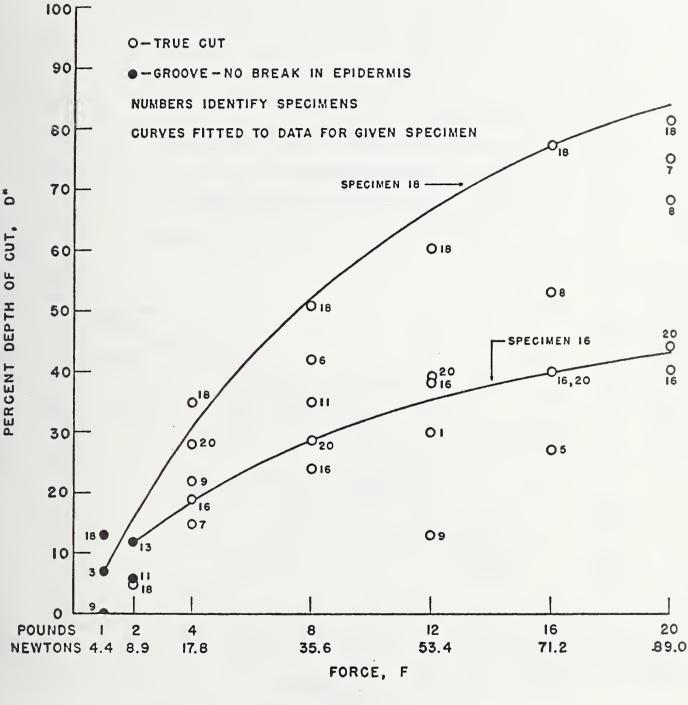


FIGURE 13. HUMAN SKIN CUT DATA FOR EDGE G

PERCENT DEPTH OF CUT.

