DEVELOPMENT OF REFINED FITTING PROCEDURES FOR LOWER-EXTREMITY PROSTHESES

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INTRODUCTION

With the development of the patellar-tendon-bearing prosthesis by the University of California at Berkeley, many new advantages in simplicity, comfort, and function were available to the below-knee amputee. However, there still exists the problem of concentrated pressures over small areas of the stump. The original design of the patellar-tendon-bearing prosthesis was intended to distribute the load over areas of the stump which were considered to be pressure-tolerant areas. These areas are quite small in relation to the overall stump surface. The concentration of pressure on the patellar tendon, the medial flare of the tibia, the distal end of the stump, and the popliteal area has in many instances resulted in stump breakdown and patient discomfort.

Refinements in the technique of the patellar-tendon-bearing prosthesis in many parts of the country have eliminated many of the problems of concentrated pressure in small areas. The concept of suspending the below-knee stump in a socket by tightly fitting the anterior-posterior dimension of the stump into the socket has fallen into disfavor in most

* Based on work performed under VA Contract V101(134)P-7.
parts of this country. Most prosthetists today strive for a “glove fit” with equal pressure concentrated over the entire stump. With this type of fitting the patient is relatively comfortable for a certain period of time. However, no matter how seasoned the amputee’s stump may be, atrophy inevitably takes place.

As the stump volume decreases the stump has a tendency to sink deeper into the socket, creating undesirable pressures on pressure-sensitive areas rather than on pressure-tolerant areas. The prosthesis must then be adjusted by compensating for the volume changes to maintain the snug total-contact fit. The geriatric with the anesthetic stump, due to diabetes, may develop ulcers because he fails to maintain proper fit of the stump-socket relationship. In this case the time involved in healing an ulcer may require prolonged inactivity or wheelchair dependency. In many instances, the expense involved in both time to the prosthetist and money to the patient for maintaining proper prosthetic fit is an undesirable complication of the conventional patellar-tendon-bearing prosthesis.

The purpose of this research is to develop a prosthetic socket which would be able to accommodate decreasing stump dimensions (atrophy) without adversely affecting the function of the prosthesis. An attempt was also made to further define the parameters affecting the final goal of the research project. This was undertaken to provide operational limits and guidelines for the research effort.

The parameters are as follows:

1. Production
   a. The prosthesis must be economical to produce.
   b. Final fabrication of the prosthesis should be amenable to the skills and equipment found in an average prosthetic facility.
   c. The use of prefabricated components and/or the ease of prefabricating the system should be a constant consideration.

2. Function
   a. The prosthesis should not show any degradation in function through a loss of 10–20 percent of the stump mass.
   b. Ease of application of the prosthesis to a stump should exceed that of present designs (especially for geriatric patients).
   c. Skin-interface pressures should be distributed as uniformly as possible.

**METHOD AND MATERIALS**

Several initial design ideas were considered and rejected, either on the basis of not meeting the design parameters, probable unreliability, difficulty of control of pressures, or excessive prosthetic weight. The
indulgence in these mental exercises began to reveal the realities that would dictate the form of a prosthesis with the best chance for successful application.

It became clear that some form of encapsulation of the stump would be necessary. The capsule would have to be infinitely variable in circumference and might either be organic to the prosthesis or detachable. There was no doubt that there would be an increase in the overall weight of the prosthesis, but it was felt that if the excess weight could be distributed proximally and kept to a minimum, overall function would not be impaired.

The key to this approach depends on a suitable lining material or combination of materials for the stump capsule which would be capable of maintaining a near-uniform pressure distribution over the stump.

Silica gel materials were considered for this application but were rejected on the basis of cost and susceptibility of the necessary envelope to trauma.

