EVALUATION OF SYNTHETIC BALATA FOR FABRICATING SOCKETS FOR BELOW-KNEE AMPUTATION STUMPS

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REPORT E-3
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EVALUATION OF SYNTHETIC BALATA FOR FABRICATING
SOCKETS FOR BELOW-KNEE AMPUTATION STUMPS

prepared by
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DIVISION OF ENGINEERING—NATIONAL RESEARCH COUNCIL

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REPORT E-3

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Evaluation of synthetic balata for fabricating sockets for ...
EVALUATION OF SYNTHETIC BALATA FOR FABRICATING SOCKETS FOR BELOW-KNEE AMPUTATION STUMPS

At the present time, most sockets for artificial limbs are made of a plastic laminate (usually polyester resin and Dacron) which has been molded over a modified replica of the stump. A replica of the stump is required because human tissues cannot withstand the temperatures generated by the exothermic reaction of the plastic as it cures. The replica is modified, using general rules established by research groups, in order to achieve a relationship between the stump and socket that is physiologically satisfactory, yet permits weight-bearing and provides stability. In addition, reliefs must be provided to accommodate bony prominences and any tender spots. A simple plaster-of-paris wrap will usually be too loose for normal use. Therefore, fabrication of plastic laminate sockets with presently available materials involves at least the following steps (Fig. 1): (a) development of a female mold of the stump by wrapping the stump with plaster-of-paris bandages, (b) casting a male model of the stump by filling the female mold with plaster of paris, (c) modification of the male model by trimming away plaster in selected areas and building it up in other areas when necessary, and (d) lay-up and cure of the plastic laminate. The average time required to make a hard socket below-knee plastic prosthesis is eight man-hours.

It has been the goal of a number of research workers to find a simpler and less time-consuming method for fabricating satisfactory sockets for all levels of amputation. After many experiments involving a number of casting methods and a variety of materials, the Veterans Administration Prosthetics Center\(^1\) by 1961 had developed a technique for molding a socket of synthetic balata directly over a below-knee stump. The first successful results were achieved by using an air-pressure sleeve over a tube of synthetic balata,\(^2\) which had been softened by immersion in hot water (160 deg. F.) and then pulled over the stump (1, 2) (Fig. 2).

Upon the recommendations of the CPRD Subcommittee on Design and Development, the Subcommittee on Evaluation undertook responsibility for the evaluation of the new technique.

\(\text{\textsuperscript{1}}\) 252 Seventh Ave., New York, N.Y. 10001.

\(\text{\textsuperscript{2}}\) From Polysar X-414 resin produced by the Polymer Corporation Limited, Sarnia, Ontario, Canada.
Fig. 1. Steps in the fabrication of a plastic prosthesis for a below-knee amputation.
Fig. 2. The air-pressure method of forming synthetic balata sockets for PTB protheses.
The claims of the development laboratory were: (a) a substantial decrease in elapsed time between measurement of the stump and production of a wearable limb, thereby speeding the rehabilitation process, (b) a substantial reduction in man-hours involved, (c) a capability for easy adjustment of the prosthesis at any time, and (d) a decrease in the amount of skill and training required to produce an adequate socket.

PROCEDURE

A protocol (Appendix A) was developed and five clinics\(^3\) were asked to participate in the evaluation. The prosthetists from the clinics were trained as a group at the Veterans Administration Prosthetics Center on November 6-8, 1968. Each clinic was requested to fit five new amputees and five amputees who had worn PTB prostheses before, and provided with sufficient material and equipment to carry out the fittings.

RESULTS

Follow-up in the spring of 1969 revealed that all the prosthetists were encountering difficulty in obtaining adequate fits in nearly all cases except those with long tapered stumps, most of the sockets being too loose proximally. To overcome this problem, the VAPC devised a method whereby the air bag was eliminated, and molding pressure was brought about by wrapping the softened balata tube with one-inch-wide elastic webbing and controlling the shape of the socket with the hands and fingers as it cooled.

All of the participating prosthetists were instructed in the revised method, and other prosthetists were instructed in the new procedure at the same time. Shortly afterwards, plastic pressure-sensitive tape was substituted for the elastic webbing (Fig. 3) *(3).*

The results with the revised procedure were considerably better. The average synthetic balata prosthesis, with pylon but without cosmetic treatment, weighed 3\(\frac{1}{2}\) lb., and could be made in 2\(\frac{1}{2}\) hr. All of the claims of the developer were substantiated with the exception of the relative amount of skill required, a factor that would be very difficult to measure

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\(^3\)Rancho Los Amigos Hospital, Duke University, the University of Miami, the Veterans Administration Hospital/Los Angeles, and the Veterans Administration Hospital/Buffalo.
Fig. 3. The tape-wrap method of forming synthetic balata sockets.
at this stage of development. At any rate, it is safe to say that no more skill is required for the new technique than for older methods.

