



orthotics and prosthetics

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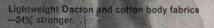
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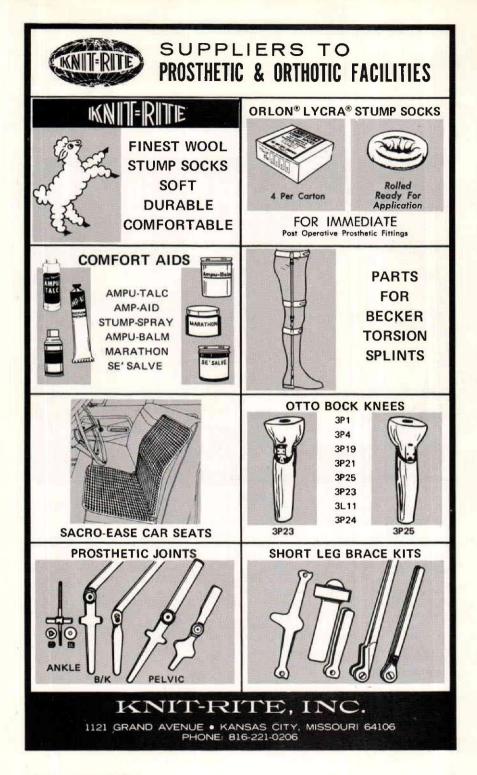
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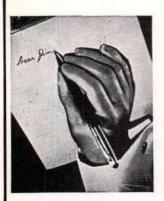


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The Dorrance Hand

A Surface Electrode Design for Myoelectric Control

by

Edwin M. Prentke, B.S.* and Joan E. Beard, O.T.R.†

There is need for a simple, rugged, and versatile surface electrode to operate myoelectrically controlled hand splints or similar devices from innervated muscles. This type of equipment has been provided for six C4 and C5 quadriplegics who are fitted with Highland View Hospital Flexor Hinge Hand Splints. Our myoelectric control, provided with rechargeable batteries, drives the splint by means of an electric motor and flexible cable. This kind of electrode is easily applied by a parent or attendant, and requires only some alcohol, adhesive tape, and electrode jelly.

The muscle sites available for obtaining useful signals in such patients are usually limited to those of the head, neck, or trapezius. We have had good results using either the right or left upper trapezius muscles, while Dr. James L. Cockrell of the University of Michigan, Ann Arbor, Michigan, has successfully used the platysma. The electrode must be located in such a position that normal head movements, eating, talking, etc., will not inadvertently actuate the device. It must also be flexible so it will conform to curved body surfaces.

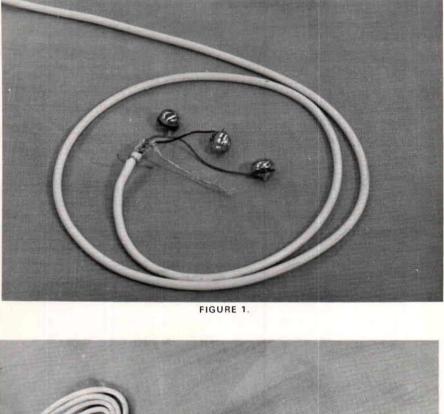
Our electrodes are made up of three stainless steel buttons meas-

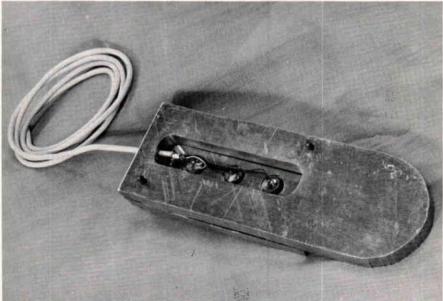
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^{*} Electronics Engineer, Ampersand Research Group, Department of Physical Medicine and Rehabilitation, Highland View Hospital, Cleveland, Ohio.

[†]Occupational Therapist in Research, Ampersand Research Group, Department of Physical Medicine and Rehabilitation, Highland View Hospital, Cleveland, Ohio.

uring 8 mm in diameter and 6 mm high, with small tips for soldering to the wires. The buttons are spaced 20 mm apart. These are placed in a metal mold and encapsulated with Dow Corning Silastic No. 588, as shown in Figures 1, 2, and 3. To prevent the cable from





pulling out, a loose knot is tied in the wire and the Silastic forms around this knot providing strain relief. A suitable cable plug, such as the Amphenol #126-217, is attached and securely fastened with the cable clamp.

In this form, the electrode can be taped to the shoulder, using Johnson & Johnson Elastikon Adhesive, 1" wide. In addition, the ends of this tape are fastened to the skin with Johnson & Johnson Band-Aid Clear Tape.

At the suggestion of Dr. Cockrell, a collar was designed to adapt the same electrode to the platysma muscle. This is seen in Figures 4, 5, and 6. It is made of 1" webbing with a Velcro closure and an elas-

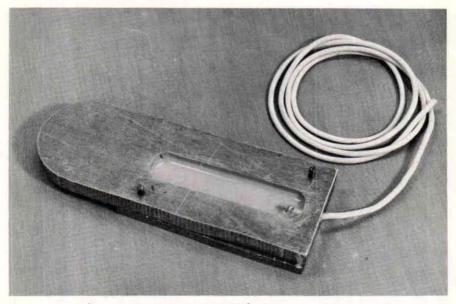


FIGURE 3.

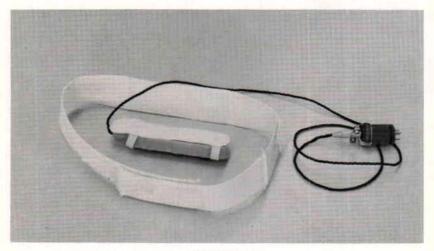


FIGURE 4.

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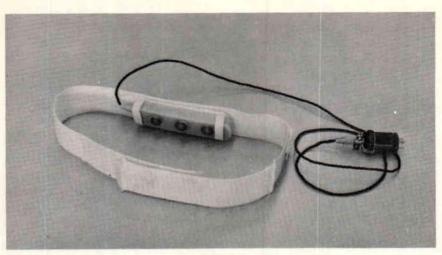


FIGURE 5.



FIGURE 6.

tic section. The Velcro strip that holds the electrode may be removed when the collar needs laundering.

Preparation of the skin surface and application of either of the two kinds of electrodes requires only about three minutes. Signals are produced by the trapezius muscle by a slight shrugging of the shoulder; while the platysma is contracted by a motion similar to yawning, that is, an almost isometric contraction.

Various cables were tested, both shielded and unshielded, as shown in the photographs. Since no problems occurred with electrical interference using unshielded wire, 3-conductor tinsel hearing aid cord, type 14D70, made by Gavitt Wire and Cable Company is now used as shown in Figure 5. It is thin and inconspicuous, yet strong and very flexible.

Before applying an electrode, the skin site should be rubbed with alcohol and dried. A very good electrode jelly is Aquasonic 100 from Parker Laboratories, Inc., Irvington, New Jersey. This may be applied thinly to the skin and the dry electrode taped on quickly; or a drop of the jelly can be put on each of the buttons, instead. For use on the shoulder, stretch three lengths of Elastikon tape, equally spaced, over the electrode and skin. The ends of the tape can be made to stick even better if they are taped down with the clear tape.

For use with the platysma, the same procedure is followed, except that the electrode is held against the neck with the collar and no tape is used.

Activities performed by patients at Highland View Hospital, using myoelectric control and surface electrodes, include eating, drinking from a glass, playing cards, using electric typewriter, operating telephone dials or push buttons, tape recording, brushing teeth, shaving, writing their name, removing objects from drawers or low shelves, underlining in school books, picking up small objects from a foam pad, and running a modified electric wheelchair. Of course, C4 patients cannot do all of these tasks.

These electrodes have been found to be effective, easy to apply, acceptable by both patient and family, and have caused no skin irritation.

A One-Piece Laminated Knee Locking Short Leg Brace *

by

Jimmy Saltiel †

In paralysis of the lower extremities, one of the major problems in ambulation is loss of joint stability. This is commonly treated by bracing. The gain in stability is however, obtained at the cost of reducing or completely limiting movement of the involved joints.

In patients with severe paralysis of the lower limb and musculature of the pelvic girdle, the most commonly used brace is a long leg appliance with a locked knee joint and limited ankle motion. More often than not, an ischial seat or pelvic band is also required. A patient using such a brace walks with a rigid knee and thus with an unphysiological gait.

Attempts have been made to design an orthosis which will stabilize the paralysed lower limb and yet enable a more physiological gait, than afforded by a rigid knee. The fact that above-knee amputees can walk freely with free knee flexion and ankle motion, encouraged orthotists to seek ways of designing appliances for paralysed limbs on principles parallel to those applied in prosthetics. One well-known example is the UCLA functional brace, where the principles applied are similar to those which enable above-knee amputees to walk freely with an adequate prosthesis.

^{*} The work presented here has been carried out under a research program (ISR 34/ 67) supported by the Social Rehabilitation Service of the Department of Health, Education and Welfare of the United States of America.

[†]Chief Orthotist, Orthotic Research Laboratory, Hadassah University Hospital, Jerusalem, Israel.

Stabilization of the knee by means of a conventional long leg brace is based on the three-point pressure principle. The brace includes two shells situated on the posterior aspect of the leg, one above and one below the knee, and a knee cap fitted over the patella. Thus two pressure points posteriorly at the thigh and shin shells are countered by an anterior pressure point at the knee joint (Fig. 1).

When hip extensors are missing, the trunk tends to collapse behind the brace and thus often gives rise to pressure at the upper edge of the thigh shell. The patient appears to be sitting on upper shell, although the the shell is not designed nor fitted for this purpose. To overcome this inconvenience, either an ischial seat is provided in order to support the trunk at the ischial tuberosity, or a pelvic band is added to prevent the trunk from collapsing (or moving) posteriorly, by the addition of the forward acting force at the pelvis (Fig. 2).

The appliance presented here has been designed as a means of stabilizing the paralysed limb without limiting the knee movement. The brace reaches only as high as the knee-joint. It is made of a reinforced laminated plastic. It comprises an arch support from beneath the metatarsal heads to the heel, two lateral uprights extending as high as the knee and joined by an anterior shell (Fig. 3).

It should be remembered that even a totally paralysed knee is usually stable in the antero-posterior direction when in full ex-

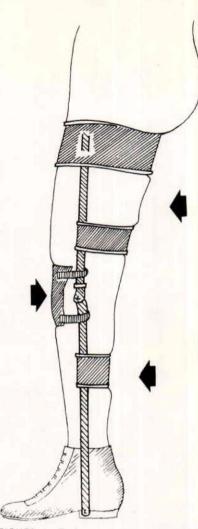


FIGURE 1—Typical long-leg brace using 3point pressure for knee stabilization.

tension. The concept applied here is the use of the patient's own weight as a force which can be made to act in the antero-posterior direction at the knee and thereby stabilize the joint in extension (Fig. 4).

The brace may be considered as a cranked lever, its lower edge at the line of the metatarsal heads serving as the fulcrum. The weight

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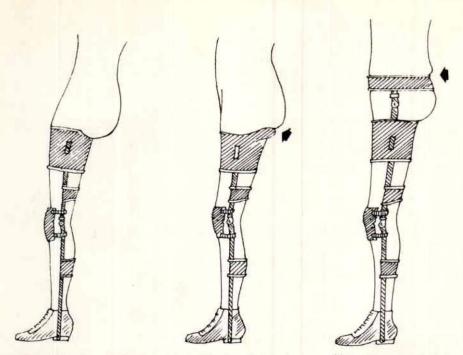


FIGURE 2-Long leg braces with modifications for use in cases of hip extensor paralysis.

of the body is applied vertically at the heel of the brace. The lever system applies its force in an antero-posterior direction at the area of the anterior shin shell thus forcing the knee into extension. It is indispensable to maintain the foot in a fixed equinus position because the force acting at the knee acts only as long as the heel does not touch the floor. The moment the heel touches the floor, the brace ceases to be functional.