This particular problem was finally discussed with Mr. Carl Mason of the VAPC Bioengineering Research Service in New York. Mr. Mason recommended a material which he thought might be promising. Coincidentally the manufacturer of this material was located in Hialeah, Florida. Subsequent personal contact with the vice-president for Research and Development of Royalty Designs, Inc., was most encouraging. One new material, which is not available to the prosthetist, has been utilized in this project as a vertical lining material. The material is a polyvinyl chloride (PVC) plastisol which is manufactured by a patented process developed by the company.

**PVC Plastisol**

PVC plastisol is available in high, low, or intermediate durometer values and may be specified in durometers of four to 50. Material of the lower durometer values approaches the pressure distribution value of the silica gel.

It may be layered or sandwiched much like a polyphasic material. It is therefore possible to have an outer surface much like PVC pipe with an inner surface having the consistency of jello. It may also be impregnated into cloths such as cotton duck or two-way stretch materials. The material may be joined by a vinyl glue supplied by the company or heat-welded at 300-330 deg. F.

Bacteriologic studies have revealed that the material has no nutrient value for fungi and does not support the growth of common human bacterial flora.

Conversations with the vice-president for Research and Development,

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b 601 W. 27th Street, Hialeah, Florida 33010.
Royalty Designs, Inc., revealed that he has seen one case of contact dermatitis within his plant. (This case occurred in the R & D Section within 3 days of continuous contact with a new experimental formulation. No other cases of contact dermatitis have been reported.)

In our experience to date no evidence of contact dermatitis has been observed among those members of our staff who have been in contact with the material on repeated occasions, nor has there been evidence of skin reaction in patients in the VA Hospital who have used wheelchair cushions made of PVC plastisol.

The PVC plastisol varies in specific gravity according to durometer. The softer samples have a slightly lower specific gravity than water and higher durometers are just slightly higher than water. For all practical purposes the density may be considered the same as water.

In its clear form (without coloring added) it may be used to chart low-pressure stress distribution (see Fig. 1) with the use of polarized light.

![Figure 1](image.png)

**Figure 1.** A clear PVC plastisol low-durometer sample showing stress lines with polarized light on the left. Load is 3 lb. Calculated stress is 15 p.s.i.

A compression-versus-strain curve for low stress values (see Fig. 2) was run for the material in our laboratory. The curve described in this graph is similar to the load-deformation curve of a Maxwell Body and is consistent with the probable macromolecular structure of the PVC plastisol.

The insulating qualities are one-tenth to one-fifth that of rigid urethane foam. The material has a high heat capacity which may make it suitable for hot or cold pack types of application.
Figure 2.—Compressive stress plotted against strain. Note the similarity of the curve to that of a Maxwell Body in reaction to load.

The tensile strength and other qualities are summarized in Table 1. Figures 3 and 4 show the samples tested and their relative compression to load.

**TABLE 1.—PVC Plastisol Material Properties**

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1.</td>
<td>Hardness—Shore “A” Durometer—too low to read on “A” scale</td>
</tr>
<tr>
<td>2.</td>
<td>Tear resistance—lb./in. thickness—.35</td>
</tr>
<tr>
<td>3.</td>
<td>Tensile strength—p.s.i.—14.7</td>
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<tr>
<td>4.</td>
<td>Elongation at Fracture—percent—300</td>
</tr>
<tr>
<td>5.</td>
<td>Water Absorption—pct. by wt.—0.1</td>
</tr>
<tr>
<td>6.</td>
<td>Compressive Strength p.s.i. to 50% comp.—2.3</td>
</tr>
<tr>
<td>7.</td>
<td>H₂O Vapor Transmission at .090 thickness 194.2 gm/sq. meter/24 hrs. (BTU in.)</td>
</tr>
<tr>
<td>8.</td>
<td>Insulative Properties—K Factor K, hr., °F.</td>
</tr>
<tr>
<td></td>
<td>@ mean temp.=75.5°F. .904</td>
</tr>
<tr>
<td></td>
<td>@ mean temp.=12.5°F. 1.01</td>
</tr>
<tr>
<td>9.</td>
<td>Resistance to Reagents (24-hour immersion)</td>
</tr>
<tr>
<td>a.</td>
<td>Sulphuric Acid 10%—not visibly affected</td>
</tr>
<tr>
<td>b.</td>
<td>Sulphuric Acid Normal Sol.—severe discoloration and stiffening</td>
</tr>
<tr>
<td>c.</td>
<td>Ammonium hydroxide—Normal Sol. not visibly affected</td>
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All material has been supplied to our laboratory free of charge by the company on the premise that they be kept informed of the usage of their product. They have assured us, however, that the cost of their material would retail at one-eighth to one-tenth the cost of silica gel materials in small quantities.
Work has progressed simultaneously in the Medical Engineering Laboratory and the Prosthetics Laboratory on the promising concept of a soft encapsulation. This approach revolves about the use of a bias-weave tube of material. The rationale for using this material stems from the operation of a "Chinese finger trap" but in reverse. The action
of the bias weave is to decrease the diameter of the tube as a load is applied to the blind end. This reaction serves to compress the entire vertical wall of the stump. Thus, vertical load is translated into a hoop stress which should act almost uniformly over the circumference of the stump surface. For this purpose Taslon fiber in tube form was used.

