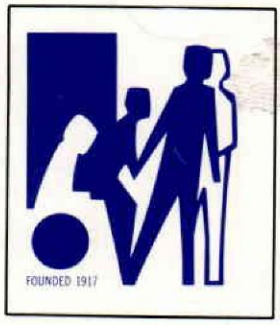
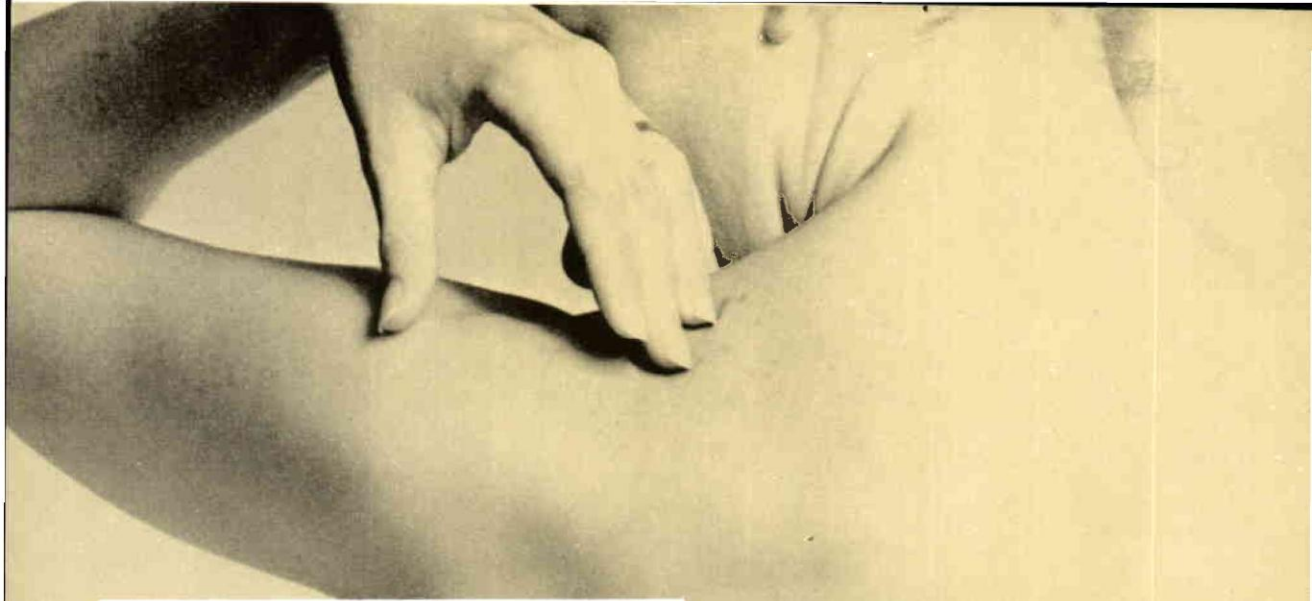
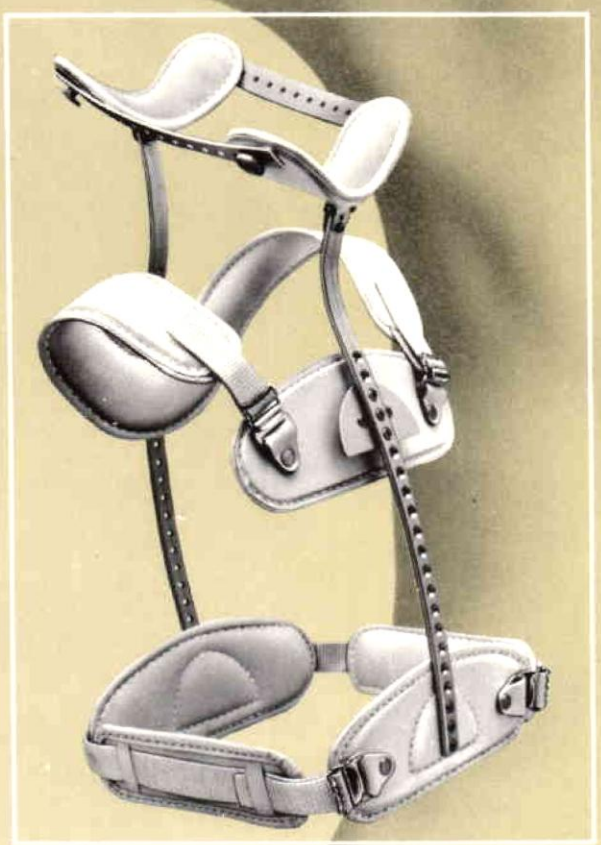



March 1980
Volume 34
Number 1

# Orthotics and Prosthetics

Journal of the American Orthotic and Prosthetic Association





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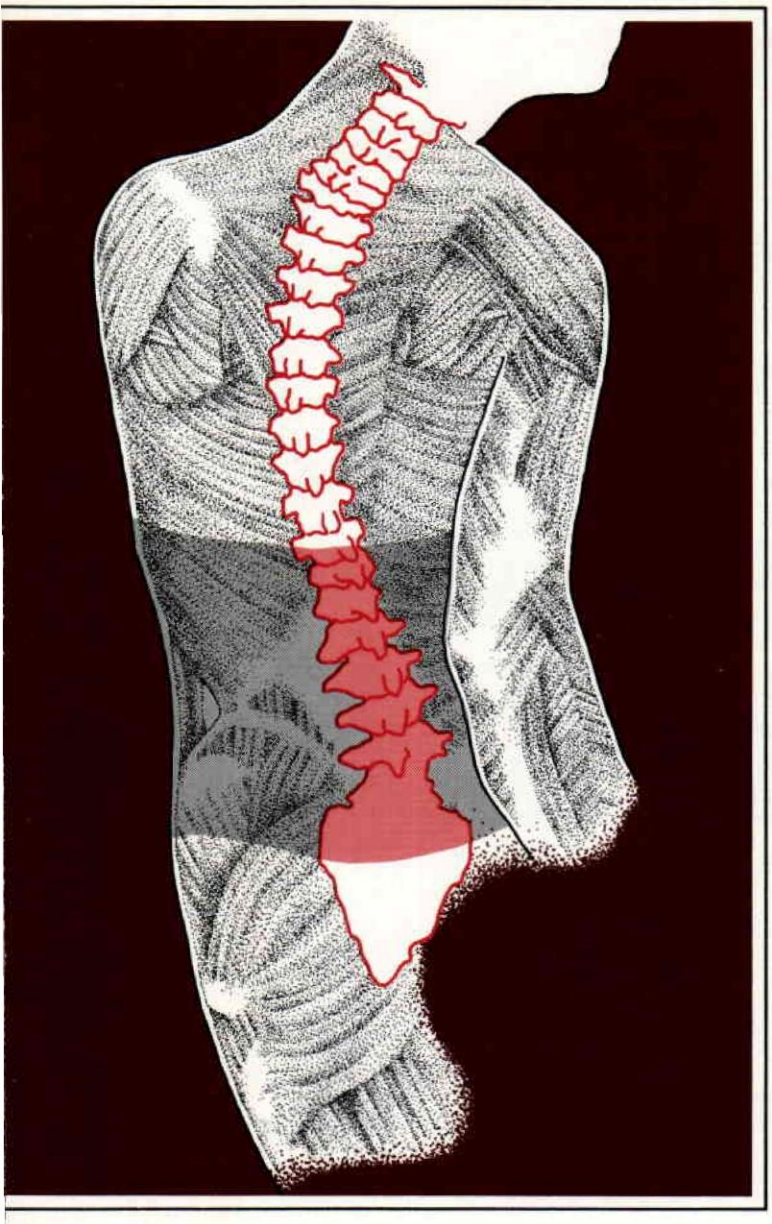

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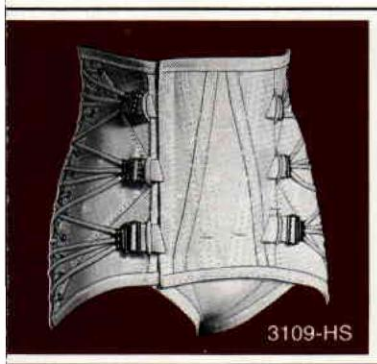
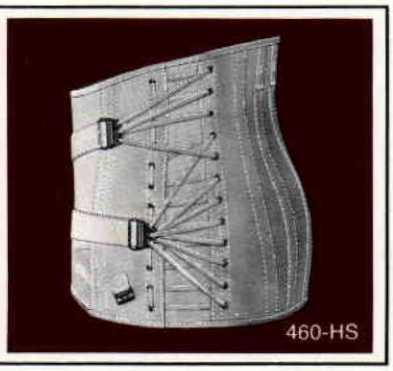
J. Wasserman and M. McNamee, Engineering Evaluation of Lumbo-Sacral Orthoses using IN VIVO NONINVASIVE Torsional Testing. Accepted for publication in the proceedings of the 10th Southeast Conference of Theoretical and Applied Mechanics.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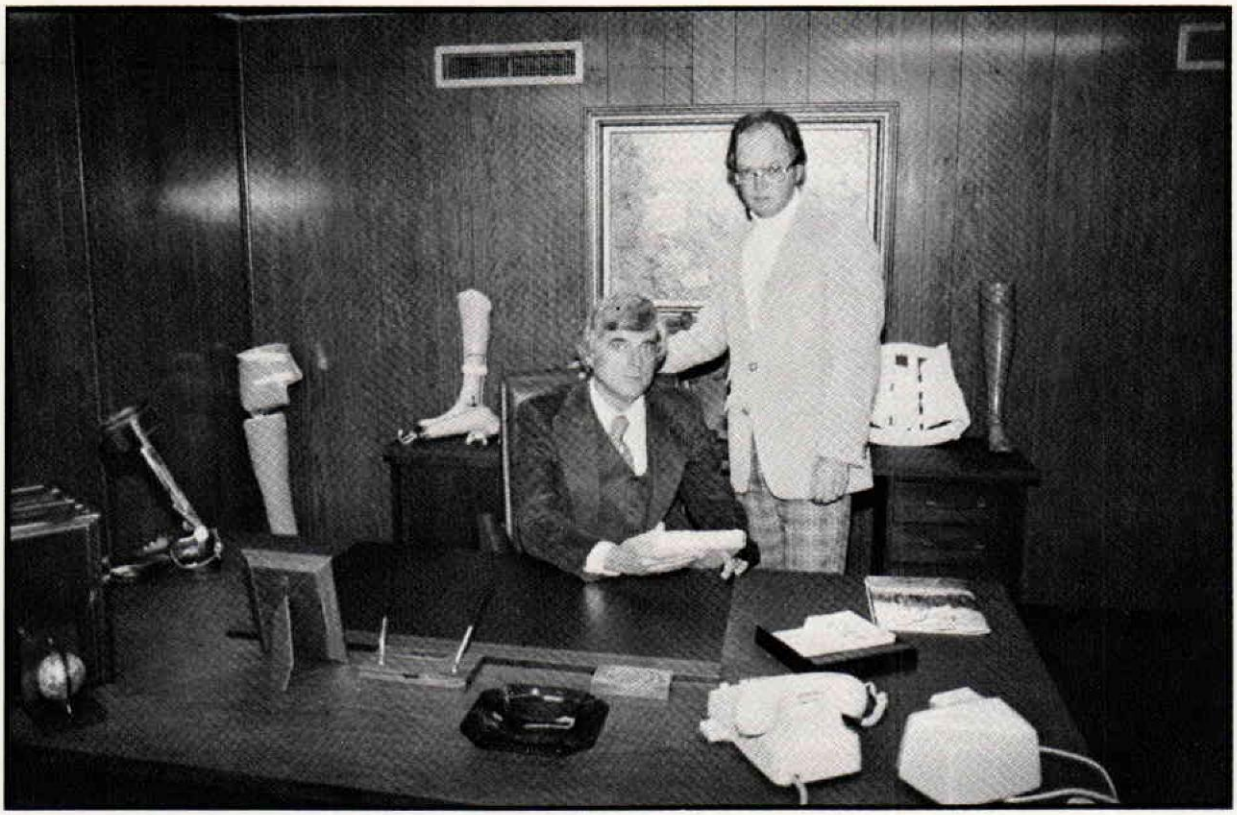

**President Bill Hamilton and Immediate Past President Bill Brady announce that the American Orthotic and Prosthetic Association has published a book entitled *Selected Reading—A Review of Orthotics and Prosthetics* which presents an outstanding review of orthotic and prosthetic procedures. Mr. Brady and Mr. Hamilton have announced that as a membership benefit each AOPA member will receive a free copy.**

The American Orthotic and Prosthetic Association (AOPA), representing firms that manufacture and fit orthoses and prostheses (braces and artificial limbs), is publishing a book entitled *Selected Reading—A Review of Orthotics and Prosthetics*, to fill a long-standing need for a comprehensive orthotic and prosthetic reference. AOPA has recognized the needs of the orthotist, the prosthetist, and the entire rehabilitation clinic team regarding a good reference book.

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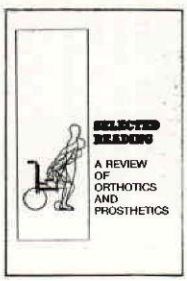


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# Orthotics and Prosthetics

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A. Bennett Wilson, Jr.

**Managing Editor and Design**
Brian A. Mastro

**March 1980 Journal** **Volume 34, No. 1**

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**1980, May 29-June 1.** Region II and III Meeting, Playboy Club, Great George, New Jersey.

**1980, June 6-8,** AOPA Region IX Meeting, Ilandia Hyatt House, San Diego, California.

**1980, June 11-13,** AOPA Regions VIII & X Meeting, Four Season Motor Inn, Albuquerque, New Mexico.

**1980, June 16-20,** Interagency Conference on Rehabilitation Engineering, Sheraton Center, Toronto, Canada.

**1980, June 19-22,** AOPA Region VI and VII Meeting, Thunderbird Motel, Bloomington, Minnesota.

**1980, June 22-27,** World Congress of Rehabilitation, International Winnipeg Convention Center, Winnipeg, Canada.

**1980, June 27-29,** AOPA Region XI Meeting, Sands Hotel & Casino, Reno, Nevada.

**1980, September 14-20,** AOPA National Assembly, New Orleans Marriott, New Orleans, Louisiana.

**1980, September 28-October 4,** Third World Congress (ISPO), Bologna, Italy.

**1981, January 27-February 1,** AAOP Round Up Seminar, Fountainebleau Hilton, Miami, Florida.

**1981, October 28-November 1,** AOPA Assembly, Sahara Hotel, Las Vegas, Nevada.

**1982, February 14-20,** AAOP Round Up Seminar, Royal Sonesta Hotel, New Orleans, Louisiana.

**1982, May 6-9,** Region IV Meeting, Nashville, Tennessee.

**1982, May 13-16,** Region II and III Meeting, Ceasar's World, Atlantic City, N.J.

**1982, October 17-24,** AOPA Assembly, Hyatt Regency, Kansas City, Missouri.

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Orthotics and Prosthetics invites the submission of all articles and manuscripts which contribute to orthotic and prosthetic practice, research, and education. All articles submitted must be sent to *Orthotics and Prosthetics,* 1444 N Street, NW, Washington, DC 20005.

All submitted manuscripts should include:

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3. Legends. List all illustration legends in order, and number to agree will illustrations.
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# Commentary

When asked to write this article, I had a good many ideas go through my mind and decided that maybe something that is controversial or thought provoking would be appropriate.

What is wrong with orthotics and prosthetic today. Seven or eight hundred people will say as many different things. Economics is our *only* problem. How can that be? Well, consider where we are in technology today. We have government spending huge sums of money to develop new and wondrous treatments for the disabled. The other side is that government will not pay for good technology already available to us. We really don't need new ideas, we need to be able to apply what we already have. Why can't we get paid for what we do and new technology? Could you tell someone how much it costs to produce all of your products and services by item? Have we for years been blind to what our costs are? Does each item of orthotic and prosthetic services have the same profit margin and carry its share of overhead? Are our fees based on reasonable profit? Are the salaries of our employees the same or higher than the skilled trades, i.e. carpenters, electricians, plumbers. Our employees go to the same store and gas station as the skilled trades people. Do we pay for our employees' education? Perhaps it would be different if a person entering orthotics and prosthetics could see the chance to make a good living. He might even pay for his own education. What in orthotic and prosthetic education or in basic education for that matter, teaches us basic laws of economics? Perhaps in orthotic and prosthetic education we should start some type of economic education! How many employees really understand that they must make a profit for the company? Do you participate in AOPA activities such as the Business Survey? Do you run a business first and then an orthotic and prosthetic practice? Can you document your costs by item and services?

Until the majority of orthotic and prosthetic owners and employees can answer these and many other questions, I believe orthotic and prosthetic problems are only one, economics.

Dan Rowe

FOUNDED 1917

Orthotics and Prosthetics, Vol. 34, No. 1, pp. 3-12, March 1980

# For Accelerated Postamputation Rehabilitation: Zoroc Intermediate Prostheses

J. M. LEAL, C.P.[1]
J. M. MALONE, M.D.[1]
W. S. MOORE, M.D.[1]
S. J. MALONE, S.W.A.[1]

The purposes of this report are to describe use of the Zoroc resin-coated plaster technique for the fabrication of an intermediate prosthesis and to determine the economic and therapeutic effects of the Zoroc prosthesis with respect to the patient and to our rehabilitation program.

We believe that this intermediate prosthesis fulfills the following requirements for a component of a successful rehabilitation program:

1. Progressive rehabilitation without loss of ambulation time
2. Objective determination, when clinically questionable, of rehabilitative potential of an amputee without the need for a large expenditure
3. Shortened hospitalization through continuous rehabilitation of the patient while the plastic prosthesis is being fabricated.

## Materials and Methods

Between July 30, 1977, and August 1, 1979, 80 amputations were performed at the Tucson V.A. Medical Center and the University of Arizona Health Sciences Center. Three techniques were employed: conventional treatment which included soft dressings and daily wrapping with elastic bandage to achieve stump shrinkage, immediate postoperative prosthesis (IPOP), and the Controlled Environmental Treatment Unit (CETU). The details of IPOP techniques and CETU have been reported elsewhere and will not be repeated in this report (1, 2, 3, 4, 5, 6).