In addition, a secondary action derives from the locking force at the knee—a posterior displacement of the femur. The benefits of this factor become apparent in cases of hip extensors. As has already been pointed out, in patients using a conventional long leg brace, the trunk has a tendency to shift posteriorly to the leg. In the brace we are presenting, the femur itself being forced backwards secures better alignment of trunk and leg (Fig. 5).

The intensity of the force acting at the knee is related to the patient's weight. It also varies according to the ratio of the length of the footpiece to that of the upright of the brace and the angle between them. Given a constant length of the footpiece and angle of equinus, the longer the upright the less the force will be exerted at the anterior shin shell by the body weight. The local pressure is also reduced by closely moulding the knee cuff in order to obtain as wide an area of contact as possible (Fig. 6).

For this reason, the upright must be extended as high as possible. However, since the locking force at the knee is related to the body weight, in excessively heavy patients, the pressure exerted at the knee by the locking force may be unbearable.

GAIT ANALYSIS

When using this orthosis for walking, there is no "heel strike" since the fixed equinus prevents the heel from touching the ground. For the same reason, there is no "foot-flat" phase either, therefore, the stance-phase of gait begins with "toe-strike". At this time, the toes dorsiflex at the metatarsal phalangeal joints. The area from the metatarsal head to the tip of the toes provides the pa-

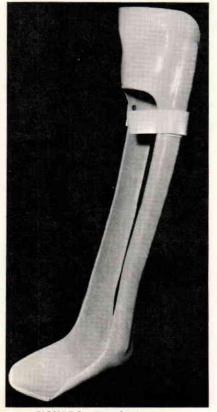
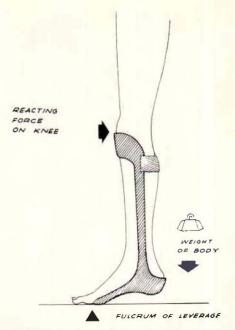
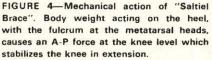


FIGURE 3-The "Saltiel Brace".





tient with a sufficient weightbearing surface. But at mid-stance, at which time the patient puts maximum weight on the affected leg, the knee is already under anterior-posterior pressure and is therefore locked and stable. The rigid ankle is of great assistance in push off. At swing phase, knee flexion shortens the distance from the hip to the floor and thereby enables a pendulum action of the leg forward without scraping the toes on the floor. The leg is swung forward and the cycle starts again with the toes striking the floor. If the patient has hip flexors, he will bring his leg forward by flexing his hip. In patients without hip flexors, the leg is carried forward by circumduction of the pel-

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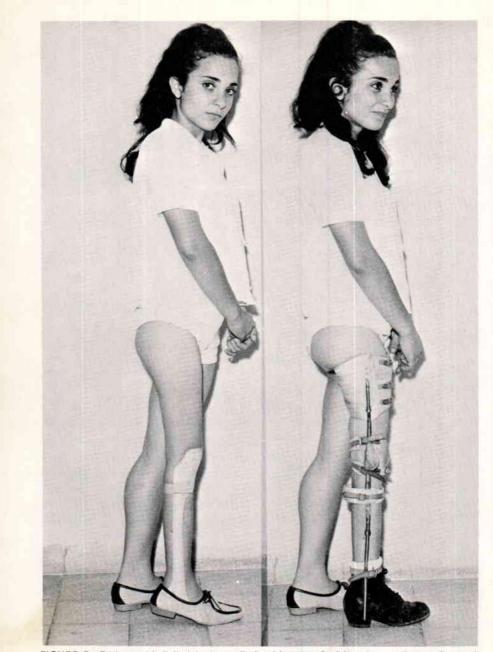


FIGURE 5—Patient with flail right lower limb with a standard long-leg appliance: the trunk obviously sags over the upper edge of the brace. This appearance is not seen when using the "Saltiel brace".

vis and the action of forward momentum.

It should be noted that, in nor-

mal joints, the knee remains locked as long as the line of gravity falls posterior to the axis of the ankle

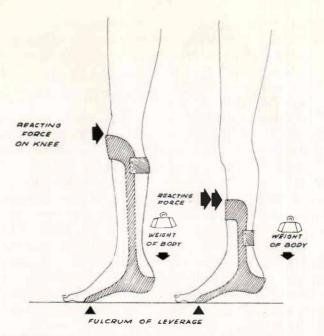


FIGURE 6—Schematic representation of effect of length of uprights on anterior pressure produced.

joint. In an unsupported paralysed leg with free ankle movement, the knee will collapse at the slightest forward inclination of the leg beyond the vertical. The use of this short leg brace enables up to $20-25^{\circ}$ of forward inclination without losing knee stability, as long as dorsiflexion of the toes continues.

DISCUSSION

Orthopaedic surgeons in the past often arthrodesed the kneejoint to do away with long leg braces. However, this form of treatment has been almost abandoned owing to the inconvenience of a rigid knee in every circumstance other than walking.

Arthrodesis of the ankle is another surgical intervention which aims at providing stability, not only of the ankle but, in certain circumstances, also of the knee. The brace described here affords all the advantages of an ankle fusion, with none of the disadvantages.

During recent years, several attempts at providing a knee stabilizing orthosis with free knee movement have been made. Perhaps the most successful so far has been the UCLA functional brace. The appliance allows ankle movement from heel strike to foot flat, and provides the patient with a large weight-bearing surface. Locking of the knee is said to be provided by abdominal and pelvic pressure at the anterior brim of the thigh shell. The pressure is transmitted through the uprights that serve as levers and extend from the thigh shell to the posteriorly eccentric knee joints. At

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mid-stance, the hydraulic damper which decelerates dorsiflexion contributes to knee-locking, moving the fulcrum forward and thereby forcing the anterior shell to apply antero-posterior pressure at the knee. By providing a mechanism of knee-locking at toe strike, we have been able to reduce the brace to below-knee level. The absence of an ankle joint mechanism highly simplifies the design and cost of the appliance. Furthermore, since the paralysed limb may often be relatively short, compensation of the leg length in equality is obtained by the equinus position. Since the brace fits inside the normal shoe, it also often allows fitting of standard shoes even when the foot of the paralysed extremity is also atrophic.

The weight of this orthosis for a child is less than 250 grams, compared to a conventional long leg brace which weighs in the region of 1.200 grams. In cases in which a shoe elevation can be dispensed with, because of the compensation afforded by the equinus position, a further 200 to 300 grams may often be saved. We have also observed the readiness of patients to accept this brace which has a relatively pleasing cosmetic appearance in addition to the more physiological gait it allows the patient. The orthosis may be dyed to any required colour to match shoes or clothing.

We find that this appliance is indicated in cases where the patient has no lateral instability of the knee-joint. They are also more readily accepted by female patients rather than males who are less worried about the cosmetic appearance of the appliances and prefer more stability.

PROCEDURE OF FABRICATION

A plaster of Paris impression is taken from the patient's leg, including the whole foot and extending up to the knee. The knee is kept in slight flexion, the foot in about 15 degrees of plantar flexion and the toes in extension horizontal to the floor. The degree of plantar flexion of the foot may be varied with consideration of the patient's ability to stabilize his knee and the amount of shortening of the affected leg for compensation.

A positive cast is then made with the insertion of a handling mandril with provision for vacuum application at the laminating stage. The plaster model when dry is adequately retouched and thoroughly smoothed.

A film of PVA or any other parting agent is applied to the surface of the plaster model.

Two layers of nylon stockinette are then pulled on to the model.

Two layers of fiberglass are fixed with sutures on the nylon stockinette to cover the plantar surface of the foot so as to form an arch support. Additional strips are placed along the lateral and medial sides of the shin and over the anterior surface proximally in order to provide for an anterior shell. Bars of "AIREX" or any other foamy light plastic material strips of approximately $1'' \times \frac{1}{8}$ th" are applied to the medial and lateral fiberglass strips. They are then covered with another two layers of fiberglass and then the whole build-up is covered with two more nylon stockinettes.

A laminate of polyester resin (80% rigid, 20% flexible) is then made on the model with the use of a PVA sleeve and vacuum as in the conventional technique used in ordinary laminating of stamp sockets in prosthetics. The "AIREX" sandwiched between the fiberglass sheets does not absorb the polyester resin and thereby produces the lateral upright in hollow secwhich tions. provides more strength while considerably conserving weight.

When the laminate is set, the

plastic is drawn and trimmed in the shape of the described appliance.

The appliance is then fitted on the patient and further trimmed and adjusted as necessary.

After the first fitting, the edges of the brace are thoroughly smoothed. A Velcro strip is attached to the tibial shell, in order to encircle the shin and secure the upper end of the appliance in place. The lower end is kept in position with a tight shoe, and therefore no additional strips are necessary. A strip may be connected at the heel when shoes are not used in the case of the patient using the brace on the beach.

A Guide to Operating Room Technique*

by

Irene Gregory, S.RN., R.S.C.N., S.C.M., R.N.†

The prevention of cross infection in the operating room is one of vital importance. Surgery is one step in the total process of restoring health to the patient and constitutes the first step in rehabilitation.

Aseptic technique is the method by which contamination with bac-

* Paper presented at an immediate postsurgical prosthetic course, sponsored by the I.A.P.O.C. in co-operation with the New York University Post Graduate Medical School, Prosthetic-Orthotic Department on January 30, 1969, St. Michael's Hospital in Toronto.

[†] Miss Gregory graduated from the David Lewis Northern Hospital, Royal Liverpool Children's Hospital, Broadgreen Hospital Liverpool and Widnes Maternity Hospital. She is on active staff at St. Michael's Hospital, Toronto and is assistant head nurse in the orthopaedic department in the operating room. She is currently serving as a member of the Project Concern Advisory Team in the Republic of South Vietnam. teria is prevented. Strict aseptic technique is needed at all times in an operating room. Freshly cut living tissue can become infected easily. It is therefore essential for all members of the operating team to know the common sources of bacteria in an operating room and the means by which they reach the sterile field to contaminate it. They must also know how to prevent contamination of a sterile The principles of sterile field. technique conscientiously carried out yield the best results and constitute a chain of protective measures for the patient. Even mild infections delay recovery and are costly to the patient in time lost and money spent. A mild infection is potentially a severe one and antibiotics have not supplanted sterile technique.

Sources of Contamination

The sources of contamination are:

- 1. The patient
- 2. The members of the operating team
- 3. All articles used in the wound and on the sterile setup
- 4. Dust in the air
- 5. Other personnel and visitors in the operating room

If the principles of sterile technique are understood, the application of it becomes obvious.

Contamination by the Patient

In the operating room we prepare the patient's skin at the operative site and surrounding area. This is known in hospitals as "the prep". The purpose is to render the operative site as free as possible from bacteria so the incision can be made through it with a minimum of danger of infection from this source.

Several solutions are used for this purpose: Bridine, Phisohex, Zephiran Chloride, Cetavlon, etc. according to the orders of the surgeon.

At the end of the "prep", the patient is covered with sterile linen—these are called "the drapes"—leaving only a minimum area of skin exposed at the site of operation. The purpose of drapes is to create and maintain an adequate sterile field during the procedure.

Contamination by Members of the Operating Team

First, we must consider attire worn by the members of the team.

A cap must cover the hair completely. It prevents contamination of the sterile field by hair. Shoes should be clean and shoe covers must be worn over shoes that are not used exclusively in the operating suite. The operating suite is composed of operating rooms and doctors' lounges, so shoes worn out of this area must be covered by overshoes before entering an operating room. The same applies to the scrub suit-it must only be worn in the operating room-if worn out of the operating suite it must be changed before re-entering the operating room. A mask is put on by all personnel prior to entry into the room. It must cover both nose and mouth and fit snugly so that air is filtered through it and does not escape around the sides.