All prosthetists who used the technique, with one exception, felt that synthetic balata is quite useful for temporary prostheses. Some have adopted the method as standard procedures where procurement practices permit use of temporary prostheses of this type.

CONCLUSIONS

When this technique is used, a considerable saving in time can be effected, and the patient can be provided with a prosthesis within a few hours. Furthermore, the use of synthetic balata permits easier adjustment of the socket later, and the adjustable pylon permits adjustment in alignment at any time.

It is therefore recommended that use by federal and state agencies of the VAPC technique for fabricating below-knee temporary prostheses be encouraged, and that the technique be included in the curricula of all below-knee prosthetics courses.

LITERATURE CITED


May 1970
PROTOCOL

BK POLYSAR SOCKET EVALUATION PROJECT

Purposes of the Study:

1. To determine usefulness of Polysar as a material for socket
2. To determine usefulness of the Gardner technique of socket fabrication using the pneumatic bag
3. To gather information on the use of pylon prostheses, including cosmetic treatment for use by designers and manufacturers

Each prosthetist is requested to fit five new patients and five patients who have worn PTB prostheses before. Instructions given in the VAPC manual should be followed as closely as possible.

A data-collection sheet including the Medical History Form A- and Lower-Extremity Prosthetic Information Form B-1 must be completed for each patient and held on file until requested by CPRD staff. (It is not necessary to complete items 3, 4, and 7 on Medical History Form.)
# MEDICAL HISTORY

**Name of Patient** ___________________________  **Date** ____________

**Male** □  **Female** □  **Date of Birth** ____________  **Height** ____________  **Weight** ____________

1 **Site of Amputation** ____________  **Type of Case**: **New** □  **Old** □

2 **Source of Patient (prosthetic prescription)**
   - □ Amputee Clinic
   - □ Name of Physician
   - **Clinic Chief** □  **Case Not Referred** □

3 **Source of Payment** ____________  **Occupation** ____________

4 **Medical Complications (check conditions that can affect type of prescription or use of prosthesis)**
   - □ Heart Disease
   - □ Arthritis
   - □ Serious Visual Impairment
   - □ Mental Disease
   - □ Obesity
   - □ Other (specify)

5 **Condition of Other Extremities**
   - □ Normal
   - □ Vascular Disease
   - □ Paralysis
   - □ Other (specify)

6 **Amputee Received Pre-Prosthetic Training**: **Yes** □  **No** □  **(specify)**

7 **Post Prosthetic Training Prescribed**: **Yes** □  **No** □  **(specify)**

8 **Amputation History**
   - **Date of First Amputation** ____________
   - **Cause of Amputation (if congenital, describe)** ____________
   - **Prosthetic Result**: □ Satisfactory
   - □ Unsatisfactory (specify)
   - **Date Prosthesis Provided** ____________

9 **Level and Side of Amputation** ____________

10 **Date of Second Amputation** ____________  **Level and Side of Amputation** ____________

11 **Cause of Amputation** ____________

12 **Prosthetic Result**: □ Satisfactory
   - □ Unsatisfactory (specify)

13 **Date Prosthesis Provided** ____________

14 **Date of Third Amputation** ____________  **Level and Side of Amputation** ____________

15 **Cause of Amputation** ____________

16 **Prosthetic Result**: □ Satisfactory
   - □ Unsatisfactory (specify)

17 **Date Prosthesis Provided** ____________

18 **Protective Surgery**
   - **Date** ____________  **Procedure** ____________  **Extremity** ____________

19 **Other Cases**
   - □ Worn Out
   - □ Outgrown
   - □ Weight Gain
   - □ Weight Loss
   - □ Present Prosthesis Unsatisfactory (Cause)

20 **Remarks** ____________
INSTRUCTIONS: FORM A

1. Site of Amputation
   Indicate side and level of amputation(s) being fitted.
   Use appropriate standard abbreviations—R for right—L
   for left. (E.g., right below-knee = RBK)
   
   FQ = Forequarter
   SD = Shoulder Disarticulation
   AB = Above Elbow
   ED = Elbow Disarticulation
   BE = Below Elbow
   WD = Wrist Disarticulation
   PH = Partial Hand
   HP = Hemipelvectomy
   HD = Hip Disarticulation
   AK = Above Knee
   KB = Knee Bearing (all cases)
   using outside joints
   BK = Below Knee
   SY = Syme
   PF = Partial Foot

2. Type of Case
   New = Stump never previously fitted.
   Old = Replacement prosthesis. (Fill out item 14 regarding cause of replacement.)