Of the 80 operations performed, 11 were toe and partial foot amputations treated with conventional techniques. Six of eight transmetatarsal amputations were treated with IPOP, and two were guillotine amputations followed by skin grafts. All of the six Symes' amputations were treated with IPOP. Thirty below-knee (BK) amputations were performed. Of these, 24 were treated with IPOP and six were treated with CETU followed by IPOP. Five knee disarticulations were treated with IPOP. Thirteen above-knee (AK) amputations were treated with conventional techniques. One AK stump revision was treated with IPOP. Two hip disarticulations were treated with conventional techniques. Two above-elbow traumatic amputations, one above-elbow stump revision, and one below-elbow stump revision were treated with func-

**TABLE 1**

AMPUTATION MANAGEMENT

| *Type of Amputation* | *Prosthetic Technique* | | | |
|---|---|---|---|---|
| | Conventional | IPOP | CETU + IPOP | Skin Graft |
| Toe and partial foot | 11 | | | |
| Transmetatarsal | | 6 | | |
| Guillotine transmetatarsal | | | | 2 |
| Symes' | | 6 | | |
| Below-knee | | 24 | 6 | |
| Knee-disarticulation | | 5 | | |
| Above-knee | 13 | | | |
| Above-knee revision | | 1 | | |
| Hip-disarticulation | 2 | | | |
| Below-elbow revision | | 1 | | |
| Above-elbow revision | | 1 | | |
| Above-elbow, traumatic | | 2 | | |
| TOTALS | 26 | 46 | 6 | 2 |

tional IPOP (Table 1).

During the treatment of these patients, it became evident that from two to three weeks of rehabilitation were lost between removal of the final IPOP prosthesis and delivery of a temporary plastic prosthesis. Using a recently described technique for the construction of a removable rigid dressing for IPOP (7) we developed a new technique for the construction of a removable intermediate prosthesis at the levels of BK, knee disarticulation, and AK amputations using Zoroc resin-impregnated plaster. Utilization of Zoroc plaster resulted in a lightweight yet durable, removable prosthesis that could be fabricated in two hours and ready for patient use in 24 hours. The basic principle of the Zoroc technique is control of the size and shape of the amputation stump by use of predesigned shapes such as the quadrilateral brim for AK amputations (Fig. 1). Ease of application is achieved by use of a medial window when necessary.

Since construction of the AK, knee-disarticulation, and BK prostheses differ slightly, the construction techniques for prostheses for each level will be described in detail.

### Above-Knee and Knee-Disarticulation Cases

The materials and devices used for the knee-disarticulation and AK prostheses are:

- Polyethylene quadrilateral brim
- Polypropylene pelvic joint with pelvic band
- AK postsurgical pylon for AK or knee disarticulation cases
- OHC polycentric knee with Dynaplex hydraulic knee control for knee-disarticulation cases
- IPOP BK waist suspension belt
- SACH foot
- 4-in. Johnson & Johnson Zoroc plaster bandage
- 4-in. Johnson & Johnson Orthoflex elastic plaster bandage

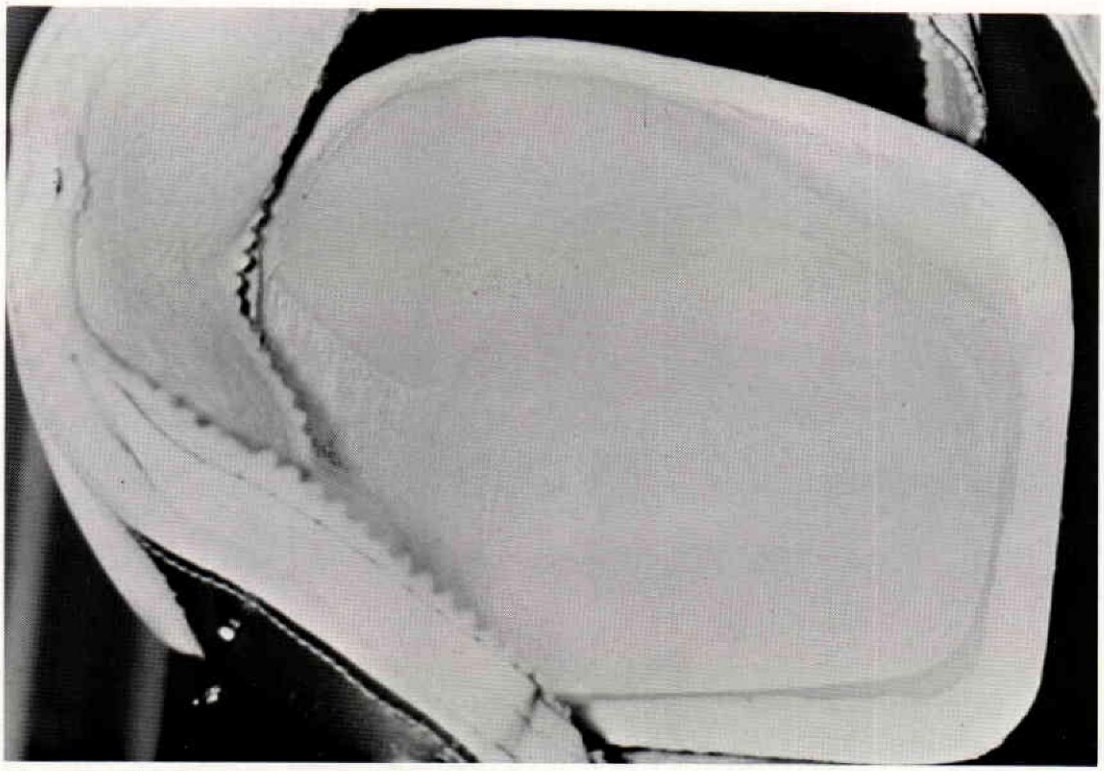

Fig. 1. Top view of a Zoroc AK prosthesis.

Velcro for knee-disarticulation cases
5-ply wool stump sock
Lambswool, .5 oz. package
Large castroom latex glove

For construction of an above-knee or knee-disarticulation prosthesis, the patient is placed on a standard examination table, and a 5-ply stump sock is drawn over the stump. While traction is applied proximally to the stump sock, with the stump in proper flexion and adduction alignment, a polyethylene casting brim of an appropriate size is held against the ischial tuberosity. A large castroom latex glove is then applied over the stump sock and taped to the brim to provide a separating agent for removal of the socket and a smooth inside wall. The fingers of the glove may be either taped down or cut off. A 4-in. wide roll of elastic plaster bandage is applied to the stump and the brim. Wrapping is carried out from distal to proximal. Most AK stumps require two rolls of bandage. The long AK and knee-disarticulation stumps may require several rolls. For the AK case, the brim and distal wrap can be removed in one unit after the plaster has set. For the knee-disarticulation case, however, a medial window is needed to allow removal of the socket. This window material is saved and used later with the definitive socket.

The polyethylene quadrilateral brim is reinforced with one roll of 4-in. wide Zoroc plaster. A flexible pelvic joint and band are then applied to the lateral wall of the AK socket with an additional roll of Zoroc plaster. A top view of the AK socket with pelvic joint and band at-

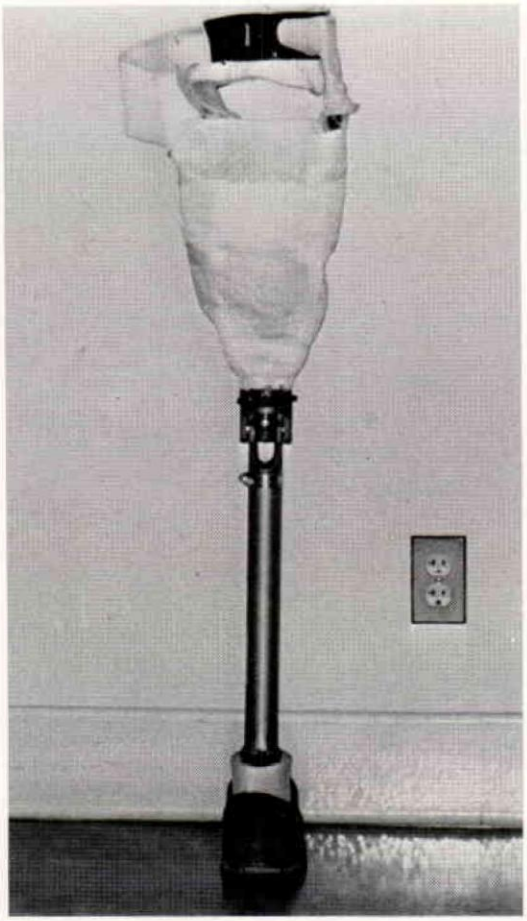

Fig. 2. Posterior view of an AK Zoroc prosthesis with pelvic joint and belt.

tached is shown in Figure 1. Using an additional roll of Zoroc plaster and standard bench alignment techniques, the prosthetic socket can be applied to either an AK standard postsurgical pylon (Fig. 2) or to an OHC polycentric knee unit in the knee-disarticulation patient (Fig. 3). For the AK patient, the BK IPOP belt is attached to the flexible pelvic band with rivets after the elastic suspension strap has been removed. The AK prosthesis is then ready for dynamic alignment by using stump socks to create a good fit and lambswool to provide total contact at the distal end of the socket.

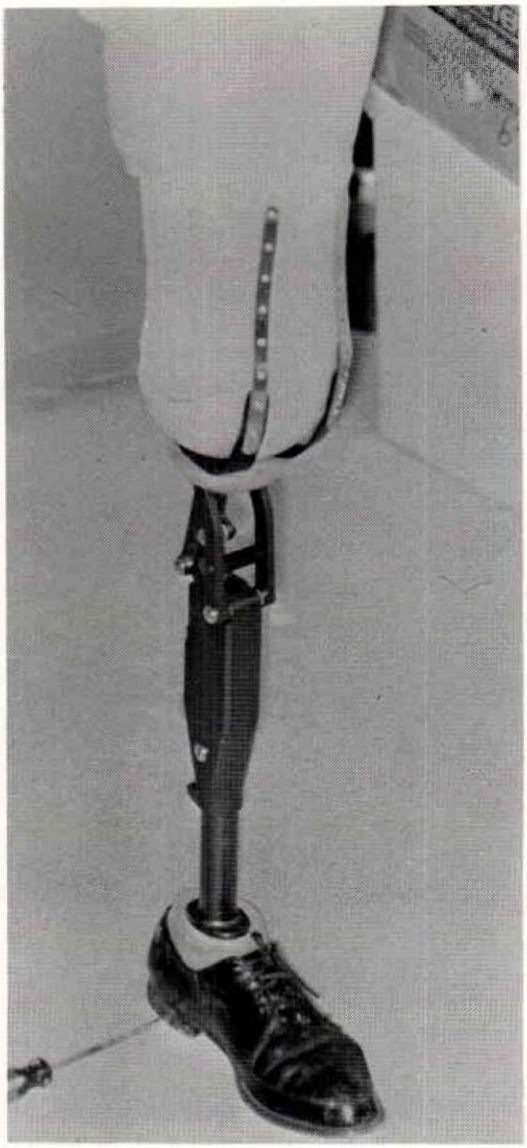

Fig. 3. Knee-disarticulation prosthesis using an OHC polycentric knee and a Dynaplex swing-phase control unit.

For the knee-disarticulation patient an additional elastic strap is attached to the lateral portion of the IPOP BK belt. Two webbed prong-buckles must be attached to the anterior and lateral walls of the socket with another roll of Zoroc plaster.

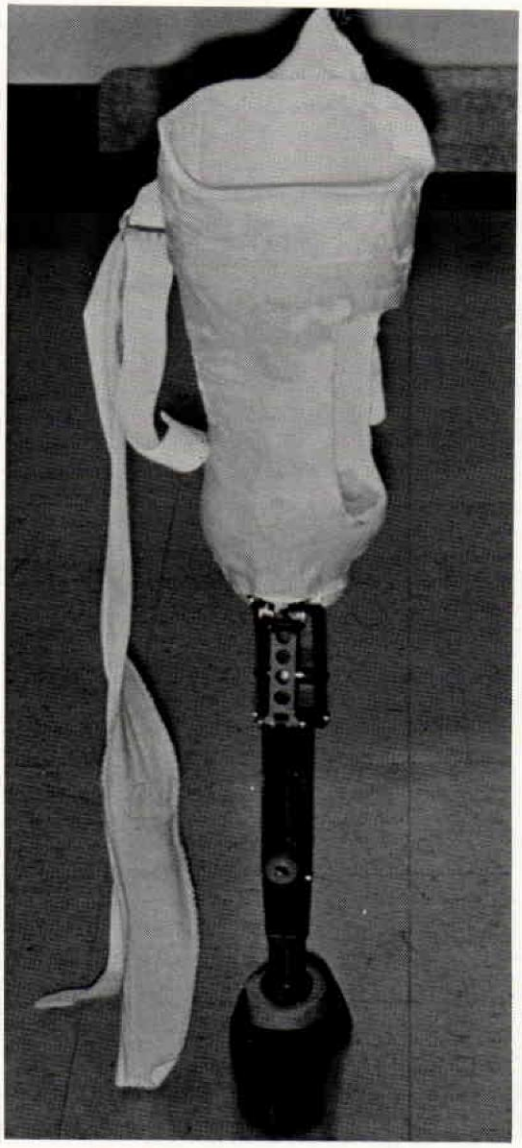

Fig. 4. Knee-disarticulation prosthesis. A medial window is provided for ease of application.

The medial window material, after reinforcement with Zoroc plaster, provides the additional suspension required for a knee-disarticulation prosthesis. The window material is held in place by Velcro straps secured with rivets.

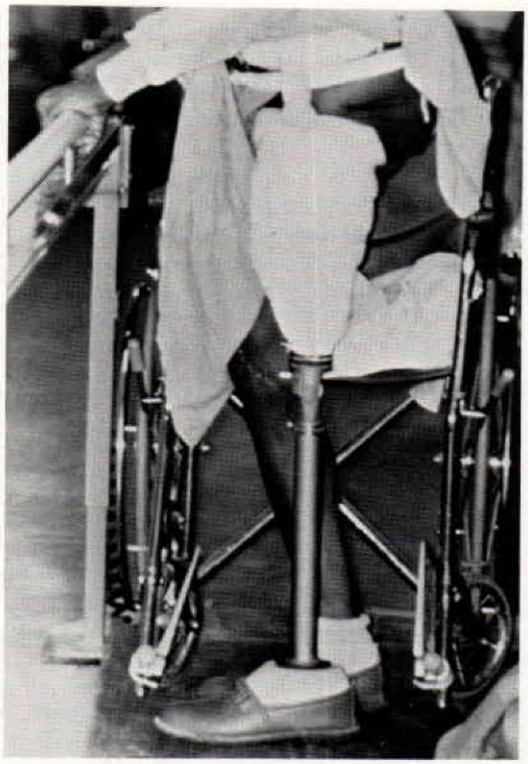

Fig. 5. Lateral view of patient with a Zoroc AK prosthesis.

A Zoroc AK prosthesis is shown in Figure 5, and a knee-disarticulation prosthesis in Figure 6.

### The Below-Knee Prosthesis

For construction of a Zoroc temporary BK prosthesis, the necessary materials and devices are:

1-in. cotton webbing, 5'
1-in. elastic webbing, 4'
4-in. Johnson & Johnson Zoroc plaster wrap
4-in. Johnson & Johnson Orthoflex elastic plaster wrap
BK postsurgical felt relief pads
IPOP felt relief pads
IPOP BK waist suspension belt
5-ply wood stump sock

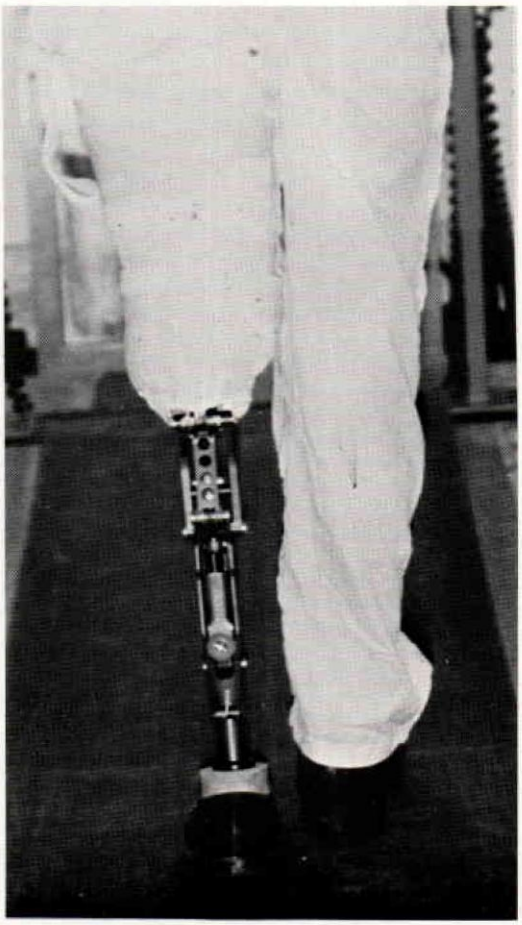

Fig. 6. Posterior view of patient with a Zoroc knee-disarticulation prosthesis.

Medical adhesive spray
Lambswool, .5 oz.
Large castroom latex glove
SACH foot
BK pylon

For construction of a BK Zoroc prosthesis, the patient is seated on a firm table, lambswool is distributed evenly over the distal end of the stump, and a 5-ply stump sock is applied. Felt relief pads are fitted over bony prominences and glued to the stump sock with medical adhesive in the same manner as they are placed on a modified male plaster mold.

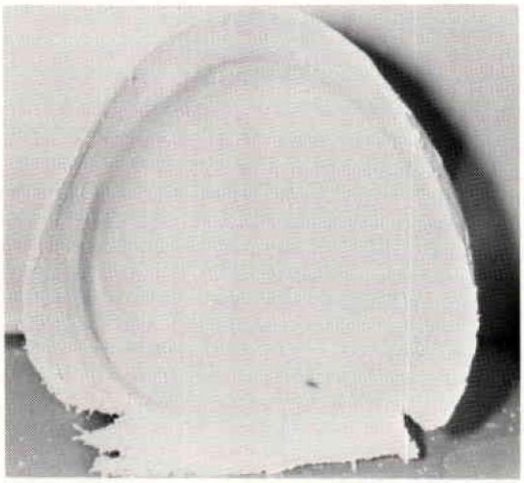

Fig. 7. Top view of a plaster PTB socket.

When the stump has a bulbous distal end, a felt pad must be applied to the medial aspect of the stump to allow for cast removal or donning the prosthesis.

A latex castroom glove is applied over the 5-ply stump sock and relief pads. The fingers of the glove are cut off. A 1-in. wide elastic strap secured around the patient's waist is used to hold the stump sock in place.

Two rolls of elastic plaster wrap are then applied over the stump, using standard prosthetic techniques to provide a negative cast. The cast is molded to achieve total contact and anterior/posterior PTB qualities.

When the plaster has hardened, the socket is removed from the patient and trimmed to provide the standard PTB brim configuration before application of Zoroc. A view inside the plaster socket is shown in Figure 7, and an anterior view of a plaster socket is shown in Figure 8. The socket is then trimmed, using standard PTB design.

With a roll of 4-in. wide Zoroc plaster bandage, the prosthetic socket is attached to a BK pylon and SACH foot, using

Fig. 8. Anterior view of a plaster PTB socket.

standard bench alignment prosthetic techniques (Figs. 9 & 10). With half a roll of Zoroc plaster, two 30-in. lengths of 1-in. wide cotton webbing are attached medially and laterally to the prosthesis to create a PTB suspension strap.