The operating team perform a surgical scrub. This is the removal of visiting "flora" and inhibits growth of resident bacteria which we all have on our hands and arms, by mechanical washing and chemical disinfection.

The solutions most commonly used are:

Bridine which is a microbicidal cleanser with the active ingredient Povidone-iodine, 7.5%.

Phisohex which contains 3%hexachlorophine, the optimum amount of this powerful, long-lasting antiseptic agent removes visiting bacteria or flora and inhibits growth of host bacteria.

Surgical soap which has proven to be very hard on the skin.

There are two accepted methods of timing the scrub. One method is by counting the number of strokes to hands and arms.

With Phisohex it is:

Strokes to	
Skin	Nails
9	15
15	25
30	50
	Skin 9 15

The second method is by timing by the clock. With Bridine, 10 minutes for the initial scrub and 4 minutes in between cases. With Phisohex, 6 to 8 minutes initial scrub and two minutes between cases.

On leaving the scrub sinks, the hands must be kept above waist level and away from the scrub suit. The towel is picked up taking care not to drop any water onto the sterile gown. Keeping the towel away from the scrub suit, the hands and arms are dried using alternate corners of the towel, starting with the hands and finishing at the elbow.

To put on the gown one should step far enough away from any non-sterile areas to avoid accidental contamination. The gown is unfolded, taking care that the hands do not touch the outside of the gown and the arms inserted. The circulating nurse will tie the gown.

Immediately after gowning, the gloves are put on. At St. Michael's Hospital we prefer to use the closed gown technique when the tips of the fingers do not protrude beyond the edge of the cuff of the gown. (This method was demonstrated to prosthetists on the course and they all found it very easy to do).

Once gowned and gloved, personnel are considered "sterile". Gowns are considered sterile only from waist to shoulder level in front and the sleeves. It is important that sterile persons keep their hands in sight at or above waist level. Hands are kept away from the face and arms are never folded as there is apt to be perspiration in the axillary region. Sterile persons must not touch their mask-if it requires adjustment, it must be done by the circulating nurse. When stating the size of stump sock required, you may point to it but you must not touch the package itself. Avoid leaning over non-sterile areas and stay within the sterile area and near the sterile tables if waiting to apply the post-operative pylon. Do not wander into another operating room to see what is happening there.

The circulating nurse carries out the same care in reverse. She avoids touching sterile areas, makes sure she does not stretch over a sterile field and faces the sterile setup when passing to prevent the danger of brushing against it and so contaminating the setup.

Contamination from Articles in the Wound and on the Sterile Setup

To avoid this contamination, all articles used in an operation have been previously sterilized. Sterilization may be accomplished by means of heat, chemical disinfection, or gas sterilization.

Heat-Heat destroys bacteria

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by coagulating the protein in the cell. This process is hastened by the addition of moisture which also causes the destruction of the bacteria at a lower temperature.

Chemical disinfection—There are numerous solutions used for chemical disinfection: Wescodyne, Zephiran, etc., and the instruments are soaked in it for the prescribed length of time to ensure sterility. With Wescodyne the soaking time is 20 minutes. Chemical sterilization of instruments is the least effective method.

Gas sterilization—The gas used for sterilization at St. Michael's Hospital is ethylene oxide. The supplies for our prosthetists are sterilized by this method. We sterilize the stump socks, AK and BK pads, and orthoflex.

In this process, air is withdrawn from the sterilizers; then gas under pressure enters. It is a 16-hour cycle with 12 high-vacuum exhausts. Heat is applied at 160°F to hasten the sterilizing action.

The disadvantage in this method is the 72-hour aeration period necessary to allow dissipation of residual gas after the final admittance of air at the end of the cycle which only partly creates the load.

Contamination by Dust in the Air

Air conditioning units may be a source of bacteria which comes through filters into the operating room. There must be proper filters and these must be changed frequently. Air pressure in operating rooms is greater than outside, so air is forced out of the rooms.

The other source of dust is from linen, so linen should be handled carefully to avoid sending dust into the air.

Contamination by Other Personnel and Visitors in the Operating Room

All visitors and ancillary staff such as X-Ray technicians or photographers must be properly attired before entry into the room. Visitors are restricted in this area.

At St. Michael's Hospital we set up a tray of sterile equipment for the prosthetists before the case commences. A mayo stand is covered by a sterile mayo cover. On it is placed a sterile tray and large basin in which to soak the orthoflex. We add a pair of straight scissors and a scalpel handle with a No. 22 blade. Routine supplies of lamb's wool-AK or BK pad according to the caseand 2 orthoflex bandages are placed beside the basin and one drape. The set is then covered with another drape.

At the end of surgery, soiled drapes are removed and after scrubbing, gowning and gloving by the closed glove technique, the prosthetists take the sterile drawsheets off the tray and drape the table again. They state the size of stump sock required and this is supplied. Sterile distilled water is poured into the bowl.

orthotics and prosthetics

The adhesive spray is applied by the circulating nurse. Aseptic technique is maintained until the orthoflex has been applied bearing in mind the difficulties with a short AK stump.

Once the orthoflex has been applied the hardware is then

REFERENCES

Berry & Kohn: Introduction to Operating Room Techniques, 3rd Edition (The brought into the room and the pylon completed.

It is hoped that the recommendations that have been outlined in this paper will help you in acquiring aseptic technique and reduce the danger of cross infection.

Blakiston Division, M Book Company, 1966)

McGraw-Hill

REPORT* Sixth Workshop Panel on Upper-Extremity Prosthetic Components of the Subcommittee on Design and Development

October 21–23, 1968 Santa Monica, Calif.

Committee on Prosthetics Research and Development

The Sixth Workshop Panel (Fig. 1) was convened at the Surfrider Inn at 8:30 a.m., Monday, Oct. 21, 1968. A list of participants is given in Attachment 1. The three-day program was organized to permit detailed examination of seven externally powered elbow systems during the first day and for consideration of the items on

the regular agenda (Attachment 2) during the succeeding two days. As a result of recently accelerated developments in externally powered devices, the Panel on Upper-Extremity Prosthetic Components was charged with expediting their transition to evaluation.

EXTERNALLY POWERED ELBOWS

The principal objectives of the first day's meeting were:

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^{*} Prepared for consideration by the Committee on Prosthetics Research and Development.

1. To identify the common and special features of each of the seven elbows to be presented.

2. To evaluate current utility for patients, requirements for production, and compatibility with current prosthetic techniques.

3. To recommend to CPRD the production and evaluation of an adequate number of models for further evaluation of one or more elbows.

Preparations for the presentation of the seven elbow systems had begun on Thursday, Oct. 17, at the Prosthetics-Orthotics Education Program, UCLA. On Thursday and Friday, Oct. 17 and 18, five above-elbow amputees including a 13-year-old girl were fitted with the following externally powered elbow systems:

- a. AMBRL electric elbow
- b. VAPC electric elbow
- c. Boston electric elbow
- d. AIPR pneumatic elbow
- e. Toronto electric elbow

Two other systems—the Gilmatic electric elbow and the Rancho Los Amigos electric elbow were fitted to other patients by the respective developers.

Due to the extremely efficient organization of the facilities and to the good offices of Mr. Bernard Strohm, this difficult and tedious task was accomplished as planned. Mr. Strohm and his entire staff, in particular Mr. Maurice Le-Blanc, are to be commended for furnishing the support without which a meeting of this type would have been impossible.

According to plan, each devel-

oper presented his patient and discussed his powered elbow and control system (Fig. 2). Each presentation included:

a. a statement by the developer on the design concept of the elbow and its control system,

b. a detailed description of the sub-systems and components of each elbow,

c. an analysis of the functional features of the entire system including items detailed in Table 1,

d. statements by Mr. Thomas Pirrello on the technical aspects involved in installing each elbow system and in fitting and harnessing patients, and

e. a standardized exercise performed by a patient using the powered elbow to grasp and release objects in a two-dimensional work space envelope.

Selection of "Standards" for Comparison

In the absence of established standards delineating desirable features for externally powered elbows, a set of "operating standards" based on two assumptions was devised for the purposes of this meeting.

The first assumption held that a powered elbow should not be significantly larger, heavier, costlier, more difficult to install or use, and yet be functionally superior to a mechanical elbow. Based on this notion, certain standards were devised using the physical and dimensional characteristics of the Hosmer E-400 elbow as the archetype (Table 1). orthotics and prosthetics



FIGURE 1.

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The second basic assumption held that it was difficult at the present time to establish valid tentative standards relating to speed, maximum lift, resistance to load, cycles per day, total life, or noise. Nevertheless for purposes of this meeting, the recommendations



FIGURE 2.

1	Standard	AMBRL	VAPC	Boston	OCCC*	Gilmatic	Rancho [*]	AIPR Pneumatic
A. Dimensions								
1. Width at axis, inside saddle	21/4 in.1	25/8	$2^{1}/_{4}$	25/8	2°/32	21/4	2 ⁵ /16	3
2. Minimum distance-axis to								
stump end	2 in.'	51⁄4	2	1 1/8	21/2	2 ³ /8	21/8	21/4
3. Total length in full extension	$3^{3}/_{16}$ in.	6 ¹³ /16	31⁄8	3 ⁹ /16	—	35/16	33/8	_
4. Can regular turntable be								
used?		No	Yes	No	Yes	Yes	Yes	No
5. Can regular forearm be used?	—	No	Yes	No	Yes	Yes	No	No
B. Weight								
1. Elbow unit only	12 oz. ¹	15.6	8.2	33.7 ²	10.5	13°	18.5	12.5
2. All additional equipment								
amputee must carry.	40 oz.	12.3	13.2	60	12.2	12	27	28
C. Range of Motion (Flexion-Ex-	Name of the owner of the							
tension)	10-135 deg. ¹	0-125	12-138	17-135	0-135	10-135	0-135	8-134
D. Speed								
(Flexion)								
1. No load	2 sec.	2.0	1.8	1.0	2.1	3.0	2.5	2.0
2. With 1 lb. at 12 in.	2 sec.	2.6	1.9	1.0	4.3	3.0	3.5	2.3
E. Maximum Lift	100 in. lb.	72	25	84	18	30	36	48
F. Resistance to Load-Flexion-Ex-								
tension Plane	600 in. lb.	192	360	-	_	50	_	_
G. Noise Level	>68 db	64	73	65	62	79	60	63
H. Estimated Cost	\$60 ¹	\$250	\$150	\$1000	\$200-250	\$150	\$300 ⁴	\$335

Table 1-Some Characteristics of Seven Externally Powered Elbow Units

Notes

Data taken from Hosmer E-400 Elbow

² Includes forearm

* Child Size

⁴ Commercially available in 3 sizes

^b Includes built-in charger ⁶ All units except AIPR are powered electrically

Includes all auxiliary equipment

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of the First Workshop Panel on Criteria for External Power (May 15-16, 1964,—Los Angeles, Calif.) were used to compare the speed, maximum active torque, and maximum resistance to load of each system. No realistic data were available upon which to base standards relating to number of cycles per day, total life, or noise level. Since then, some data have become available on the number of cycles of elbow flexion/extension performed daily by aboveelbow amputees.

The mechanical and functional characteristics of an elbow are not the only criteria for judging its value. In evaluating the potential utility of an elbow it is important to know whether its application generates peripheral problems, i.e., how readily a unit can be integrated into the existing technology. We need to know if an elbow can be installed in an existing prosthesis as a replacement for the mechanical elbow or whether a new but reasonably conventional type of prosthesis is required. This type of information helps assess the costs and prescription indications. If a new but exotic type of prosthesis were required for an elbow, the present acceptability of the systems to prosthetists might be limited. Problems related to the special training of prosthetists might develop. If the elbow control requirements were radically different from conventional methods, retraining of amputees might be required with perhaps some limitation on the acceptability of the item.