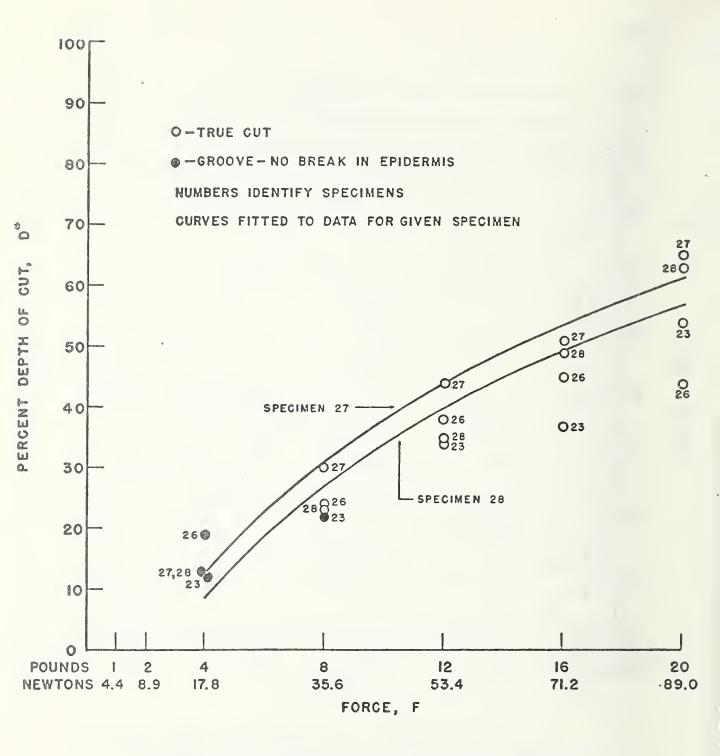


FIGURE 14. HUMAN SKIN CUT DATA FOR EDGE H

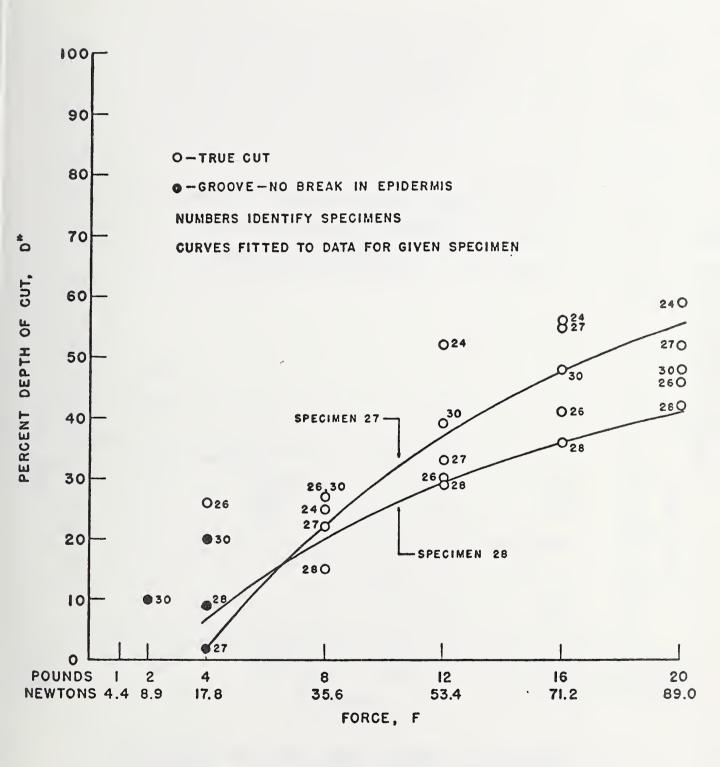


FIGURE 15. HUMAN SKIN CUT DATA FOR EDGE I

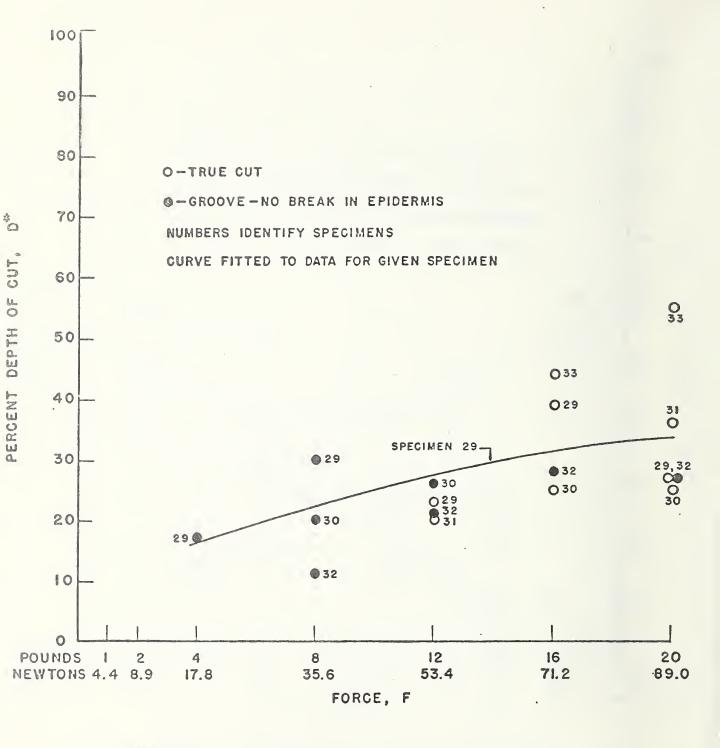


FIGURE 16. HUMAN SKIN CUT DATA FOR EDGE J

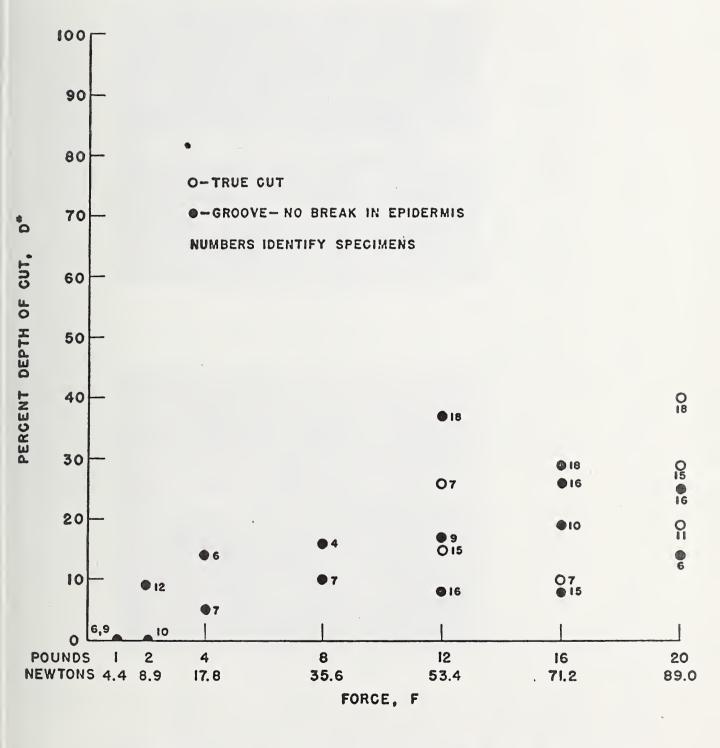
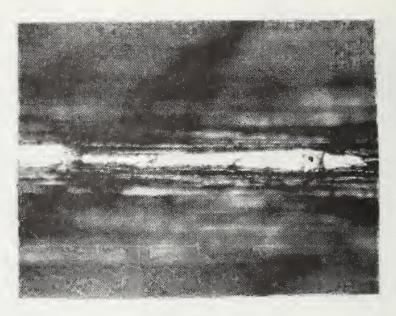
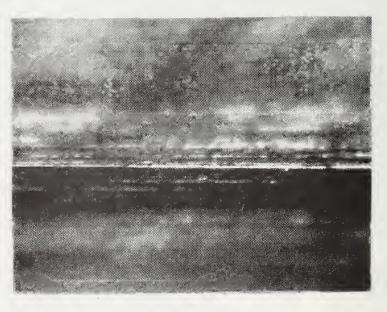