The BK prosthesis is fitted to the patient, using an appropriate number of stump socks. Lambswool in the bottom of the socket provides for total contact. The lateral and medial straps are wrapped around the knee in a figure-8 shape and secured on the anterior side. Additional suspension is achieved by attaching the elastic strap of the IPOP BK belt to the PTB suspension strap. After the patient has donned the prosthesis (Figs. 11 & 12) it can be aligned dynamically.

Fig. 9. PTB Zoroc socket mounted on a standard IPOP BK pylon.

## Discussion Concerning Prosthetic Results

Under normal circumstances in our facility a temporary plastic prosthesis is

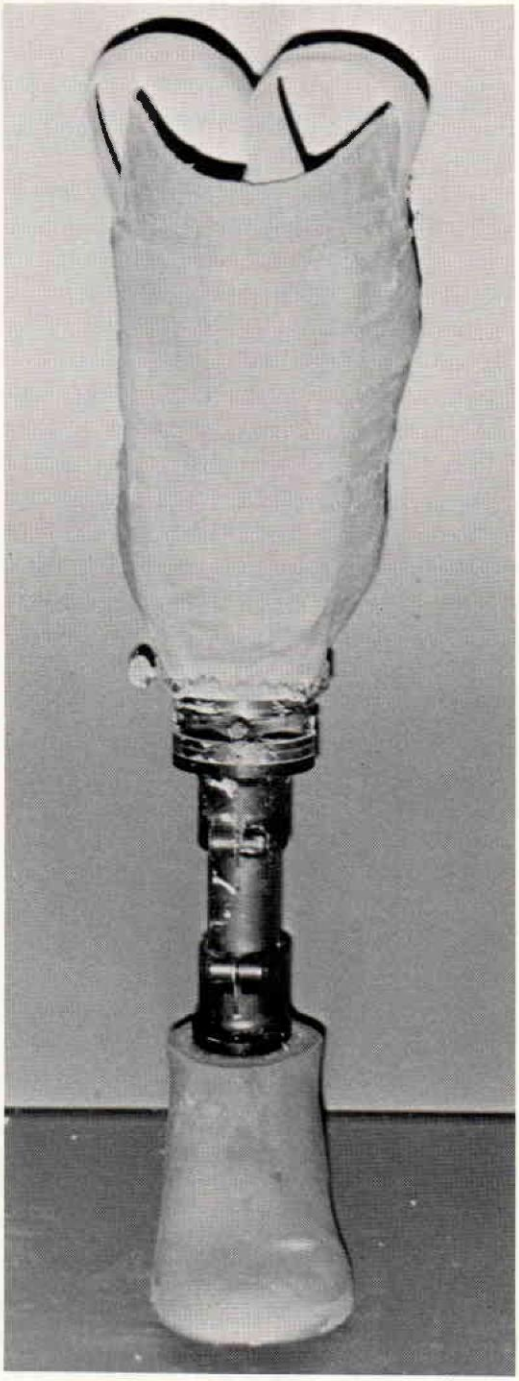

Fig. 10. Completed Zoroc PTB prosthesis ready for dynamic alignment.

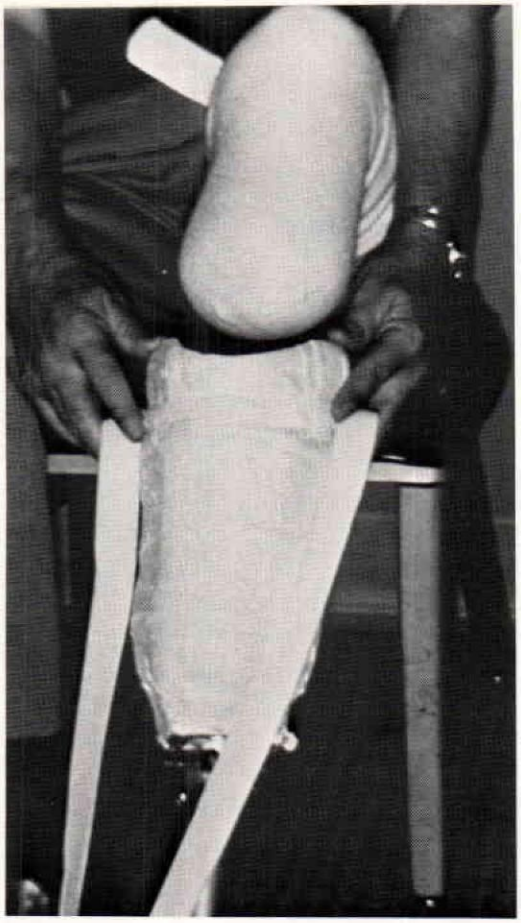

Fig. 11. Patient donning a Zoroc BK prosthesis.

provided within two or three days after removal of the final IPOP. Our recent move and construction of a new Prosthetic Research Laboratory, however, caused us to rely on outside facilities for fabrication of all temporary prostheses. An inordinate delay of 2-4 weeks between removal of the final IPOP plaster cast and delivery of a plastic temporary prosthesis forced us to develop a new technique for making a removable, temporary plaster prosthesis that allows continuing accelerated rehabilitation during the period

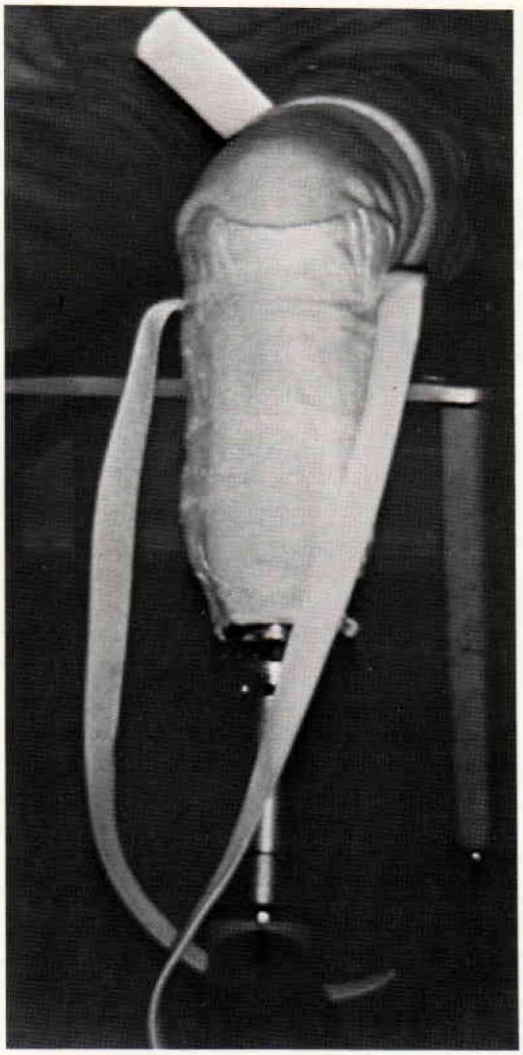

Fig. 12. Zoroc BK prosthesis in place, ready for figure-8 strap attachment and dynamic alignment.

required to fabricate the plastic temporary prosthesis. Using techniques described in this report, we employed Zoroc resin-coated plaster to construct an intermediate prosthesis for 19 of 80 patients undergoing amputation through the lower limb. Involved were 12 BK, 3 knee-disarticulation and 4 AK cases.

Use of the Zoroc prosthesis in these 19 patients reduced the time of hospitalization and enhanced stump maturity. In one patient, the Zoroc intermediate prosthesis offered daily assessment of secondary healing without a break in the rehabilitation procedure. In contrast to standard plaster, Zoroc resin-coated plaster provides a strong, durable, lightweight plaster socket which maintains good fit and prosthetic alignment for two or three months of hard use. Patient confidence in achieving independent ambulation is improved by use of a Zoroc prosthesis during daily physical medicine training. When rapid delivery of temporary plastic limbs is available, the Zoroc technique adds little to a rehabilitation program; however, in those cases where there is an inordinate delay in provision of a temporary plastic prosthesis, a Zoroc prosthesis provides obvious advantages. It does not replace a plastic temporary prosthesis, but serves as an interim device between removal of the IPOP cast and the manufacture and fitting of a more permanent, plastic artificial limb. The Zoroc technique can be used on an outpatient basis, but should be controlled and evaluated by a prosthetist at all times. We feel that the ease of application, short fabrication time, and minimal cost make the Zoroc temporary prosthetic technique an important tool in amputee rehabilitation, especially in those centers where cost and length of rehabilitation time are prominent considerations.

Patient acceptance has been excellent. The rehabilitation program is not suspended with the removal of the last IPOP, and started again two or three weeks later when the plastic temporary prosthesis is delivered. The Zoroc temporary prosthesis offers the amputee an opportunity for quicker recovery and thus, a better chance to become functional in society.

## Conclusion

Since the introduction of immediate postoperative prosthetics, much progress

has been made toward early ambulation and progressive rehabilitation. We feel that the Zoroc intermediate prosthesis complements the immediate postoperative prosthesis program and, in those centers where rapid fabrication of temporary limbs is impossible, the Zoroc technique allows rapid and continuous patient rehabilitation.

### Footnotes

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Orthotics and Prosthetics, Vol. 34, No. 1, pp. 13-24, March 1980

# The VAPC Functional Elbow Orthosis

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A majority of functional upper-limb orthoses now available are designed for patients in wheelchairs, and are not suitable for use by ambulatory patients with partial upper-limb muscle involvement resulting from brachial plexus injury or other neurological disorders. The present method of managing these ambulatory patients is to provide an arm orthosis which usually consists of an elbow lock and a cable to lift the hand into a functional position. This arrangement requires strong shoulder muscles, which are usually absent, and the devices provided are often bulky, heavy, and too difficult to operate.

To overcome these problems, the VA Prosthetics Center has been experimenting with an orthosis that uses a pneumatic device to assist elbow flexion. The original design consisted of a shoulder cap, forearm cuff, and a five-bar elbow linkage, and the force of gravity and the force required to flex the elbow were counterbalanced by the energy stored in a pneumatic-spring cylinder. Only a minimal force was needed to initiate elbow flexion, and an increase in flexion produced a non-linear increase in force. Because the force needed to extend the system is greater than the force needed for flexion, some extension activity by the user was required. After the device was fitted to a patient, it was found to be too bulky and inefficient; but it showed promise of useful function.

The cylinder and moving components were redesigned to meet the requirement of lifting the forearm more efficiently. The shoulder cap was altered to obtain an upper-arm cupping effect that provided more arm stability during elbow flexion. The mechanical components were made smaller and more compact, and the attachment points were modified to permit freer motion about the elbow joint. Stability and suspension are now controlled adequately by the shoulder cap and wrist cuff.

The new design allows non-linear forces to be generated to: 1) balance the force of gravity against the weight of the forearm; 2) produce the force required to stretch the triceps; 3) overcome the resistance encountered when the forearm becomes compressed against upper-arm tissue; and, 4) counteract an increase in force when the cylinder is compressed.

The device produces a strong pulling action between the wrist and upper-arm section, as illustrated by the two arrows in Figure 1. A counterbalance is produced between forces used to extend the cylinder during flexion and compress it during extension, permitting the system to be stable against the weight of the forearm.

Fig. 1. A strong pulling action is exerted between the wrist and upper arm.

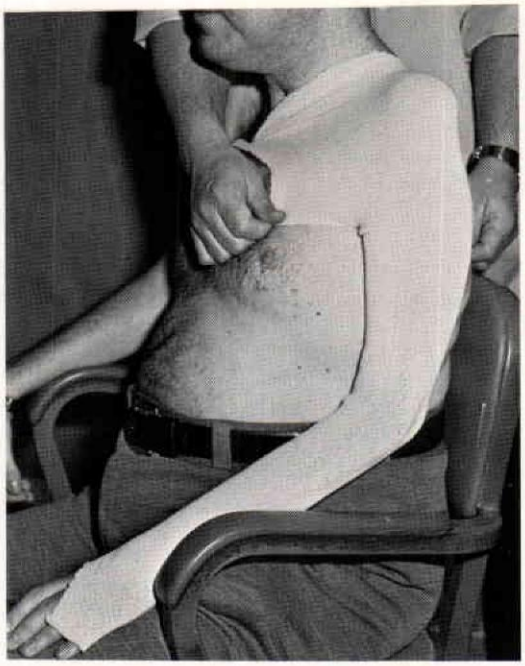

Fig. 2. The shoulder and upper arm are covered with a cotton stockinet.

Once the elbow has been flexed moderately, objects weighing up to 1 lb. (448 grams) can be supported easily. Once flexion has been initiated, the unit continues to flex until the triceps are activated to either retard flexion or stop it altogether. A slight elbow extension moment is required to maintain a fully extended position. At full flexion, more extension force is needed to extend the arm, but the force required diminishes as the arm is extended.

Further evaluation of the system with patients indicated that different load ranges to lift the forearm were needed. Thus, in the final design, provisions have been made for interchangeability of three different cylinders, which provide, respectively, 200, 300, or 400 newtons of force. Clinical applications have shown this system to be lightweight, functional, and adequate cosmetically. However, the patient requires help in donning and doffing the device.

## Fabrication

Fabrication of the Functional Elbow Orthosis requires: casting and modifying the cast, vacuum forming over the molds, and fitting and delivering the device.

### *Casting and Modification of the Cast*

1. Cover shoulder and upper arm with cotton stockinet (Fig. 2), and secure in place with elastic straps and Yates clamps.

2. Mark all bony prominences and sensitive areas on shoulder, upper arm and forearm (such as the spine of the scapula, clavicle, acromium process, and

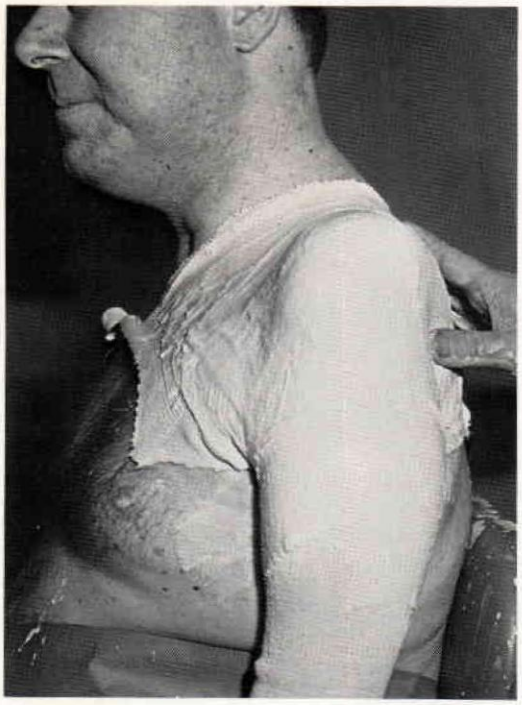

Fig. 3. A continuous plaster mold is made over the shoulder and upper arm.

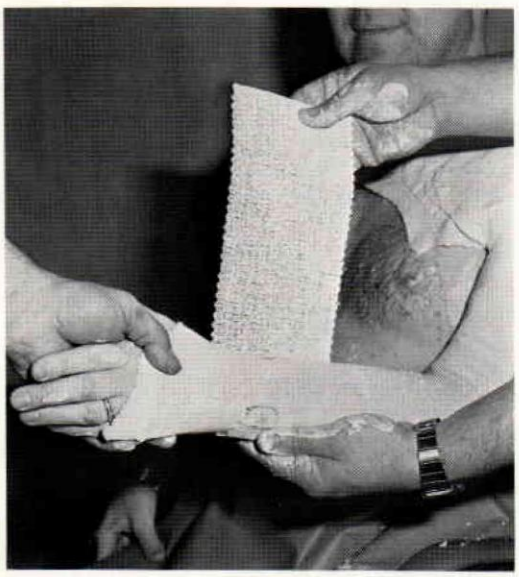

Fig. 4. A moist, 4-in. wide plaster bandage is wrapped over the stockinet that covers the wrist area.

the styloids of the wrist joint).

3. Cast the upper arm with the shoulder joint placed in about 10 deg of abduction and 5 to 10 deg of flexion to provide a position that allows the hand to get closer to the head during elbow flexion than is the case when no abduction or flexion are provided. Place wet 4-in.-wide by 18-in.-long plaster bandage strips over the shoulder and upper arm to form one continuous mold (Fig. 3). The plaster strips are placed on the upper arm so as to cover no more than three quarters of the arm's circumference, leaving a medial opening for removal of the cast without the need for a cast cutter. Four layers of plaster strips are usually used.

After the cast has hardened sufficiently, remove it by cutting the stockinet with bandage scissors on the medial portion.

4. For the forearm cuff, cover the wrist area with stockinet and mark all bony prominences. Wrap a moist 4-in. plaster bandage approximately four turns over the stockinet (Fig. 4). Allow the plaster to dry and remove it with bandage scissors.

5. Fill shoulder and wrist molds with plaster. Ensure that all modification marks are transferred to the positive mold.

6. Begin cast modification by removing all stockinet markings from both positive molds. The maximum amount of buildup over bony and sensitive areas is 1/8 in. since a Pelite or Plastazote liner will be added to both molds.

7. After completing all cast modifications, make a 3/16-in.-thick Pelite or Plastazote liner over each mold, using established prosthetic procedures (Figs. 5 and 6).

8. The molds are now ready for vacuum forming.

*Vacuum Forming Over the Molds*

When equipment for vacuum forming or drape molding is unavailable, regular laminating procedures may be used to

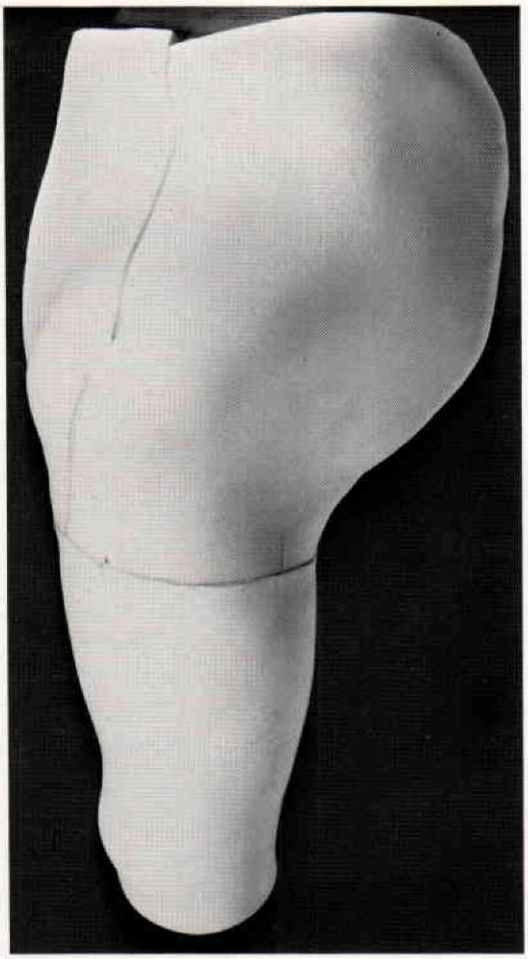

Fig. 5. A Pelite liner is molded over the positive model of the shoulder and upper arm.

