THE I.N.A.I.L. EXPERIENCE FITTING UPPER-LIMB DYSMELIA PATIENTS WITH MYOELECTRIC CONTROL

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In the early 1960's, because of widespread use of thalidomide, a sedative taken by women in early pregnancy, a large number of children were born with severe congenital anomolies, notably dysmelia. These children, now approaching early adulthood, require the application of acceptable functional cosmetic prostheses to serve both their personal needs and to enable them to enter into the social and occupational environment of the community.

Until recent years, for the very severe forms of dysmelia, the only means of prosthetic treatment has been with pneumatically powered prostheses (Fig. 1). Regrettably, our surveys indicate that a very high percentage of children have rejected this type of upper-limb prosthesis. The parents may be a major factor in this rejection because, in performing the activities of daily living for these children, they have diminished the children's desire to help themselves and to be independent. Another reason often cited is the complexity of the prosthesis itself and the difficulty of securing fresh supplies of energy. Special equipment is required for refilling the gas cylinders (Fig. 2) and this restricts the distances wearers can travel from home unless they carry the necessary cumbersome equipment with them.

There are also limitations from the standpoint of function, limitations which do not actively permit all desired movements. (For example: at the elbow, flexion is active and extension is by gravity; at the wrist, supination is active while pronation is by a spring; and at the shoulder, flexion and extension are passive motions with a pneumatic lock.)

These disadvantages naturally diminish considerably the desirability of using pneumatic power for dysmelics.

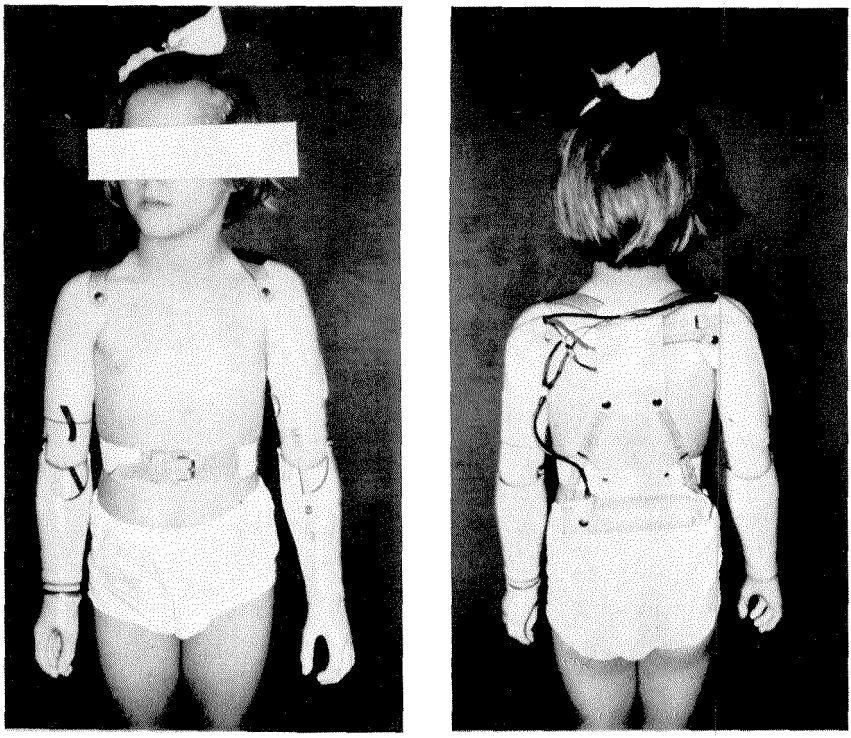


FIGURE 1.—Subject with bilateral upper-limb congenital malformations fitted with pneumatic prostheses.

Following development of reliable myoelectric prosthetic control components, we began fitting large numbers of bilateral upper-limb amputees, including patients with shoulder disarticulations, with electrically powered prostheses. Functional results were superior to those obtained with any other type of prosthesis.

These results became known, and our Rehabilitation Center at Budrio began receiving inquiries from people with severe congenital upper-limb malformations. This caused us to evaluate the feasibility of starting a program for dysmelics using myoelectrically (EMG) or electronically (switch) controlled prostheses.

This program was begun in 1972. Today it is possible to state that the system we developed, utilizing myoelectric control of the prostheses, gives greater satisfaction and provides the patient with better function than the pneumatically powered prostheses we previously used. This system has been applied to persons of different nationalities, having congenital amputations of various types, and with varying degrees of neuromuscular and intellectual ability.

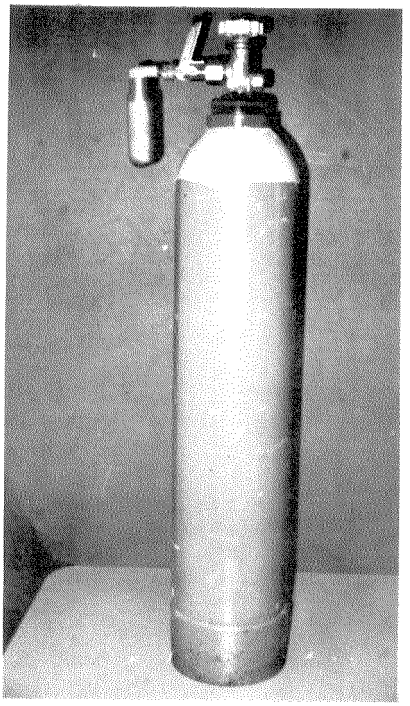


FIGURE 2.—Cylinder for recharging small CO_2 cylinders.

From our large patient population, it is possible to note some statistical trends. At first it was thought that electrically powered prostheses could not operate as naturally, or deveop as strong a prehension force, as pneumatic prostheses. This assumption has been shown to be incorrect. Table 1 lists comparisons between pneumatic and electrically powered systems and compares various technical specifications of the two systems with which our center has extensive experience.

From our studies, as evidenced in Table 1, the prostheses utilizing electrical energy have surpassed the pneumatic prostheses. Furthermore they have the additional advantage that, for recharging the power pack, no special containers are necessary; any standard electrical power outlet of 125 to 220 V can be used. All that is needed is a battery charger about the size of a pack of cigarettes. A disabled person is no longer restricted but can move about freely and confidently; he can travel without having to carry large CO_2 gas supply cylinders and other specialized equipment with him.

TABLE 1.—*Pneumatic vs. Electric Prosthesis Power: Some Technical Specifications Compared*

Technical specifications		
	Otto Bock pneumatic hand system	Otto Bock electrical hand system
System pressure or voltage	5 atm (506 kPa)	12 V
Maximum opening	65 mm	100 mm
Maximum prehension force	7 kPa	15 kPa
Speed of movement	45 mm/s	80 mm/s
Total weight	340 g	450 g
Average number of grip movements per charge of power pack (48 g (5 bar) of CO_2; 450 mAh battery charge).[a]	1300	4200
	Otto Bock pneumatic wrist rotation unit	Otto Bock electrical wrist rotation unit
System pressure or voltage	5 atm (506 kPa)	12 V
Maximum range of rotation	190 deg	360 deg
Maximum torque	7.5 cm-kPa	10 cm-kPa
Weight	140 g	120 g
Average number of rotation movements per charge of power pack (48 g (5 atm) of CO_2; 450 mAh battery charge).	1050	1350
	Otto Bock pneumatic elbow unit	Otto Bock I.N.A.I.L electrical elbow unit
System pressure or voltage	5 atm (506 kPa)	12 V
Range of motion (flexion)	0-130 deg	0-130 deg
Speed of flexion	3 s	1.8 s
Speed of extension	3.5 s	2 s
Weight	320 g	410 g
Average number of flexion-extension movements (full range of motion) per charge of power pack (48 g (5 atm) of CO_2; 450 mAh battery charge).	420	750
	Otto Bock CO_2 power pack	Otto Bock 12 V rechargeable nickel-cadmium battery
System capacity	48 g (5 atm) CO_2	450 mAh
Weight	350 g	280 g
Dimensions	36 × 140 mm	16 × 58 × 150 mm

[a]Definition of average grip movement: an average grip movement as here defined begins with the hand opened to 50 mm. The hand is closed 30 mm to grasp an object 20 mm thick with a force of 3 kPa. It then releases its grip and opens 30 mm to the original starting position of 50 mm opening to begin a new grip movement.