FIGURE 17. HUMAN SKIN CUT DATA FOR EDGE K

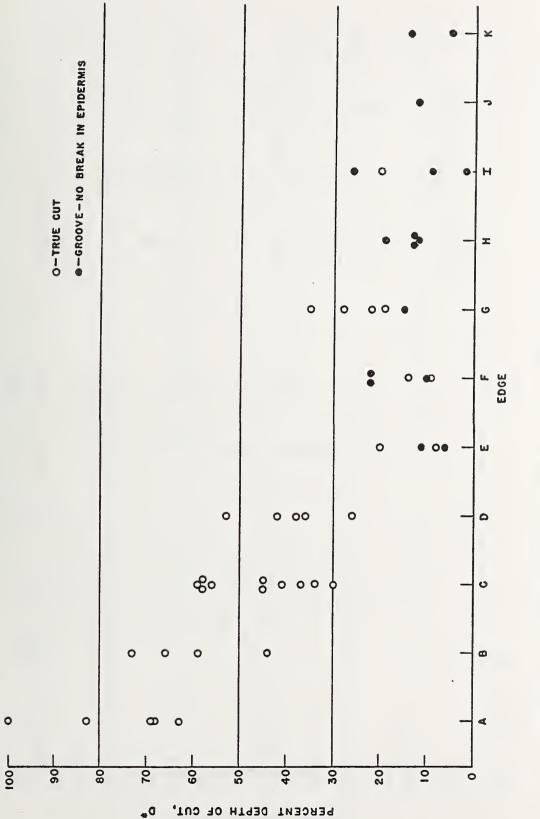


(a) TEST EDGE F

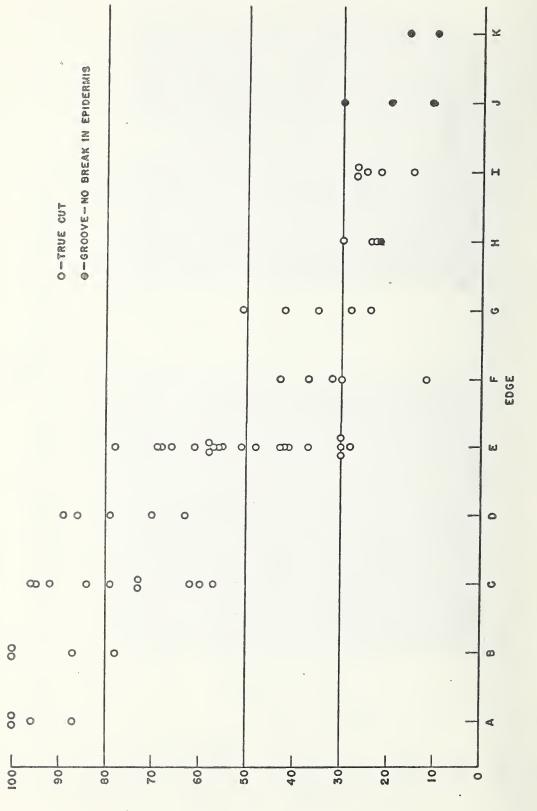


(b) TEST EDGE B

FIGURE 18. EDGE-ON PHOTOGRAPHS OF THE TWO 90°, NO RADIUS TEST EDGES AT 100x MAGNIFICATION. THE TIP OF EACH EDGE APPEARS AS A BRIGHT HORIZONTAL LINE IN THE CENTER OF THE PHOTOGRAPH.