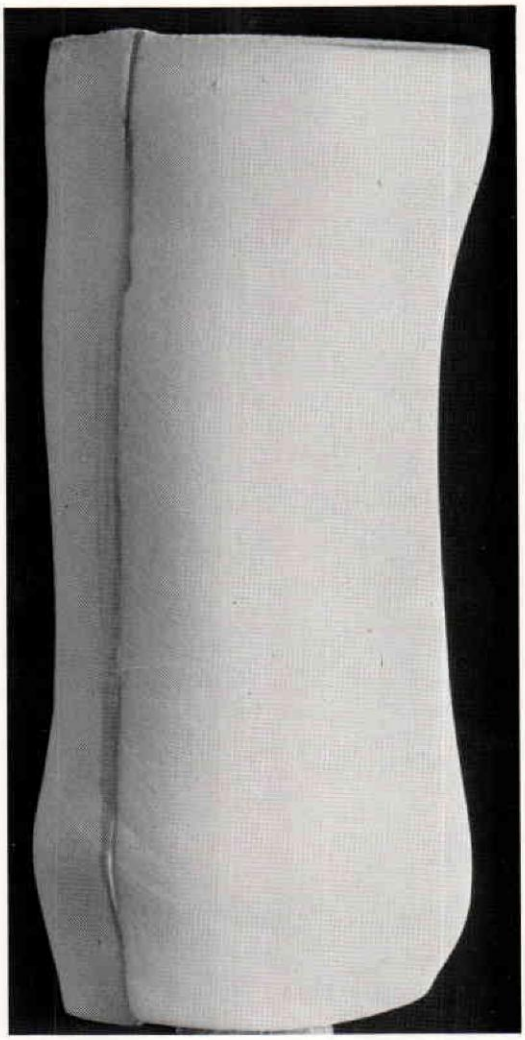

Fig. 6. A Pelite liner is molded over the positive model of the wrist area.

make the shoulder cap and forearm cuff. For vacuum forming, low density polyethylene is used. For the shoulder cap, 3/16-in. thick material is appropriate; for the wrist cuff, 1/8-in. material. Using regular vacuum forming procedures, vacuum form over both molds and their liners (Fig. 7). After the material has cooled, trim and sand all sharp edges.

*Fitting and Delivery*

For the fitting process the patient should wear a short-sleeved undershirt beneath the device for added protection of the skin under the shoulder cap and in areas where the chest strap makes contact with the body.

1. *Fitting the shoulder cap.* Fit the shoulder cap, with its liner, on the patient. Mark all required areas for trimming, i.e., the neck, axilla and elbow joint areas (Fig. 8). The shoulder section should fit snugly with no restrictions while providing shoulder and arm stabil-

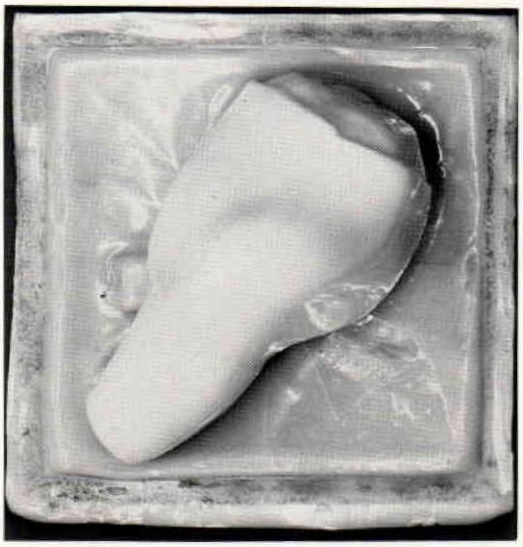

Fig. 7. Vacuum molding of the shoulder and upper-arm section.

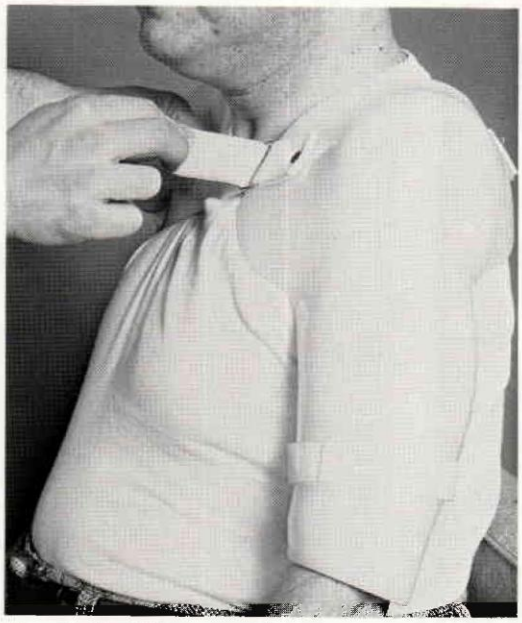

Fig. 9. Shoulder cap with cross-chest and upper-arm straps.

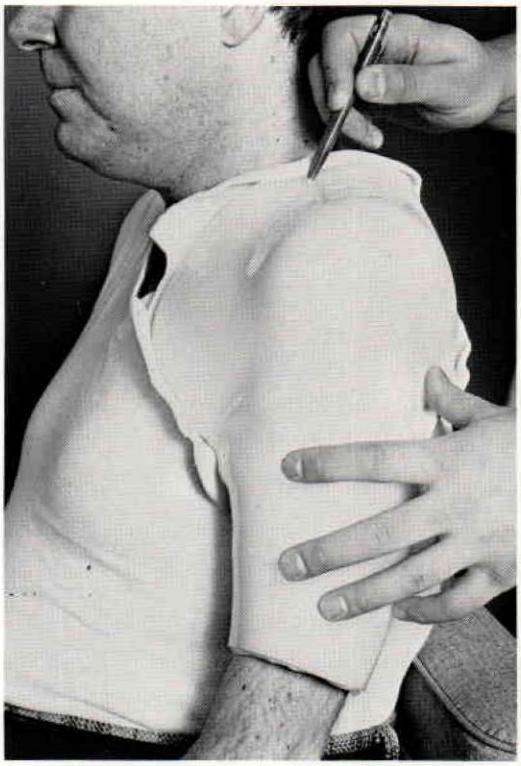

Fig. 8. Fitting and marking the trim lines for the shoulder and upper-arm section.

ity. The upper-arm section should be long enough to reach the bicipital fold at the elbow without restricting elbow flexion.

After the shoulder cap has been trimmed and smoothed, replace it on the patient, and locate the attachment points for the cross-chest and upper-arm straps so as to provide adequate support (Fig. 9). Use 1½-in.-wide webbing for the cross-chest strap, and 1-in.-wide Velcro for the upper-arm strap. Provide a tongue of a thin sheet of polyethylene on the medial side of the upper arm. The exact locations of these straps are optional, as long as they keep the shoulder cap in place and the patient is comfortable. Use tubular rivets to fasten straps and tongue in place.

2. *Fitting the Wrist Cuff.* Fit the molded cuff, with its liner, on the patient's wrist. Trim the distal and proximal edges to allow wrist flexion and extension. Its total length should be approximately 4

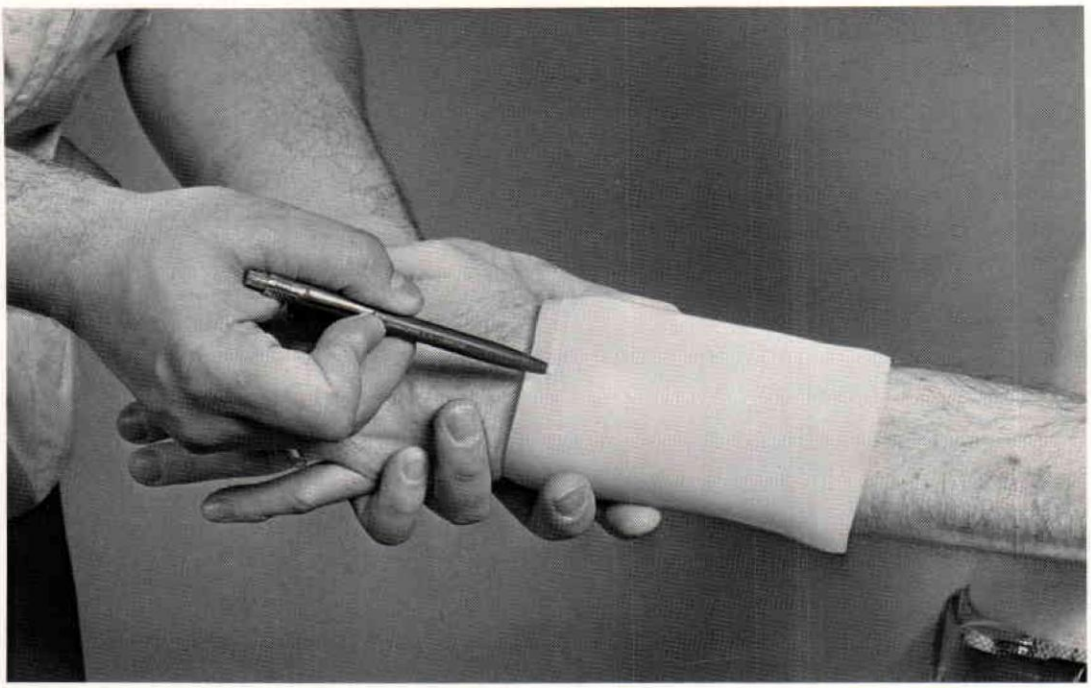

Fig. 10. Marking the wrist cuff for trimming.

in. (Fig. 10). On the initial fitting, the length of the wrist cuff is kept at 4 in. until the patient has used the device for several weeks. If it is felt after several weeks that this is too long, it can be trimmed appropriately. Because the system exerts a strong pulling force toward the elbow at the wrist, the more surface covered initially, the less pressure created on the patient's tissues. The fit should be snug, to support the pulling force.

After trimming and smoothing the edges, add one or two 1-in.-wide Velcro straps and a tongue to the wrist section by riveting them in place with tubular rivets. Location and number of the straps are optional.

3. *Fitting and Aligning the Unit.* Place the shoulder cap on the patient and secure all straps. Remove the two screws

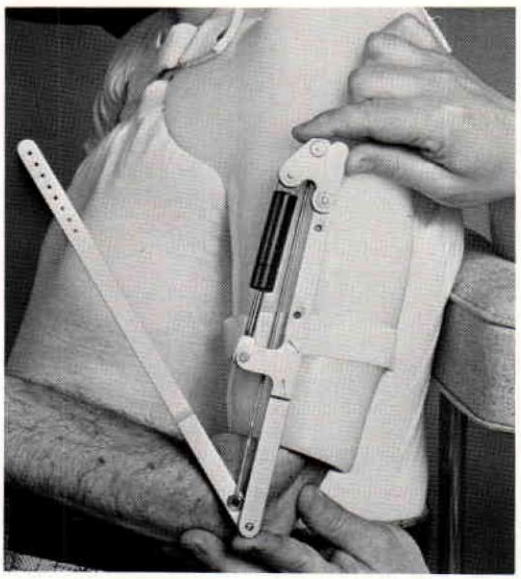

Fig. 11 Aligning the upper bar on the shoulder cap.

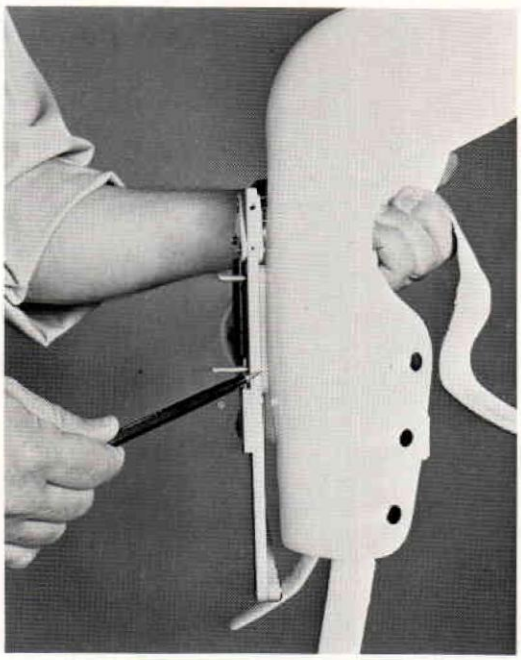

Fig. 12 A plastic spacer is placed between the upper bar and the plastic mold.

holding the plastic cover on the device. These two screw holes will be used to secure the device to the shoulder section.

*Hold the patient's elbow at 90 deg while performing the following procedure.* Align the orthotic joint with the anatomical elbow joint while simultaneously centering the upper section on the orthosis so that it bisects the upper arm (Fig. 11). The orthosis should be perpendicular to the floor. Mark the two holes while the orthosis is held in this position. Remove the shoulder cap and drill through these two marks with a #11 drill. Re-drill the two holes in the upper section of the orthosis with a #21 drill. Thread the holes with a 10-32 UNC tap. Using two 10-32 by 1-in. flathead screws, secure the orthosis to the shoulder cap, placing the screws from the inside portion of the arm out into the upper arm of the orthosis. Do not cut the screws that protrude from the orthosis, since they will be used to hold the cover in place when the orthosis is finished. It may be necessary to place a 1/4 to 3/16-in. plastic spacer behind the upper bar, to allow the moving arm to function without interference on the plastic of the upper arm (Fig. 12).

Place the shoulder cap and wrist cuff on the patient, and secure all straps. Position the patient's elbow at 90 deg and extend the forearm bar until it bisects the wrist cuff (Fig. 13). Exercise care at this point, since the cylinder is now activated and will pull the bar back into flexion. Mark the position of the bar on the wrist cuff. Remove the entire orthosis and drill two attachment holes with a #28 drill. Rivet the wrist cuff to the bar with a #12 copper rivet. Two rivets should be used to hold the wrist cuff in place due to the force generated by the system.

Place the entire unit on the patient, shoulder cap first, and secure the cross-chest and upper-arm straps. Flex the patient's elbow to 90 deg or greater to attach the wrist cuff to the patient's forearm. Open the wrist section, slip the patient's wrist into place, and secure the Velcro straps. Ensure that the anatomical elbow and mechanical joint are aligned properly.

At this point, check the fit of the lower bar near the elbow. The bar should fit near the joint and skin, while not creating pressure. Adjustments can be accomplished either by changing the thickness of the plastic spacer beneath the upper section of the orthosis, or by shaping the lower section to free the elbow joint. Check the same area while the patient flexes and extends the elbow. Adequate space should be available around the elbow to allow flexion and extension without pinching, and the orthotic joint should not protrude.

When the patient begins to flex and extend the orthosis, he or she should be able to accomplish this task effortlessly. Observe whether the orthosis is lifting the

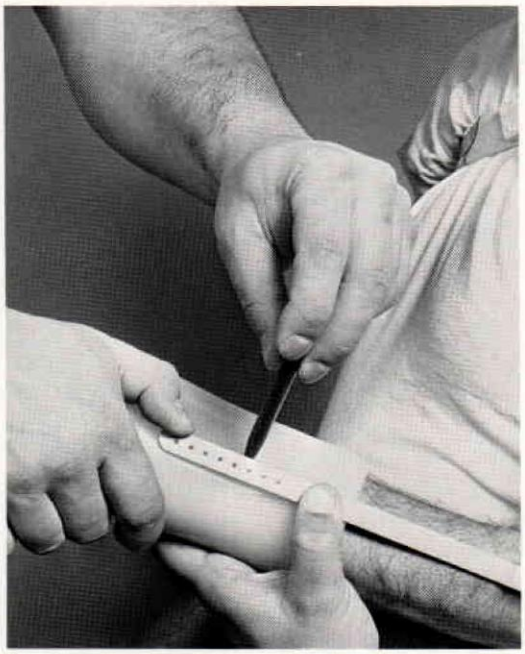

Fig. 13 Marking the lower bar on the wrist cuff.

Fig. 14. Completed orthosis.

arm at this point, since the cylinder may be either too strong or too weak. Instructions for changing the cylinder are given in an appendix to this article. If there are no problems, replace the plastic cover by using the two 10-32 UNC screws protruding from the upper bar of the orthosis. These screws should not protrude beyond the surface of the plastic cover. The completed orthosis is shown in Figure 14.

After all the adjustments have been accomplished, instruct the patient how to use the device. As with most other orthotic devices, patients need to build up a tolerance to it. Patients should begin using the device for an hour at a time and gradually increase to a full day over a two-week period. Generally, any pressure or irritations caused by the shoulder cap or wrist cuff after one hour or more of use indicates that further adjustment is required.

Patients should be seen after a period of two to three weeks to ensure that no problems exist due to fit or the forces applied. Never provide a patient with a cylinder that produces a force greater than the strength of his or her triceps.

The VAPC thus far has fitted three patients with this system: one polio patient, one patient with a brachial plexus avulsion (C5-C6), and one patient with a neurological disorder. Two of these patients have bilateral involvement, but were fitted on only one side. The patient with the brachial plexus injury has been using the system for over a year and half, exhibiting improved range of motion at the elbow and increased strength in the triceps.

Figures 15 through 18 show the functional arm orthosis on a patient at various degrees of flexion and extension and

Fig. 15. Patient standing, arm fully extended—lateral view.

shows the cosmetic value of the system.

The development of this system has led into an investigation on the possible use of non-linear systems in other orthotic and prosthetic applications.

A program for evaluation of the elbow orthosis is planned. Orthotists interested in participating in an evaluation program should contact the senior author.

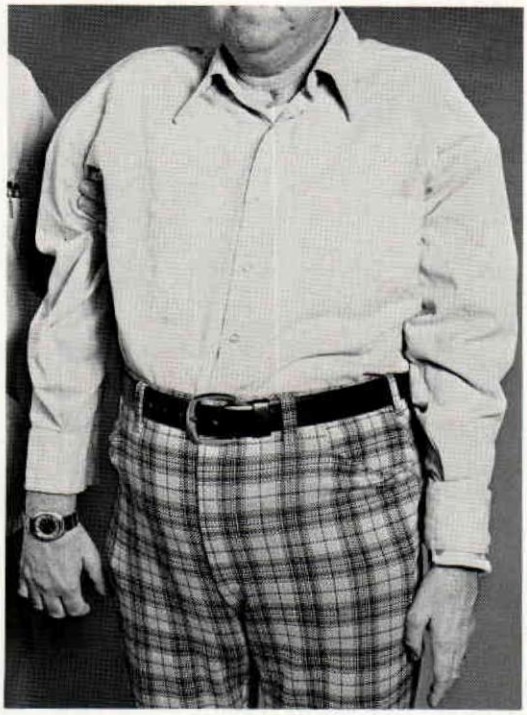

Fig. 16. Patient standing, arm fully extended—anterior view.