Physical and Functional Characteristics of Externally Powered Elbows

All six of the electric elbows were designed to operate on 12 volts in accordance with recommendations set forth at an earlier workshop conducted by CPRD. Incorporation of any of the seven elbows in an artificial arm system does not interfere with control or operation of the terminal device.

Each of the seven elbow systems is described below in terms of the data (items A through H) given in Table 1.

1. AMBRL Electric Elbow (Fig. 3)

a. Size. This unit is slightly and substantially longer wider than the conventional Hosmer E-400 elbow. Although only 1/8 in. wider at its axis of rotation, due to the placement of the motor and drive system axially through the turntable, the over-all length is approximately 63/4 in. as against $3^{5}/_{16}$ in. for the conventional Hosmer elbow. The motor and the drive system take up approximately $5\frac{1}{4}$ in. above the axis of rotation thereby imposing a "limitation" on its application to AE amputees with relatively long stumps. Dr. Fred Leonard and his group expressed the view that the need for powered elbows only becomes significant at higher levels of AE amputation and that therefore the length of the AMBRL elbow did not represent a realistic limitation.

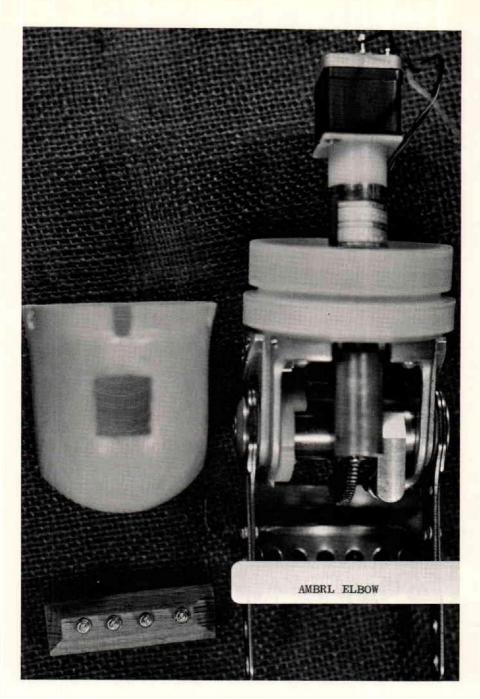


FIGURE 3.

b. Weight. The elbow unit, together with its motor and gear box, weighs 443 grams, or approximately 15.5 oz., a figure in excess of the weight of the standard Hosmer elbow at 10.4 oz. The switch and battery pack weigh an additional 350 grams or approximately 12.3 oz. which is significantly below the operating standard of 40 oz. for all accessory hardware.

c. Range. Although the unit is rated as providing a range of 0 to 125 deg. of flexion (operating standard 10 deg. to 135 deg., or a total range of 125 deg.), the model demonstrated provided a range of 115 deg.

d. Speed vs. Load. The AMBRL unit is capable of rotating through its entire range of flexion from a full extension to full flexion within 2 sec. and in this respect it complies with the operating standard (2 sec.). Under a load of one lb. it required 2.6 sec. to rotate from full extension to full flexion. It was capable of lifting a maximum of 6 lb. at 12 in. from the center of rotation, i.e., 72 in. lb. of torque, a figure somewhat below the operating standard of 100 in. lb. According to the developer, positioned at 90 deg. the elbow will resist a static load of approximately 200 in. lb. (operating standard 600 in. lb.).

e. Life. Although no standards have been established for the minimum number of cycles required per day, or for the total life span of electrical elbows, this unit was considered by the panel to be adequate in both respects. This judgment is based on opinions of the design and its components.

f. Noise. The unit was tested by

the procedure outlined in Attachment 3 at 64 db.

g. Applicability. Installation of the AMBRL elbow does not interfere with control of the terminal device regardless of type or power source. It requires no significant changes in the design of a prosthesis and its use does not interfere with or cause the loss of other functions. It does, however, require a new socket and is not designed for replacement of conventional elbows without replacement socket. The only auxiliary of equipment required is a conventional battery charger. Patient training and retraining requirements are minimal since the unit can be operated by any of several "pull" switches.

h. Special Features. This unit features a convenient disconnect to facilitate removal for repair or adjustment, external adjustment of the turntable friction, and a "free swing" which allows the forearm to be free to flex and extend, a feature considered desirable especially during walking.

i. Cosmesis. Although a highly subjective matter, this unit seems entirely acceptable as regards appearance in relation to the conventional Hosmer E-400.

j. Cost. Dr. Leonard estimated that these units would cost approximately \$250 each in lots of 50.

2. VAPC Electric Elbow (Fig. 4)

a. Size. The VAPC elbow is essentially the same size as the conventional Hosmer E-400.

b. Weight. The elbow unit

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FIGURE 4.

weighs 237.7 gms. or approximately 8 oz., two ounces less than the Hosmer E-400 elbow. The battery, belt, and the operating switch weigh 13.2 oz., a figure significantly below the operating standard of 40 oz.

c. Range. The unit produces a flexion range from 10 deg. to 135 deg., meeting the operating standard. It is electrically blocked from exceeding these limits and does not waste power if activated in the end positions.

d. Speed vs. Load. Unloaded, the VAPC elbow rotates through its entire flexion/extension range in 1.8 sec. With the standard load of 1 lb. in the terminal device, it traversed the complete range in 1.9 sec., well within the operating standard of 2.0 sec. The unit lifted a maximum load of 2.1 lb. placed 12 in. from the elbow center. This function is well below the operating standard of 8.3 lb. at 12 in. from the center of rotation. The unit resists external loads of approximately 30 lb. before yielding.

e. Life. The unit has been cycled for 25,000 cycles with no discernible wear. Although no standard has been established, 25,000 cycles are estimated as equivalent roughly to 4-6 month's use. The unit provides over 250 cycles per battery charge.

f. Noise. The unit was tested and rated at 73 db.

g. Applicability. It requires no changes in the present prosthesis and minimal retraining of patients. The only auxiliary equipment required is a conventional battery charger.

h. Special Features. The control switch is designed to employ a very small range of the same control motion and shoulder flexion as the conventional system.

i. Cosmesis. This unit does not have a cosmetic cover at present.

j. Cost. The estimated cost of the unit in lots of 50 is \$150.

3. Boston Electric Elbow (Fig. 5)

a. Size. The Boston elbow is somewhat narrower (2⁵/₈ in. at the elbow axis) than the conventional Hosmer (2¹⁵/₁₆ in.). More space than in the Hosmer is available (1⁷/₈ in.) between the axis of rotation and the point which a stump might reach. In theory at least, stumps of even greater length could be accommodated. Its overall length at $3^{9}/_{16}$ in. is slightly longer than the Hosmer at $3^{5}/_{16}$ in.

b. Weight. At 924.5 grams, or 33.7 oz., the unit is heavier than the Hosmer at 15.5 oz. The battery pack and electrode section weigh a total of 1710 grams or approximately 60 oz. compared to the operating standard of 40 oz.

c. *Range*. Although the rated range of flexion/extension was from 0 to 135 deg., the range of the model demonstrated was 118 deg. from 17 deg. to 135 deg.

d. Speed vs. Load. The "Boston Arm" was capable of moving through the full range of flexion/ extension in 1 sec., well under the operating standard of 2 sec. Moreover, it moved through the same range under a standard load of 1 lb. in exactly the same time, a demonstration of the torque and velocity feedback features inherent in this unit. By means of semiconductor strain gauges, force along the lead screw axis generates feedback signals. Differentiation of the potentiometer output measuring elbow angle provides velocity feedback. The net effect is a constant speed of elbow flexion regardless of load within the limits of the load-lifting capacity. This unit produced a maximum lift of 7 lb. at 12 in. from the center of rotation or approximately 84 in. lb. Although below the operating standard of 100 in. lb., this elbow was capable of generating higher torques than any of the others demonstrated. This unit was also capable of resisting static loads up to 50 lbs. 12 in. from the center of rotation with the elbow positioned at 90 deg. This is well below the operating standard of 1440 in. lb., but it is equal to the requirement for nonyielding elbows such as the Hosmer unit with the lock engaged (600 in. lb.).

e. Life. The unit is designed to operate over 500 cycles per battery charge, a figure deemed more than adequate for a single day's use. No figures were available as to its total life.

f. *Noise*. Audio energy radiating from the unit was measured at 65 db under the test conditions.

g. Applicability. Application of this unit does not interfere with the control or operation of the terminal device. As an EMG-controlled electric elbow system, the only auxiliary equipment required is a battery charger. An instru-

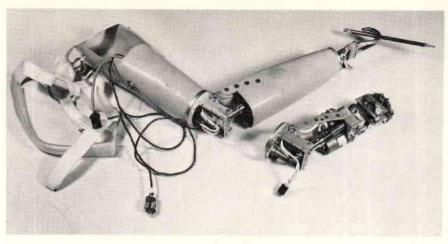


FIGURE 5.

ment to sample EMG outputs in order to determine optimum sites for electrode placement was deemed useful, although not absolutely necessary.

Installation requires a new forearm and a new socket. The unit does not require major changes in conventional prosthesis design. The training of patients to actuate the system by means of EMG signals is not significantly different from conventional requirements. The utilization of electrodes does not entail the loss or diminution of other functions. However, certain motions of the stump, as for example shoulder abduction, may be restricted since they may cause inadvertent operation.

The forearm as presently designed is about 13 inches long. This dimension is satisfactory only for large persons and consideration should be given to providing a range of sizes.

h. Special Features. This unit provides proportional control of torque by means of internal velocity and force feedback loops, i.e., the speed of elbow flexion remains relatively constant and proportional to the input EMG signal regardless of the load being lifted up to 7 lb. at the terminal device. In the configuration demonstrated, the battery pack makes sitting awkward by reason of its bulk and location.

i. *Cosmesis*. Installed in a forearm and covered with an appropriate cosmetic cover, the unit is reasonably acceptable in appearance.

j. *Cost*. A very rough estimate of the cost of this unit was given as approximately \$1000 each in lots of 50.

4. AIPR Pneumatic Elbow (Fig. 6)

a. Size. Designed originally as one component of a completely powered system, the AIPR elbow is slightly wider and longer than the Hosmer E-400 elbow. It is 1/16in. wider at the axis, its over-all length at $3^{11}/_{16}$ in. is approximately 15/16 in. longer. These di-



FIGURE 6.

mensional differences are not functionally significant but indicate noninterchangeability with conventional components.

b. Weight. At 356.4 gm., or 12.5 oz., this elbow is 2 oz. heavier than the Hosmer. The twin cannister power pack and valve weigh approximately 800 gm., or 28 oz., a figure well within the 40 oz. specified for auxiliary equipment.

c. *Range*. The demonstrated unit provided a range of flexion/ extension of 130 deg. adequately meeting the standard.

d. Speed vs. Load. Unloaded, the AIPR elbow flexes through its complete range in 2 sec. Under a standard load of 1 lb. it required 2.3 sec. to traverse the full flexion range. It was capable of lifting a maximum of 4 lb. at 12 in. from the center of rotation (48 in. lbs.) compared with the operating standard of 100 in. lb. The unit was capable of resisting approximately 25 lb. placed 12 in. from the center of rotation with elbow positioned at 90 deg. This is approximately half the specified static resistance to load.

e. *Life.* The unit is adequate with respect to number of cycles per day and total life. This judgment was based on the previous experience with the unit of several panel members.

f. Noise. The AIPR unit produces a "hissing" sound measured at approximately 63 db.

g. Applicability. Installation requires a new socket and new forearm but does not require any changes in the basic prosthesis design. Operation of the unit by patients does not entail training requirements beyond those of a conventional elbow. However, the cannisters in the power pack are charged by means of a special filling device. This operation requires some training and attention to detail. Utilization of this unit by patients does not affect other functions. The auxiliary equipment required for this system includes a special filling device, bottled compressed CO_2 , and a weighing device.

h. Special Features. Precise application of force to the components which valve CO_2 into the actuators will permit a trained amputee to adjust the rate of gas flow and hence the speed of flexion-extension.

i. *Cosmesis*. The elbow itself is adequately cosmetic in appearance.

j. Cost. The current cost of these units is given as \$150 for the elbow in lots of 50, \$55 for the valves, and \$90 for a dual storage tank. The cost of the filling device is estimated at \$40. The total cost, therefore, is approximately \$335 exclusive of the cost of the bottled gas.

