

# The Unitized Below-Elbow Infant Prosthesis\*

by

Carl Sumida, C.P. & O.<sup>1</sup>, Julie Shaperman, M.A., O.T.R.,<sup>2</sup>  
Wallace Sumida, B.S.E.E., C.P.,<sup>3</sup> Yoshio Setoguchi, M.D.<sup>4</sup>

It has become accepted practice to fit a passive prosthesis to below-elbow infant amputees as soon as they have attained stable sitting balance. (1) In this way, the child's developmental experiences include the prosthesis from the beginning of his active life, for when an infant of this age is not sleeping or eating, he is ac-

tively exploring his own abilities in manipulating himself and his world. He rolls over, pushes up from the floor, leans on his arms while sitting, he crawls, climbs, and falls. He stabilizes and supports objects with his arms, clasps, pushes and holds a variety of shaped and textured objects. All of these locomotor and manipulative activities are enhanced or improved when the infant amputee has, and uses, a prosthesis. Early experience with a prosthesis has the additional advantage of preparing the child for spontaneous and skillful prehensile function when introduced to an active prosthesis, at approximately 24-30 months of age.

Arm motions of an infant tend to be gross due to the incompletely matured neuromuscular

---

This work supported by grant #00489 National Institute of Child Health and Human Development, National Institutes of Health, Department of Health Education and Welfare; grant #C-199 (R 2), Childrens Bureau, Department of Health Education and Welfare; and conducted at the Child Amputee Prosthetics Project, Departments of Pediatrics and Orthopaedic Surgery, University of California, Los Angeles, 1000 Veteran Avenue, Los Angeles, California 90024.

<sup>1</sup>Chief Research Prosthetist

<sup>2</sup>Research Occupational Therapist

<sup>3</sup>Research Design Prosthetist

<sup>4</sup>Medical Director

system. He flings his arms against objects; plays in sand, dirt, water, his food, and anything else available. His interests often lead him to lift loads which are very heavy in relation to his own body weight. The prosthesis which is actively included in the activities of an infant must stay on; must be easily cleaned; certainly must be durable; but above all must be valuable to him in pursuit of his interests and desires.

It has long been the practice at the UCLA Child Amputee Prosthetics Project to fit infant short and very short below-elbow amputees with a double wall polyester laminated socket and forearm which is pre-flexed fifteen degrees. The prostheses have a constant friction wrist unit, full polyethylene cuff attached to the socket with rivet insert hinges, a Dorrance 12 P or 10 P hook, and a figure-eight harness for suspension. In other words, the present standard procedure is to fit below-elbow infant amputees with a modified and miniaturized adult prosthesis.

Unfortunately the body proportions of an infant are not a miniaturization of the adult, and his activities and movement patterns are not the same. The adult may bend, lift, and reach, but never goes through the contortions of the infant. If the infant functions differently from the adult, and his body proportions are also different, his prosthetic requirements must also differ. It has long been recognized that miniaturization of adult devices is less than satisfactory, but recorded obser-

vation of activity patterns and requirements was necessary before the functional needs of the infant amputee could dictate a new design criteria. Data collected on a large number of infants with below-elbow limb deficiencies over a thirteen-year period have been analyzed in an effort to isolate the offending factors in the conventional components of the below-elbow prosthesis and to thereby determine a new design criteria.

These general observations together with specific functional criteria suggested a radically new approach in design. The standard prosthesis is constructed on an "exoskeletal" concept, in which the supporting framework is the exterior shell and the interior is hollow to the point where the terminal device is attached. In contrast, the unitized prosthesis which was designed is hollow only in the socket area which fits over the patient's stump, and the remainder is constructed on an "endoskeletal" concept in which the basic structure is internal and other materials fill the space around it to complete the arm.

The unitized prosthesis is constructed largely of plastics which have sufficient strength and durability to survive the approximately two years of infant wear. Plastics have additional advantages over conventional materials in that they are lightweight; have a soft appearance suggesting flesh turgor; require little maintenance as they are not subject to corrosion; and are less expensive. To fulfill the general design crite-



ria components were developed which, when combined, create a unitized arm (2). These components are not applicable individually to standard prostheses as they are inter-related to each other. Design criteria were established by considering each component separately.

## TERMINAL DEVICE

### *Observed Needs and Problems*

When the adult hook is reduced in size for an infant, some of its excellent features become distorted or reduced in effectiveness. The infant with his inexperienced eye-hand coordination cannot easily place objects precisely into the hook. Objects therefore often wobble precariously between the two unyielding "fingers" opposing each other in a scissor-type motion. This skill in eye-hand coordination will improve with maturation and of course can be improved by occupational therapy sessions, but until acquired its lack often results in frustration.

The "cant" of the hook is lost in the very small sizes and the stationary finger is designed to curve above the moving finger for no apparent reason, so that the only objects which can be held securely are long, thin objects which utilize the "thumb" for three-point stability.

Children prefer to play with large objects, but the opening of the hook is very small. Neuromuscular ability to open the hook is poor yet the need for prehen-

sion force is great. Plastisol covering on the small size models is helpful for gross non-prehension stabilization and for clasping, but the plastisol is too slippery to hold objects in the hook with security and confidence.