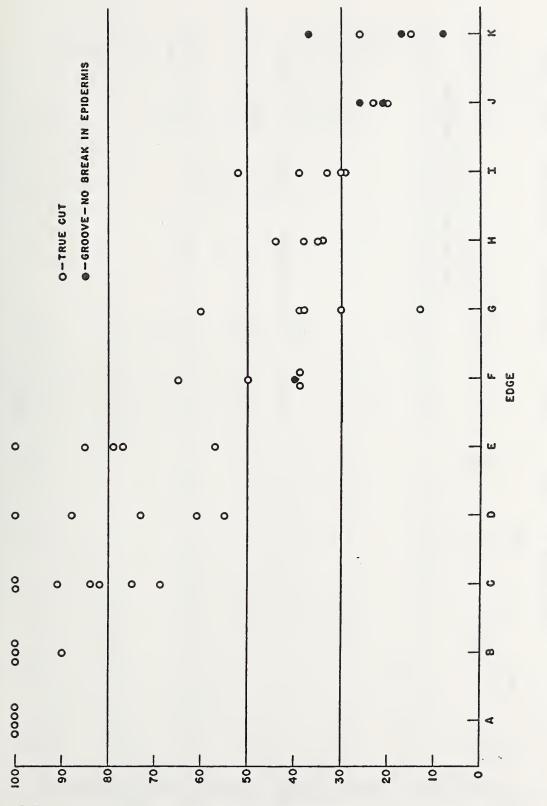


HUMAN SKIN CUT DATA FOR ALL TEST EDGES AT 4 POUNDS (17.8 NEWTONS) FIGURE 19.



HUMAN SKIN CUT DATA FOR ALL TEST EDGES AT 8 POUNDS (35.6 NEWTONS) FIGURE 20.

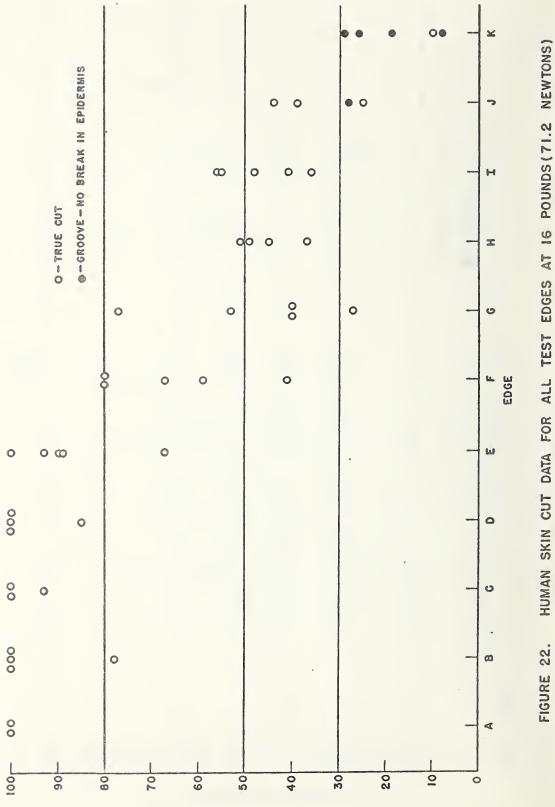
PERCENT DEPTH OF CUT, D.