## Acknowledgments

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### Footnotes

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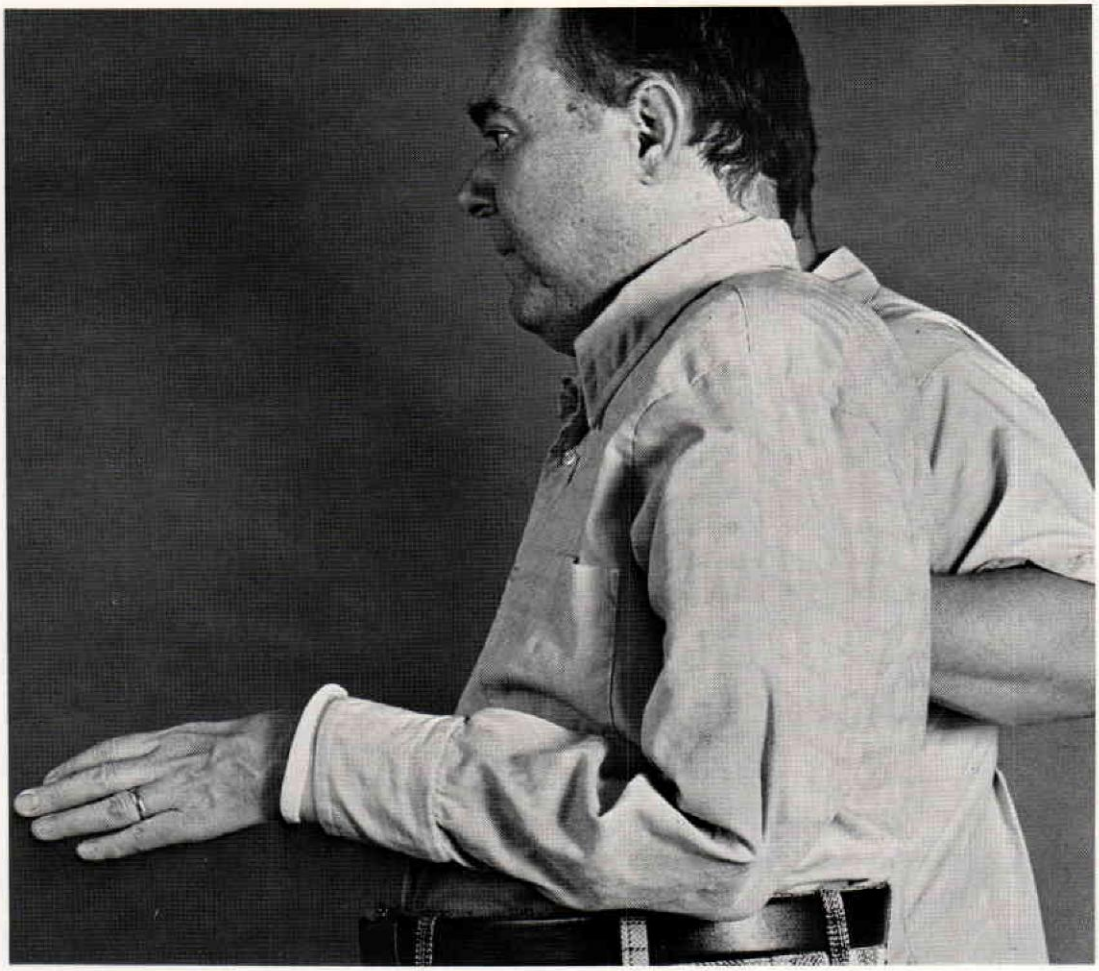

Fig. 17. Patient's elbow flexed to 90 deg—lateral view.

## Appendix

*How To Change the Cylinder*

The cylinder can be changed either before or after fitting the patient with the orthosis. To change the cylinder, proceed as follows, and refer to Figure A for all required procedural steps:

1. Remove unit from shoulder cap by removing two 10-32 screws. Remove the plastic cover. Remove set screw shown in Figure A,4.

2. Secure upper bar (Figure A,10) in a vise. A vise with smooth jaws is preferred to prevent marking of the aluminum bar.

3. Either retract adjustment screw (Figure A, 2,7, and 12) until screw head is flush with inner surface of bar or remove screw completely.

4. Extend lower bar to expose upper portion of upper bar. This bar must be held down until cylinder pressure is released, otherwise it will flex.

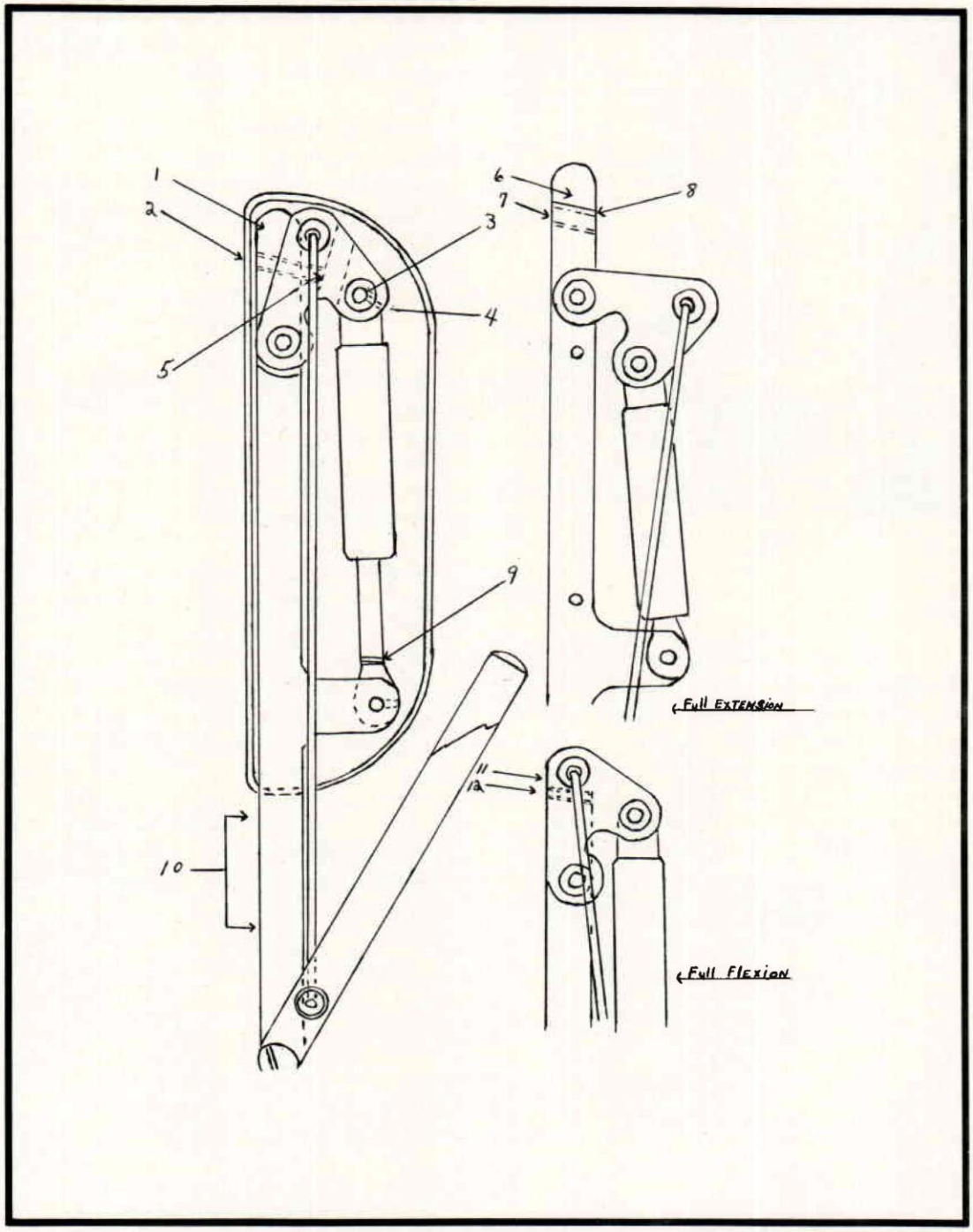


Fig. A. Cylinder locations: **1** & **6** – Excessive material that must be removed; **2, 7** & **12** – Adjustment screws; **3** – Pin used to secure cylinder in place; **4** – Set screw used to secure bushings in place; **5** – Adjustment screw used to maintain cylinder pressure; **8** – 3/32-in. space that exists between cut and set screw; **9** – Lower part of cylinder, which is unscrewed; **10** – Area used to secure cylinder to a vise; **11** – Area where excess material has been removed to allow the cylinder to extend fully.

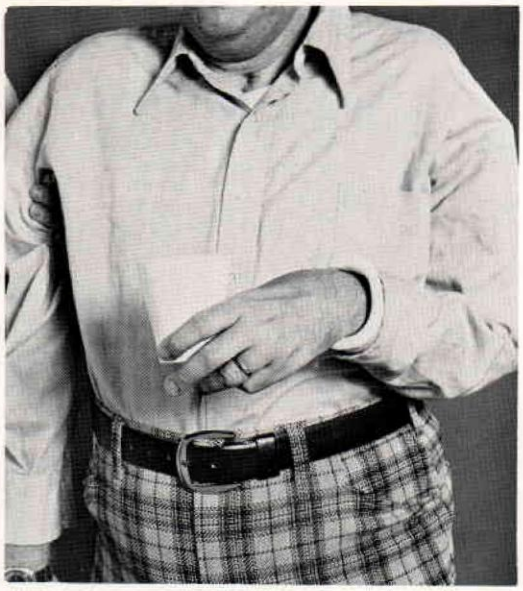

Fig. 18. Patient's elbow flexed to 90 deg—anterior view.

5. Mark top section (Figure A,8) just above adjustment screw. About 1/32 in. of bar should be left after removing excess material. This is sufficient to hold adjustment screw. Sand all edges smooth.

6. Allow lower section to flex back as far as possible, to allow cylinder to extend to its full length. Using 5/32-in. drift pin, lightly tap pin (Figure A,3) out while securing the body of the cylinder in place. Exercise care to avoid damage to bearings securing unit in place.

7. After removing pin (Fig. A,3), slide upper portion of cylinder out of its slot. Unscrew lower portion (Figure A,9) of cylinder from its bracket. If difficulty is encountered in unscrewing cylinder, use smooth jawed pliers or vise to loosen cylinder. Do not mark or bend cylinder rod, as this would impair its function.

8. Once cylinder is removed, install new cylinder. (*Note:* Before installing new cylinder, check upper sections of old and new cylinder to ensure that they are identical. Some cylinders have been sanded to fit into upper slot).

9. If both cylinders are identical, replace new cylinder by reversing above removal procedure.

10. Once cylinder is in place, set adjustment screw to apply a slight tension on cylinder. Work unit by hand several times to ensure proper operation. Replace unit on shoulder cap and refit patient to ensure that pressures are not excessive. (*NOTE:* Ensure that all filings are removed; clean and lubricate system as needed.)

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# A Prosthesis for Very Short Below-Knee Stumps

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Amputation surgery is improving constantly, and it is our impression, based on limited statistics, that the ratio of below-knee to above-knee amputees has increased significantly during the last few years.

The advantages of amputation below the knee versus amputation above the knee are self-evident when gait patterns of both types of patients are compared. From the physiological and mechanical aspects, the knee joint provides the activation of the prosthesis and a "feedback" signals source. In any level of amputation below the knee a certain amount of the musculature and most of the proprio receptors are preserved. However, the mechanical solution for the prosthetic replacement becomes more complicated with the reduction of stump length (1). The transfer of power via the stump-prosthesis interface is almost impossible with very short stumps when conventional fitting techniques are used. The proprioception however is almost fully retained, and this, in itself, is important enough to justify very short BK amputations.

In the present work, the research and development of a BK prosthesis for very short stumps was carried out with the aid of a bilateral amputee. The patient, a war veteran, was amputated bilaterally at equal level, resulting in two 5 cm-long stumps (Figs. 1 and 2). Assuming that for walking purposes a socket longer than the stump can be provided, three different solutions were explored. The major obstacle in the use of such a socket is painful compression of the posterior wall against the hamstrings during knee flexion. This was compensated for in the various solutions. The option of using a thigh corset with side bars was ruled out since the eccentricity of the axis of the side bars in relation to the natural knee centrode together with the geometry of the stump would result in a very limited knee function.

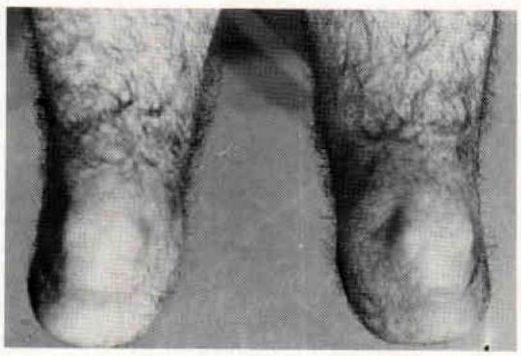

Fig. 1. Anterior view of stumps of the patient.

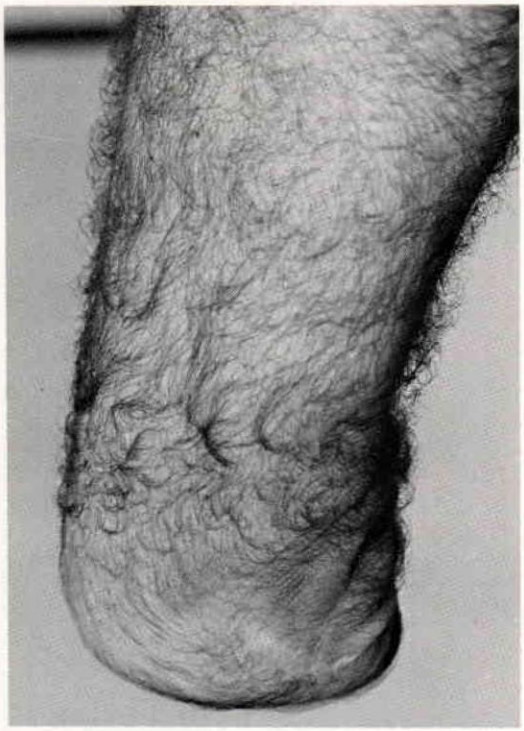

Fig. 2. Lateral view of right stump of the patient.

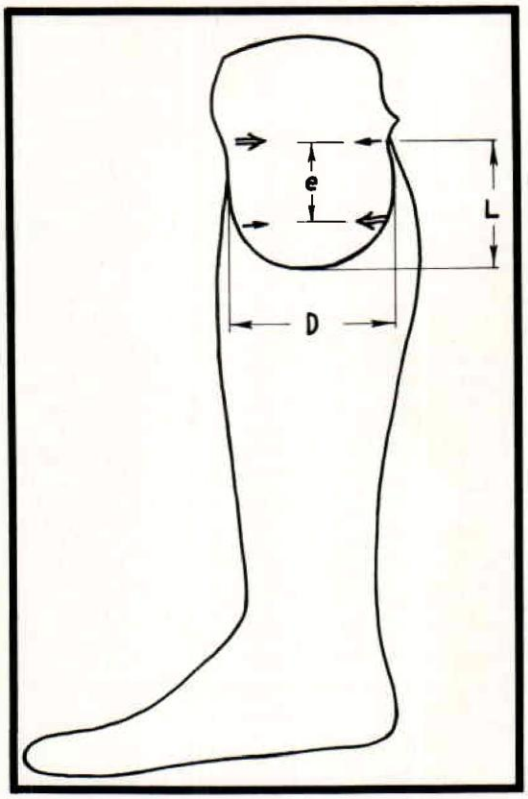


Fig. 3. Geometry of the socket for a short below-knee stump. L—stump length; D—stump width; e—eccentricity of the forces.

## Problem Definition

The design of the conventional patellar tendon bearing (PTB) prosthesis is based on specialized regions of load transfer. The vertical load is carried mainly on the impression of the socket in the region of the patellar tendon. The regions on both sides of the tibial crest, the distal posterior surface, and the poplitea provide additional support in standing and ambulation. When the stump is short it becomes spherical and the moments transfer mechanism becomes quite inefficient (Fig. 3). In order to reduce the sphericity of the socket a supracondylar suspension type of PTB socket can be used with an extra long posterior wall. The posterior wall will then limit the ability of the knee to flex due to its projection against the distal portion of the hamstrings. However, with an extra extension of the posterior wall of about 5 cm the knee is still capable of flexing to 30 or 40 degrees. This amount of flexion is nearly satisfactory for level walking but may cause severe inconvenience in walking up and down inclined surfaces. For steep inclines, stair climbing, and sitting this type of arrangement is unsatisfactory. It was assumed however that a dynamically variable socket wall could provide satisfactory compensation for excessive flexion.

Initially, the sitting position seemed to be the most troublesome but later this proved to be only part of the problem. It was assumed that the stretched hamstring

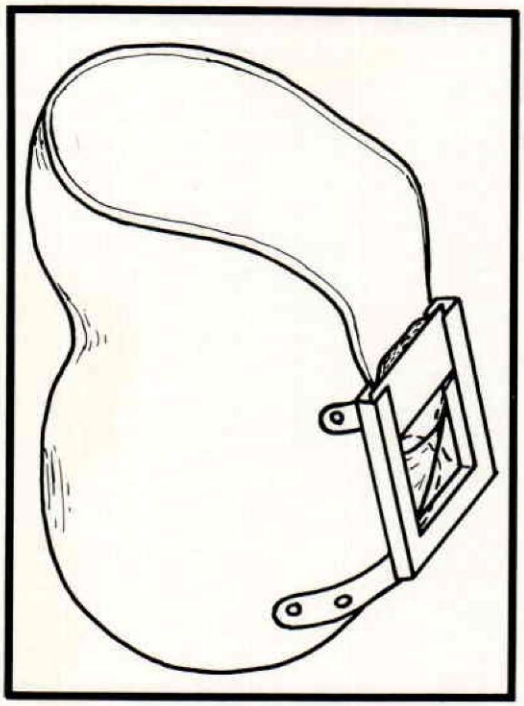

Fig. 4. Schematic diagram of a sliding posterior flap arrangement.

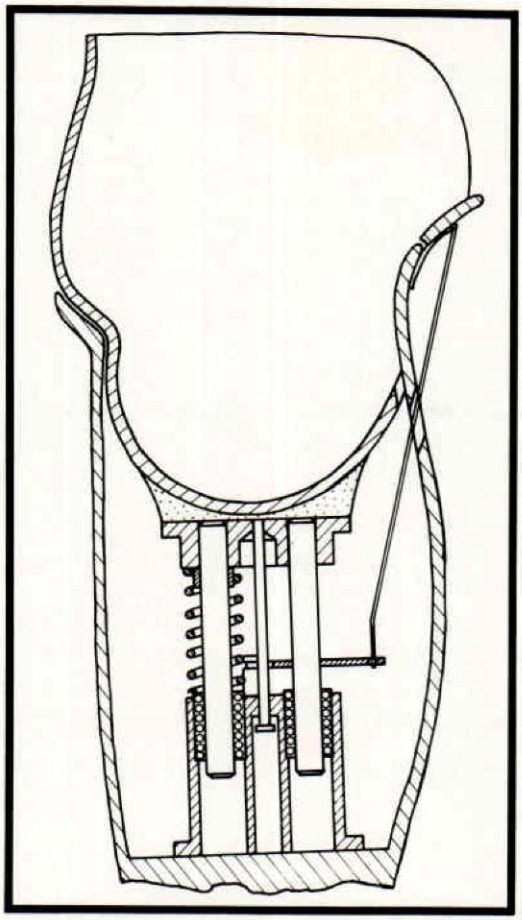

Fig. 5. Schematic diagram of a double socket arrangement.

during excessive knee flexion forms a triangular wedge pressing obliquely against the edge of the prosthetic wall. This pressure could be relieved by providing a translatory movement of the upper section of the wall distally from the hamstrings. It was found later that the real source of the problem was a combined wedging and bulging of the soft tissue in the popliteal region during flexion.