### *Design Criteria*

The terminal device for infants should be capable of holding haphazardly placed objects securely and should resemble the cable controlled device to facilitate later transition from the passive to an active prosthesis (3). Rather than having a scissor-like action, it would be preferable for the terminal device to simulate the function of a two-finger-to-thumb grasp position of the hand. The device should have a large opening span and increased prehension grip without requiring a commensurate increase in strength on the part of the infant to operate it. This would be possible through the use of increased surface contact and resilient materials. Enough friction is required on the outer surfaces of the device to assist in stabilization.

### *Component Designed*

A terminal device was designed consisting of a wide curved finger section which extends from a broad base and stud, and a thumb which is a narrow curved projection hinged to the base. The distal portion of the finger section is covered on both sides with neoprene crepe. The palmar surface is contoured. The thumb is covered with rubber tubing. The device simulates the grasp pat-

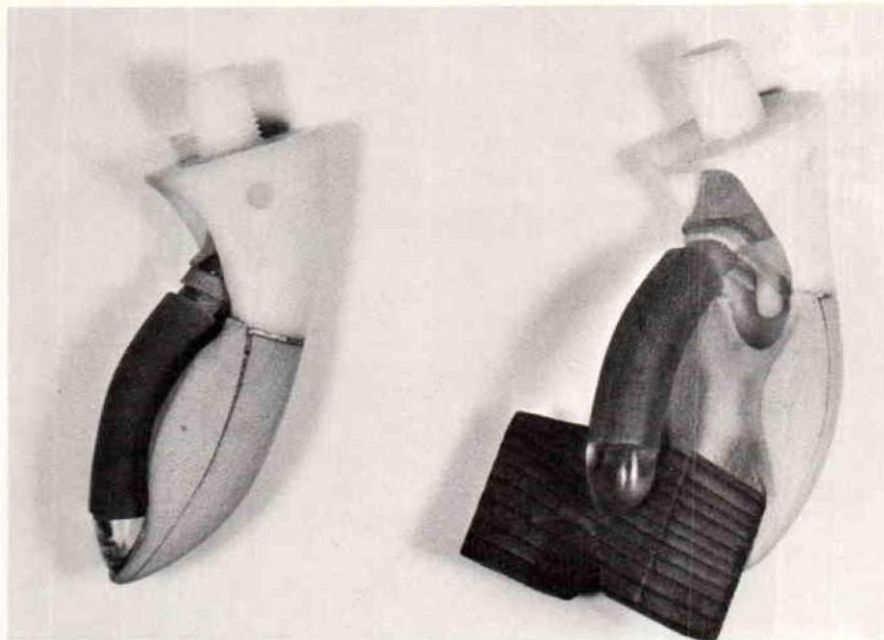


FIGURE 1—Terminal device.

tern of slightly flexed fingers opposed by a moving thumb. The width, resiliency, and friction of the neoprene covered finger section provides increased prehension stability. The narrow thumb allows good vision of objects grasped. The size of the opening is comparable to that of the Dorrance 99 X hook while the total terminal device length is only as large as the Dorrance 10 X hook. The basic device is made of Delrin\* and, when inserted into the wrist unit, is the same circumference as the distal forearm, creating a continuous flowing line to the arm. In addition, this terminal device can be used on either the right or left side (see Figure 1).

\* Delrin, E. I. DuPont De Nemours and Co., available at plastic distributors.

## WRIST UNIT

### *Observed Needs and Problems*

Although pre-positioning is beyond the skill and understanding of the infant, parents and therapists occasionally desire to position the terminal device for specific activities. This little used component adds terminal weight to the prosthesis, but some connection is necessary between the terminal device and the forearm to permit exchange of terminal devices.

### *Design Criteria*

A lightweight constant friction wrist rotation unit without complex external adjustment is needed, made of a material that is inexpensive and requires minimal maintenance.



## **Component Designed**

A wrist unit was made from a rod of nylon having a 1" outside diameter. When the thread was cut internally into this rod the final  $\frac{1}{4}$ " was diminished in depth to provide resistance. As the terminal device stud goes into the wrist unit it meets the section with less thread depth. Because the nylon of the wrist unit is a softer material than the Delrin of the terminal device, the threads yield under pressure, providing the desired amount of friction.

## **SOCKET**

### ***Observed Needs and Problems***

When a very short below-elbow stump flexes beyond 90° it tends to retract into the antecubital fold, thus reducing the effective leverage area, permitting the stump to pop out of the socket. Rivet hinges which permit hyperextension can also result in loss of stump hold. Sometimes a figure-eight epicondyle strap will hold the stump in the socket, but this device markedly limits the range of forearm motion.

Adjustments are needed to maintain proper fit on the changing size and shape of the growing infant's stump. From six months to two years of age, stump circumference increases only 0.5 cm., but changes in shape and contour occur due to loss of baby fat and definition of musculoskeletal structures. Only limited modifications are possible with a conventional prosthesis to accommodate these

changes. Thicker laminated areas may be ground out, but this is inexact, because the position of the stump in the socket changes with growth.

## **Design Criteria**

Maximum loading is tolerated at 90°, but flexion beyond 90° results in loss of purchase on the stump. The socket was therefore designed for total contact to retain maximum purchase on the stump by taking the cast at 90° of flexion. To insure that the stump does not flex beyond 90° a high cut rolled trim line was designed to act as a stop to further flexion.