RESIDUAL LIMB FUNCTION AS A CRITICAL FACTOR IN THE DESIGN OF A PROSTHESIS AND ITS CONTROL SYSTEM

Special care must be given to the evaluation of the function and efficiency of the residual limb, and how it may be utilized and incorporated in the prosthetic system. A fundamental concept which must always be borne in mind is that the control mechanism of the prosthesis must be located on the same side as the amputation. This factor is of the greatest importance in the case of bilateral involvement because it is a necessary condition for the achievement of independent control of the two prostheses.

Once an evaluation has been made of the degree of function of the residual limb which may be utilized, it is necessary to decide whether the remaining prosthetic function can be controlled with a single myoelectric controller or if it is necessary to use additional controls (such as microswitches, transducers, or mechanical devices).

Because, in cases of congenital malformation, the myoelectric potentials required for prosthesis control are not always available, we have developed a fitting protocol. Our protocol successfully involves utilization of the following components, singly or in various combinations, as the severity and level of involvement increase:

1. A myoelectric amplifier for control of a single function from each muscle (Fig. 3). (Note the size as compared with the U.S. one-dollar coin.)

2. A multi-channel myoelectric amplifier and electrodes for control of two functions using signals from one muscle (Fig. 4). This is achieved by using a minimal to sub-maximal signal to proportionally control movement of a prosthetic component in one direction. (For example: hand closing, wrist supination, or elbow flexion might be controlled by a myoelectric signal whose amplitude is between 20 and 60 μV.) A maximal contraction (exceeding the previous upper threshold) is used to control movement of the prosthesis in the opposite direction at a fixed rate (for example: hand opening, wrist pronation, or elbow extension might be controlled at that same electrode site by a myoelectric signal whose amplitude is between 60 and 100 μV.).

3. Specially constructed myoelectric amplifiers which respond solely to special levels of muscle potential that a given patient is capable of generating (Fig. 5).

4. Electrical control (Fig. 6) by means of—
   a. Pressure-operated microswitches, which for example may

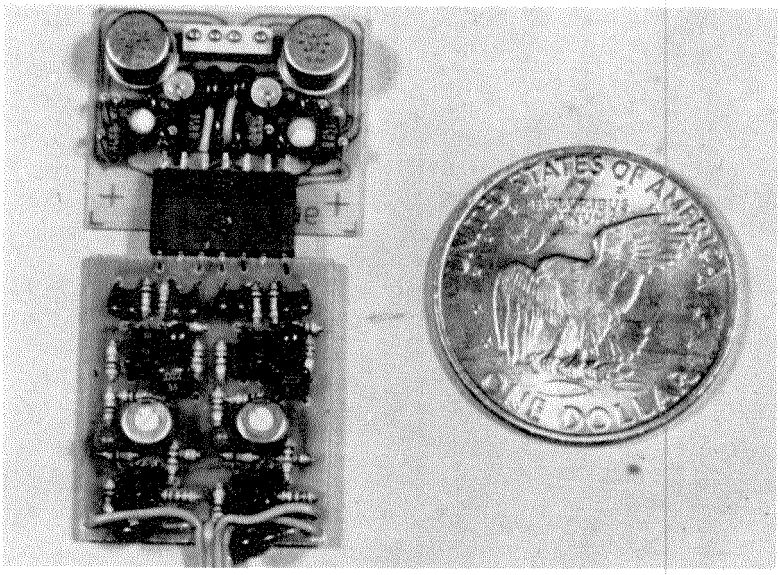


FIGURE 3.—Single-channel myoelectric amplifier. The illustration shows the items at approximately their actual size.

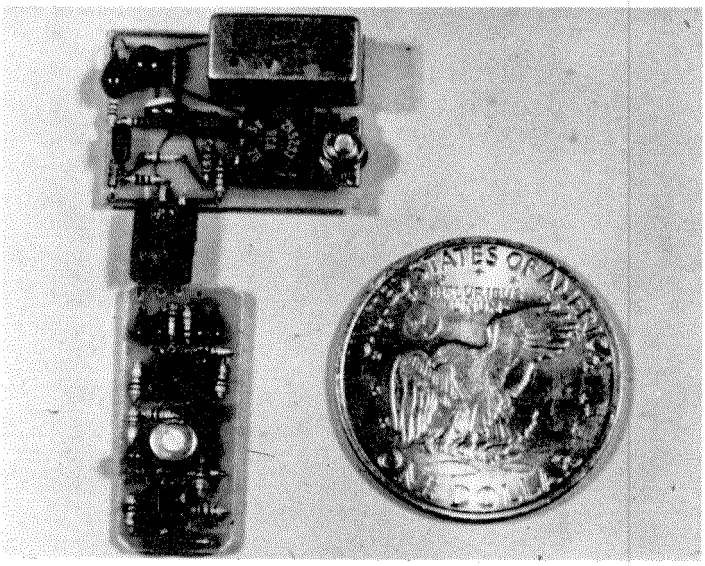


FIGURE 4.—Multichannel myoelectric amplifier with small scale integrated circuit (SSI) elements. The illustration shows the items at approximately their actual size.

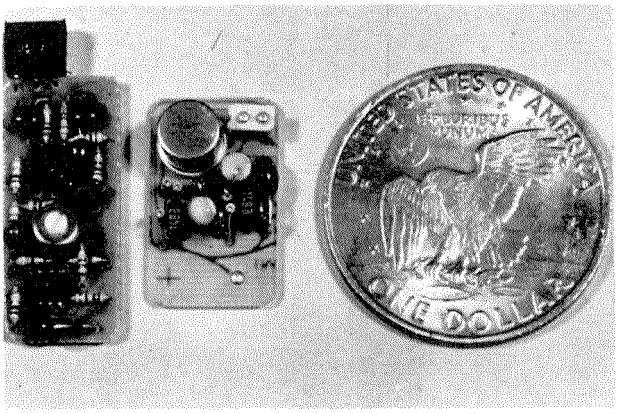


FIGURE 5.—Amplifier made with special characteristics that respond solely to special levels of muscle potential. The illustration shows the items at approximately their actual size.

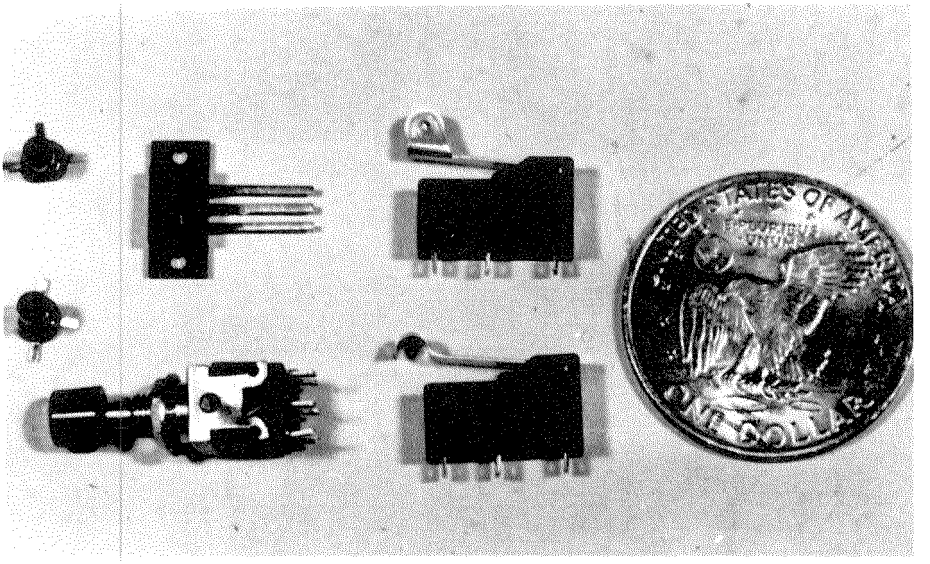


FIGURE 6.—Various microswitches and sensors (capacitance switches) for control of prostheses. The illustration shows the items at approximately their actual size.