From the point of view of efficiency of moments transfer to the prosthesis during ambulation, a long posterior wall is superior. However, when an adjustable wall is considered, the length is limited by the obliquity of the compression of the soft tissues. Three alternative solutions to the problem were therefore outlined:

1. A sliding posterior wall with limited translation of 25 mm (Fig. 4).

2. A double socket arrangement (one within the other) with relative axial movement between them. The posterior support being provided by the outer socket while the rest of the support (anterior and mediolateral) is provided by the inner socket (Fig. 5). When excessive flexion occurs, the inner socket is unlocked automatically from the outer socket, thus relieving the pressure.

3. A stabilized socket attached above a specially designed four-bar mechanism (Fig. 6). At a predetermined degree of

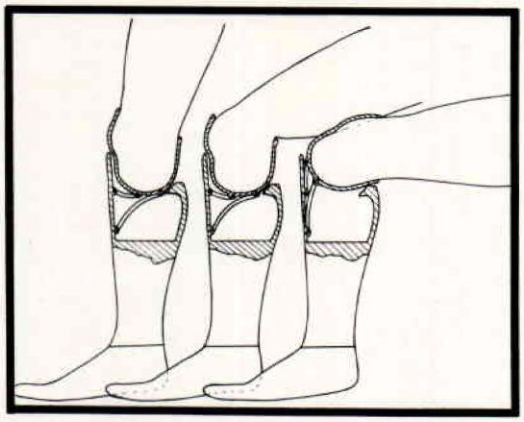

Fig. 6. Schematic diagram of a stabilized rotatory socket arrangement.

knee flexion the socket unlocks and rotates with respect to the shank guided by the four-bar linkage. In this way the amputee can sit with his anatomical knee extended while the shank is vertical. Because the stumps are very short the cosmetic appearance arising from this arrangement is not disturbing.

The advantage of the second and third solutions over the first is the ability to use an extra large extension of the socket wall; in the order of 50 mm and more. The disadvantages are in the technical complexity of these solutions and some functional restrictions.

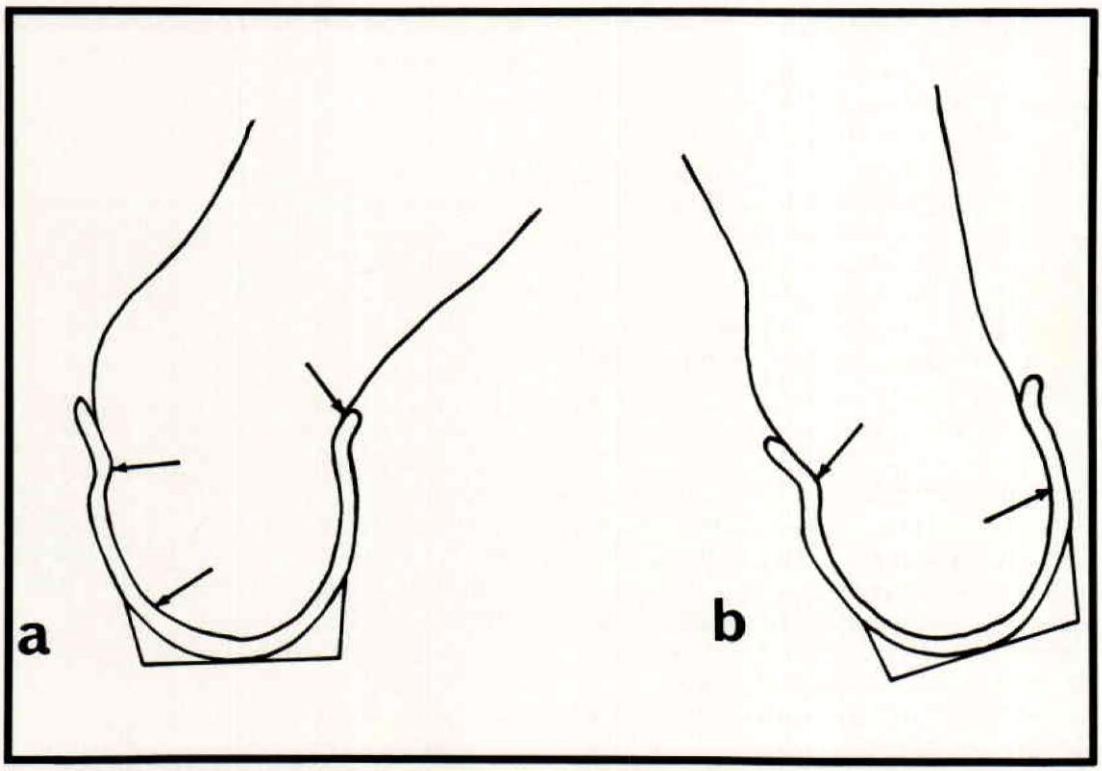


Fig. 7. Schematic Illustration of the concentrated force resultants applied on the socket wall by the stump; 7a relates to flexion under load; 7b relates to active pushing.

## The Mechanical Solutions

### *Adjustable Posterior Wall*

Figure 7 describes the forces acting on the proximal part of the posterior socket wall. Figure 7a relates to flexion of the knee when the major forces acting on this section are those applied by the hamstrings and the bulging of the soft tissue. Figure 7b relates to the push-off phase of ambulation.

It is evident from the orientation of the resultant force vector that a linearly sliding posterior flap such as the one described in Figure 4 will be subjected to various locking effects. Such an arrangement was tested and failed to produce the desired results. It was therefore decided to produce semi-linear displacement by rotating the flap about hinges which were positioned in the civinity of the center line of the socket. The socket posterior flap was cut from the socket itself and was inclined slightly obliquely to the fixed wall. The hinges and the guiding bars were positioned on the line normal to the flap, in order that the forces and the displacement be compatible. Pushing action of the stump ensured full recovery of the socket length, and knee flexion pushed the socket wall distally and posteriorly. Location of the hinge and geometry of the wall is illustrated in Figure 8. The final socket and prosthesis are illustrated in Figure 9.

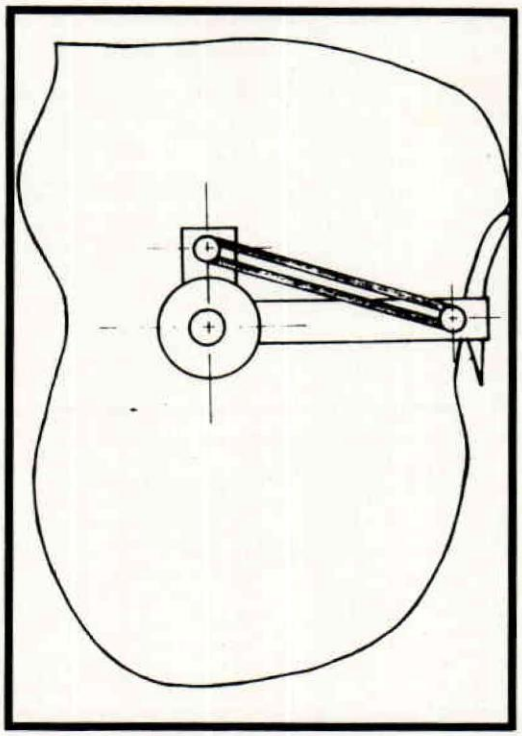

Fig. 8. Geometry of the rotatory flap arrangement.

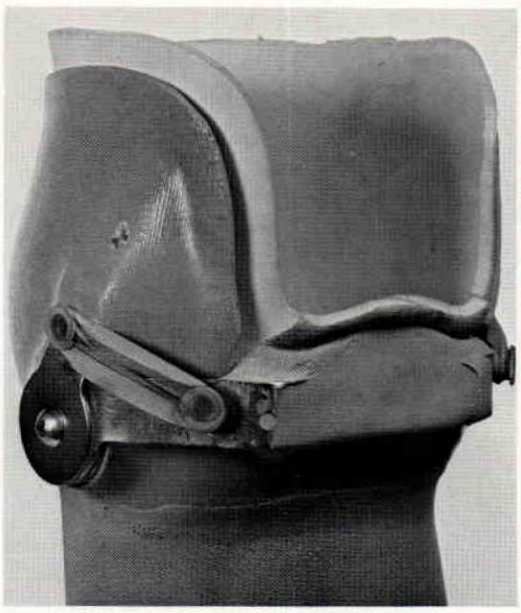

Fig. 9. The rotatory flap socket as built for trials.

### *Double Socket Arrangement*

A PTB socket, conventional in every respect except for an extended posterior wall and supracondylar suspension, was made. An extension to the socket imitating the layout of a section of the leg was made of foamed polyester. A second extended socket was then produced by employing the ordinary casting procedure and using the first socket as a casting form. When the polyester was removed

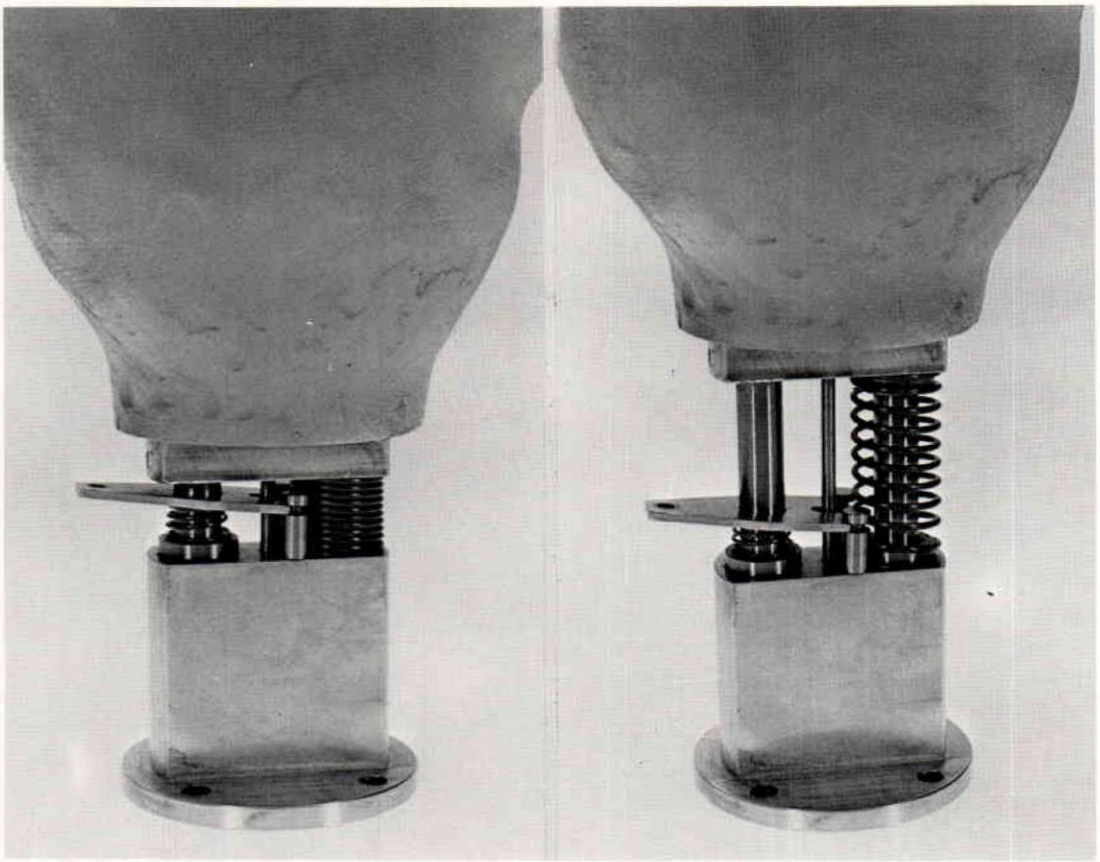

Fig. 10. A linear guiding mechanism with a self-locking arrangement.

the two sockets fitted exactly, one inside the other with a space between the distal ends. A section of the posterior wall was cut from the inner socket and glued to the corresponding part of the outer socket. A linear guiding mechanism with a self-locking arrangement was fitted in the space between the two sockets (Fig. 10). The mechanism is normally locked and the two sockets are held together tightly. When the unlocking lever is compressed, the inner socket is ejected with the aid of a compression spring up to a stroke of 40 mm. The lever is compressed directly by the action of the hamstrings via a connecting rod. The ejection of the inner socket exposes the recess in the posterior wall and the pressure on the hamstrings is relieved. This arrangement has the characteristics of a simple position servo, and the inner socket will continue to come out only as long as pressure is applied on the hamstring. It will therefore be normally exposed only to a fraction of its stroke which allows bending of the knee.

This mechanism allowed, therefore, adequate knee flexion during gait and full flexion during sitting. Additionally, it supported the stump sufficiently to provide adequate stability during ambulation.

*Rotating Socket Assembly*

The rotating socket design was meant primarily for sitting. A four-bar mechanism was synthesized to produce the

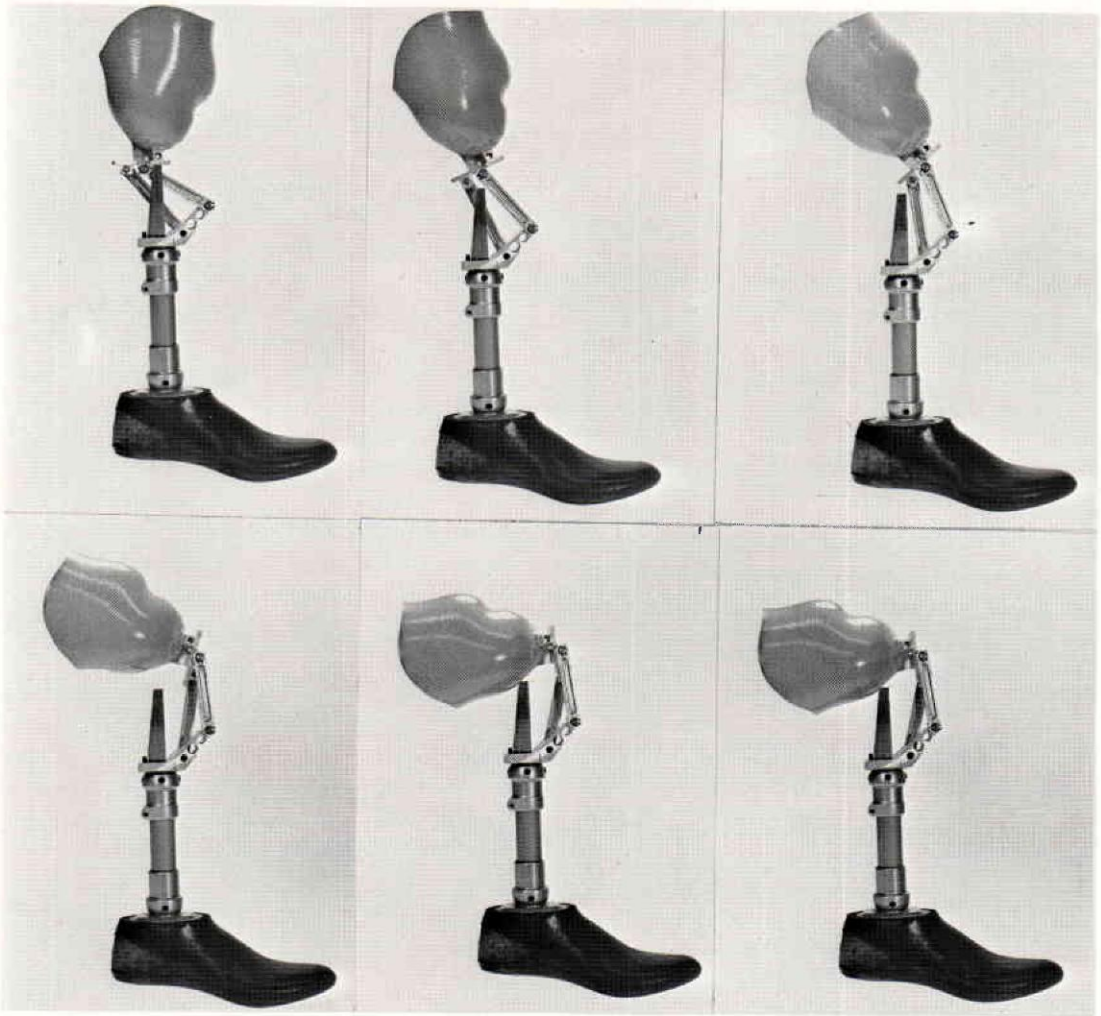

Fig. 11. A prosthesis incorporating the rotatory socket and a four-bar mechanism.

movement as specified (Fig. 6). The linkage was determined by performing a computer analysis of the path of the socket. The characteristics of a whole range of mechanisms were investigated and the optimal solution was selected. The linkage was assembled on a standard Otto Bock modular shank as illustrated in Figure 11. It can be seen from the figure that in the normal standing position the instantaneous center of rotation of the socket (the point of intersection of the two moving bars) is posterior to the center line of the prosthesis.

The initiation of flexion in the mechanism is accompanied by elevation of the socket, an energy consuming action that stabilizes the knee under load. In other words, when the mechanism is flexed slightly and a load is applied to the socket the mechanism will rotate toward full extension.

The rotating socket mechanism does not require an extension lock, and a simple elastic strap can be used to keep it in the extended position.

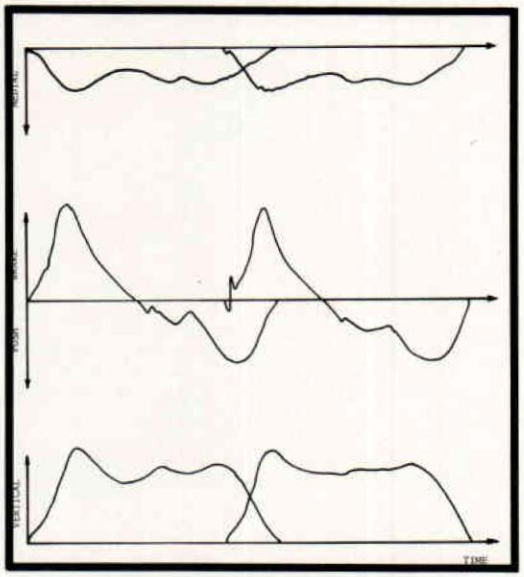

Fig. 12. Representative results of ground reaction forces during walking by a bilateral below-knee amputee using prostheses with the rotatory mechanism.