Lexan,\* a completely transparent thermoplastic material which can be heated and formed directly over a male cast, was the material chosen for the socket. It is semi-flexible with strong resistance to impact and is very lightweight. The transparency provides the prosthetist with the opportunity to visually examine the fit of the socket over the stump and to directly observe the pressure areas. Adjustments can be made by heating and contouring the offending location. Lexan is commercially available in tubular shape  $\frac{1}{16}$ " thick with inside diameters of  $1\frac{7}{8}$ " or  $2\frac{1}{8}$ ".

## **FOREARM**

### ***Observed Needs and Problems***

It is difficult for an infant to stabilize objects against the

\* Lexan, Chemical materials division, General Electric Co., Pittsfield, Mass.

smooth, hard texture of a laminated plastic forearm. Pushing up from the floor or leaning on the forearm while crawling are precarious activities for infants with these slippery forearms and it is uncomfortable to roll over or fall on a hard surfaced prosthesis. Leaning and crawling on hard surfaces with a hard forearm causes wear on clothing, and the prosthesis clatters when placed on a table.

During the period from six months to two years of age, forearm length increases 5.0 cm. (4), but the conventional prosthesis can be lengthened only by substituting a larger terminal device for a smaller one.

### *Design Criteria*

Some form of friction surface is needed for the forearm. Polyvinylchloride (PVC) and leather gauntlets which are sometimes applied are unattractive and do not stay in place. It is desirable to have a pliable surface that yields and allows contouring when the child falls or clasps an object, functioning similarly to the skin of the human arm. Soft, textured forearms would also reduce impact noise and wear on clothing.

Observation of infants with unilateral below-elbow amputations has led us to believe that they need to flex their forearm beyond  $90^\circ$  but do not necessarily need a full  $135^\circ$  of flexion. Similarly, full extension and even hyperextension which are sometimes permitted by conventional prostheses are not needed as these children have free shoulder mo-

tion and another sound arm. The forearm should therefore be placed in the most optimal functional range which will allow the child to manipulate his terminal device within a range of approximately  $20$  to  $120^\circ$  of flexion.

### *Component Designed*

The forearm consists of a 1" inside diameter central tube of Lexan which is covered with a foam filler and an outer sleeve. The Lexan tube is flared to conform to the rounded socket end. The forearm is bonded to the socket at approximately  $30^\circ$  of

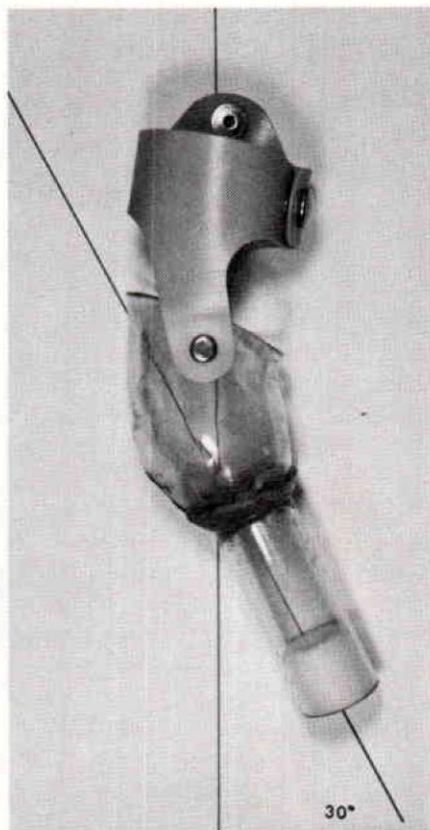


FIGURE 2—Pre-flexion angle of the forearm.



pre-flexion (see Figure 2). The length of tube added to the socket determines the length of the forearm section of the prosthesis, as the wrist unit fits inside the tube rather than adding to its length.

A foam material made of a lightweight compound of polyurethane is used to fill the space around the forearm tube and to complete the contour of the forearm from the socket to the terminal device. It is wider at the proximal end, as it needs to conform to the girth of the widest part of the socket, and it tapers at the distal end to the desired girth of the wrist. Made with a hole in the middle, it slips over the Lexan forearm tube. The prosthetist cuts it to the correct length and shapes the proximal end so it fits up against the base of the socket. He also shapes the outer contour to taper to the desired size. It is not necessary to provide any permanent attachment of the foam to the arm, for it stays in place well. It can be slipped off easily for repairs.

Covering the foam filler is a sleeve made of RREP.\* Sleeves of PVC were tried and although they were flexible, gave good friction, and had an attractive appearance, they tore and stained easily. RREP is slightly less frictional and flexible but it is more stain resistant and does not tear as easily. Replacing the sleeve is a simple and relatively inexpensive procedure. However, even RREP

---

\* Plastic formula developed by the U.S. Army Medical Biomechanical Research Laboratory, Walter Reed Medical Center, Forest Glen Section, Washington, D.C.

stains more than is desirable. The sleeve covers the entire prosthesis up to the socket brim, giving the arm a finished appearance. It conceals and encloses all parts and provides a look of continuity (see Figure 3).

## CUFF

### *Observed Needs and Problems*

No change in design was felt to be necessary as the only objection to the polyethylene material is that it tends to elongate at points where hinges are attached.