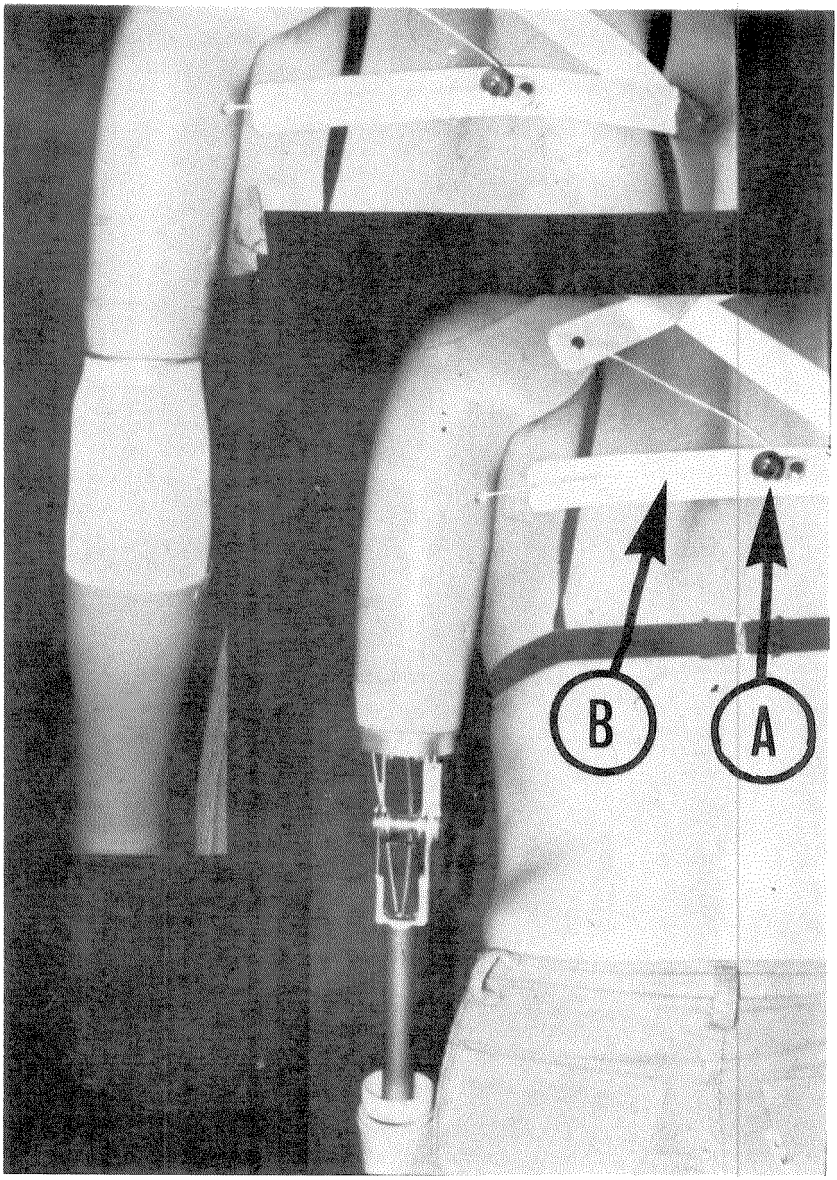
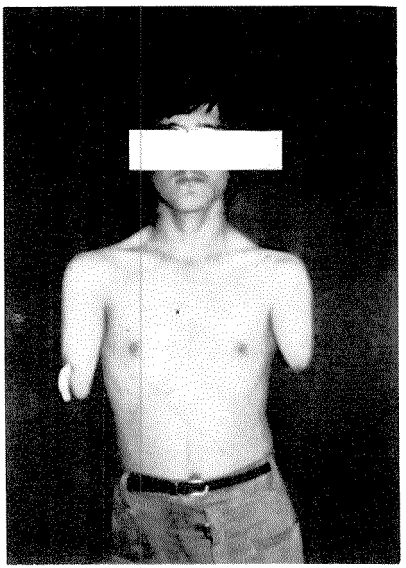


FIGURE 7.—Mechanism for control of a kinematic (body-powered) elbow joint. Arrows indicate pulley (A) and control cable (B). Another view of the same prosthesis, above and to the left, shows elbow and forearm with cosmetic covering in place.



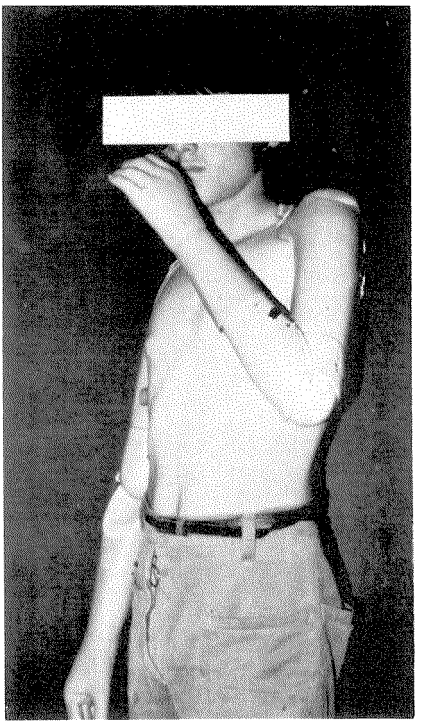


FIGURE 8.—Patient with congenital bilateral amelia demonstrating a specially designed mechanism for simultaneous or individual control of elbow joints.

(Fig. 8 continues on pages 26 and 27.)