5. Ontario Crippled Children's Centre Elbow (Fig. 7)

a. Size. The Ontario Crippled Children's Centre elbow is slightly larger than the Hosmer child'ssize elbow. It is interchangeable with the Hosmer elbow and forearm. No limitations are placed on stump length which may be fitted with the unit.

b. Weight. The unit weighs 10.5 oz., approximately the same as the adult standard Hosmer E-400. The Nicad power package weighs 12.2 oz., well below the operating standard of 40 oz. for auxiliary equipment.

c. Range. The OCCC elbow unit provides 125 deg. of flexion/extension ranging from 10 deg. to 135 deg.

d. Speed vs. Load. Without

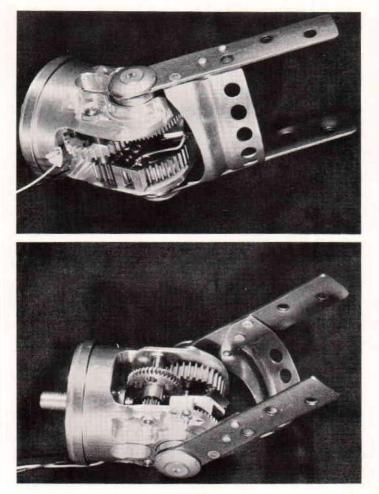


FIGURE 7.

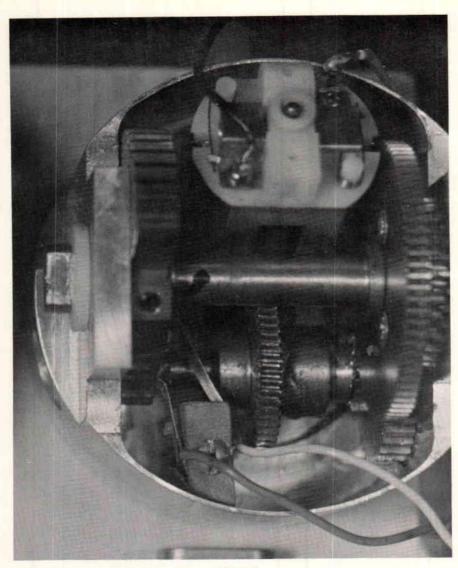


FIGURE 8.

load, the elbow rotates through the full range of flexion in 2.1 sec. When the standard operating load was applied, flexion required 4.3 sec. or more than twice as long as the operating standard, 2.0 sec. The maximum lift to stall was 1.5 lb. Though well below the operating standard for adults, as a child's elbow it may be adequate in this respect.

e. Life. Models of this elbow have been used by children at OCCC. Although exact figures on the number of cycles per day or on total life are not available, these factors have not been a problem according to the developer. f. Noise. The OCCC elbow is relatively quiet, being rated at 62 db. The use of a special low speed, high torque motor has helped reduce the noise level.

g. Applicability. No changes in conventional fabrication methods are required to install the elbow. The unit is interchangeable with the Hosmer standard child's elbow. A small Nicad battery charger is required. The unit does not affect terminal-device control and only minimal retraining is necessary.

h. Special Features. An overload clutch is featured which yields under load to prevent breakage.

i. Cosmesis. The unit is adequately covered with a cosmetic cover and appears similar to the standard Hosmer unit.

j. Cost. The estimated cost of the elbow in lots of 50 is between \$200 and \$250, the most expensive item being the special motor.

6. Gilmatic Electric Elbow (Fig. 8)

a. *Size*. The Gilmatic elbow is the same size as the Hosmer E-400 unit.

b. Weight. The elbow with its internal charger weighs 13 oz., only 1 oz. over the 12-oz. operating standard. The battery pack weighs 8 oz., far below the operating standard of 40 oz.

c. *Range*. The unit rotates through a range of 125 deg., from 10 deg. to 135 deg.

d. Speed vs. Load. The Gilmatic elbow required 3.0 sec. to position or lift a standard test load. This is significantly slower than the operating standard of 2.0 sec. The maximum load lifted was 2.5 lbs., well below the operating standard (8.3 lbs.) but not significantly different from the other devices being tested. It can sustain a static load of 50 lb. at 12 in. from the center of rotation conforming to the requirement of 600 in. lb.

e. *Life*. The number of cycles per day provided was generally assumed to be adequate on the basis of the components used.

f. Noise. Tested by the standard procedure, the unit was rated at 79 db.

g. Applicability. Application of the Gilmatic electric elbow to a prosthesis does not interfere with the operation or control of the terminal device. It requires minimal retraining and no changes in the prosthesis design. No auxiliary equipment is needed; the battery charger is incorporated in the unit.

h. Special Features. Although not fully operable at the time of the demonstration, the unit was designed for control by means of a switch actuated by a muscle bulge.

i. Cosmesis. This unit does not have a cosmetic cover.

j. *Cost*. The cost estimate in lots of 50 is \$150 per unit.

7. Rancho Los Amigos Elbow (Fig. 9)

a. Size. The Rancho elbow is built on a standard Hosmer frame and is the same dimensionally except for the motor extension into the forearm. It is available in three sizes.

b. Weight. The elbow in the

orthotics and prosthetics

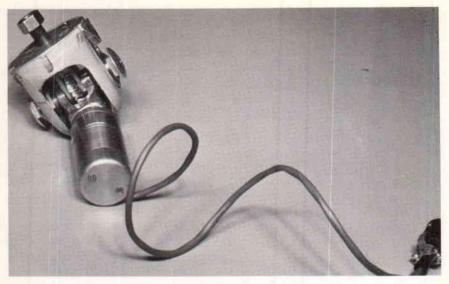


FIGURE 9.

adult size weighs 18.5 oz. with a large part of the weight distal to the elbow. The operating standard is 12 oz. The battery package weighs 27 oz., a figure within the standard of 40 oz.

c. *Range*. The range of elbow rotation is 0 to 135 deg.

d. Speed vs. Load. The Rancho elbow rotates through its entire range in 2.5 sec. (.5 sec. slower than the standard). It lifts the standard lift load in 3.5 sec. (1.5 sec. slower than the standard). The maximum resistance to load has not been tested.

e. *Life*. The unit is commercially available and has apparently provided adequate daily and total-life service.

f. *Noise*. The Rancho elbow was rated at 60 db.

g. Applicability. Application of the Rancho elbow requires no significant alterations of either prosthesis design or fabrication methods. A number of special controls including EMG are available from the manufacturer. A battery charger is the only auxiliary equipment necessary. It does not interfere with the terminal device control.

h. Special Features. The unit is commercially available in three sizes.

i. Cosmesis. This unit has a partial cosmetic cover which leaves some working parts exposed.

j. Cost. In lots of 20 or more the elbow costs \$300, the battery pack \$40, the charger \$12.50, and the battery case \$7.50. It is available from Electric-Limb Corp., Hollywood, Calif.

DISCUSSION

In the absence of adequate clinical feedback information it was difficult for the panelists to assess the various features of each of the systems. Who, for example, could state with certainty at this time that 2 ft. lb. or 10 ft. lb. is a desirable maximum torque output for an elbow? An elbow delivering 2 ft. lb. is principally a positioning device that is capable of lifting perhaps 90-95 per cent objects normally handled of the by a patient in daily living activities. An elbow delivering 10 ft. lb. is a "live lifting" device with perhaps far more specialized application. Questions such as this and also the question of the length of AE stumps are best answered by broad clinical experience. Yet to obtain broad clinical experience powered elbows must be fitted and therefore from those available several should be selected for early field testing.

The Panel was charged by the chairman with the task of recommending one or two elbows for early trials. The fabrication and delivery of the selected elbows to clinics would be expedited in order to initiate the feedback of clinical information as rapidly as possible. It was made clear to the Panel that the recommendation of one or more elbows in no way meant that these elbows were, in the opinion of the Panel, superior in basic design, engineering, or potential utility for patients to those not recommended at this time. Their recommendation would simply mean that of those elbows demonstrated at this meeting, one or more were, or with minor redesign could be, minimally adequate for use by patients at this time. The developers of those elbows not recommended for immediate application are encouraged to continue development, particularly in the light of the information which hopefully will be fed back shortly from the field study. The bases for these recommendations, therefore, include minimally acceptable functional adequacy, low cost in order to provide the maximum number of units and the greatest amount of information, most compatibility with existing technology, minimum training of prosthetists and amputees, and simplicity of manufacturing in small lots.

RECOMMENDATION

After extended discussion the Panel recommended that a sponsor undertake to fund and supervise the fabrication of an equal number of the Gilmatic Electric Elbow and the AMBRL Electric Elbow.

Although the AIPR Pneumatic Elbow was found by the Panel to be in a highly advanced state of development it was not selected because it is already being obtained for a field study. Both Rancho and the OCCC elbows were presented in child sizes, a special application which the Panel agreed to defer for field application. The VAPC elbow was considered excessively noisy in the configuration demonstrated, and the Boston Arm was considered too expensive to provide adequate numbers of units for the intended purposes.

This recommendation is contingent upon the presentation to the Chairman of the Subcommittee on Design and Development of two fully operational systems of each of the two designs. When it has been determined that these models comply substantially with the data on which the original recommendation was based, negotiations for fabrication will be undertaken.

STANDARDS

This meeting clearly brought out the need for extensive consideration of standards and specifications for powered elbows as well as for other powered components. Time did not permit adequate examination of currently available criteria and the "operating standards" established for purposes of this meeting. The consensus of the Panel, as judged by the chairman, was that the operating standards used during the meeting represented a reasonable approach to the development of valid criteria. The operating standards include items relating both to the physical and funcetional characteristics of the elbows, and to the compatibility of an elbow with conventional prosthetics technology and with the prosthetics skills of patients. Several previously established standards relating principally to the size, weight, shape, and cost of the conventional Hosmer E-400 elbow were employed. Also included were arbitrarily determined standards relating to the power feature of these elbowsspeed/load, relationships, maximum torque output, and control methods.

In establishing tentative standards for powered elbows the need must be recognized for at least two sets of standards. One set relates to a type of powered elbow which is essentially a powered of the conventional analogue Hosmer elbow, offering only the same functions performed perhaps differently and better. The second set of standards incorporating the first set should include other items relating to the design and function of elbow mechanisms which furnish functions beyond those of the conventional elbow, i.e., rotation in the transverse plane or perhaps more sophisticated control elements. On the basis of general experiences with conventional elbows and the Panel discussions, the following are recommended as tentative standards for the design and the evaluation of powered systems of the first order discussed above.

Size

It is unnecessary to specify dimensionally the standard for size because the dimensional aspects of the elbow are only significant in relation to cosmesis, length of stump which can be accommodated, and compatibility with other conventional components of prostheses. The cosmetic acceptability of an elbow is more readily controlled by criteria for compatibility with components proximal and distal to it.