The Laboratory Model

A model socket was built incorporating the prime features of the concept under consideration. The purpose of this model was to gather empirical data pertaining to the materials and the function of the general system.

The model was simply constructed using a 6-in. o.d. acrylic tubing with a length of 6-in. dia. Taslon clamped to the upper end (see Fig. 5 and 6). The Taslon tube had been gathered and tied at the unclamped end. Different inserts were then put into the Taslon in order to test the reactions of the system under load conditions. The inserts varied from regular-shaped cylinders to male plaster casts of an amputee's stump. Loading was produced in the low ranges (0–30 lb.) by a spring gage and in the higher ranges (100–160 lb.) by a hydraulic bench press.
of the tube as a load is applied to compress the entire tube is translated into a hoop pressure test: the circumference of the 6-in. o.d. acrylic tubing at the upper end (see Fig. and tied at the unclamped Taslon in order to test the inserts varied from 6 of an amputee's stump. lb.) by a spring gage and a 6-in. PVC plastisol vertical liner dic cylinder, clamp, and ½-in.-

The prime features of the this model was to gather and the function of the

\[ Z_0 = R_\theta \tan \phi_0 \ldots \ldots (3) \]

**Mathematical Analysis of Taslon Stretch**

The Taslon fiber weave, illustrated in Figure 7, produces a situation in which lengthwise stretch is accompanied by a decrease in radius. This analysis will show the mathematical relationship between these two parameters. A schematic of one Taslon fiber is illustrated in Figure 8.

Figure 9, shows an infinitesimal section of this fiber. Thus,

\[ \frac{dZ}{R_\theta \, d\theta} = \tan \phi_0 \ldots \ldots (1) \]

and

\[ \frac{dZ}{dx} = \sin \phi_0 \ldots \ldots (2) \]

The initial length of the sock is \( Z_0 \), the initial radius is \( R_\theta \), and the initial fiber length is \( x_0 \). So, integrating equation (1),

\[
\int_0^{\Theta_0} \frac{dZ}{R_\theta \tan \phi_0} = \int_0^{\Theta_0} \frac{dO}{O} \\
Z_0 = R_\theta \Theta_0 \tan \phi_0 \ldots \ldots (3)
\]
and integrating equation (2),

\[ Z_0 = \int_{0}^{x_o} \sin \phi \, dx \]