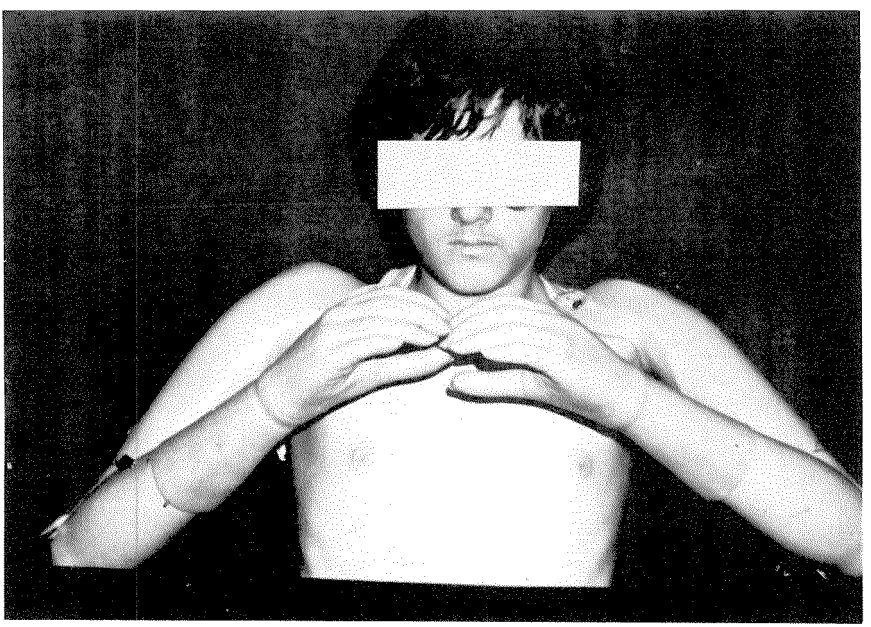
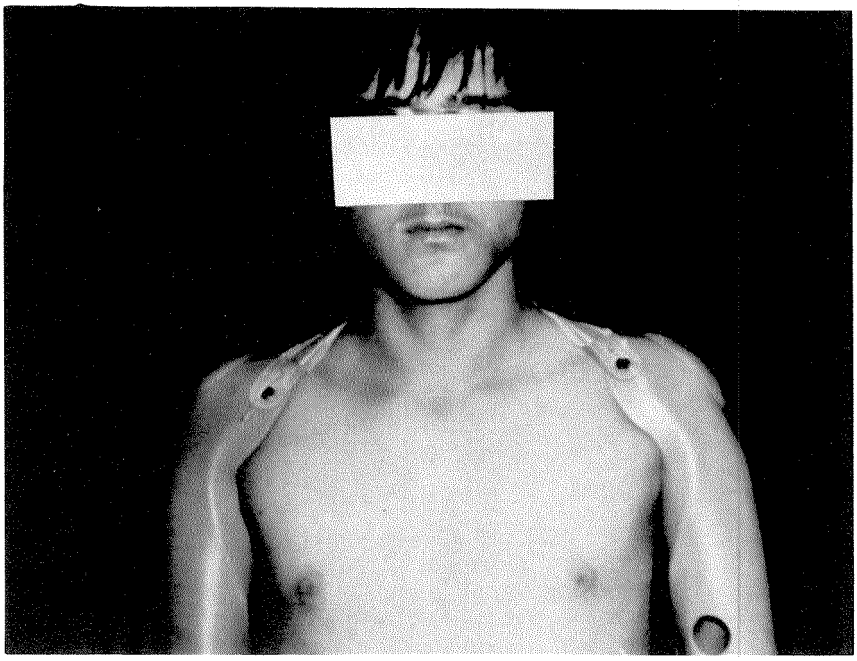
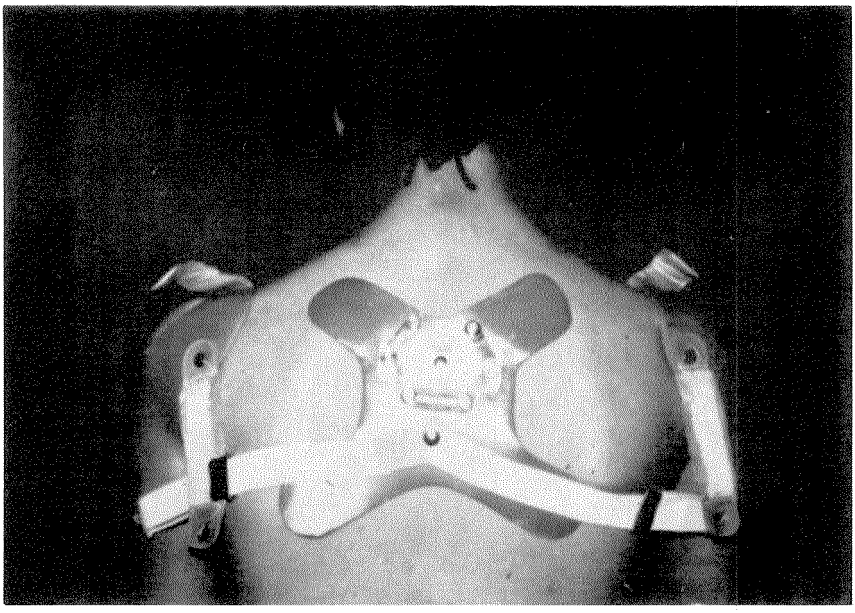
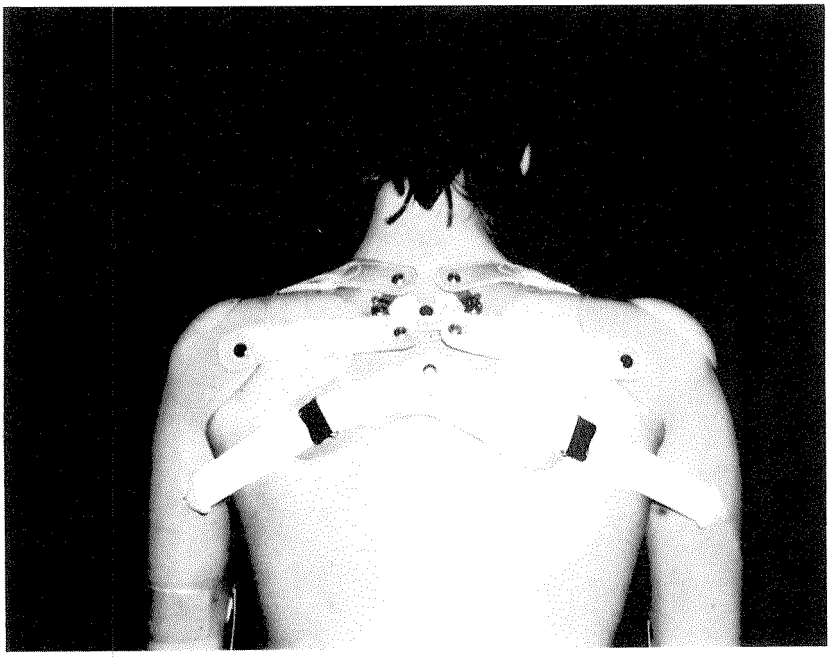


FIGURE 8 (continued).





Flexible back piece with control and suspension straps disconnected.



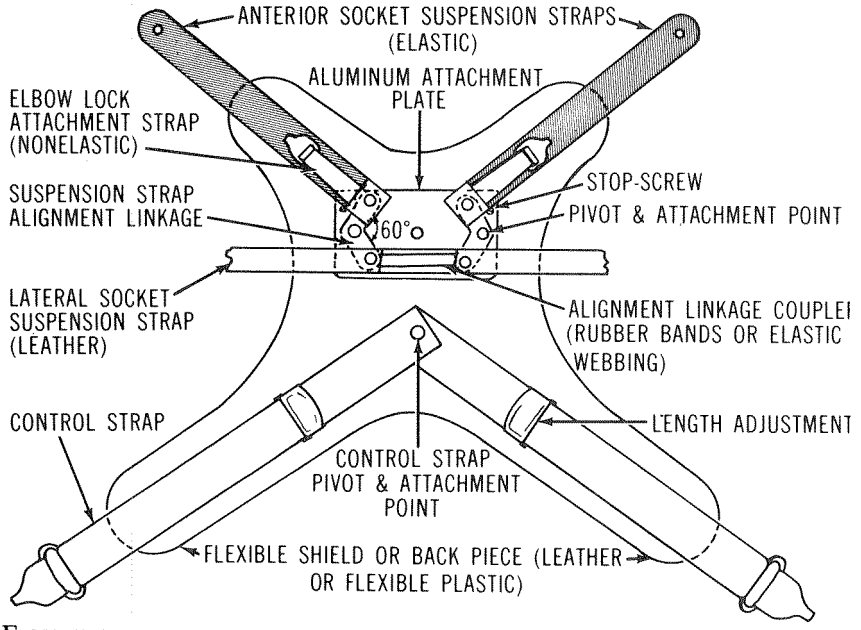


FIGURE 9.—Schematic of mechanism for simultaneous or individual control of elbow joints in cases of bilateral congenital malformations.

be operated by rudimentary fingers in phocomelias;

b. Traction-operated switches, which for example may be operated by scapular abduction, shoulder elevation, etc.; and

c. Sensors (capacitance switches).

5. A mechanical control for flexion-extension of the elbow with a multiplier system associated with elbow locking (Fig. 7). (This device includes a small pulley, around which the control cable travels, located on the chest strap portion of the harness. This mechanism serves two purposes: (i) to keep the angle of pull on the control cable such that it always falls across the distal 1/3 of the scapula, thus optimizing the amount of excursion obtainable from residual gleno humeral flexion and scapular abduction, and (ii) depending upon the diameter of the pulley used, it amplifies the amount of excursion obtainable from scapular abduction by an appropriate ratio.)

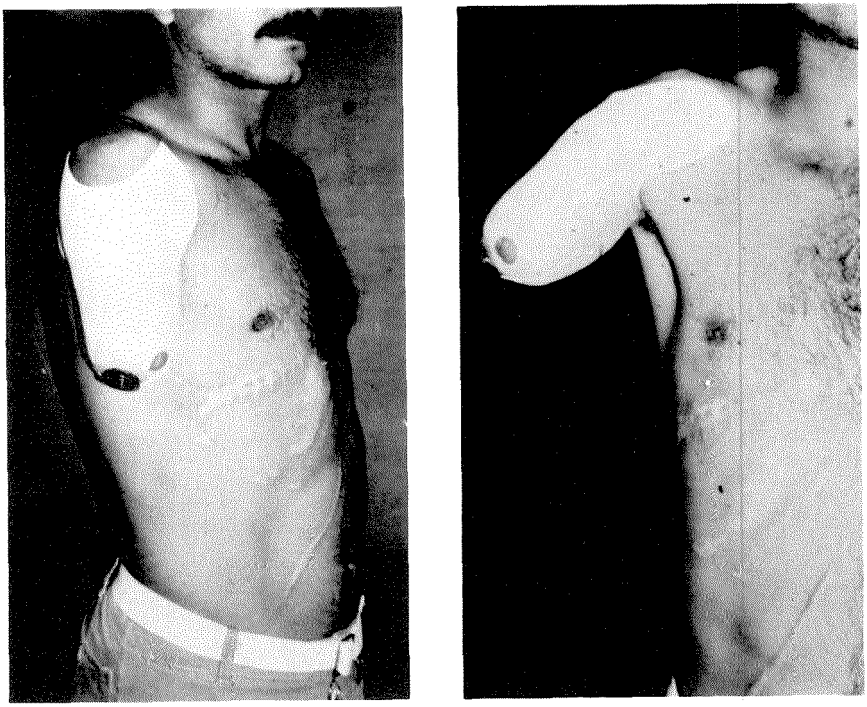


FIGURE 10.—Socket with partial shoulder cover and good freedom of movement in abduction.