At the present time the potential value of externally powered elbows over conventional elbows is not conditioned on the level of AE amputation. Therefore any powered elbow which is potentially superior to a conventional elbow is applicable to any AE amputee. Because the type of elbow referred to in these standards is designed principally to reduce excursion requirements for operating the elbow, and to eliminate individual locking/unlocking functions, compatibility with other components is the only principal physical criterion. The tentative standard governing size therefore can be stated as follows: the size of the elbow should not limit its application to any particular level of AE amputee, and its dimensions should be such that it readilv accepts and is readily accepted bv conventional AE forearm/ saddle assemblies and conventional elbow turntables.

Weight

There seems to be no essential reason why elbows of the type being considered should not be designed not to exceed 12 oz. including all components contained within the elbow unit and its cosmetic cover. The weight of all other components of the powered elbow system should not exceed 24 oz. including power pack and controls.

Range of Rotation

The position of maximum flexion should not be less than 135 deg. The total rotation range should not be less than 125 deg. nor should the elbow hyperextend beyond 0 deg. of flexion.

Speed vs. Load

Standards for speed of elbow rotation cannot be sensibly considered without also considering load factors. Experience to date and current opinion are that optimum control by a patient requires that speed of elbow rotation fall between 1 and 2 sec. At speeds above 135 deg. per sec. it is difficult to control elbow position. At speeds below 135 deg. per 2 sec., patients have to "wait" for the forearm to come up.

Current experience and opinion also indicate that "live-lifting" more than 1 to $1\frac{1}{2}$ lb. by AE and SD patients is extremely rare. Prosthetic elbows are used principally as positioning devices and for live-lifting only relatively light loads. It was difficult for the Panel to identify common objects weighing in excess of 11/2 lb. which amputees might normally "live lift." We may therefore express a useful standard:-powered elbows should be capable of rotating through 135 deg. with a load of 1.0 lb. 12 in. from the center of rotation within two sec. In the unloaded condition the speed of rotation should not exceed 135 deg. per sec. Minimum torque output (live-lift) should be 1.5 ft. lb. No purpose is served by specifying "maximum" torque output.

Resistance to External Load

Powered elbows should maintain a position of flexion under static loads of 25 ft. lb. without damage.

Noise

On the basis of the noise levels measured on the seven powered elbow systems, subjective reactions indicate that noise levels not

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exceeding 68 db are minimally tolerable. Noise level should be determined by the technique employed here and described in Attachment 3.

Cycles per Charge

The only available data bearing on the number of elbow flexions normally performed by an AE amputee are those recently collected on a single highly active patient using a conventional elbow. The data indicate that approximately 250 cycles is the average daily use over a period of a week ranging from a maximum of 338 per day to 97 per day. In view of the relationship between cycles per charge and power source, size and weight, an adequate minimum standard would be 300 cycles per charge.

Powered elbows should be designed to give a minimum of $2\frac{1}{2}$ yr. of service during which a total of 250,000 cycles are completed without requiring the repair or replacement of major components.

Cosmesis

The elbow should present a clean, smooth exterior surface without protrusions or exposed moving parts. Its general shape and dimensions should permit it to be faired smoothly into the socket.

Applicability

Since these tentative standards relate to a powered elbow intended for use in systems in which the other components may be either conventionally or externally powered, the compatibility of a powered elbow with other conventional prosthetic components is significant. Although it is not possible to specify all the elements of compatibility, this standard should indicate the desirability of matching the powered elbow to the other components of a conventional prosthesis with respect to color, fittings, and the like.

OTHER UPPER-EXTREM-ITY COMPONENTS AND TECHNIQUES (See Attachment 2)

The discussions of each item on the regular agenda of the Panel are reported below.

Group A

1. Gilmatic Electric Elbow Lock (Fig. 10)

This device is a solenoid-operated electric-elbow lock installed in a modified Hosmer E-400 elbow. It incorporates a power-conserving switch which keeps the solenoid inactive except while locking or unlocking. This model is slightly different than the one submitted at the last Panel meeting in that the control is effected by a "pad"-type of switch consisting of two contact plates held apart by a sheet of plastic foam. The switch is mounted in the socket and activated by bulging residual muscles. An evaluation conducted by VAPC indicated far displacement, less over-shoot. and "body english" when com-

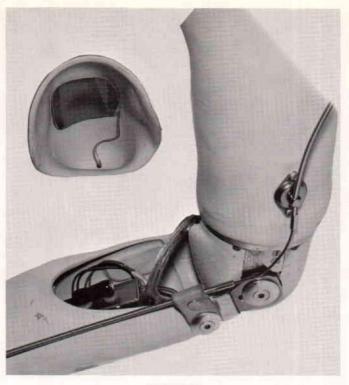


FIGURE 10.

pared to the conventional method of locking the elbow.

It was the feeling of the Panel that the device offers an improvement over the conventional systems. It was recommended that twelve models, 6 for adults and 6 for children, be fabricated for testing on amputees. Mr. Leavy expressed interest in manufacturing these prototype models. In the interim Gilmatic will make available one unit to Mr. Chester Nelson for clinical trial.

VAPC Direct Forming of Upper-Extremity Sockets (Fig. 11)

Mr. Dolan reported that NYU had completed a preliminary eval-

uation in which three subjects for periods varying from two to four months wore sockets of synthetic balata (Polysar X414) formed directly over the stump.

All three experimental prostheses were considerably heavier than the conventional prostheses; however, none of the subjects commented negatively regarding the weight. In two cases, cosmetic finishing was considered to be unsatisfactory; irregularities in the foam showed through the vinyl cosmetic cover and the foam collapsed proximal to the wrist fitting. NYU had suggested the use of a more opaque cover and a somewhat denser foam mixture.

After five weeks of use, one

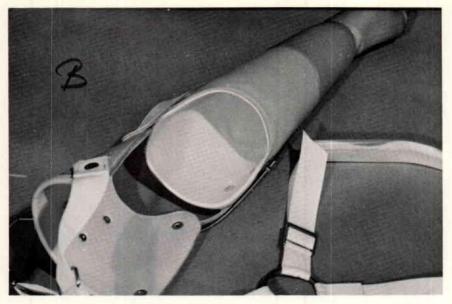


FIGURE 11.

subject experienced socket discomfort and skin irritation from the embossed ridges caused by the stockinet on the inner surface of the socket. The other two subjects reported that they preferred the synthetic rubber socket to their previously worn prosthesis.

As a result of these findings, several changes have been made in the technique to reduce weight, and to improve fit and cosmetic appearance.

Several fittings using the revised technique are now in progress at NYU.

3. Rimjet Turntable (Fig. 12)

This body-powered humeral rotator, designed by Mr. J. Ivko, a bilateral amputee, consists of two disks, the lower of which rotates with the elbow and forearm. Rotation is adjustable through a range of approximately 180 deg. A spring-loaded plunger locks the unit in any of seven positions. The humeral rotator is normally controlled by the same body motions which lock and unlock the elbow.

VAPC undertook to fit a suitable patient with this device. Due to its weight and special harnessing requirements, and the small number of appropriate patients available, no fittings had been completed. The assistance of Mr. Titus of Duke University was requested in an effort to fit a suitable patient. Mr. Titus reported that none has been located to date. The Panel felt that the device at 12.5 oz. was rather heavy, and should be fabricated of aluminum for test purposes. Mr. Ivko, the developer, believes that the substantial weight of the device is a functional aid. Mr. Leavy has been in contact with Mr. Ivko to discuss the possibilities of manufacturing the device.

Group B

1. CAPP Mark IV Infant Passive Hook

This device is constructed of Delrin with the thumb fabricated of Lexan and covered with surgical tubing. The palmar pad is made of neoprene crepe. A number of these hooks have been fabricated for clinical tests at child amputee clinics. This item will be referred to the Sub-committee on Evaluation and no longer carried on this agenda.

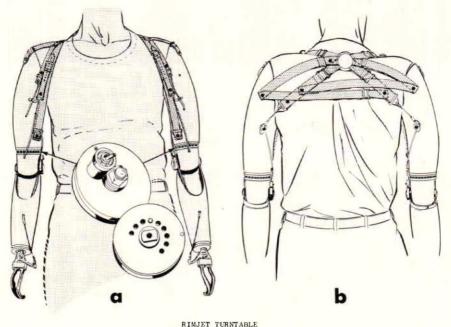
2. Gilmatic Combined-Motion Adjustable Screw

Activator for Shoulder-Disarticulation Prosthesis

Mr. Motis stated that development of this device is at the breadboard stage. Several design changes are required to put it into working order. Mr. Motis was encouraged to continue development.

Gilmatic Extendo-Flex with either External or Axial Control

Mr. Motis demonstrated two models at a previous meeting. One was designed for axial cable control and the other for external control. Models of each unit will be made available for limited clinical trials. Mr. Muilenburg requested one unit for trial in his



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FIGURE 12.

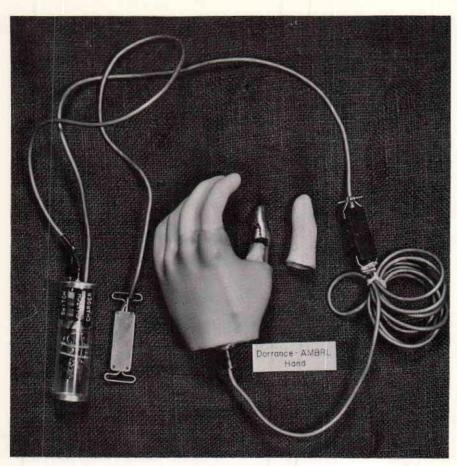


FIGURE 13.

area. Mr. Chester Nelson will also fit a patient with the device.

- AMBRL Electric Elbow (Discussed in Elbow section)
- 5. AMBRL Piezo-Electric Hand (Fig. 13)

A pre-production model of this hand was demonstrated by Mr. Brown of the D. W. Dorrance Co. It incorporates the slippage-detection system (piezo-electric crystal) developed at AMBRL. The hand mechanism and servomotor are self-contained within the skeletontype hand frame and the exterior is resilient foam plastic. and electronic com-Batteries ponents are packaged in a cylinder one and one quarter inches in diameter by four inches long. It weighs approximately 11 oz. The hand provides pinch forces of 1 to 12 lbs. as required. AMBRL will test and evaluate this model to determine its compliance with existing AMBRL standards and specifications.

6. Toilet Care Devices (Fig. 14)

Dr. Peizer reported the experience of a bilateral SD amputee using the American Bidet in his home. After 4-months' use the patient expressed highly positive reactions. The device was reliable, efficient, and easily operated. He no longer needed the assistance of family members for toilet care. The Panel felt that this device, despite its initial cost of \$250, represented an adequate solution to this problem in the home.

The device is available from WORLD INDUSTRIES, INC., 2 Division St., Somerville, N. J. 08876.

The value of portable devices for this purpose was discussed but the consensus was that toilet care for high level bilateral amputees remains a problem.

7. AIPR Wrist-Flexion and Rotation Unit (Fig. 15)



FIGURE 14.



FIGURE 15.

Dr. Kiessling demonstrated a device that provides up to 25 deg. of voluntary flexion of the wrist with passive pronation and supination. The device will be available in nine different lengths ranging from child to adult sizes. These units are part of the AIPR system and will be evaluated in a field study.

8. Northwestern University Power Assist

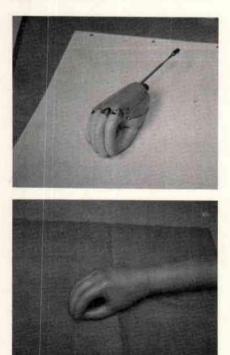
Mr. Grahn reported that this previously demonstrated device

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has been successfully used during the past 26 months by three amputees, one a forequarter. A fourth unit will be fabricated for use with the NU wrist rotator and electric hand to be controlled by a seven-mode controller.