### Evaluation Procedure and Results

Altogether five sockets were produced. One socket was fitted with a sliding posterior wall. This solution was found inadequate because of its failure to produce smooth sliding under load. The mechanism was also rather bulky. Two other sockets were fitted with a hinged posterior flap. The recovering moment was provided by elastic bands as described in Figure 8. The sockets were assembled on Otto Bock modular shank units and the prostheses were supplied to the bilateral amputee for use outside the laboratory. During a routine checkup the patient was examined by the medical team and his gait was evaluated with the aid of a television system and force plate dynamometers.

The amputee expressed full satisfaction with the performance of the prostheses. This was also evident from his gait. The adjustable wall of the sockets could be seen moving during walking as well as during stair climbing and sitting.

The ground force characteristics as obtained from the "Kistler" force plate dynamometers during one routine check are illustrated in Figure 12.

The degree of symmetry of the forces of both legs is within the range of normal walking. This was expected since the patient is a symmetrical bilateral amputee. From the A-P force characteristics it can be seen that the left leg is more active in braking and less active in pushing than the right leg. The total impulse is balanced and the activity of both legs as assessed by impulse measurements is equal. There is a certain degree of A-P instability at mid-stance of both legs which is expressed by the "slowing down" of the force development. This is a result of the degree of "slackness" when the supporting surfaces of the socket change roles between "braking" and "pushing".

The mediolateral force characteristics are balanced with respect to impulses. The medial force is rather high, a characteristic typical of wide-base gaits. There is no component of lateral force, and during the whole cycle the forces act only medially. This is also a feature resulting from a broad-base gait and indicates a tendency of the amputee not to cause lateral instability by alternating moments on the stump.

The features however are very good compared to normal gait and indicate excellent control during most phases of the walk cycle.

Two double socket mechanisms were produced and assembled on Otto Bock shank units. The prostheses were tried on the patient in the laboratory only. As fair as gait stability and control were considered this arrangement was very good. However this solution which is practically an inversion of the previous one failed to produce the desired results when knee flexion under load took place. This was especially severe in stair climbing. The mechanism itself however functioned sat-

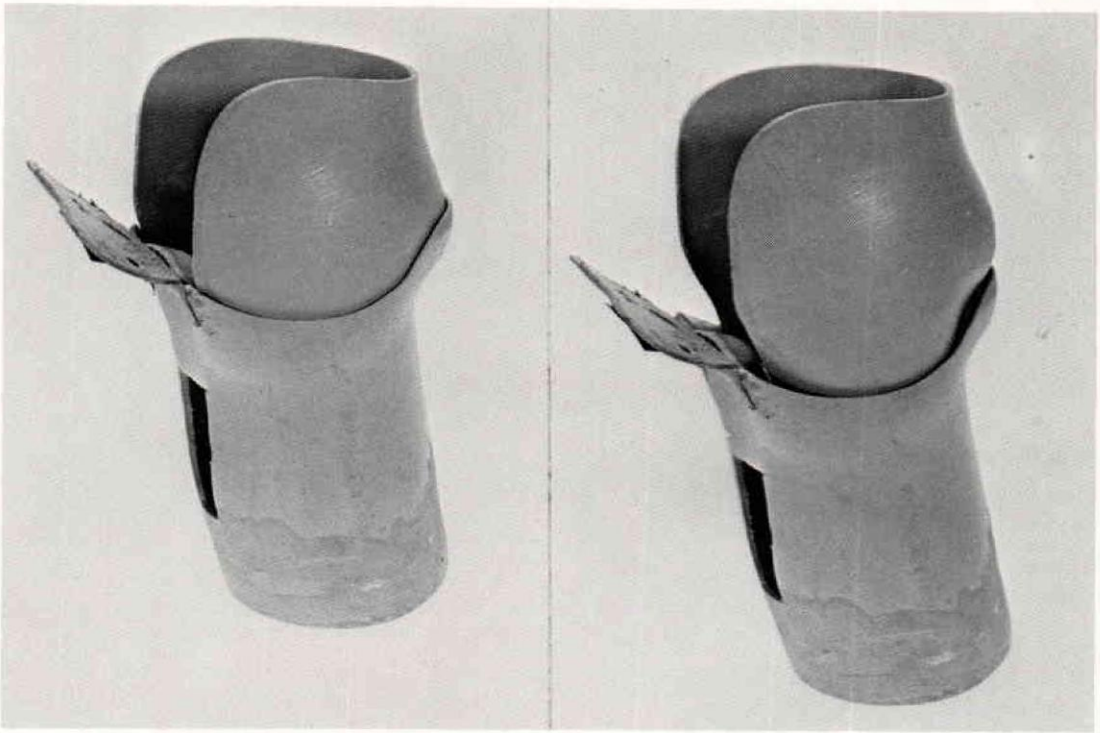

Fig. 13. The double socket arrangement in the compressed and ejected positions.

isfactorily and conformed with the design criteria. Figure 13 shows the socket in compressed and ejected positions.

One socket was fitted with a four-bar mechanism and assembled on the Otto Bock shank unit (Figure 11). This arrangement was in doubt from the early stages of the evaluation of the other prostheses. The doubt arose from the change of criteria during the examinations. The mechanism however was developed in order to investigate its kinetic properties and its potential use in more severe cases of unilateral BK amputations. This mechanism which differed in its concept from the four-bar knee mechanism is worth exploring further. Its potential to serve as a polycentric stabilized knee is of great interest. The two major difficulties were associated with the fact that the four-bar unit acted as a polycentric toggle mechanism. The increased stabilizing moments of the mechanism in the early stages of flexion were good for level walking but inhibited the ability to initiate flexion for other purposes. The second inhibiting factor was the fact that the prosthesis was used for a bilateral amputee. Initiation of uncontrollable flexion in both knees could be hazardous. This solution however could be good for unilateral ultra short stump amputation when the good leg is capable of controlling the loadbearing required of the prosthesis.

## Clinical Follow-up and the Patient's Subjective View

During a period of nine months the patient was invited to the clinic periodically for examination by the medical staff. In each meeting objective gait examinations

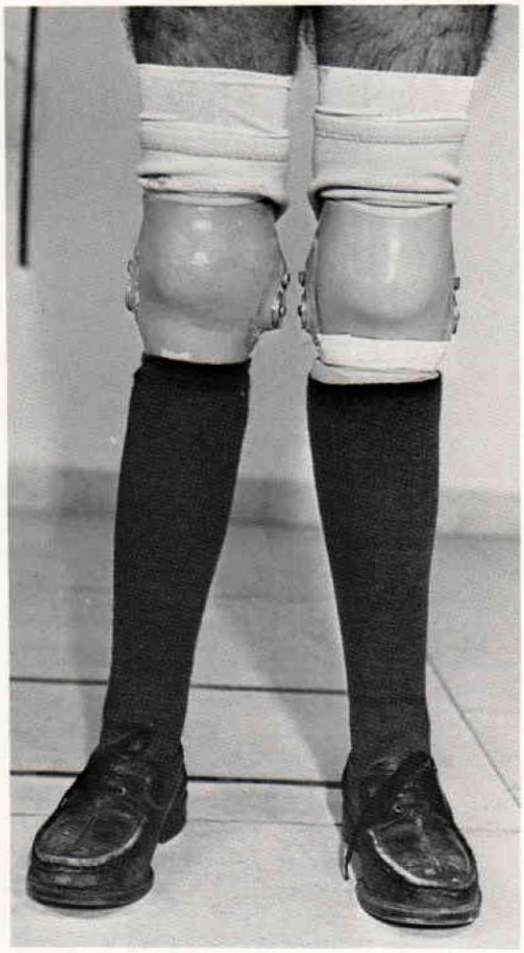

Fig. 14. Anterior view of the prostheses with the rotatory flap.

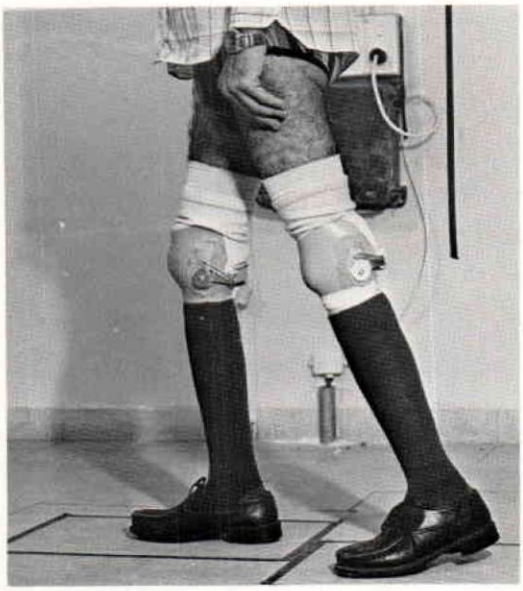

Fig. 15. Collection of data concerning the use of the prostheses with the rotatory flap.

were also carried out. The gait features were almost identical in all the examinations as described in Figure 12. Occasionally realignment of the prostheses caused slight alterations to the force records but this is outside the scope of the present work.

Medically the examinations gave excellent results. All the pressure sores and erosion of soft tissue in the stump, especially in the hamstrings and the popliteal region disappeared. A general weakness of which the patient complained while using his previous prostheses also disappeared presumably due to reduced energy requirements and reduced mental strain. A certain degree of excessive valgus was detected in one of the knee joints of the patient which seems to have been caused by the inadequate, unstable prosthesis worn previously.

The patient was satisfied fully and insisted on demonstrating to the staff his ability to control the limbs in accelerated gait, stair climbing and ladder climbing. So far, after a period of a year, the patient has not found it necessary to visit the clinic at his own initiative or to complain about faulty action or mechanical breakdowns.

## Acknowledgments

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cal Engineering, the Biomechanics Department of Loewenstein Rehabilitation Hospital, and "Gapim" Ltd. Israel Orthopaedic Industries.

The authors wish to express their sincere gratitude to Dr. Kimhi who coordinated the research and to Mr. A. Ben Artzi who helped with the evaluation of the prostheses. The contributions of the technical and administrative staff of all three institutions are gratefully acknowledged.

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## Footnotes

[1]Julius Silver Institute of Biomedical Engineering Sciences, Technion-Israel Institute of Technology, Haifa, and Biomechanics Department, Loewenstein Rehabilitation Hospital, Raanana.

[2]Loewenstein Rehabilitation Hospital, Raanana.

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# Why Most Patents Are Invalid

THOMAS W. COLE[1]

Other than the "trade secret," the patent is the only way for a corporation or independent inventor to protect his invention from being stolen by others. Yet, about 60 percent of all the patents sued upon in the federal courts are held invalid, and hence unenforceable. Why are the vast majority of corporations and inventors finding it impossible to enforce their patent rights in a court of law? What can the corporation or independent inventor do to obtain court enforceable patent rights? This article will attempt to answer both of these questions.

In order to understand the answer to the first question as to why most patents are invalid, some minimum amount of background is necessary. Specifically, one must first know both what a patent is, as well as the legal process for obtaining one.

Basically, it is a document issued by the U.S. Patent and Trademark Office which grants to its owner a seventeen year monopoly on the invention described therein. The patent document includes one or more printed sheets of specification and drawings which describe the invention. The law requires that the specification describe the invention in specific enough detail "so . . . as to enable any person skilled in the art to which [the invention] pertains. . . . to make and use the same, . . ."[2] The specification is concluded by one or more definitions of the invention, called "claims." Legally speaking, a patent is a seventeen year right to exclude others from making, using, or selling the "claimed" invention. Thus the claims are the heart and soul of the patent.

To better illuminate just exactly what a claim is, let us suppose that Thomas Edison has just applied for a patent on his incandescent electric light bulb. As you might recall, Edison discovered the first commercially practical light bulb by passing an electric current through a *carbon* filament in a high-vacuum glass bulb. Prior to this discovery, most everyone had been futilely experimenting with *metallic* filaments which glowed for a while and then melted. Following the specification, Edison's patent attorney might have defined or claimed Edison's invention in the following terms: "An electric incandescent lamp including a carbonaceous filament enclosed in a glass bulb, and means for passing an electric current through the filament."[3]

So much for what a patent is. Now let's look at the legal process of obtaining a patent.

The process begins when an inventor approaches a patent attorney with what he believes to be an invention. At this juncture, the patent attorney usually advises the client to have a "preliminary search" made of the "prior art" (i.e., the

records of all earlier patents and technical literature) on file at the U.S. Patent and Trademark Office. The purpose of this search is to determine whether or not the inventor in fact actually made a patentable invention. The purportedly new features of the invention are compared to the results of the prior art search. If, in the attorney's opinion, the invention is patentable in view of the prior art, a patent application, complete with specification and claims, is filed in the U.S. Patent and Trademark Office.

In the next step of the process, the application is examined by a federal employee called a Patent Examiner who carefully reads the specification and claims of the application. The primary function of the Patent Examiner is to decide whether or not the claimed invention is legally patentable in view of the prior art. He does this by searching the pertinent prior art, and carefully comparing the claimed invention with the best prior art he finds.

In making the decision as to whether or not the claimed invention is patentable, the Patent Examiner, among other considerations, applies two legal toests to the claims. First, he checks to see if the claimed invention is identical to any of the inventions disclosed in the prior art.[4] In other words, the Examiner checks to see if the invention has been invented before. If the invention is not so disclosed, he applies the second (and more difficult) test of patentability, and determines whether, in his opinion, the claimed invention would be "obvious . . . to a person of ordinary skill in the [pertinent] art . . ."[5]

If, in the Examiner's opinion, the invention defined by the claims is either "disclosed" or "obvious" in view of the prior art he finds, he "rejects" the patent claims and sends a copy of his opinion to the patent attorney. The patent attorney then normally "amends" the claims of the original application by rewriting the claims at the end of the specification so that they define the invention in more narrow or limited terms. The attorney then submits the amended application back to the Patent Office, and the cycle may be repeated.

Finally, the attorney and the Patent Examiner usually arrive at some sort of agreement as to how broad or narrow the claims may define the invention without the prior art either disclosing or rendering obvious the claimed invention. To cast some light on this step of the process, let's follow up on our electric light bulb example. As you recall, Edison, in our semi-fictitious example, claimed "An electric incandescent lamp including a carbonaceous filament enclosed in a glass bulb . . .". Let's suppose that the Examiner searches the prior art on file at the U.S. Patent and Trademark Office and finds a reference disclosing an electric lamp which utilizes a carbonaceous filament in a glass bulb filled with an inert gas. The Examiner would "reject" Edison's claim as identically disclosed by the prior art. In response to such a rejection, Edison's patent attorney might *amend* (or narrow) the claim to read "An electric incandescent lamp including a carbonaceous filament in a *substantially evacuated* glass bulb . . ." The Examiner, finding no references in the prior art which either disclose or render obvious the use of carbonaceous filaments in substantially evacuated glass bulbs as specifically defined by the claim, *allows* the application, and a patent is issued to Edison, which gives him a 17 year right to exclude others from making, using or selling his carbon filament, substantially evacuated light bulb.

We are now in a position to understand why most patents are invalid. The short answer is: Most patents are invalid because the inventions claimed in them are either disclosed by or rendered "obvious"

by the prior art, and therefore fail one or both of the legal tests for patentability that we discussed earlier. But hold on! Haven't the patent attorney and the Examiner both searched the prior art on file in the U.S. Patent and Trademark Office and found the "best", or most pertinent prior art? Unfortunately, the answer to this question, more often than not, is "no". In fact, it has been estimated that "uncited prior art" (i.e., pertinent prior art *not* found by either the patent attorney or Patent Examiner, but later discovered during an infringement trial) figures into the result of about 72 percent of all the court holdings of patent invalidity![6]

To illustrate exactly how this works, let us suppose that Edison discovers that a corporation by the name of the Electric Pirate Company is manufacturing and selling incandescent light bulbs identical to the one he patented. Let us further suppose that Edison and his patent attorney bring a law suit against the Electric Pirate Company for patent infringement.[7]

Prior to the trial, the patent attorney for the Electric Pirate Company knows that he stands a good chance of successfully defending his client at the infringement trial if he can prove that the Patent Examiner did *not* consider the "best" prior art when he made his final determination that the claimed invention was neither disclosed nor rendered obvious by the prior art. So he rolls up his sleeves and makes a diligent, *exhaustive* search of *all* the prior art in the U.S. Patent Office and anywhere else he can think of. And lo and behold! . . . he finds a reference disclosing an incandescent electric light having a carbonaceous filament in a *partially* evacuated glass bulb! Later, at the trial, the judge compares this new, better prior art with the claimed invention (i.e. "An electric incandescent lamp including a carbonaceous filament in a *substantially* evacuated glass bulb . . ."), and re-applies the two tests of patentability discussed earlier. Unsurprisingly, the judge rules that the claimed invention would be "obvious . . . to a person of ordinary skill in the [electric lighting] art . . .",[8] and is therefore invalid. The Electric Pirate Company wins, and yet another patent becomes part of the sixty percent invalid majority, all because the attorney and the Patent Examiner failed to *locate* "best" prior art.

Just why isn't the "best" prior art located by either the attorney or the patent examiner? In the case of the patent attorney, the answer may be summed up in one word—time. Most inventors do not expect to pay more than $250-$300 for a preliminary patentability search. Further, it is not unusual for a patent attorney to charge $50 an hour for searching the prior art at the U.S. Patent and Trademark Office and writing the report. The opinion and search report typically takes one hour to write. This often leaves the patent attorney with the formidable task of sifting out the few "best", or most pertinent prior art references from the hundreds or thousands of pertinent references on file in U.S. Patent and Trademark Office *in four or five hours!* Although the patent attorney uses such devices as the U.S. Patent Office Classification Manual to abridge his task, it is apparent that, at best, only a "spot check" search of the prior art may be made—and *not* an exhaustive or complete search.

As to why patent *Examiners* typically do not locate the *best* prior art, the answer may be summed up in the same word—time. As Judge Baldwin stated in the case of *Norton v. Curtis:*[9]

> "With the seemingly ever-increasing number of applications before it, the Patent Office has a tremendous burden. While being a

> fact-finding as well as an adjudicatory agency, it is *necessarily limited in the time permitted* to ascertain the facts necessary to adjudge the patentable merits of each application." [Emphasis added.]

Furthermore, the Examiner's rate of career advancement is largely dependent on what the Civil Service terms his "rate of disposals," i.e., how many patent applications he examines and acts on within a given period of time. The *validity* rate of the patents issuing from these patent applications makes *little* or *no* difference on the Examiner's career advancement. Although most Examiners are quite diligent in attempting to find the "best" prior art in the Patent Office when examining claims, is it any wonder that, under the time and incentive limitations they work under, they often overlook the "best" prior art?

Under normal circumstances, then, neither the patent attorney nor the Patent Examiner has the time to locate the "best" prior art on file in the Patent Office.