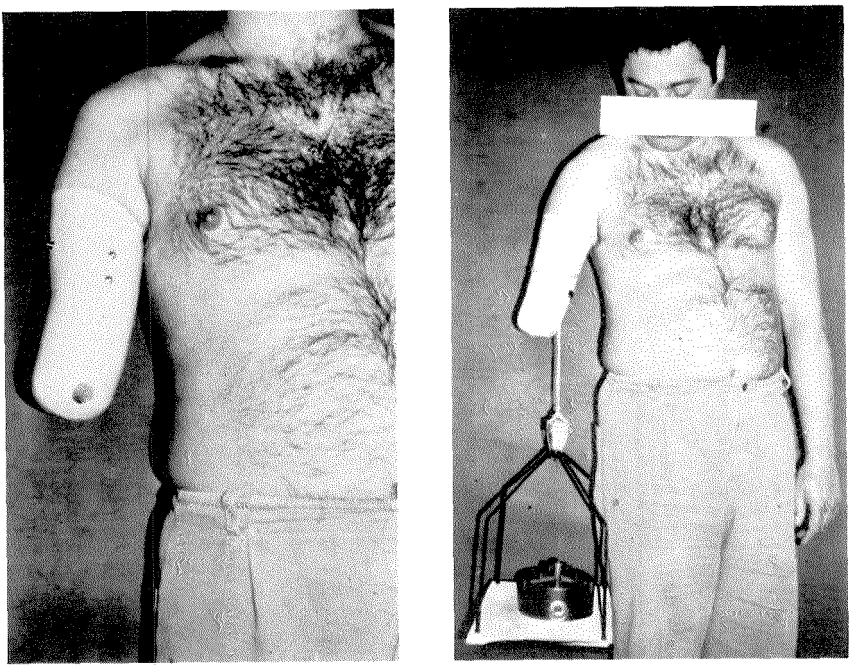


FIGURE 11.—Total contact socket; one can note the total contact even when loaded with a weight.

6. For bilateral above-elbow amputations, a mechanism has been designed where Hosmer locking elbow joints are used. This mechanism permits simultaneous or individual control of kinematic elbow joints and prostheses in cases of bilateral congenital malformations. It serves to always maintain optimal suspension of the prostheses and optimal alignment of the control strap and elbow lock attachment strap for each prosthesis irrespective of the position of the other prosthesis (Fig. 8 and 9).

The degree of function of the overall prosthetic system depends on two factors:

a. the maximum utilization of any remaining function of the residual limb and
b. the control of the single movements, such as control of terminal device grasp, or elbow flexion-extension.

In order to secure maximum utilization of the residual or malformed limb from the standpoint of functional capacity of the prostheses, and in order that the movements of the residual or the malformed limb shall control the movements of the prosthesis, it

is necessary that there be total contact between the prosthesis and the residual limb, or rather there must be created almost a single unit between the prosthesis and the residual limb itself (Fig. 10 and 11). For this purpose it is of the greatest importance that the socket be made with the utmost care especially in the case of malformations. The design of the socket cannot be standardized; in many cases special designs must be created which are suitable to the malformed limb. Only in this way is it possible to obtain the maximum range of motion or work envelope (Fig. 12).

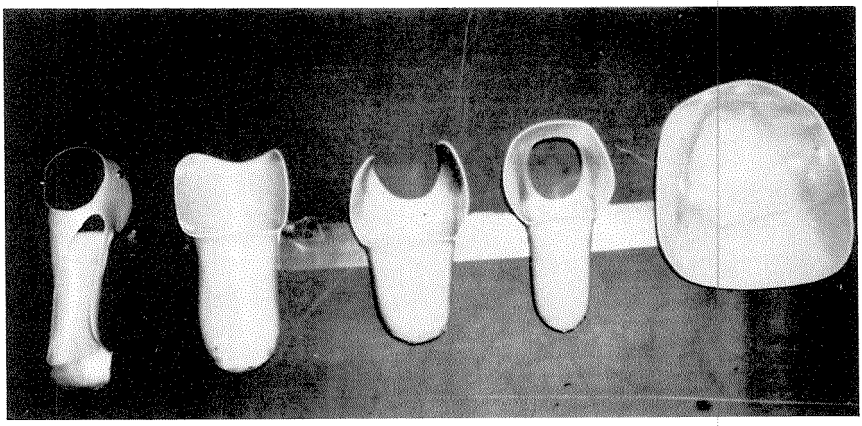


FIGURE 12.—Types of socket design illustrating the variety of designs required for particular prosthetic management.

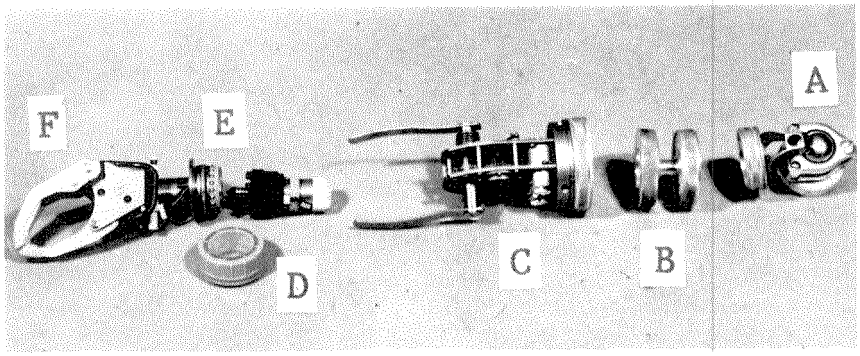
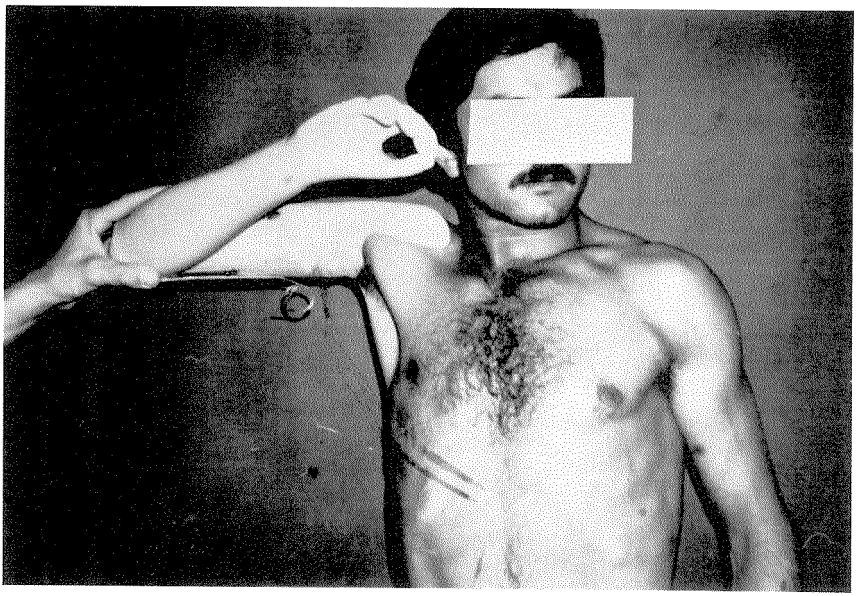


FIGURE 13.—A complete upper-limb prosthetic system and its component parts: a. passive-friction gleno-humeral joint; b. passive-friction adaptation (upper arm joint); c. I.N.A.I.L. elbow; d. quick-disconnect wrist unit; e. Otto Bock wrist rotation unit; and f. I.N.A.I.L. hand.