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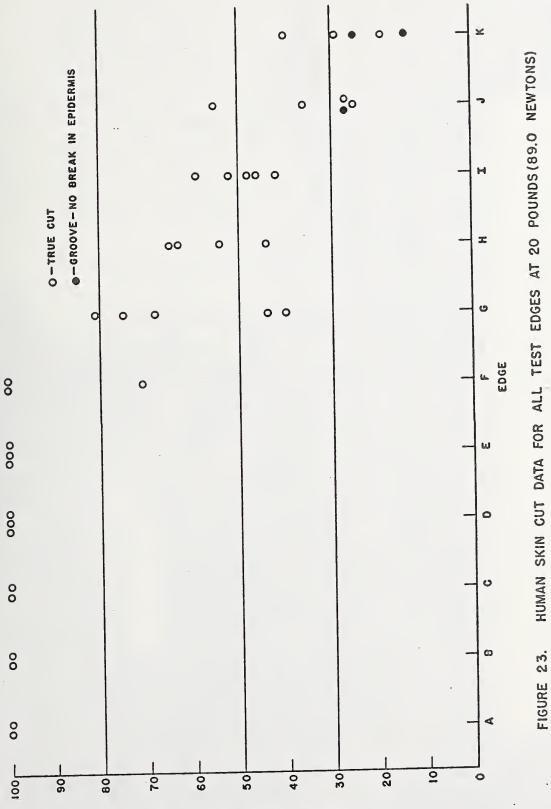
HUMAN SKIN CUT DATA FOR ALL TEST EDGES AT 12 POUNDS (53.4 NEWTONS) FIGURE 21.

РЕВСЕИТ DEPTH OF CUT, D*



PERCENT DEPTH OF CUT, "O

000



PERCENT DEPTH OF CUT, ۵.

F D*	4	8	12	16	20	
80%	VI	¥	TY	IV	III	
50%	V	IV	ш	ш	I	
30%	V	III	п	I	Т	
NO Blood	ш	ш				

(a)