Now, as illustrated in Figure 8, if a force is applied in the +Z direction, the sock will lengthen to \( Z_t \), the radius will decrease to \( R_t \), and \( \phi_t \) will increase to \( \phi_t \). The fiber length, \( x_o \), may increase slightly but this increase is much less than \( Z_t - Z_o \). Thus, we may assume that the fibers are
nonelastic. Also, the top of the sock is anchored and the force is applied such that $\Theta_o$ will remain constant. From Figure 9,

\[ \frac{dZ}{R_c d\Theta} = \tan \phi_r \ldots \ldots (5) \]

and

\[ \frac{dZ}{dx} = \sin \phi_r \ldots \ldots (6) \]

integrating (5),

\[ \int_{0}^{Z} dZ = \int_{0}^{\Theta_o} R_t \tan \phi_r d\Theta \]

\[ Z_r = R_t \Theta_o \tan \phi_r \ldots \ldots (7) \]

and integrating (6),

\[ \int_{0}^{Z} dZ = \int_{0}^{x_o} \sin \phi_r dx \]

\[ Z_t = x_o \sin \phi_r \ldots \ldots (8) \]

Now, dividing equation (8) by equation (4),

\[ \frac{Z_t}{Z_o} = \frac{\sin \phi_r}{\sin \phi_o} \ldots \ldots (9) \]

and dividing equation (7) by equation (3)

\[ \frac{Z_t}{Z_o} = \frac{R_t}{R_o} \frac{\tan \phi_r}{\tan \phi_o} \ldots \ldots (10) \]
combining equations (9) and (10)

\[
\frac{\sin \phi_r}{\sin \phi_o} = \frac{R_r \tan \phi_r}{R_o \tan \phi_o}
\]

\[
\frac{\cos \phi_r}{\cos \phi_o} = \frac{R_r}{R_o} \ldots \ldots \ldots \ldots (11)
\]

Equations (9), (10), and (11) give the theoretical solution to the problem of stretch.

**EXPERIMENTAL RESULTS**

In an experimental setup, a small metallic cylinder with both ends sealed was wrapped in two layers of 3/16-in.-thick PVC plastisol and was inserted into a Taslon sock anchored to the top of a 6-in.-o.d. Plexiglas tube. The initial parameters were:

- Initial diameter \((D_0) = 4 \frac{3}{16}''\)
- Initial length \((Z_o) = 7\frac{1}{2}''\)
- Initial gel width (2 layers) = \(\frac{3}{8}''\)
- Can diameter = \(3-7/16''\)
- Can height = \(3-13/16''\)
- \(\phi_o = 52^\circ\)
A green circular piece of 1/2-in.-thick PVC plastisol was placed on the bottom of the can. Pressure studies were conducted using three Sensotec transducers, model #M-7BW (0–30 lb. p.s.i.) imbedded in the PVC plastisol: one transducer was placed in the middle of the end-bearing PVC plastisol, and the other two transducers were positioned opposite one another in the middle of the PVC plastisol lining on the vertical wall of the cylinder (Fig. 10 and 11).

The load was increased in 20 lb. increments to 160 lb. total and the results were plotted. The measured pressure readings are contained in Figure 12 and graphed in Figure 13. Other measured parameters at 160 lb. were:

Final diameter \((D_f) = 3\frac{3}{8}''\)

Final length \((Z_f) = 8''\)

Using the equations developed in the mathematical analysis of Taslon stretch and the experimental parameters, the accuracy of the theory can be checked.
Using:

\[
\begin{align*}
R_0 &= \frac{D_0}{2} = 2.09'' \\
R_\ell &= \frac{D_\ell}{2} = 1.93'' \\
\phi_0 &= 52^\circ \\
Z_0 &= 7.5'' \\
Z_\ell &= 8.0''
\end{align*}
\]

Using equation (11):

\[
\cos \phi_\ell = \frac{\cos \phi_0 R_\ell}{R_\ell} = \frac{\cos (52^\circ) 1.93''}{2.09''} = 0.57
\]

\[
\phi_\ell = 55.5^\circ
\]

Using equation (9):

\[
Z_\ell = Z_0 \sin \phi_\ell = \frac{7.5'' \sin (55.5^\circ)}{\sin (52^\circ)} = 7.85''
\]

**Figure 12.**—Pressure readouts from experimental model (see also Fig. 11 for schematic of model).
Sarmiento et al.: Refined Fitting Procedures

**Figure 13.**—Lab model results. Load plotted against cylinder wall pressures. Curves A and B are side-wall pressures. Curve C is bottom pressure.