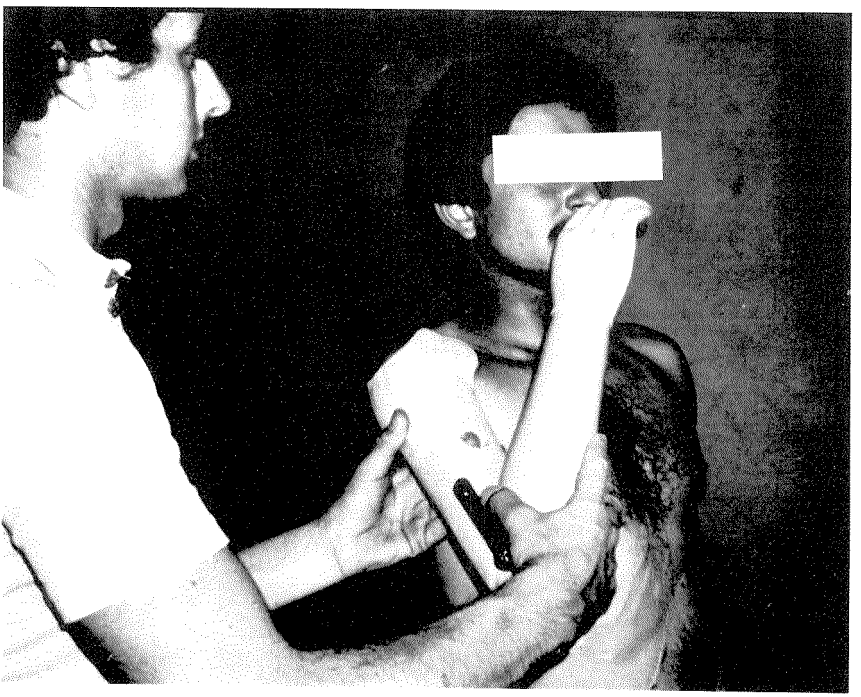


FIGURE 14.—The two illustrations above demonstrate the range of motion required of the assembled prosthesis to achieve the amount of mobility desired.

Once the socket has been fabricated and fitted, and does not restrict motion, the various components of the prosthesis are attached—(Fig. 13):

the hand,
the wrist joint,
the elbow joint, and
the shoulder joint.

At this time evaluation is made as to the degree of mobility of the various components connected together so that the prosthesis can assume all the positions required (Fig. 14).

If this objective is not achieved, it is necessary to add, by means of passive articulations, supplementary passive friction joints which render possible the positioning of the prosthesis to all the positions necessary for maximum functional capacity.

All this is absolutely necessary because the best prosthetic device made is completely useless if within the range of its functional capacity there are limits in its movements (Fig. 15).

Only after it has been demonstrated that the patient is capable of achieving a full range of motion (ROM) with his prosthesis, and of spatially controlling the prosthesis with his residual limb in all positions, and, above all when it is certain that the socket remains in place with no movement about the residual limb during operation of the prosthesis, do we proceed to determination of control sites or methods for operation of the various components such as the hand, wrist, and elbow. For example, when confronted with a shoulder disarticulation one must select three sites for three degrees of freedom of motion (hand, wrist, and elbow). Once sites are selected which have good myoelectric signals, the subject is trained to control the hand, wrist, and elbow, independently. Whichever muscle the subject is best able to use to control the elbow, for example, is the muscle site designated for the elbow. (Similarly, control sites for the hand and wrist are designated.)

As has been pointed out previously in this paper, the mechanisms and controls of the prosthesis must always be located on the affected side.

Before beginning installation of the control system it is important, first of all, to evaluate carefully the individual case. In the case of a unilateral congenital amputee, the function of the prosthesis almost always serves only as an aid to the remaining hand, or arm and hand. But in the case of bilateral involvement, the prosthetic devices are of vital importance.

The present state of progress in the development of myoelectric or electric prosthesis control has led, in the case of patients with congenital bilateral malformation of the upper limbs, to a consider-

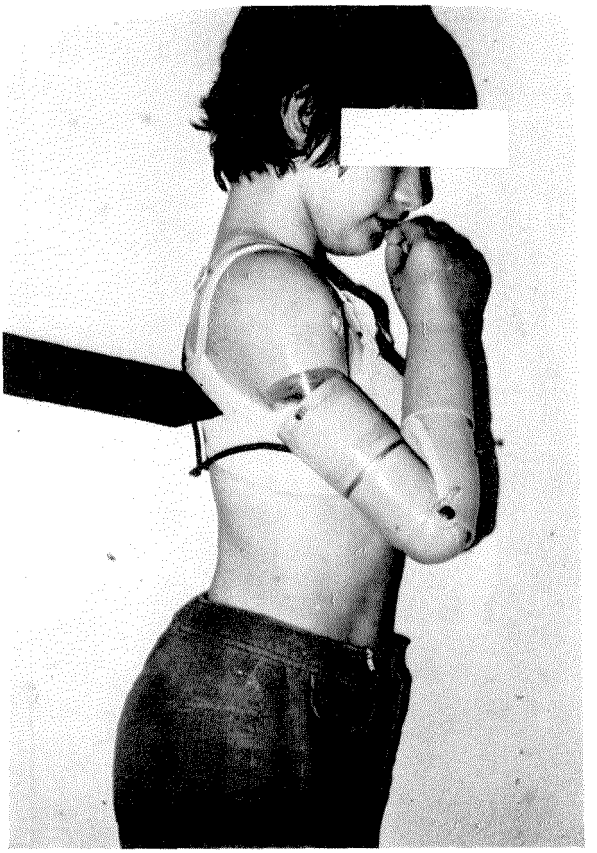


FIGURE 15.—Adaptation of the prosthesis with further friction articulation (arrow). This enables the patient to position the upper arm passively in order to position the elbow and hand in a functional position, i.e., adds more freedom of motion.

able advantage as compared with other existing prostheses because it makes possible the utilization of both prostheses simultaneously—as well as independently, one from the other. This is possible because all the control systems of each prosthesis are to be found on the side of the prosthesis itself. For this reason, choice among control systems must be made with special care and adopted only after their various capabilities have been compared.

It is always important to begin with the simplest controls (from the point of view of activation and control) and then pass on to the more difficult ones, without unduly complicating the system in the

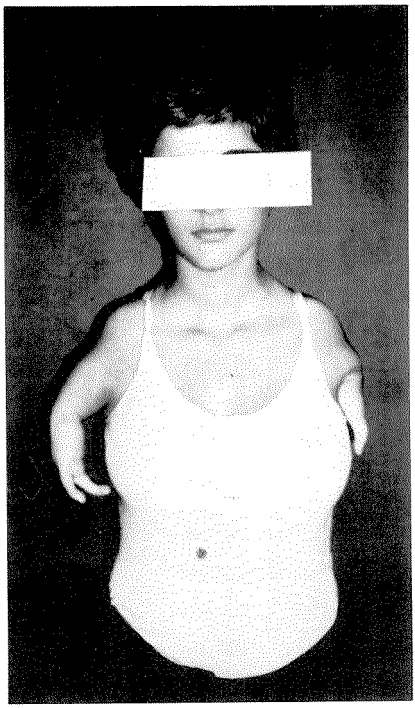
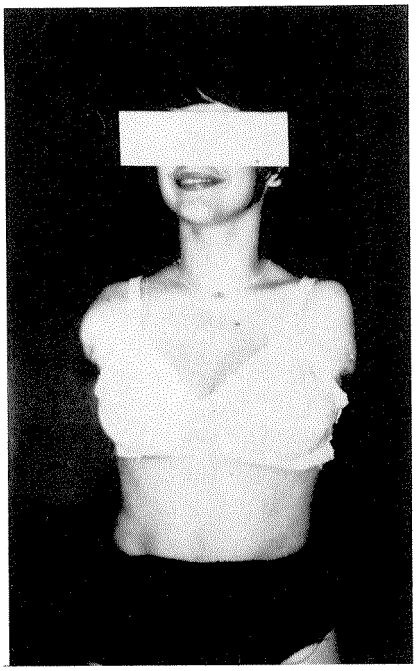


FIGURE 16.—In cases of congenital malformations of the upper limbs, account must be taken of the various systems of control for the prosthesis movements in peromelia (above), phocomelia (above, right), and amelia (right).



patient's eyes. Above all, avoid creating an unnecessary state of tension in the patient.

The application of prostheses for congenital malformations of the upper limbs can be divided into three large groups, each group with its particular system of control. The three groups (Fig. 16) involve (i) forms of peromelia, (ii) forms of phocomelia, and (iii) forms of amelia.

In the case of peromelia, where there exist residual limbs almost similar in form to those of a traumatic amputation, those residual limbs can be utilized for a myoelectric, mechanical, or kinematic control. In these cases use is generally made of the biceps and the triceps for single or multichannel myoelectric control for opening and closing the hand and for pronation and supination of the wrist, respectively. For extending and flexing the forearm and locking the elbow, movement of the residual limb is used. Because they have proved to be very satisfactory, we use Hosmer locking elbow joints in this particular application. For the very short residual limb having limitations in range of motion, a special system, which provides excursion amplification, makes possible the complete control of elbow flexion-extension and locking from 0 deg to 130 deg (Fig. 17). See also Figure 7.