### *Design Criteria*

Cuff material which is more cohesive than polyethylene but otherwise has similar properties should be explored.

### *Component Designed*

The cuff is a standard full cuff with a snap in the front. It is made of Ortholen† which is  $\frac{1}{16}$ " thick, flesh colored, medium- to high-density plastic. Polyethylene opaque of medium density can be used but Ortholen was found to have less tendency to elongate and therefore rivets do not tend to pull through as easily. The cuff was made so it did not extend high into the axilla area. It was attached to the socket by rivet hinges which lie just inside the cosmetic covering.

---

† Kellogg Corset Company, Jackson, Michigan.

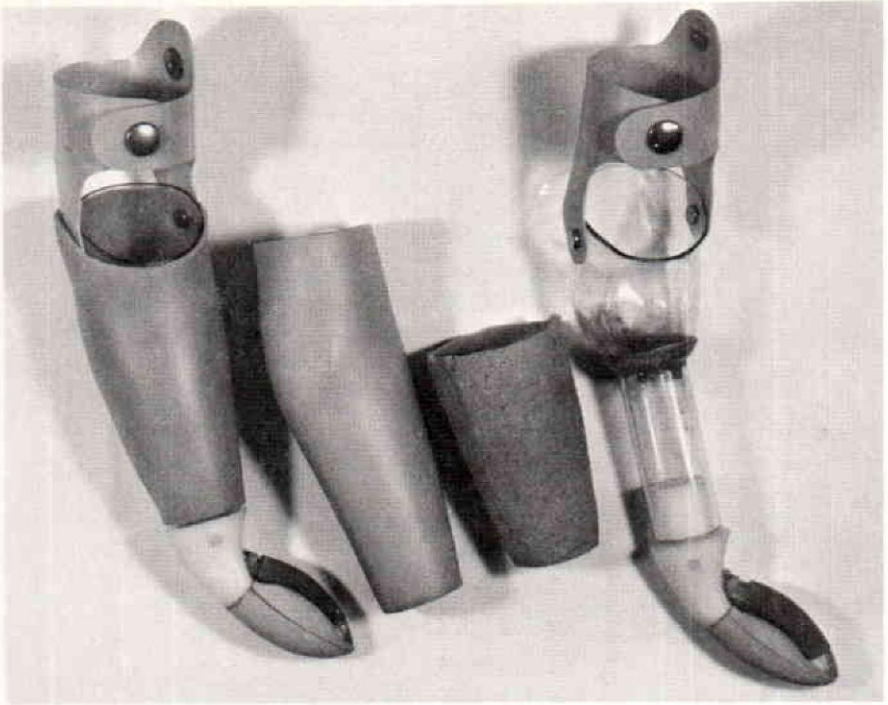


FIGURE 3—Forearm: Components separated and together.

## SUSPENSION

### *Observed Needs and Problems*

For infants, the primary function of the harness is to suspend the prosthesis, but because of the soft, rounded body contours, effective suspension is difficult to achieve. The soft body tissues of an infant are easily marked and displaced by tight straps, so that when the conventional harness is tight enough for good suspension, redness and eventually a callous formation on the skin may result. To avoid these undesirable effects, the harness must be fitted carefully which is difficult to achieve due to the lack of well-defined

skeletal and muscular structures; and difficult to maintain due to the constant physical changes resulting from growth.

Since an infant's first motions are primarily lateral and initiate from the shoulder, the front support strap of the conventional harness often slides off the shoulder. A front chest strap therefore must be added to prevent this from happening. Unfortunately the extra strap restricts freedom of arm movement.

Because of the rapid increase in the chest circumference of an infant, the conventional harness requires frequent adjustment. From the age of eight months to the age of two years, chest circumference increases approxi-



mately 5.0 cm (5). Data on a group of twelve infants showed that all together they required fifty-one harness releases in one year from their first to their second birthdays, averaging a harness adjustment approximately every 2.5 months (6).

### *Design Criteria*

A harness should be made which will provide direct counterforces to supply vertical suspension of the prosthesis. The harness should not fall off the shoulder, cause axilla pressure, require critical fit in the chest area, or need frequent adjustment. It should allow a maximum of shoulder motion and, as with any harness, a minimum of straps would be desirable.

### *Component Designed*

The harness was made of  $\frac{1}{2}$ " dacron tape and nylon utility cord (see Figure 4). It consists of a chest strap, over-shoulder strap,

axilla cord and swivel tab. The over-shoulder strap and axilla cord together form a suspension loop which fits on the prosthetic side. The swivel tab slides on the axilla cord permitting free arm movement. This tab snaps to the cuff and is the only attachment point by which the harness suspends the prosthesis.

Vertical load forces are carried by the suspension loop which is fitted tightly enough to prevent the socket from being pulled off the stump. The nylon axilla cord must not bind the axilla and usually lies about one inch below it, allowing freedom of arm flexion and extension. It does not limit abduction if the swivel tab is set high enough.