This is a 1.88 percent error over the experimentally determined $Z_t$ of 8.0 in. This is a very small percentage but it must be remembered that it represents the cumulative effect of all errors. There were three probable sources of error. In point, $\phi$ varied over the length of the sock since the Plexiglas tube had a $5\frac{1}{2}$-in. i.d. and the can plus PVC plastisol had an initial diameter of $4\frac{3}{16}$ in. The final diameter around the can varied slightly due to a bunching of the PVC plastisol material near the bottom of the can. Also, the mathematical model does not account for any stretching of the base of the Taslon sock.

Now, the experimental analysis may be carried one step further and curve. With a 160-lb. load, $D_0 - D_f = 5/16$ in. This decrease is due to combined with the pressure readings and the PVC plastisol stress-strain compression of the PVC plastisol rather than compression of the cylinder. Since the initial PVC plastisol thickness was $\frac{3}{8}$ in., its strain was 0.42. From Figure 2, this corresponds to a normal stress on the cylinder of 2.8 p.s.i. From Figure 12, the measured pressures at 160-lb. loads were 2.25 p.s.i. and 4.0 p.s.i. This variance was probably due to the location of the transducers, the one being near the base of the cylinder, where the PVC plastisol experienced less strain, reading less pressure. For the purposes of analysis an average experimental normal stress of 3.1 p.s.i. will be used. The pressure reading on the base of the cylinder was 5 p.s.i. The base area was 9.3 sq. in. This means that 46.5 lb. of the 160 lb. was taken on the bottom. The other 113.5 lb. were distributed as a shearing stress over the sides of the cylinder. The surface area of the
sides was 41.4 sq. in. which means that the average shearing stress was 2.74 p.s.i. Thus, it may be concluded that \( \frac{3}{4} \) of the weight is distributed as shearing stresses and \( \frac{1}{4} \) is taken on the end of the cylinder. From this information, it can be seen that as the total load increases a greater proportion is taken by the vertical walls and that at maximum load the ratio is almost 3 to 1 for side-wall to end-bearing load. Undoubtedly the side-wall pressure is related to the compression caused by the decreasing diameter of the Taslon. Proportional to this force there is also an increase in the frictional force at the interface of the insert in the capsule which increases the resistance to shearing forces at the sidewall. This combination of inter-related forces acting in concert accounts for the favorable distribution of pressure seen with increasing loads.

In relating these pressure results to human stumps fitted in the prosthesis, it was theorized that the greater surface area of the stump will further reduce the pressures involved.

**Prototype Fittings**

To date two patients have been fitted with prototype below-knee prostheses. The first patient, P.T., had been wearing a PTS-type hard-socket patellar-tendon-bearing prosthesis with a soft distal end-pad. This patient was transferred to the prototype prosthesis consisting of a plastic container fabricated over a positive mold which had been built up \( \frac{1}{4} \) in. in height and an additional \( \frac{1}{2} \) in. in diameter. Tubular 3-in.-nylon stockinet four layers thick was glued to the inner proximal periphery of the socket. The distal portion of the stockinet was tied on. Windows were cut into the socket on the medial and lateral aspects so that the displacement of the stump and the stockinet inside the socket could be observed. The patient ambulated with this prosthesis for a number of hours without noticeable discomfort.

Due to the inability of the nylon material to retain its length, eventual bottoming of the stump in the socket was evident. At this point the patient was transferred to his second prototype prosthesis (see Fig. 14) consisting of a laminated plastic container. However, in this instance Taslon material was used in place of the nylon stockinet. The patient experienced no discomfort whatsoever in the prosthesis but did experience some medial-lateral instability due to the fact that the Taslon was not fastened distally to the socket. The prosthesis was removed and the distal portion of the Taslon was cemented to the distal portion of the socket. The patient returned and the prosthesis was fitted as modified. X-rays were taken of the patient in full weight-bearing in the prosthesis, showing good alignment of the tibia in relation to the femur in both the medial-lateral and anterior-posterior planes.