Where there is bilateral peromelia, it has been necessary to develop a special device which, connected to the control cables, makes it possible to operate both elbows simultaneously as well as independently (Fig. 8 and 9).

Only when it is not possible to follow the procedure just described is it necessary to utilize an electric elbow. It must be pointed out that experience has shown, in forms of peromelia, that it is unlikely in their present state of development for an elbow dependent on external energy (in our case electric energy) to give movement as smooth as that controlled and powered by the residual limb itself.

In forms of phocomelia, we are faced with a different situation in which the malformed limb (almost always without skeletal connection with the trunk) can be utilized solely to activate control mechanisms for the various joints of the prosthesis.

In a very few cases, the small malformed limbs can also be used to control movements of the prostheses, in the same way as in forms of peromelia. In these types of malformation it is rare that one can use myoelectric controls. Certainly one *could* use rotator cuff or shoulder girdle muscles as a source of a signal, but that

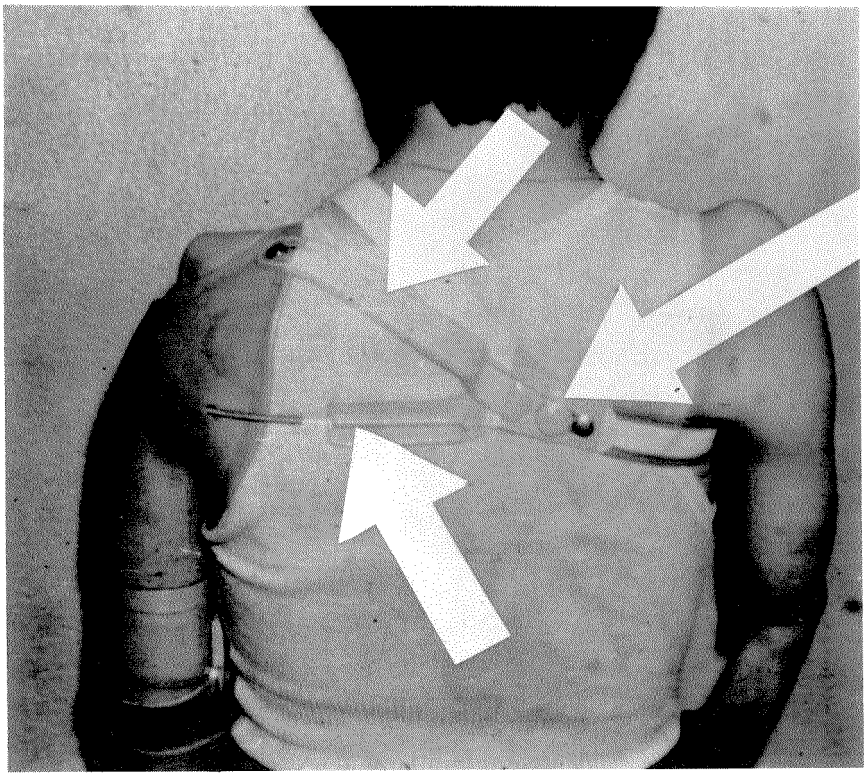


FIGURE 17.—A control mechanism which provides excursion amplification enabling full range of motion of the elbow in cases of very short residual limbs. At right: illustrating the prosthesis in use. Above: the multiplication system (excursion amplification). The arrow at right locates the pulley, and the pair of arrows at the left indicate the course of the control cable.

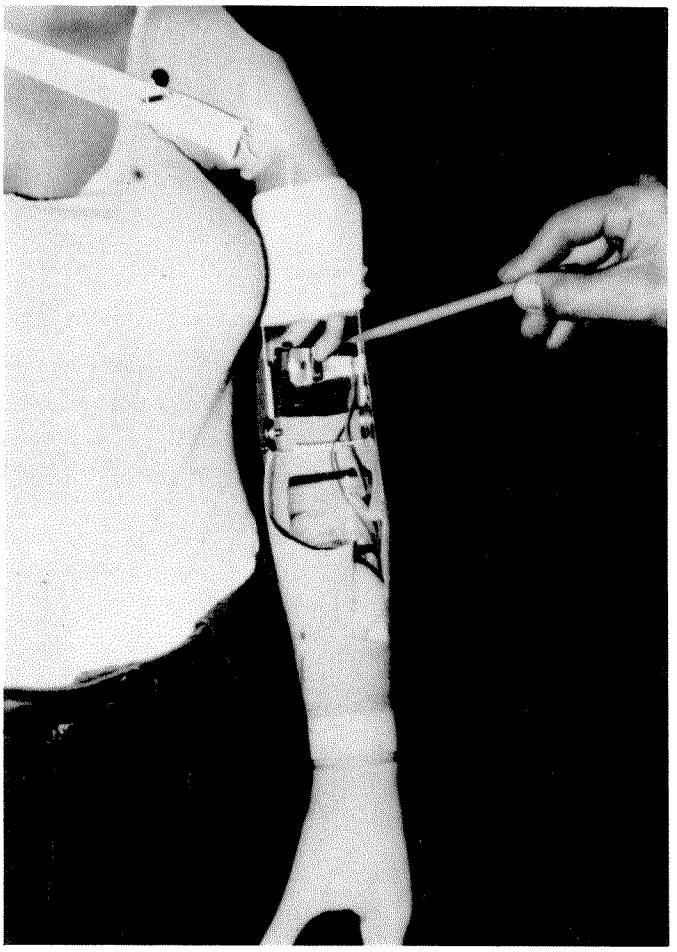


FIGURE 18.—Illustration of the use of microswitches in the control of a prosthesis for phocomelia.

would make it necessary to encapsulate the shoulder in the socket, thereby sacrificing range of motion. Therefore, instead of myoelectric controls, small microswitches or sensors are used. These are especially suitable because, for their operation, it is possible to make use of malformed parts of single fingers which, though without any strength, are capable of making a movement, however slight, to actuate the controls (Fig. 18).

For this reason it is possible to state with assurance that the prosthetic device for bilateral phocomelia has been considerably reduced as regards bulk. Improvement has been made in its func-

tion and appearance and, consequently, in the outward attitude of the disabled person toward his prosthesis—which also means improving the patient's functional capacity with his prosthesis.

In forms of amelia, use is made exclusively of myoelectric controls for the various movements, since up to the present no other system of control or combination of controls has given more satisfactory results.

Today it can be said that in the most serious dysmelic malformations such as amelia, the possibilities of achieving functional capacity have been improved by virtue of myoelectrically controlled prostheses. This has come about because, on the residual limb (in this case the shoulder) slight movements such as the forward and backward or elevation motions have been utilized by means of special sockets, and are of considerable importance for the functional capacity of the prostheses themselves.

Generally speaking one succeeds by using five pairs of electrodes (Fig. 19), with a multichannel amplifier, to control ten movements. This is amply sufficient for the entire arm.

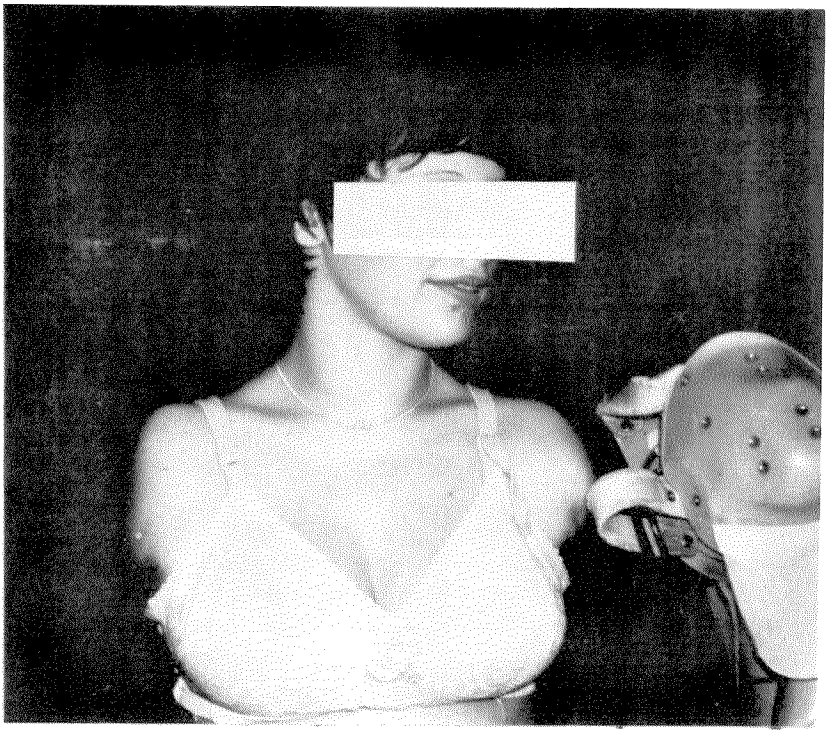


FIGURE 19.—Socket for a patient with amelia: five pairs of electrodes are clearly visible.