3. Source of Patient
   a. List official name of amputee clinic and physician clinic chief for all clinic cases.
   b. List name of physician who refers a non-clinic case.
   c. Check "Case Not Referred" in all instances where prosthetist writes the limb prescription.

4. Source of Payment
   The more common sources of payment for a limb are:
   State Bureau of Vocational Rehab.
   Veterans Administration
   Workmen's Compensation
   Insurance Company
   Public Welfare Agency
   Amputee or Family

5. Medical Complications
   Consult clinic physician or doctor who referred case for proper item(s) to be checked.

6. Condition of Other Extremities
   Include loss of toes, fingers or partial foot or partial hand amputations, if present.

7. Post-Prosthetic Training
   If answer is "No," specify. The remark, "Previous prosthetic wearer," will apply in most cases where training is not prescribed.

8. Amputation History
   Many diabetic and arteriosclerotic cases have had one or more previous amputations involving one or both of their lower extremities. This form provides space for three such amputations. Do not record a "partial foot" as a separate amputation on this form. Record as a separate amputation a reamputation at a higher level. A high percentage of such reamputations occur within six weeks of the original amputation and are due to a failure of the wound to heal properly. Record the cause of such reamputations as "Failure of amputation of (date) to heal." These stumps are never fitted, so the items "Date Prosthesis Provided" and "Prosthetic Result" would be left blank. Multiple amputations that occasionally occur in injury cases should be recorded as a single amputation, listing the two or more levels (left above elbow and right below elbow as LAE-RBE). In old amputations, if exact dates are unknown, record an estimate.

9. Level and Side of Amputation
   Use standard abbreviations as listed above.

10. Cause of Amputation
    For a correct diagnosis, consult with the clinic chief or physician who refers the case. One of the following listed causes will apply in nearly all cases:
    Injury (specify type)  
    Thrombosis  
    Arteriosclerosis  
    Embolism  
    Diabetes  
    Buerger's Disease  
    Malignant Tumor  
    Infection

11. Date Prosthesis Provided
    Record the date of the initial check-out of the completed prosthesis. Leave this item and the following item "Prosthetic Result" blank in all new cases since the tear-off Form A will have been forwarded to the National Academy of Sciences before this information is known. At periodic intervals, you will receive a list of the new cases you have sent and, at that time, by referring to your facility copy of Form A, you will be able to furnish this information.

12. Prosthetic Result
    Consider the age and physical condition of the amputee as well as the purpose for which the device was provided in recording this item. In an elderly person, limited ambulation about his home might be considered as "Satisfactory."

13. Protective Surgery
    An increasing number of vascular cases are today receiving protective surgery to prevent or delay amputation. Consult the clinic chief or referring physician for type of procedure used. These include: sympathectomy, thrombendarterectomy, arterial graft, and venous graft.

14. Old Cases
    Indicate reason for replacing present prosthesis.

15. Remarks
    This space can be used to note any item of importance not covered previously or to add additional information on any of the above data items.
LOWER-EXTREMITY PROSTHETIC INFORMATION

Name of Patient ____________________________

Site of Amputation ____________________________ Right ______ Left ______

Clinic ____________________________ Physician ____________________________

(Show Location of Stump Details, Identify with Code Letters)

<table>
<thead>
<tr>
<th>BELOW KNEE</th>
<th>ABOVE KNEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior</td>
<td>Anterior</td>
</tr>
<tr>
<td>Posterior</td>
<td>Posterior</td>
</tr>
<tr>
<td>Medial</td>
<td>Medial</td>
</tr>
<tr>
<td>Lateral</td>
<td>Lateral</td>
</tr>
</tbody>
</table>

| Stump Length: _______ inches |

BELLOW-KNEE STUMP CHARACTERISTICS

<table>
<thead>
<tr>
<th>Stump Shape: ___________</th>
<th>Distal Padding: ___________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subcutaneous Tissue:</td>
<td>Heavy □ Light □</td>
</tr>
<tr>
<td>Distal Pressure Tolerance:</td>
<td>None □ Slight □ Good □</td>
</tr>
<tr>
<td>Condition of Thigh Musculature:</td>
<td>Atrophy □ Normal □</td>
</tr>
<tr>
<td>Condition of Stump Musculature:</td>
<td>Atrophy □ Normal □</td>
</tr>
<tr>
<td>Knee Stability: ___________</td>
<td></td>
</tr>
<tr>
<td>Range of Knee Motion: ___________</td>
<td></td>
</tr>
<tr>
<td>Degrees of Knee Contracture: __ °</td>
<td></td>
</tr>
<tr>
<td>Condition of Cut Bones: Tibia □ Fibula □</td>
<td></td>
</tr>
<tr>
<td>Remarks: __________________________________________________________________________________</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ABOVE-KNEE STUMP CHARACTERISTICS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stump Musculature: ___________</td>
</tr>
<tr>
<td>General □ Hamstring Group □ Gluteal Group □ Rectus Femoris □ Adductor Longus □</td>
</tr>
<tr>
<td>Subcutaneous Tissue: Heavy □ Light □</td>
</tr>
<tr>
<td>Ichiium: Toughened □ Pressure Sensitive □ Prominent</td>
</tr>
<tr>
<td>Muscle Padding □ Prominent</td>
</tr>
<tr>
<td>Position of Trochanter: Anterior □ Midline □ Posterior □</td>
</tr>
<tr>
<td>Previous Ischial Bearing: Yes □ No □</td>
</tr>
<tr>
<td>Stump Lateral Convex □ Concave □</td>
</tr>
<tr>
<td>Contour: Out □ Flat □ In □</td>
</tr>
<tr>
<td>Degree of Contracture: Hip Flexion □</td>
</tr>
<tr>
<td>Stump Adduction □ Abduction □</td>
</tr>
<tr>
<td>Remarks: __________________________________________________________________________________</td>
</tr>
</tbody>
</table>