The function of the chest strap is to retain the suspension loop on the shoulder and take care of lateral extended loads that are placed on the prosthesis. Therefore, it need not be fitted snugly around the chest and can allow enough slack for several fingers

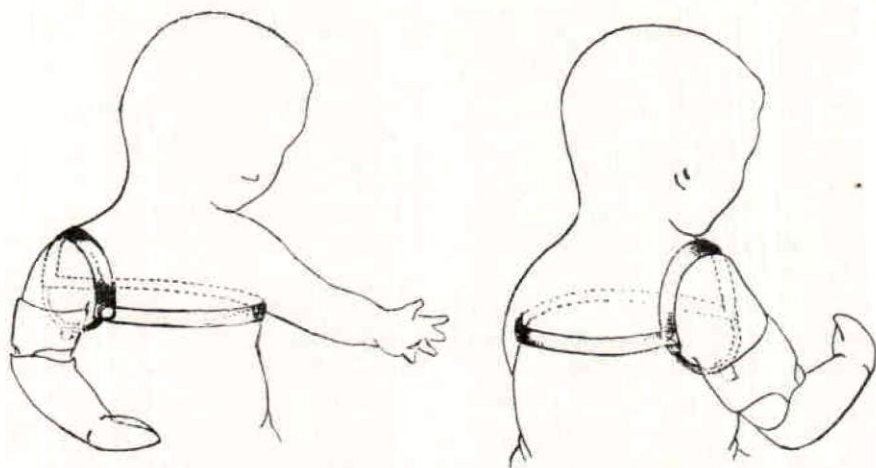


FIGURE 4—Harness.

to be placed under it and still be effective.

## CARE AND REPAIR

### *Observed Needs and Problems*

Care and repair required for an infant's prosthesis is considerable due to the growth and varied activities. Adults who used their prostheses similarly would be considered extremely heavy duty users of their limbs. Care of a conventional prosthesis requires regular cleaning and lubrication of the metal parts to prevent rusting and wear on moving components. Repair of the conventional prosthesis may involve relamination; repair of the broken part; or refabrication of the entire prosthesis.

### *Design Criteria*

Simplified, low-cost repair procedures for infant prostheses are needed. Inexpensive, standardized parts which would permit simple replacement would be desirable. Materials which clean easily and would not require lubrication would simplify care problems.

### *Components Designed*

Other than the socket, cuff, and harness, all parts of the unitized prosthesis were designed to be prefabricated and thus simple and inexpensive to replace. All metal except for three snaps have been eliminated. This extensive use of plastics allows the prosthesis to be scrubbed well without fear of rust or corrosion.

## PROFESSIONAL REQUIREMENTS

### *Observed Needs and Problems*

Infants, with their soft rounded contours, small size, and activities which demand extreme ranges of motion, make prosthetic fitting a challenge to the prosthetist. Often prostheses are not uniform in quality, resulting in unpredictable wear and use patterns. These limbs take as much time and more skill to fabricate than adult prostheses, yet families are reluctant to pay large sums of money for infant prostheses. A prosthesis is needed which will eliminate as much human error in its fabrication as possible.

### *Design Criteria*

With less need to individualize prostheses, more uniform results could be expected. If standard production techniques were employed and individual components prefabricated, assembly should be easier, require less time and skill, and be less expensive.

### *Components Designed*

The unitized arm has been designed to utilize primarily prefabricated plastic parts. The primary skill still required is in taking the wrap and shaping the socket. Simplified methods for cast taking and harness manufacture have been designed to further provide quality control. These methods are being tested but results to date are inconclusive.



## WEIGHT

### *Observed Needs and Problems*

One objectionable characteristic of the standard below-elbow prosthesis has been its weight (7). Although some of these little prostheses weigh only eight ounces, they often seem very heavy in relation to the musculature available to manipulate them. With experience and maturation, infants fitted with these prostheses have been observed to adapt well to them and to eventually become proficient users. Nevertheless it would be helpful if the weight of infant prostheses could be reduced and redistributed so that it is not concentrated at the distal end. When 33% of the prosthetic weight is in the terminal device, a potential hazard exists from the random banging of the infant's arm against furniture, windows, and people.

Weight demands an unnecessary amount of energy expenditure; does not contribute to efficiency of motion; is non-functional and actually decreases functional range. It does not seem to assist in balance and appears to inhibit use of the arm.

Muscular development of the affected side seems to be influenced by use and activity. Mere resistance against gravity is not effective. With lighter weight, use should increase and muscle development become more symmetrical.

### *Design Criteria*

A lighter weight prosthesis with a more natural distribution

of the weight should be developed.

### *Component Designed*

Total weight of the unitized prosthesis has been approximately six ounces, representing an average 25% reduction in weight as compared to the conventional prosthesis.

## APPEARANCE

### *Observed Needs and Problems*

Conventional prostheses appear metallic and clumsy to parents of infants. The hook shape may frighten other children and appear to be a weapon. The prosthesis has a "hard, cold" appearance and texture. Parents are concerned at first about the potential danger of the hook, wear on clothing, and damage to furniture. Acceptance of the prosthesis is usually in relation to the functional advantages of having any prosthesis over none at all.

### *Design Criteria*

Prostheses for infants should appear more pleasing, less weapon-like, and eliminate the suggestion of "Captain Hook". Rather than appearing mechanical they should appear aesthetically pleasing with flowing lines. They need not attempt to look like real body parts, but should not attract attention. They should have a pleasing color without incurring the expense entailed in precisely matching the color of human skin.