AIPR Phase Shift Control

Dr. Kiessling described a control system permitting the patient to shift from one to another operational mode. A phase channel distributor permits selection of a mode of operation in which available body-control motions would activate servos to flex the elbow, rotate the wrist, and operate the terminal device. Voluntarily selecting a second mode will permit





the same body-control motions to activate servos for other functions, for example, combining elbow flexion, humeral rotation, and wrist flexion. Two prototypes will be used in an upcoming field study program of the AIPR components.

10. CAPP Activated Terminal Device

Mr. Sumida described this device as similar to the Mark IV infant hook described above except for the thumb which is fabricated of 24ST aluminum instead of Lexan. Several units have been fabricated for evaluation at child amputee clinics. This item has been referred to the Subcommittee on Evaluation.

11. CAPP Constant-Friction Wrist Unit

Made of Delrin with a stainlesssteel face plate, several units have been fabricated for evaluation. This item has been referred to the Sub-committee on Evaluation.

12. Dorrance Size 1 Mechanical Hand (Fig. 16)

Developed for children, the hand provides prehension forces of about two pounds with a pull of approximately five pounds. The over-all weight including the cosmetic glove is about six ounces. The hand has been successfully fitted in sufficient numbers to warrant reference to the Subcommittee on Evaluation. This hand is commercially available from the D. W. Dorrance Company at a price of \$125 each.



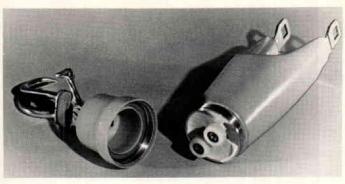


FIGURE 17.

Gilmatic Electric Powered Elbow (Described in Elbow section)

14. Gilmatic Multiple-Contact Switch

Mr. Motis described a design concept for a switch located in the AE socket which will provide up to six contacts for electrical control of various prosthetic components. The contact switch is actuated by residual muscle bulging. The Panel encouraged Mr. Motis to continue his development efforts.

15. NU Three-Mode Myo-Electric Controller

Mr. Grahn described Dr. Childress' development of a threemode controller which may be operated in several ways. In its present form, a light muscle contraction turns a switch on, a moderate contraction turns it off, and a heavy contraction produces the second mode which is proportional to the strength of contraction above a fixed level. The device is off when there is no contraction. This is actually a four-level unit with three operating modes. A prototype device with textured stainless steel electrodes is in process of being fitted to an amputee subject.

16. NU Multiple Functional Controller

This unit makes use of two control sites with three-mode controllers at each site. This theoretically makes it possible to generate nine control modes but so far only seven modes have been obtained, making it possible to control three functions from two electrode sites. This is a considerable improvement over the conventional myo-electric systems which use two sites for only one function. It is hoped that this unit will lead

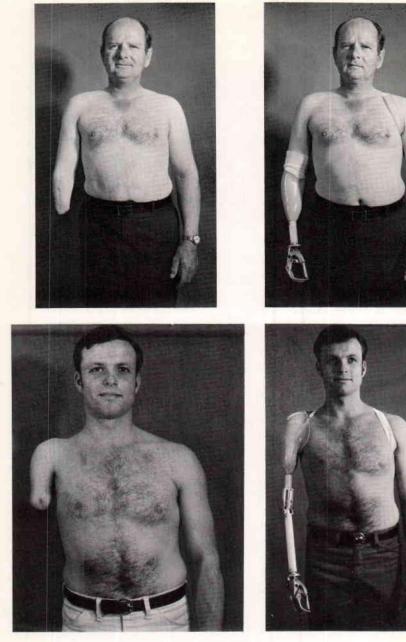


FIGURE 18.

tions of prehension, supinationpronation, and elbow flexion-extension controlled by two muscle Mr. Grahn described a wrist groups (e.g., biceps and triceps). rotation unit which utilizes a

to a powered arm with the func- 17. NU Powered Wrist Rotator (Fig. 17)

harmonic drive for power transmission. Maximum output is 36 RPM at zero torque and the stall torque is 215 in. oz. Two units are being installed in forearms for evaluation on amputees. A third unit is being constructed utilizing a frameless direct-current torque motor with a relatively large axial hole through the rotor. This will allow it to be used with a center controlled hook or an electrical hand with integral or remotely (proximally) mounted motor.

18. Endoskeletal Upper-Extremity Prosthesis (Fig. 18)

Mr. LeBlanc of UCLA showed a motion picture of the endoskeletal arm whose rigid structure and controls are inside a soft covering. The purpose of this design is to provide better cosmesis as a result of greater freedom in the shaping and resiliency of the covering and by use of internal controls. A BE and an AE prototype are being fabricated consisting of polyester sockets. nylon tubing. Teflon bearing surfaces and braided Dacron cabling. The prototypes are operated by standard BE and AE shoulder harnesses.

Group C

- Rehabilitation Institute of Montreal Myo-Electric Control (to be discussed at next meeting)
- 2. University of New Brunswick Myo-Elec-

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tric Control (to be discussed at next meeting)

- 3. Viennatone Myo-Electric Control (to be discussed at next meeting)
- I.N.A.I.L. Myo-Electric Control (Italy) (to be discussed at next meeting)
- 5. VAPC Humeral Rotator (Fig. 19)

Dr. Peizer reported experiences with a laboratory model of a "humeral rotator." Rotation is controlled by means of two doublethrow shear switches which are built into the wall of the socket and remain in contact with the stump. The two switches control an "and" circuit, that is, when the stump is rotated axially, both switches must be activated in the direction of rotation to activate the elbow. This reduces the chance of accidental activation due to any motion of the stump other than rotation in the transverse plane. Twenty-seven rechargeable double-plate nickelcadmium batteries provide operating power to a miniature electric motor that rotates the elbow turntable. The unit can also be manually rotated. The rotator is attached to the socket in the standard manner with a knurled laminating ring.

Although the unit functioned adequately in initial tests, control by means of the shear switches was inadequate. A new control switch similar to the one

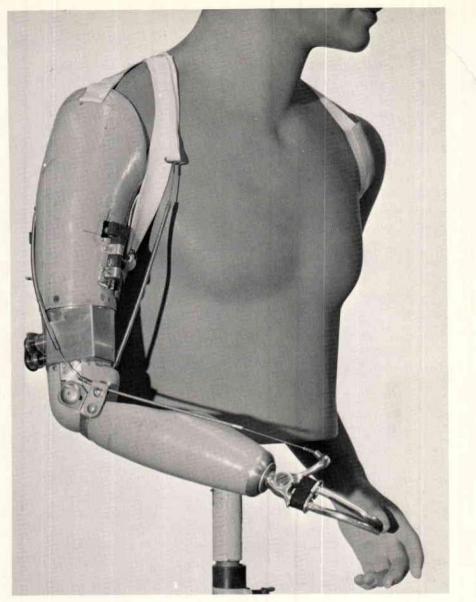


FIGURE 19.

used for the VAPC elbow is being fabricated.

6. AMBRL Sequencing and Positioning Switches (Fig. 20)

Mr. Salisbury and Mr. Colman

demonstrated a variety of switches for control of external power. Included were harness-controlled three-level switches, two-level sequencing switches, a three-level strain gauge switch with sequencing at the two active levels, a stump-operated, 8-position joy stick, a three-level muscle bulge switch, and a three-level miniature switch utilizing a transistor bridge.

Interest was expressed in the switch demonstration model as a training aid and for selecting the optimum control switch for a given patient.

7. AMBRL Myo-Sonic Control System (Fig. 21)

Mr. Salisbury presented a control system which utilizes a threelevel switch for control of the duration and direction of prosthetic or orthotic functions. The desired function is selected by voice command, a concept demonstrated by means of an AE prosthesis. English names for the voice command (hand, elbow) and a three-level muscle bulge were used. One advantage of the system is that the addition of more functions would not require the use of more control sources on the amputee but only the addition of more electronic components and more command words. It is anticipated that this control approach would offer the bilateral amputee or quadriplegic patient greater functional regain than is available with the present control system.

8. UCLA Biotechnology Laboratory

Dr. Lyman and his three associates, Dr. Horst Arp, Mr. Amos Freedy, and Mr. Jack Aldrich, reported on their work in the field of fluidic control systems, arm

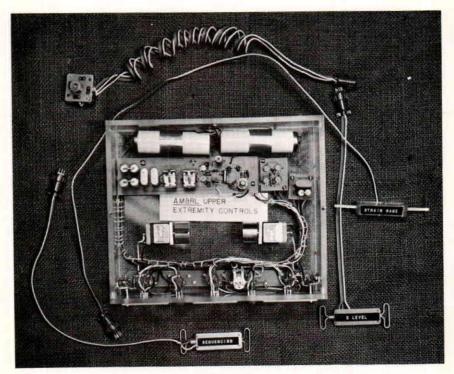


FIGURE 20.

orthotics and prosthetics

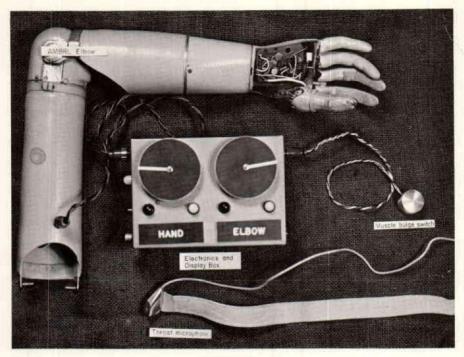


FIGURE 21.

motion simulators, and control signal conditioning. Dr. Arp discussed the feasibility of several actuation systems and related control circuitry problems.

Supplementary to the current investigation of suitable electronic circuits, a pneumatic control system utilizing fluidic devices was designed. The control concept was originally based on the principle of a position-feedback servo-mechanism. However, due to the unavailability of appropriate lightweight pneumatic feedback transducers, and in order to prevent oscillatory actuation, the principle was changed to open-loop operation. This is an approach which necessitates signal differentiation to achieve proportional operation of a displacement-type actuator. Furthermore, because of the unavailability of proportional acting interface devices which would raise the control signals' pressure level as required for actuation, switched valves had to be employed. Therefore, to maintain direct controllability through forceproportional signals. a fluidic signal detection and amplitudeconversion circuit was designed. A simple actuator system attached to the shoulder joint of an AIPR arm. and a newly developed pneumatic force-to-pressure transducer complete the test system, thus providing a concept for controlling movements of one degree of freedom

This basic movement control unit in turn is intended to become a portion of a movement pattern generating system whose logic description also has been

developed. The movement coordination system is to be operated through two transducers and provides for an automatic control signal subsequence for the task of arm lifting; it allows for independent corrections of direction or distance, respectively, and it inopposing signals autohibits matically. Further development of this concept in order to control and coordinate movements of more than two degrees of freedom intended after experimental is studies on the performance of the system so far devised have been made. Simultaneously, an investigation of the feasibility for utilizing stepping (motor) devices to improve the positioning accuracy and the "hold" function of the actuators has been undertaken.

An attempt is being made to ease the decision load of a patient as he handles prosthetic devices or a human operator handling manipulative devices. The approach is called semi-autonomous remote manipulation and it refers to a feasibility study into a control concept of systematically reducing the number of control decisions required of the operator (or patient wearing a powered prosthesis) through an adaptive aiding system. The aiding system's function will be to respond to both the operator's skills as he handles the manipulative device over a learning period and to information about the environment such as blocking obstacles, etc. It is expected that through the establishment of favored paths of movement and the sharing of the decision load between the man and the device the control assist can be optimized.

To support the establishment of mathematical models to simulate arm motions, a series of dataacquisition experiments has been conducted to study arm motions of four degrees of freedom. The experiments were carried out with the cooperation of the Rancho Los Amigos Hospital, utilizing their special orthosis that permits movements through six degrees of freedom. Evaluation of the experiments is in progress and the first results indicate that specific attention has to be paid to the time relations between arm motions according to different degrees of freedom. It is expected that a careful evaluation of the test data will provide an idea about the interaction of ballistic and proportionally controlled motion phases as observed for target approach tasks. This in turn will determine the feasibility of corresponding control systems to operate powered prosthetic or manipulative devices.