Further compounding the attorney and Examiner's time problem is the fact that the prior art on file at the Patent Office is *not* a complete record of *all* the prior art. Legally speaking, "prior art" includes *every* prior technical publication *in the world!* Thus, even if the attorney or the Examiner should spend the time to locate the "best" prior art on file at the Patent Office, there is always the chance that the resulting patent may later be invalidated in a federal court by an attorney who succeeds in finding a better piece of prior art among the millions of technical references that exist outside of the files of the Patent Office.

So what can an individual inventor or corporation do to obtain strong patent protection?

Obviously, the single most effective technique in obtaining strong, court enforceable patent protection is to make sure that the Examiner considers the "best" prior art during the prosecution of the patent application. Let's see how this can be accomplished.

Since, as we have previously indicated, the Examiner often cannot locate the best prior art within the time and incentive constraints imposed upon him, the applicant must either locate the "best" prior art himself, or have someone else find it for him.

For the prior art existing outside of the Patent Office, the inventor himself is often in the best position to locate references pertinent to his invention. A good place to start searching may be either the inventor's own personal library, or, if the inventor works in a corporation, the corporate technical library. From there the inventor might go to his local public library, or to the library of a university or technical institute.

If such personal searching is impractical, the inventor might consider hiring any one of a number of technical literature research services to perform such searching for him. Examples of such include the search service offered by the National Technical Information Service located at Springfield, Virginis, and the Dialog Service offered by the Lockheed Corporation of Palo Alto, California.

For the prior art existing *inside* the Patent Office, it is again possible for the inventor to make his own search inside the U.S. Patent and Trademark Office located in Crystal City, Virginia. Again, if personal searching is impractical, the inventor can authorize his patent attorney or other competent patent searcher to make a *diligent, exhaustive* search (as opposed to the "preliminary patentability search" discussed earlier) of *all* the pertinent prior art on file in the Patent Office.

Even though such a procedure would raise the *initial* cost of obtaining a patent by hundreds of dollars, it could save the

applicant thousands of dollars later on if he should ever attempt to enforce his patent in court against an infringer.

So much for patent applications which are either already pending in the Patent Office or about to be filed there. But what about patents that have already been issued? Is there any procedure whereby the validity of an existing patent may be strengthened? The answer, fortunately, is "yes". The law has long provided a procedure by which an existing patent may be "re-examined" by a Patent Examiner and "reissued" if found to be potentially invalid" . . . by reason of the patentee claiming more . . . than he had a right to claim in the patent . . ."[10] Thus, it is possible for the patentee to have his patent attorney and technical literature search service make an exhaustive search of the prior art to see whether or not the Examiner considered the "best" prior art when prosecuting the application. If the exhaustive search discloses that the Examiner did *not* consider the "best" prior art, it is then possible, pursuant to the "reissue" procedure, to resubmit the patent to the Patent Office with *amended* claims which redefine the invention in terms which are neither disclosed nor "obvious" in view of the newly found "better" prior art.

While the technique of performing an exhaustive prior art search either before or after the issuance of a patent application cannot *guarantee* that the courts will hold the resulting patent valid, it *can* enhance the chances of a patent surviving a court test. And enhanced chances are reason enough to utilize such a technique in an era where the courts are striking down six out of every ten patents brought before them.

**Footnotes**

[1]Patent Bar Registration No. 28, 290, Irons and Sears, 1785 Massachusetts Avenue, N.W., Washington, D.C. 20036. Phone (202) 466-5200.

[2]35 United States Code §112.

[3]Although Thomas A. Edison was in fact awarded U.S. Patent 223,898 on January 27, 1880 for his carbon filament light bulb, the claim language used throughout the examples in this article differs from the actual claim language used in the prosecution of this patent in order to more clearly illustrate the points of this article.

[4]35 United States Code §102.

[5]35 United States Code §103.

[6]Koenig, *Patent Invalidity: A Statistical and Substantive Analysis*, §5.05, page 5-49 (1976).

[7]Although Edison's U.S. patent number 223,898 was in fact subsequently involved in an infringement trial, the trial example given in this article is wholly fictitious.

[8]In actual fact, the federal courts held the invention claimed in Edison's original incandescent bulb patent to be valid. The language of the semifictitious claim used throughout this article is designed to illustrate how a patent obtained on a perfectly bona fide invention may later be held invalid by the courts when the best prior art is not considered by the U.S. Patent and Trademark Office prior to issuing the patent. Remember that Edison's actual discovery was that a practical incandescent light could be made by passing an electric current through a *carbonaceous filament in a high vacuum* bulb. However, in our semifictitious example Edison's patent attorney, actually *claimed* "An electric incandescent lamp including a carbonaceous filament in a *substantially evacuated* glass bulb . . ." in order to get the broadest patent protection possible. Because the *claimed* invention was somewhat broader than the *actual* invention, the resulting patent was vulnerable to being invalidated by the prior art, even though the inventor in this case actually produced a patentable invention.

[9]433 F.2d 779, 794 (CCPA 1970).

[10]35 United States Code §251.

Orthotics and Prosthetics, Vol. 34, No. 1, pp. 41-42, March 1980

*Technical Note*

# A Tri-Correctional Upper-Limb Orthosis

A 45-year-old, white female acquired a hairline fracture of the proximal third of the ulna. She was treated by the application of a full arm cast for six weeks. After removal of the cast, she had a flexion contraction of the elbow and both pronation and supination of hand were limited. The prescription was simply a request to fit the patient with an orthotic device for correction of the flexion contraction of elbow, pronation and supination of the hand.

At the onset, I would like to say that we have a very good working relationship with the Department of Physical Medicine at the Methodist Hospital in Memphis, and we often see patients with very difficult orthotic and prosthetic problems. Most problems are solved successfully, but a few are not. This case, to me, seemed to be one of the most difficult presented. During the 28 years of my practice, I had never been successful in designing an orthotic device that provided correction of pronation and supination.

In this case, our first concern was function. The second was ease of donning and doffing, the patient being able to change the correctional parts independently. A third concern was cosmesis. The end results were acceptable to all four members of the clinic: the patient, the orthotist-prosthetist, the occupational therapist, and the physician.

A turnbuckle type device (Fig. 1) with a band and cuff at the proximal end, a free-motion elbow joint medially, a single bar, band and cuff on the distal portion, and a special elbow joint on the lateral side was provided. For the lateral side, I used a swivel ball joint from a "four-poster" cervical orthosis. The bottom portion of the ball joint was silver-soldered to the head of a metal joint 1 inch distal to the axis. The top part of the ball joint was welded to a 1/4-inch stainless steel rod that was long enough to reach from the ball joint to the distal end of the radius. The hand portion of the device is

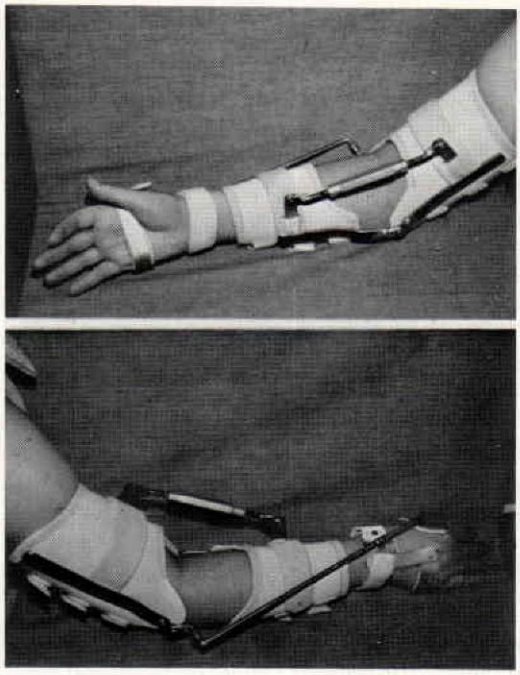

Fig. 1

a simple opponens splint extended to the wrist, with a piece of one-inch square, 1/16-inch-thick steel attached by rivets at the proximal end. The joint at the styloid of the radius is simply a 1/4-in. ID tube, 3/4 inches long with a 10-24 screw silver-soldered to the bottom and a 8-32 nut silver-soldered to the top to allow for an Allen-head set screw. On the plate at the radial styloid, I silver-soldered a 10-24 nut and tapped it out to allow the tubing to act as a swivel joint there.

This orthotic device works well in all three functions. The portion of the orthosis to correct flexion (turnbuckle) at the elbow, is simple and has worked many times. The portion of the orthosis that provides pronation and supination of the wrist is not quite as simple. The design is successful because of a combination of three factors. First, the distance from the axis of the elbow to the ball joint, 1 inch, allows the 1/4-inch rod to rise over the distal portion when pronation occurs. This arrangement also allows the rod to be in alignment with the swivel joint at the wrist when the hand is in supination. Second, the ball joint at the elbow allows the rod to be in alignment with the tube at the wrist in all positions. Third, the 1/4-in. ID tube at the wrist allows the rod to elongate when the wrist is either pronated or supinated. The 10-24 screw on the tube is a simple way to have a swivel joint that allows two things: the tube stays in alignment with the rod and allows ulnar and radial deviation at the wrist during work and play.

In order to change position of the hand, the patient only has to loosen the ball joint nut at the elbow and the set screw at the wrist. The turnbuckle simply has to be screwed out to correct flexion. In the case of this patient, the changes only had to be made once a day.

A full arm cast is needed for fabrication of the orthosis. I believe fabrication time to be approximately six hours.

I would like to express my appreciation to Trudy Smith, O.T. and Dr. John D. Huffman for their help in providing this patient with a functional orthosis.

Willard F. Benton, C.P.O.
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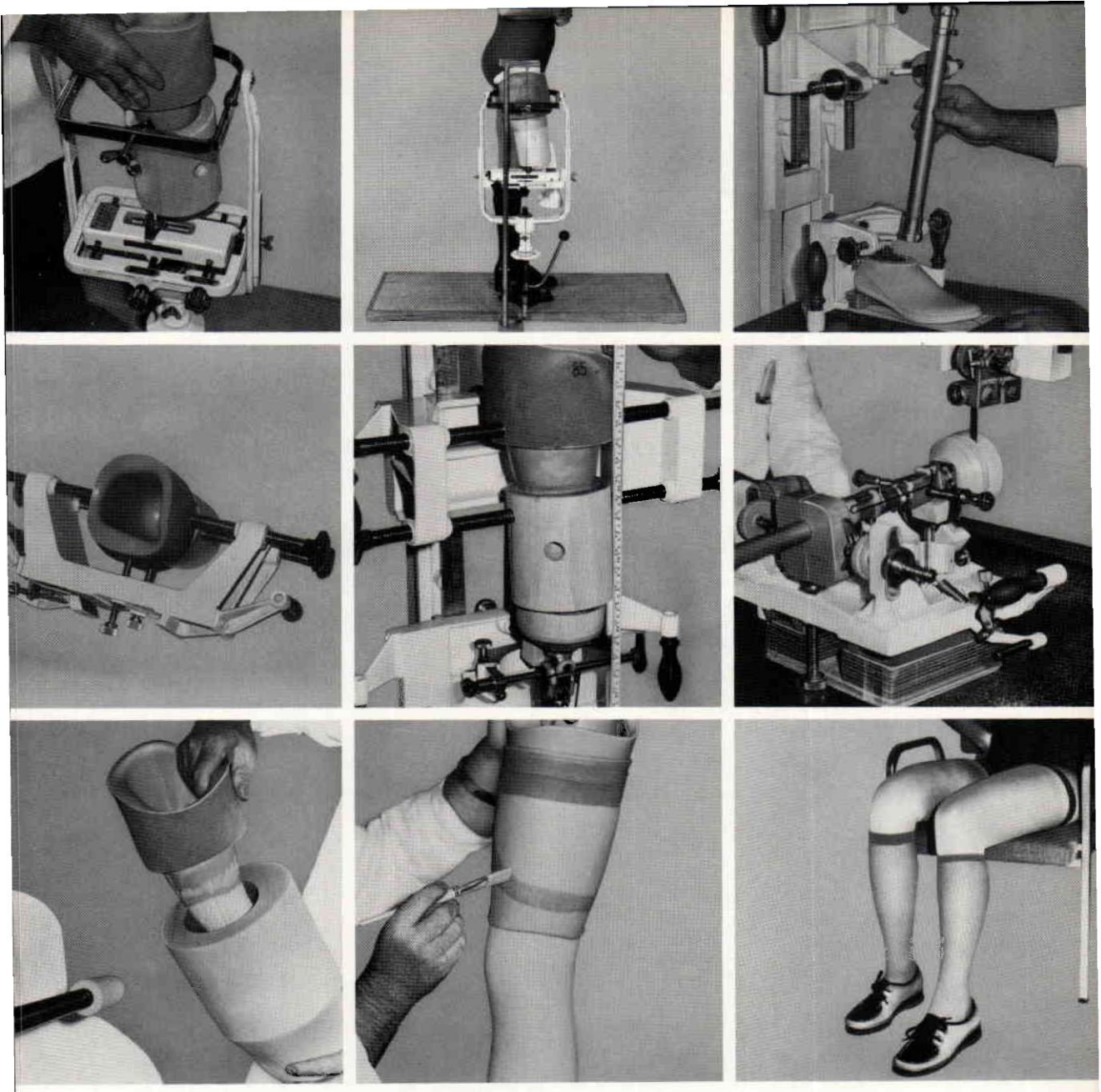

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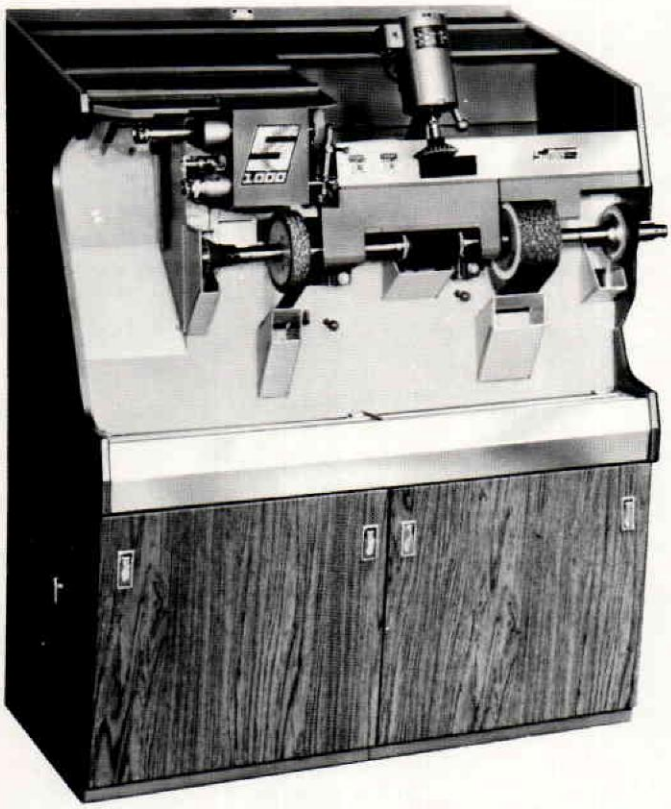


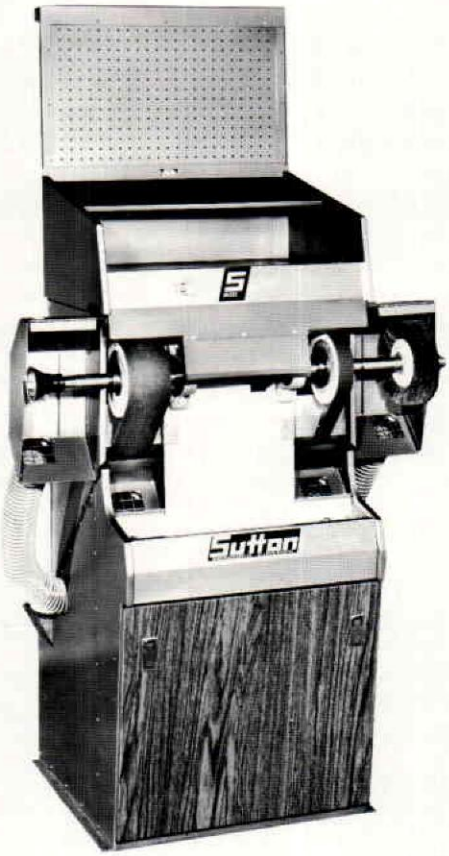


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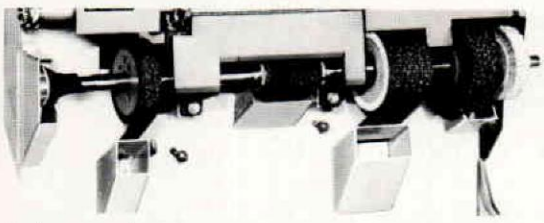

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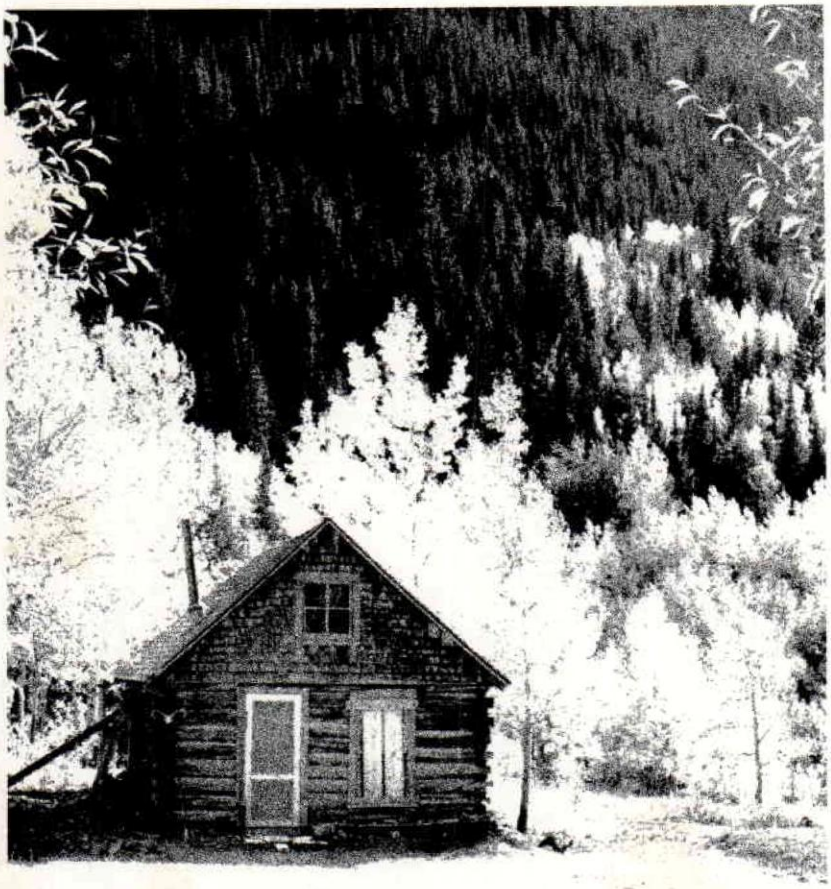

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