## Components Designed

The unitized prosthesis appears to be one continuous piece. It does not have an obvious separation between the terminal device and the forearm. The terminal device is not hook shaped. It does not look like a body part, but does not attract attention. Except for the snap on the cuff and two snaps on the harness, all metal has been eliminated, thus making the prosthesis appear less mechanical and more pleasing for babies. The forearm cover is made in standard arm and leg color and does not attempt to match each child's skin. The softness and pleasing color also reduce the metallic appearance, making this arm more appropriate for this age group.

## EVALUATION

To determine the extent to which the unitized prosthesis satisfies the design criteria, six infants were fitted with unitized arms at the Child Amputee Prosthetics Project. They wore unitized prostheses from their initial fitting at between eleven and fourteen months of age until the evaluation period of from fourteen to twenty-one months was completed. At that time all were converted to conventional prostheses with Dorrance 10 X hooks.

All six infants in the study had unilateral congenital below-elbow limb deficiencies. All were seen monthly on an out-patient basis through the period of their participation in the study. Parents requested additional appointments for repairs if they were needed.

Detailed data was maintained on all components and on the fit and function of the prostheses throughout the study period.

## Terminal Device

Much as they do with a conventional plastisol covered hook, the infants used the terminal device primarily for stabilizing objects and themselves in manipulative and locomotor activities. There was natural use of the prosthesis and terminal device for holding down objects and clasping objects between the terminal device and sound hand.

The curve of the experimental terminal device was often used effectively when it served to prop long protruding objects held under the arm and it also curved over the objects it held down, causing a very effective hold. When supinated, it was used as a scoop and in any position was leaned upon for crawling, sitting, and pushing up from the floor.

Several of the children manually opened the terminal device and, when it was held open by an adult, they would place objects into it. This was gross placement, but objects stayed in place and did not fall out. Only  $\frac{1}{8}$ " of rubber band tubing was used, providing  $\frac{3}{4}$  of a pound of prehension force. The fact that objects did not fall out of the terminal device when held with such minimal rubber band loading was highly promising for function in the period when the terminal device will be actively operated.

Material used in the terminal



device appeared generally satisfactory. The major problem occurred with the neoprene crepe covering which absorbed dirt and wore through along the edges and at the tip of the dorsal surface where the children used them a great deal. Records showed that the neoprene crepe covering needed to be replaced at an average rate of once every three and a half months.

Three of the terminal devices broke at the stud when the children fell on them. This weakness is felt to be due to the individual fabrication technique and it is believed they will be less likely to break when design changes are made in this area by increasing the thickness.

### *Wrist Unit*

For most activities the terminal device was left in a position part way between pronation and mid-position. Although the wrist unit was not used a great deal, it was considered an important component for those few activities in which parents or therapists needed to position the terminal device. In all six cases, the wrist unit held friction well and the terminal device turned smoothly throughout the range of motion. The wrist units required no maintenance, but it was considered important to carefully insert the terminal device into the wrist unit to avoid stripping the threads. In no case were the threads stripped.

### *Socket*

Design of the socket effectively prevented stump pop-out. No

accessory straps were required even though five of the six infants fitted have very short stumps with an average length from epicondyle to tip of stump of only  $2\frac{1}{4}$ ". The longest stump was  $2\frac{3}{4}$ " and the shortest was 2". All six infants wore stump socks. Two, who tried periods of wearing the prosthesis without a sock, found the Lexan uncomfortable when they began to perspire. Transparency appeared to be a distinct advantage in determining fit of the socket during use and in assuring that load tolerance was as desired.

Cracking appeared in the material with two prostheses after eight months of wear and with one prosthesis after sixteen months of wear. Strangely, the cracking did not occur at points of obvious stress. The exact cause of this cracking at present has not been identified.

### *Forearm*

All of the children were fitted with approximately  $30^\circ$  of forearm pre-flexion. They could all straighten their arms enough to lean on the terminal device while sitting on the floor, and they could all flex their forearm well past  $90^\circ$  to clasp objects.

Shrinkage, twisting, soiling and tearing occurred with the use of PVC as a forearm covering, and all were replaced with RREP coverings which were commercially molded and stayed in place well. RREP coverings resisted tearing well, did not shrink or soil as much as the PVC and were gen-

erally more satisfactory. Three RREP coverings were replaced due to soiling although the most persistent soil problem came from ball point pen ink.

The core of Lexan tubing cracked on one prosthesis after eighteen months of wear. As the crack was near the wrist unit its cause is probably related to the same factor that caused the Lexan sockets to crack.

Foam forearm fillers were durable and functional. Four of the six patients wore their prostheses at the beach or into the swimming pool. The covering needed to be pulled back so the foam could be cleaned and dried after these activities to prevent rotting and deterioration from moisture. The foam fillers used initially were considerably softer than the ones that were produced later. The firmer fillers provided less resilience but were more durable.

Function of the textured resilient forearm was excellent. Friction provided by the texture and resilience aided secure clasping of objects, provided security when children leaned on the forearm, and gave excellent grip on furniture or other obstacles which children climbed upon. Contouring of the forearm was not visually apparent except when a firm grip was made on objects or when body weight rested upon it as in climbing.

### *Suspension*

The harness was stable and comfortable for the children. Freedom of arm movement was especially evident when dressing the child and when the child was engaged

in play activities. Infants were at various stages of crawling, walking and climbing. Their postures for these very gross body movements place the arms in extreme positions of abduction, external rotation, and circumduction. They place considerable body weight on their arms in all these positions and at no time was any restriction in arm motion observed, nor was there any shifting of straps during these strenuous activities.