A second patient, O.G., was fitted with a prototype prosthesis (see
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a prototype prosthesis (see

Fig. 15), which was similar in construction to the first prototype but with different areas of the plastic socket windowed. A soft PVC plastisol material was used to act as a buffer between the Taslon and the inner socket surface. The material was placed in areas where high-pressure concentration normally would be anticipated, namely the anterior-distal end of the tibia and the lateral-distal aspect of the fibula. The second patient ambulated in his prototype prosthesis for a total of 6 hours without discomfort or evidence of pressure concentration.

We are presently in the process of fitting six more prototype prostheses in an attempt to evaluate the feasibility of using the Taslon material and to evaluate the overall technique. Prototype experience in fitting these two amputees has shown that the concept is advantageous and promising.

DISCUSSION

There are, indeed, several problems to be resolved prior to the advent of full clinical trials. These center about the areas of mechanical stabilization, wearability of materials, and fabrication. However, it is felt that these problems are amenable to rapid solutions through the use of a continued laboratory investigation and a patient prototype program.

It is anticipated that normal progress will lead to the resolution of the present problems by the end of the third quarter of fiscal 1971-72. At that time the project will be moved into its full-scale clinical testing phase. Simultaneously, the engineering effort will be directed toward de-
developing “off-the-shelf” components and economical, rapid methods of fabrication.

Work is now under way to solve the following present and anticipated problems:

Pressure Studies

Due to the extreme difference in calculated stress and that “seen” by the Sensotec transducers under various environmental conditions and the unreliability of calibration under certain of these conditions, a new type of transducer is being sought. International Technical Industries of Santa Cruz, California, produces magnetostrictive devices and their devices are now being considered for encapsulation and use in this segment of the program. Failure of this approach may dictate the need for a straight hydraulic system for the measurement of real pressures at the skin-prosthesis interface.

The NASA Bioapplications team at the Research Triangle Institute in North Carolina has also been contacted in relation to this problem for the purposes of technical advice and the possibility of applying existing aerospace hardware.

Load cells have been ordered for application to the pylon of a prototype prosthesis so that loading curves can be correlated with the pressure studies.
Materials

The Taslon nylon tubing frays with handling and its large threads present a rather rough surface to human skin. Availability also seems to be limited to 2-in. increments in diameter.

The Knit-Rite Company has been contacted concerning these problems and has agreed to supply us with a bias-weave material, to our specifications, on an experimental basis.

The PVC plastisol has an apparent role as an end-bearing material. Stress analysis using this material may lead to counter-relieving of the end pad in an effort to further off-load the stump end. Consideration is also being given to this material for pressure distribution at the tibial crest and fibular head areas either as a separate material or impregnated into the bias-weave material.

Fabrication Techniques

A low-cost plastic forming machine has been ordered to allow us to explore several time-saving techniques involving the socket fabrication. It is hoped that a general socket design will be evolved which would be amenable to a production approach. Clear Plexiglas sockets will also be made for the purpose of visual observation of the stump-socket relationships and possibly stress analysis.

CONCLUSION

The mechanical concept presented in this report appears to represent a sound and promising approach to the problem of a total-contact, adjustable socket for prosthetics. We have been favorably impressed by the properties of the materials experimented with, and we are certain that there may be other useful applications for them.

This project has now entered the prototype stage, and we believe that this is the approach which will bear fruit in the shortest length of time. All prototype changes will be made in the quest for specific answers and will be guided by sound engineering logic. Patients who have been fitted with this type of socket have claimed that it is extremely comfortable and have been able to ambulate in the initial prototypes without undue difficulty. Stability has been proclaimed as a problem in these early tests. Several possible approaches to this problem are now being investigated and we believe a solution is imminent.

We sincerely believe that the forthcoming answers evolving from this research will be of great benefit to the prosthetics field and its patients.