3 Rx for Prosthesis:

<table>
<thead>
<tr>
<th>4 Foot Comp. Model</th>
<th>4 Knee Comp. Model</th>
<th>Socket Materials</th>
<th>Type of Symes</th>
<th>4 Hip-Joint Model Type</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>4 Ankle Comp. Model</th>
<th>Type of Socket</th>
<th>Shank Materials</th>
<th>Hip Disartic. Type</th>
<th>Type of Suspension</th>
</tr>
</thead>
</table>

(Consult instructions on back for all items marked with numbers)
## Lower-Extremity Prosthetic Measurements

**Name of Patient:** ____________________________  
**Phone:** ____________________________  
**Date:** ____________________________

**Address:** ____________________________  
**City:** ____________________________  
**State:** ____________________________

**Male ☐ Female ☐ Date of Birth: ___________ Height: ___________ Weight: ___________

**Type Prosthesis:** ____________________________  
**Right ☐ Left ☐**

<table>
<thead>
<tr>
<th>Shoe Furnished:</th>
<th>One ☐ Both ☐ None ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shoe Lace Opening:</td>
<td>Top ___________ In. Bottom ___________ In.</td>
</tr>
<tr>
<td>Extra Light-Weight Limb:</td>
<td>☐</td>
</tr>
<tr>
<td>Extra Strong Limb:</td>
<td>☐</td>
</tr>
<tr>
<td>KB or BK Knee Joints:</td>
<td>Size ___________ Style ___________</td>
</tr>
<tr>
<td>Ankle Joint:</td>
<td>Size ___________ Style ___________</td>
</tr>
<tr>
<td>KB or BK Thigh Lacing:</td>
<td>Eyelets ☐ Hooks ☐</td>
</tr>
<tr>
<td>Other:</td>
<td>____________________________</td>
</tr>
</tbody>
</table>

**Thigh Lacer Height:** ____________________________  
**Shoulder Loop Size:** ____________________________  
**Waist Belt Size:** ____________________________  
**Finish of Limb:** Plastic Laminate ☐  
Rawhide Enamel ☐  
**Color:** Caucasian ☐ Negroid ☐  
Light Brown ☐ Medium ☐ Dark Brown ☐  
**Check Strap:** Lace ☐ Leather Strap ☐  
**Measured by:** ____________________________

**Shop Alterations**

Lengthen Thigh ___________ In. Shorten Thigh ___________ In.  
Lengthen Shin ___________ In. Shorten Shin ___________ In.  
KB or BK Lace Opening: Top ___________ In. Bottom ___________ In.  
Set BK Lacer on Joints:  
Higher ___________ In. Lower: ___________ In.  
Lateral BK Joint Head:  
Set In ___________ In. Set Out ___________ In.  
Medial BK Joint Head:  
Set In ___________ In. Set Out ___________ In.  
Fit Foot In Shoe: Tight ☐ Loose ☐ Medium ☐  
Make Heel Cushion: Soft ☐ Medium ☐ Firm ☐  
Special Changes: ____________________________

Fitted By: ____________________________

Finished BK Limb, Knee Center to Floor: ___________ In.  
Finished AK Limb, Ischium to Floor: ___________ In.  
Weight of Finished Limb: ___________ lbs. ___________ oz.  
Special Features: ____________________________

**Date Completed:** ____________________________

---

**Below Knee**

**Stump Diameter at Level of Patella Tendon**  
**A-P**  
**M-L**

**Below Knee**

**IMPORTANT — Mark all Bony Prominences on Cast**  
**Cost of Stump**  
**Limb Tracing**

**Above Knee**

**A-P Dimension of Socket**  
**Distance from Ischial Tuberosity to Adductor Longus Tendon**

**B-1**