At times, the chest strap appeared tight when it was not. Fit was checked by placing two fingers under the strap while the child was seated. The chest strap needed adjustment more frequently than any other part of the harness due to rapid increase in chest circumference during this period. Chest strap release was done on the average of once every 3.9 months during the study. It was felt that the interval could be lengthened if the prosthetist initially made the chest strap as loose as possible without letting the over-shoulder strap fall off the shoulder.

The main suspension loop appeared tight but did not seem uncomfortable for the children. It was found that correct fit of this loop was important to the fit and comfort of the harness, as it determines the angle at which the chest strap rides. It was also important to comfort for the axilla cord to begin low on the back and yet be long enough to allow full range of flexion and extension.

Placement of the swivel tab was important to good comfort and function. Dacron tape proved more comfortable than polyethylene



and was easier to adjust. The tab needed to be short and high enough to allow free abduction, but not so short that it was uncomfortable. Adjustments to the suspension loop and/or tab were done approximately every six months and not more often than three times for each child.

Stump pop-out was effectively prevented with these children. The combination of forearm flexion with high brim socket design plus correct fit of the harness made it unnecessary to have any accessory straps. Pop-out occurred when the main suspension loop was too large or when its attachment through the swivel tab was too loose. The tendency to pop out was easily detected by pulling the supine baby to a sitting position by holding the terminal device and sound hand. This placed a vertical load on the harness and showed whether or not the socket was held tightly enough on the stump. Intimate socket fit plus freedom of arm movement allowed by this harness may also have been responsible for the almost immediate spontaneous arm movements observed in these children.

### *Care and Repair*

All of the infants in the study wore their prostheses for a long enough period of time to present a clear picture of repairs required. Seven socket adjustments were required. Three of these were aided by the transparency of the socket material while the other four were to flare or re-shape the trim line, procedures which were not influenced or aided by transparency. All of these adjustments

were accomplished by heating and contouring the Lexan. It was during the heating of the Lexan that two forearm coverings which had been folded back were cracked. Following this experience, coverings were completely removed before heating the Lexan.

Time required for repairs related to the availability of prefabricated parts. Re-covering the neoprene of the terminal device took most time and would have been considerably shortened if these had been commercially available during the study. Many harness adjustments done with this particular group of infants were of an experimental nature and would not be repeated with another group.

Care of the prosthesis did not seem to be a problem to the families. At first, some families had difficulty cleaning the inside of the base of the terminal device, but they found that a small brush and water did the job well. Some of the families complained about the need to wash the forearm covering frequently, but this was reduced by the use of the RREP which seemed easier to keep clean. One mother placed the prosthesis in the washing machine with the family clothes, but was advised that hand washing was preferable. In general, those families that would take the trouble to clean any prosthesis, found the unitized arm no problem to keep clean.

### *Professional Requirements*

The lack of prefabricated components in a large part of this study made professional require-

ments difficult to evaluate. The prosthesis appeared simple to fabricate when made by the designer who clearly understood the purpose and design. A second group of infants is currently being fitted by another prosthetist and details of fabrication as well as professional requirements for fitting and repairs are being documented.

### **Weight**

It was hypothesized that added weight decreased use and control of the prosthesis. Observation of the six infants with the unitized arm tends to uphold this theory. Most of these children were observed to move and include their prostheses in activities very soon after fitting. For evaluation of prosthetic inclusion a small control group wearing conventional prostheses was used. It was found that the infants wearing the unitized prosthesis included the prosthesis in the early phases of wearing more frequently and with more natural mannerisms than the infants wearing the conventional prostheses. It was felt that the lighter weight was an important contributing factor to the earlier usage.

### **Appearance**

Families accepted the unitized prosthesis very well. They felt it looked better than the conventional prosthesis. Some commented that the terminal device seems to be part of the whole arm rather than a separate piece. Several reported being with relatives or friends who watched the baby play for some time before realiz-

ing that it was wearing a prosthesis. The unitized arm did not appear hard and cold and seemed quite appropriate for a baby. All of the families commented on the fact they did not experience remarks from strangers until the children were fitted with conventional prostheses.

## **CONCLUSIONS**

A comprehensive study of the needs and problems of infant below-elbow amputees has resulted in development of a new prosthetic device based upon an endoskeletal concept. Criteria established for the design of components and the current status of the device designed are summarized:

### **Design Criteria**

#### *Terminal Device:*

1. Weigh no more than two ounces.
2. Have an opening range equal to that of the Dorrance 99X hook or larger.
3. Have improved prehension qualities related to shape and friction surface and simultaneously reduced amount of force required to open the device.
4. Require less precision for object placement.
5. Should resemble the prototype designed for cable control.

#### *Wrist Unit:*

1. Weigh less than the conventional wrist unit.
2. Require less maintenance and care.
3. Be less expensive to manufacture.
4. Maintain constant friction con-



cept of the conventional wrist unit but utilize a simplified mechanism.

*Forearm:*

1. Provide friction surface with resilience.
2. Pre-flex the forearm to transfer the 90 to 100 degrees of stump motion to the more functional range of 30 to 120 degrees of forearm motion.