An experimental study is in progress to compare various signal sources as to their suitability for generating appropriate control information. Two transducers and three types of control signals are being studied: 1) An EMG meanfrequency system, 2) an average EMG power-level detector, and electromechanical strain 3) an gauge transducer which is activated by muscle displacement and force. The experimental apparatus has been designed and is being constructed. Preliminary

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experimental runs will begin shortly.

9. Moss "Multiple-Axis Myoelectric Control"

Mr. Roy Wirta presented a motion picture and discussed the development of myoelectric control system for multiple-axis prostheses. The objective is to develop a suitable control for positioning and orienting the terminal device in a reliable, natural manner requiring the least amount of conscious effort. Pattern recognition techniques are used to discriminate activities of muscles in the back, chest and shoulder for providing simultaneous control of elbow flexion and extension, and of humeral and forearm rotation.

The engineering model shown was highly versatile and will serve as a test bed to determine operational characteristics under varying conditions of use by an AE amputee.

Plans for future activities on this project include the systematic resolution of the present problems and the application to the severely handicapped upperextremity amputee.

SUMMARY

Twenty-six of thirty items on the agenda were discussed, three in Group A, eighteen in Group B and five in Group C. Four items in Group B-1, 10, 11, and 12 were referred to the Subcommittee on Evaluation. Items 4 and 13, externally powered elbows regularly carried on the agenda, were discussed on the first day of the meeting. Items 1, 2, 3, and 4 in Group C were not covered because they will be discussed at the proposed meeting on powered terminal devices.

Several participants undertook specific tasks in support of other developers:

A. Mr. Motis will make available for study one Gilmatic Electric Elbow Lock to Mr. Chester Nelson (Group A, item 1).

B. Messrs. Muilenburg and Nelson will fit the Gilmatic Extendo-Flex unit to patients in limited clinical trials (Group B, item 3).

The meeting was adjourned at 3:00 p.m. on Wednesday, October 23, 1968.

Feb. 21, 1969

ATTENDANCE LIST

James Allen Kaare Lind Horst Arp John Lyman L. Berger (SWR) Leonard Marcus Carl Mason Ernest Bontrager Vert Mooney John Bray Gilbert M. Motis Milo Brooks Noel Brown Alvin L. Muilenburg Robert Brown Chester Nelson Orlyn C. Oester-Roddy Chupurdia eich Albert B. Col-Cord Ohlenbush man Ivan A. Dillee David Osborne Clvde M. E. Thomas Pirrello, Dolan Jr. Edward C. Grahn Charles W. Radcliffe Lloyd Salisbury J. Morgan Greene **Rex Harrison** Charles M. Scott Louis Holz George C. Sponsler Andrew Karchak Anthony Staros Edward A. Kies-Bernard R. sling Strohm Robert Klebba Carl Sumida Wallace Sumida Jerry Leavy Bert R. Titus Maurice A. Le-Blanc Fred Leonard A. Bennett Wilson, Jr.

Earl Lewis

Roy Wirta

Measurement of Noise Levels of Prosthetic Devices

It is suggested that since various motor-driven prosthetic devices do create certain noise levels a uniform method for describing this noise level should be outlined. It is apparent that descriptions such as "sounds quieter than...," "isn't as noisy as...," etc., are entirely subjective, unspecific, and impossible to quantify.

Therefore, it is suggested that a standard procedure for measuring noise levels be established. Two suggested procedures are outlined below:

1. Quick look procedure: Using a sound level meter (calibrated with A, B, and C scales) the prosthetic device will be placed 1 meter from the face of the microphone. Using a slow scale (slow meter deflection, rms type averaging) output measurements will be obtained on the "A," "B," and "C" scales. These measurements are in db SPL.

2. Detailed procedure: Using a level recorder, sound level meter (or spectrometer) with condenser microphone, measurements over time (a time of 1 minute should be sufficient) will be obtained for each device for the "A," "B," and "C" scales and at one other octave band (such as 2000 hertz at which man's hearing is quite sensitive). The purpose of making measurements over time is that it is apparent that various devices vary in intensity depending on whether the task is to raise, lower, or keep stable the prosthetic device. By using a time-intensity scale differences over time will be obtained. Again, measurements should be obtained in rms, but in this instance either the fast or slow scales may be used. Probably, it would also be wise to use overall intensity, but one of the above "A," "B," or "C" scales will be close (because of its built-in weighing network) to a "noisiness" classification. If possible, a separate reading should be obtained using a frequency analyzer and level recorder to record differences in frequency bands over time to demonstrate at which frequency the maximum intensity appears. (If, for example, one instrument has its greatest output at 10,000 hertz where man's hearing is not so sensitive, it would probably appear to be less noisy than one at which the maximum intensity reading was obtained at 1,000 hertz.)

AGENDA

Sixth Workshop Panel on Upper-Extremity Prosthetic Components

Subcommittee on Design and Development Committee on Prosthetics Research and Development

October 21-23, 1968

Santa Monica, California

L Welcome and General Discussion

Chairman: Edward Peizer

II. Topics

Group A

The following represent completed devices or prototype models which have undergone preliminary evaluation. Discussion to determine disposition is indicated. Gilbert Motis

- Gilmatic Electric Elbow Lock
 VAPC Direct Forming of Upper-Extremity Sockets
- 3. Rimjet Turntable

Group B

New designs including "breadboard" or developmental models of components or complete systems.

- 1. CAPP Mark IV Infant Passive Hook
- 2. Gilmatic Combined-Motion Adjustable Screw Activator for Shoulder-Disarticulation Prosthesis
- 3. Gilmatic Extendo-Flex with either External or Axial Control
- AMBRL Electric Elbow
 AMBRL Piezo-Electric Hand
- 6. Toilet Care Devices
- 7. AIPR Wrist-Flexion and Rotation Unit
- 8. Northwestern University Power Assist
- 9. AIPR Phase Shift Control
- 10. CAPP Activated Terminal Device
- 11. CAPP Constant-Friction Wrist Unit
- 12. Dorrance Size 1 Mechanical Hand
- 13. Gilmatic Electric Powered Elbow
- 14. Gilmatic Multiple-Contact Switch 15. NU Three-Mode Myo-Electric Controller
- 16. NU Multiple Functional Controller
- 17. NU Powered Wrist Rotator

18. Endoskeletal Upper-Extremity Prosthesis Group C

Included are myo-electric and electric control systems for operation of various components. (Discussion of applications is indicated.)

- 1. Rehabilitation Institute of Montreal Myo-Electric Control
- 2. University of New Brunswick Myo-Electric Control
- 3. Viennatone Myo-Electric Control 4. I.N.A.I.L. Myo-Electric Control (Italy)
- 5. VAPC Humeral Rotator
- 6. AMBRL Sequencing and Positioning Switches

Carl Sumida

Clyde Dolan

Thomas Pirrello

Gilbert Motis

Gilbert Motis Fred Leonard Fred Leonard Edward Peizer Edward Kiessling Edward Grahn Edward Kiessling Carl Sumida Carl Sumida Jerry Leavy Gilbert Motis Gilbert Motis Edward Grahn Edward Grahn Edward Grahn Maurice LeBlanc

Edward Peizer

Edward Peizer Edward Peizer Edward Peizer Edward Peizer Lloyd Salisbury Albert B. Colman

 AMBRL Myo-Sonic Control System
 UCLA Biotechnology Laboratory
 Moss "Multiple-Axis Myo-Electric Control" Group D

Lloyd Salisbury John Lyman Roy Wirta

Items in this group are suggested areas for feasibility studies, problem analyses, and design requirements.

- 1. External Power Applications, Components and Systems
- 2. Control Sites for Externally Powered Components
- 3. Terminal-Device Design and Specifications

4

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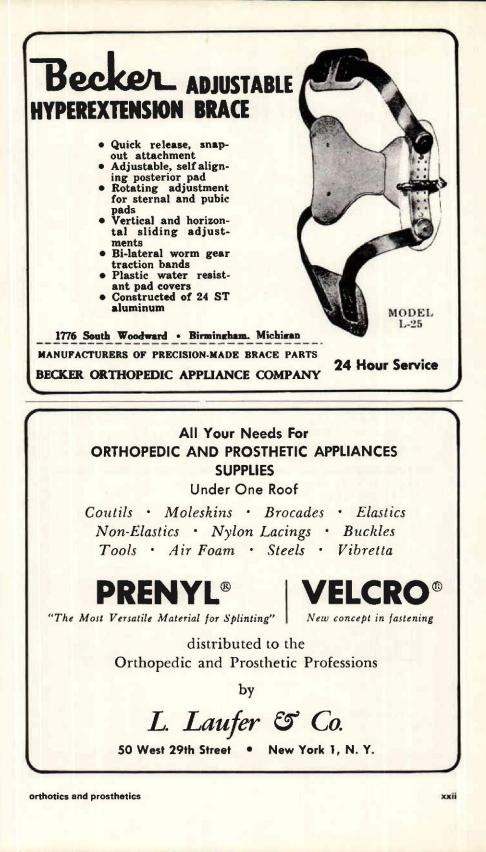
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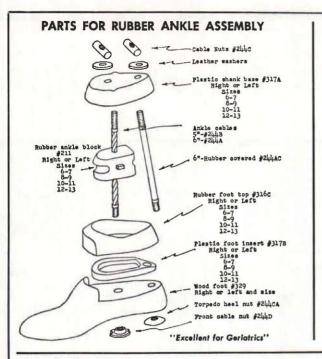
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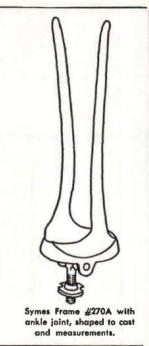
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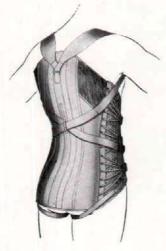
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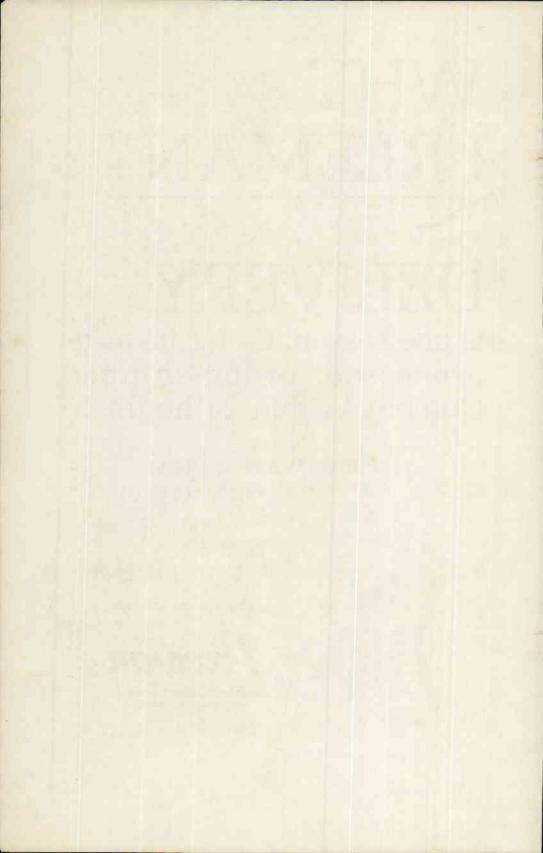
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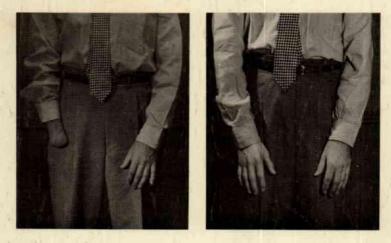
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