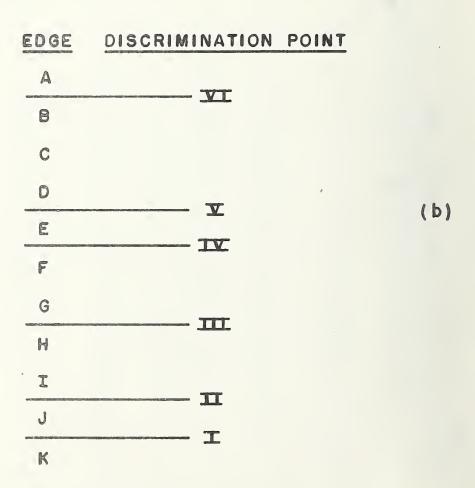


FIGURE 24. EDGE DISCRIMINATIONS FOR POSSIBLE SAFETY CRITERIA

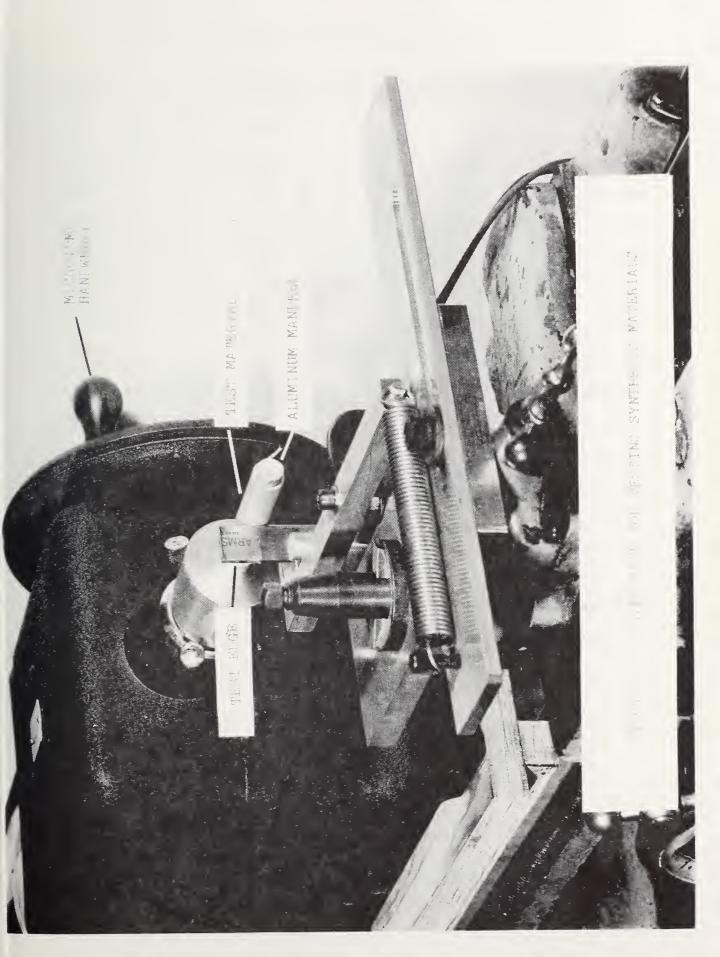


FIGURE 26. SOME REPRESENTATIVE SYNTHETIC MATERIALS TESTED

Material	General Description	Thickness
		(mm)
SM-1	Silicone gel "A" with 1% rayon fibers added	1.78
SM-2	Silicone gel "B"	2.16
SM-3	Silicone gel "B"	0.94
SM-4	Paper #1, coated with gel "A"	0.30
SM-5	4/1 mixture of gels "B" and "A"	0.81
SM-6	Plastisol film #1	1.17
SM-7	PVC foam* <u>1</u> /	6.35
SM-8	PVC foam *	1.57
SM-9	TFE sheet	0.36
SM-10	TFE sheet	0.25
SM-11	PVC sheet	0.56

*Commercially manufactured materials

1/ Single stroke test method

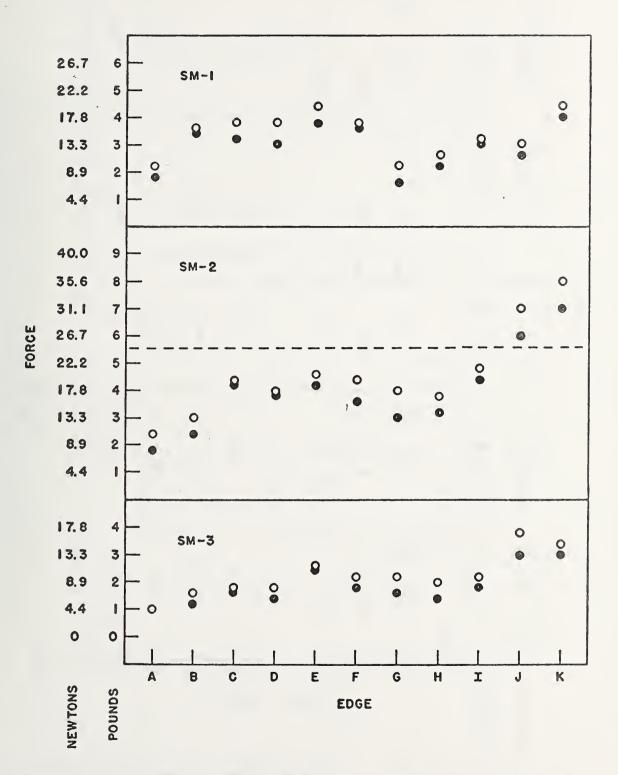


FIGURE 27. RESULTS OF CUTTING TESTS ON SOME SYNTHETICS. O-FORCE ABOVE WHICH MATERIAL WAS ALWAYS CUT THROUGH O-FORCE BELOW WHICH MATERIAL WAS NEVER CUT THROUGH

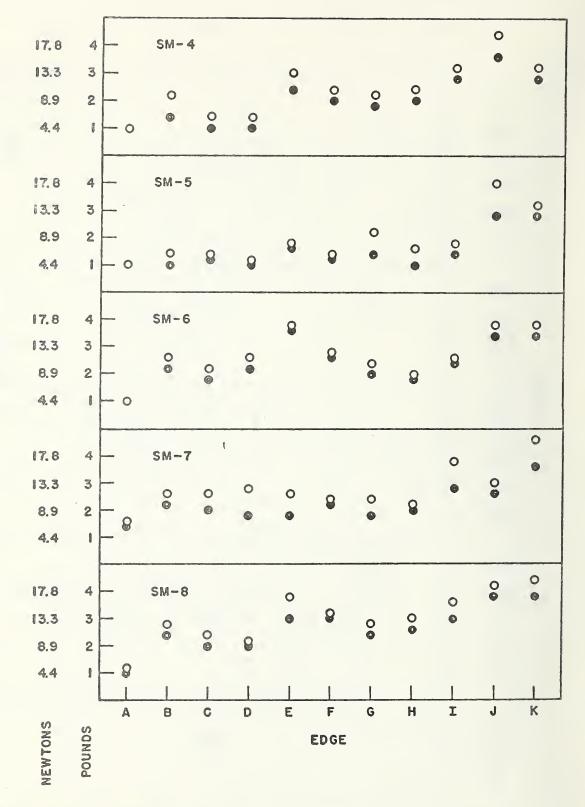


FIGURE 28. RESULTS OF CUTTING TESTS ON SOME SYNTHETICS. O-FORCE ABOVE WHICH MATERIAL WAS ALWAYS CUT THROUGH O-FORCE BELOW WHICH MATERIAL WAS NEVER CUT THROUGH