*Socket:*

Design to allow a stump range of motion from 90 to 100 degrees without permitting the stump to pop out.

*Cuff:*

Use a plastic which will not elongate at the rivets.

*Suspension:*

1. Design a harness that will provide adequate counter forces against vertical pull and horizontal loading without restricting range of motion or binding soft tissue.
2. Design a harness with straps that do not fall off the shoulder and that does not require critical fit in the chest area.

*Care and Repair:*

1. Utilize materials that are easily cleaned, do not require lubrication, can be spot molded to accommodate changes in stump contour.
2. Design components for simple interchange or replacement.

*Professional Requirement:*

Design a prosthesis which will be easier to assemble, fit, adjust and maintain.

*Weight:*

Overall weight should be six ounces or less, with the weight evenly distributed rather than concentrated distally.

*Appearance:*

1. Design a prosthesis which is aesthetically pleasing and not conspicuous.
2. Eliminate the weapon-like, "Captain Hook" appearance.

*Current Status of Unitized Prosthesis*

*Terminal Device:*

1. Weight is 1.54 ounces.
2. Opening is 2 $\frac{3}{4}$  inches as compared to the 3-inch opening of a 99X hook.
3. Due to the textured resilient cover and special shape, prehension stability is good. Pinch force has been reduced from the average 1 $\frac{1}{2}$  pounds of the 10X hook to  $\frac{3}{4}$  of a pound.
4. Because the "finger" section is 1 $\frac{1}{4}$  inches wide in contrast to the usual width of only  $\frac{3}{8}$  inch of the conventional infant hook, there is a much greater margin of error permitted in the placement of objects within the hook.

*Wrist Unit:*

1. Smooth constant friction is provided and the unit proved sufficiently durable to require no replacement during the infant period.
2. Unit is made of plastic which is inexpensive to manufacture.
3. Unit utilizes the simple friction principle of changing thread depths.

*Forearm:*

1. The textured, resilient forearm covering contours around objects, providing a secure grip.
2. Pre-flexion of the forearm provides a range of forearm motion from 30 to 120 degrees.

### *Socket:*

1. Socket design effectively prevented stump pop-out and allowed 90 to 100 degrees of stump motion.
2. Material used requires additional study.

### *Cuff:*

Elongation at the rivets did not occur in cuffs made of Ortholen as the material apparently does not stretch as rapidly as polyethylene although it has the other satisfactory properties.

### *Suspension:*

1. Harness design satisfactorily met the criteria.
2. Harness adjustments for growth were required at approximately four-month intervals as opposed to adjustments required every two and a half to three-month intervals for the conventional figure-eight harness.

### *Care and Repair:*

1. The prosthesis is easily cleaned and requires no lubrication as it is all plastic.
2. A longer forearm tube, filler and cover could be applied to compensate for linear growth on the normal side without remaking the entire prosthesis.

### *Professional Requirements:*

1. Prefabricated forearm and fillers have led to uniformity in quality. Other parts should provide the same uniformity when commercially produced.
2. Socket and harness fabrication

continue to require skill on the part of the prosthetist.

### *Weight:*

1. Unitized prosthesis weighs approximately six ounces, representing a 25% reduction from the conventional limb.
2. Weight at the distal end has been reduced.

### *Appearance:*

1. Parents, without exception, prefer the appearance of the unitized arm to the conventional arm. There is, of course, always room for improvement.

Under a grant from the U. S. Children's Bureau, Research Division, arrangements are in process to produce the terminal device from molds. When completed the devices will be clinically evaluated at selected child amputee centers throughout the United States.

A detailed procedure for fitting and fabricating the socket and harness is currently under preparation, together with a description of the techniques involved in making socket and harness adjustments to compensate for growth. The method of socket casting and harness fitting differs from methods used for the conventional prosthesis. Analysis of these procedures is currently under study and an article on fabrication and assembly will be prepared for publication when these studies are completed so that the below-elbow unitized prosthesis will become available for wider application.



## REFERENCES

1. Wilson, A. Bennett Jr. *Limb Prosthetics Today*, **Artificial Limbs**, Autumn, 1963, pp. 38-40.
2. Brooks, Milo B. and Setoguchi, Yoshio. *Unitized Arm for Infant Below Elbow Amputees*, **Eleventh Annual Report**, Child Amputee Prosthetics Project, University of California, Los Angeles, 1965, pp. 2-8.
3. Shaperman, Julie. *A Comparison of Two Terminal Devices*, **Inter-Clinic Information Bulletin**, May, 1964, pp. 1-6.
4. Maresh, Marion M. *Linear Growth of Long Bones of Extremities From Infancy Through Adolescence*, **American Journal of Diseases of Children**, 89: 725-742, June 1955.
5. Nelson, Waldo E. **Textbook of Pediatrics**, W. B. Saunders Company (Philadelphia and London), 1954, pp. 60-63.
6. Wendt, Jeannine. *Infants Fitted With Active Controls for Hook Operation*, Study completed, report in preparation, Child Amputee Prosthetics Project, University of California, Los Angeles.
7. Sumida, Carl, and Setoguchi, Yoshio. *The Unitized Arm, A New Concept in Child Prosthesis Design*, **Prosthetics International**, 3: (2-3), 1967, pp. 15-18.