FORCE

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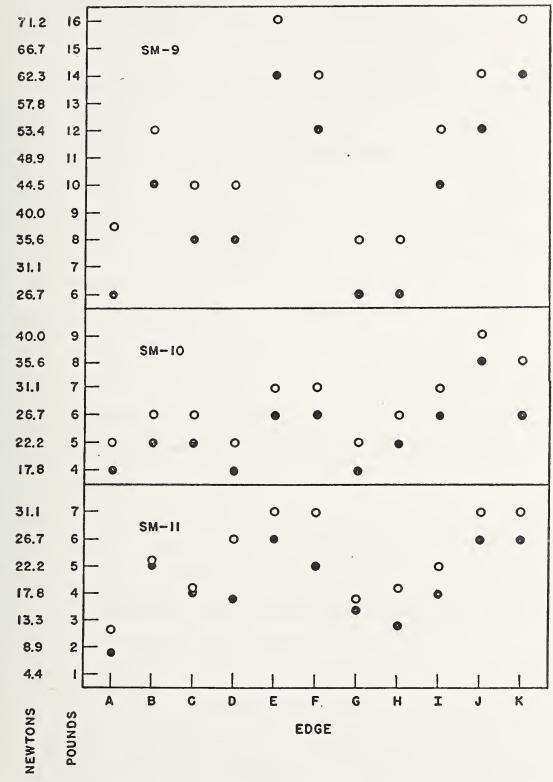


FIGURE 29. RESULTS OF CUTTING TESTS ON SOME SYNTHETICS. O-FORCE ABOVE WHICH MATERIAL WAS ALWAYS CUT THROUGH O-FORCE BELOW WHICH MATERIAL WAS NEVER CUT THROUGH

FORCE

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j.

Appendix. Fitting Empirical Curves to the Relationship Between Force and Percentage Depth of Cut

An empirical family of curves was fitted to the data, using the following procedure:

- 1. From the total data of percentage depth of cut at the various force levels, two tables were extracted: the first covering all cases in which data were obtained at the forces: 1, 2, 4, 8 and 12 pounds; the second covering all cases in which data were obtained at the forces 4, 8, 12, 16 and 20 pounds. These are referred to as Tables A and B (which follow at the end of this section). All of the following steps were carried out separately on Tables A and B.
- 2. The column-averages of each table, denoted by the symbol D*, were fitted against the force values, using an equation of the type 14/

$$\hat{\mathbf{D}}^* = \mathbf{K} - \mathbf{M} \mathbf{e}^{-\beta \mathbf{F}} \tag{1}$$

Where D^* represents the column-average, and F represents the corresponding force. It was noted that for both tables, the parameters K and M were practically identical. Hence the final equation fitted was

$$D^* = K(1 - e^{-\beta F})$$
 (2)

The values of K and β resulting from these fits were:

<u>Table</u>	- K	$\beta(1bs^{-1})$
A	101.6	.158
В	76.2	.080

Both fits were very good, as can be seen in Figure Al.

3. For each table, and for each edge/specimen combination, the D* values were then fitted, by means of straight lines, to the corresponding D* values, using the method of least squares. This yielded, for a given edge and specimen, an equation of the form:

$$D^* = \alpha + \delta D^*$$
(3)

4. Combining equations (2) and (3), we obtain

 $D^* = \alpha + \delta K(1 - e^{-\beta F})$ or: $D^* = \alpha + \gamma (1 - e^{-\beta F})$

Such an equation was obtained for each edge/specimen combination in Tables A and B. The values of α and γ are also given in these tables.

Discussion

The above procedure is, of course, purely empirical. Equation (2) is merely an intermediate step, allowing us to fit the exponential type curves with far better precision than if the fits had been carried out directly in terms of D* vs. F for each edge/specimen combination.

No claim of theoretical validity is made for the empirical fits, therefore no attempt should be made to draw conclusions from the numerical values of the parameters α , β , and γ . Nevertheless, the empirical fits can be considered as useful summarizations of the data and are believed to give reasonably accurate representations of the type of dependence of percentage depth of cut on force. TABLE A

Edge	Specimen	D*	Values 2	for the 1 4	Force (11 8	bs.) 12	Coeffic a	cients Y
A	18	23	43	69	96	100	12.0	111
А	16	22	52	63	87	100	15.5	100
В	18	7	22	6 6	87	100	-9.0	134
С	14	18	39	56	95	100	3.7	118
С	18	10	27	45	73	91	-5.1	111
С	16	20	14	41	62	69	2.3	79
С	30	16	22	34	60	75	0.3	84
С	29	28	44	58	84	100	14.8	99
D	16	0	26	36	63	73	-7.9	98
D	18	2	29	42	70	88	-9.0	113
D	29	11	33	53	89	100	-4.1	126
F	18	11	7	14	32	65	-8.9	71
G	18	13	5	35	51	60	-4.4	76
Averag	∧ .es, D*:	13.9	27.9	47.1	73.0	86.2		

Edge	Specimen	D* 4	Values 8	for the 1 12	Force (11 16	bs.) 20	Coeffic: a	ients γ
С	18	45	73	91	93	100	22.9	103
D	16	36	63	73	85	100	7.5	114
Е	18	20	66	85	90	100	-9.8	147
F	18	14	32	65	80	71	-20.0	129
G	16	19	24	38	40	40	6.6	47
G	20	28	28	39	40	44	-17.3	46
G	18	35	51	60	77	81	12.75	91
Н	23	12	22	34	37	54	-9.1	73
Н	27	13	30	44	51	65	-12.1	95
Н	28	13	23	35	49	63	-15.5	93
Н	26	19	24	38	45	44	3.1	56
I	27	2	22	33	55	52	-25.2	104
I.	28	9	15	29	36	42	-10.6	66
I	26	26	27	30	41	46	12.4	39
I	30	20	27	39	48	48	3.1	6 0
I	29	12	30	23	39	27	7.4	34
Avera	∧ ges, D*:	20.3	35.0	47.2	56.6	61.0		

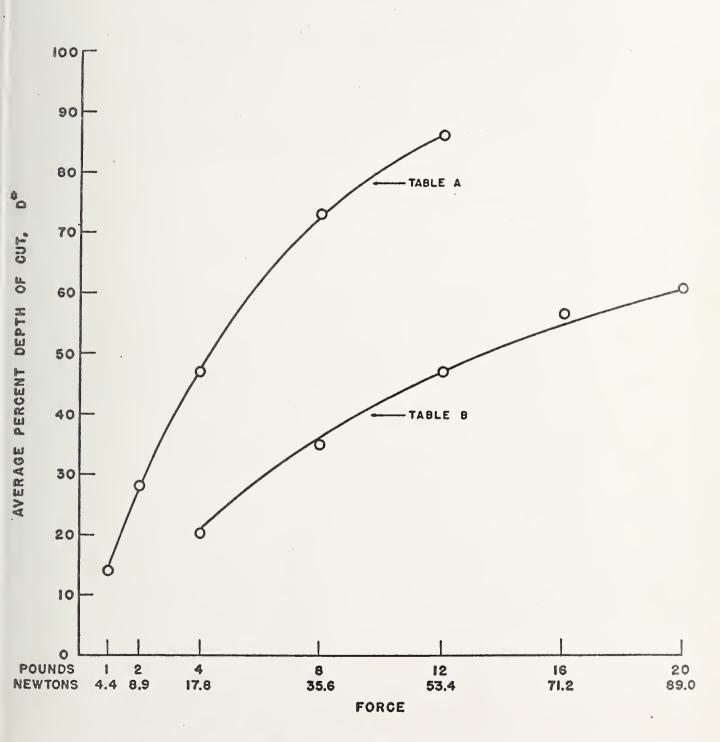


FIGURE AL. EMPIRICAL FITS OF AVERAGES (SYMBOL, O) IN TABLES A AND B

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Human skin specimens were cut in vitro with edges of				
over a normal force range of 0 to 89 newtons. Gene				
the smaller the included angle and tip radius of an resulting cut. For a given edge and skin specimen.				
to the data indicate that the depth of cut increase	-			
this rate of increase diminishes exponentially. Ba				
data, a convention was proposed for labelling the o				
Synthetic materials were sought which, when applied	-			
the test edges, would be completely penetrated by				
hazardous. Then such materials could be used in an unknown edges. Tests were conducted on many synthe				
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