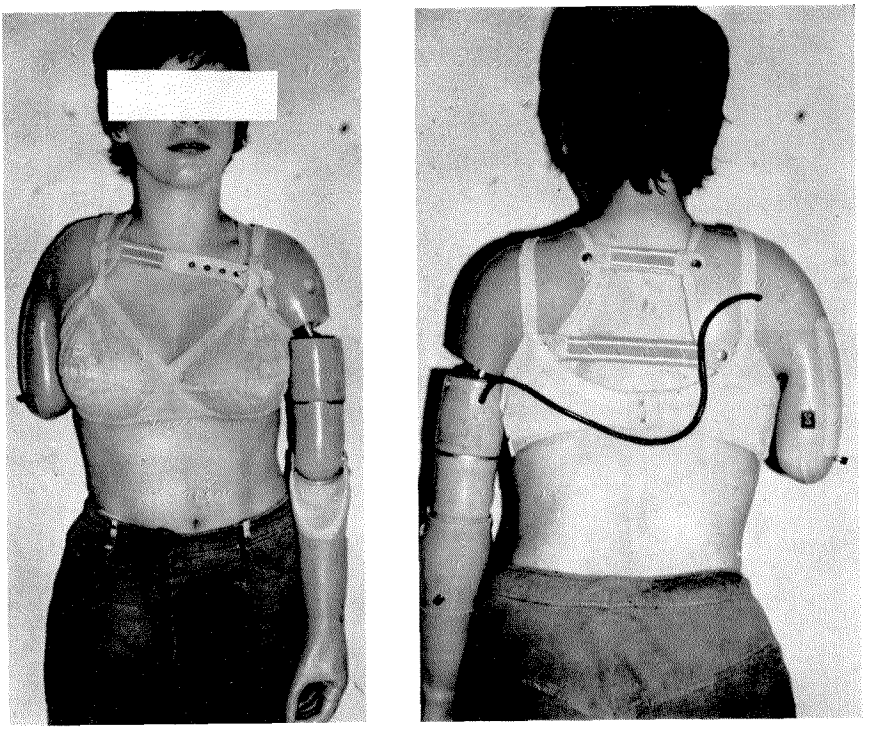


FIGURE 20.—Prosthetic treatment of one side, as initial phase, in a case of amelia.

Here again, it is only after a certain period of training the patient in the use of the various muscles that the entire prosthesis is constructed and the control site for each motion selected. Prosthetic treatment is carried out on one side first (Fig. 20). Then, after an interval of about 6 months, the other prosthesis is fabricated. The reason for this is to enable the patient to concentrate his entire attention on the operation of one prosthesis. Only after a suitable period of practice is he fitted with the second prosthesis and trained in using two prostheses simultaneously (Fig. 21).

The patient is also given the possibility of voluntarily eliminating movements such as those of the hand or the elbow, of pronation and supination, by means of microswitches or traction (pull) switches (Fig. 22 and 23). This temporary elimination of certain movements, willed and controlled by the patient himself, gives him a degree of assurance in certain uses of the prosthesis without upsetting the smoothness of the movements it is desired to accomplish.

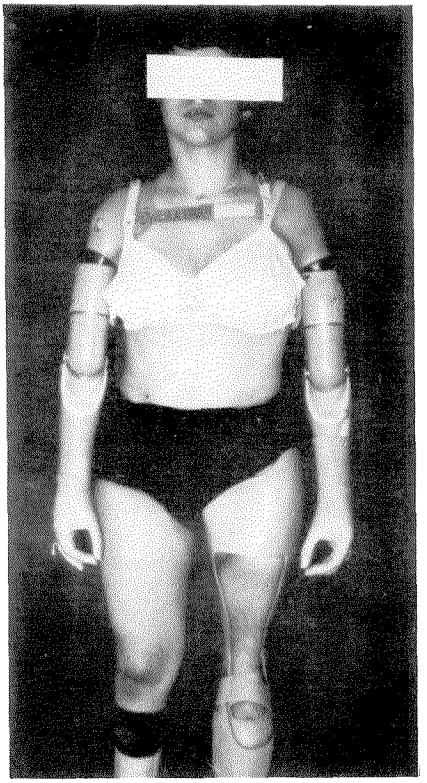


FIGURE 21.—Bilateral prosthetic management after an interval of about 6 months.

In practice this system makes possible the control of all the single movements without limitations. It also makes it possible to lock and eliminate within the prosthesis itself certain movements as compared with others.

CONCLUSION

In conclusion, it is possible to state that myoelectric and electric control systems have given a strong impetus to successful prosthetic restoration of congenital amputees. But, it is also necessary to point out that it is very unlikely that this kind of management can be carried out except in specialized centers. For the construction of these prostheses, in addition to highly qualified personnel in certain disciplines or branches of science, costly equipment is necessary. The small number of cases of severe dysmelia to be found in each country might not justify purchasing this equipment. Therefore, specifically to limit costs and reduce the burdens of amortization, it

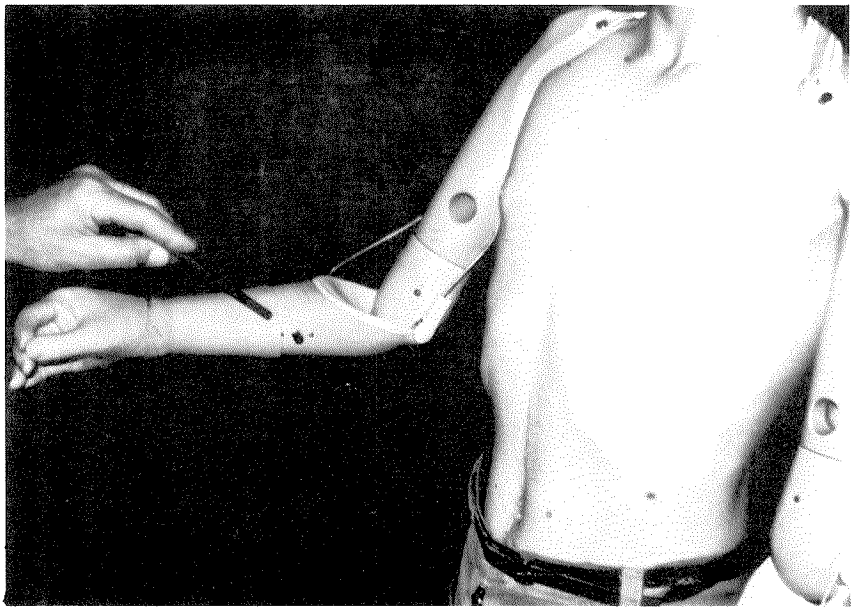


FIGURE 22.—Adaptation of a microswitch for the exclusion of certain movements of the prosthesis. It is located in the forearm and is manually operated by the other arm or by using the edge of a table, etc.

would seem logical to consider carrying out treatment on an international level.

At the present time we are in a position to treat the various forms of dysmelia of the upper limbs from the age of about 13-14 years and on. For younger children (fortunately few in number) the components do not exist, or rather, a beginning has only just been made in this direction. Here I should like to mention the Variety Village Electro-Limb Production Centre in Canada, which has undertaken the manufacture of components for electric prostheses for small children. We are just now at the stage of testing these components for inclusion in our program of prosthetic management of dysmelic children.

We are convinced that future prosthetic management, of both upper-limb traumatic amputation and of persons disabled by congenital malformation, lies with prostheses activated by electrical energy. We are confirmed in this conviction by the results of the prosthetic management of persons affected by congenital malformations of the upper limbs who have been supplied with myoelectric or electrically controlled prostheses.

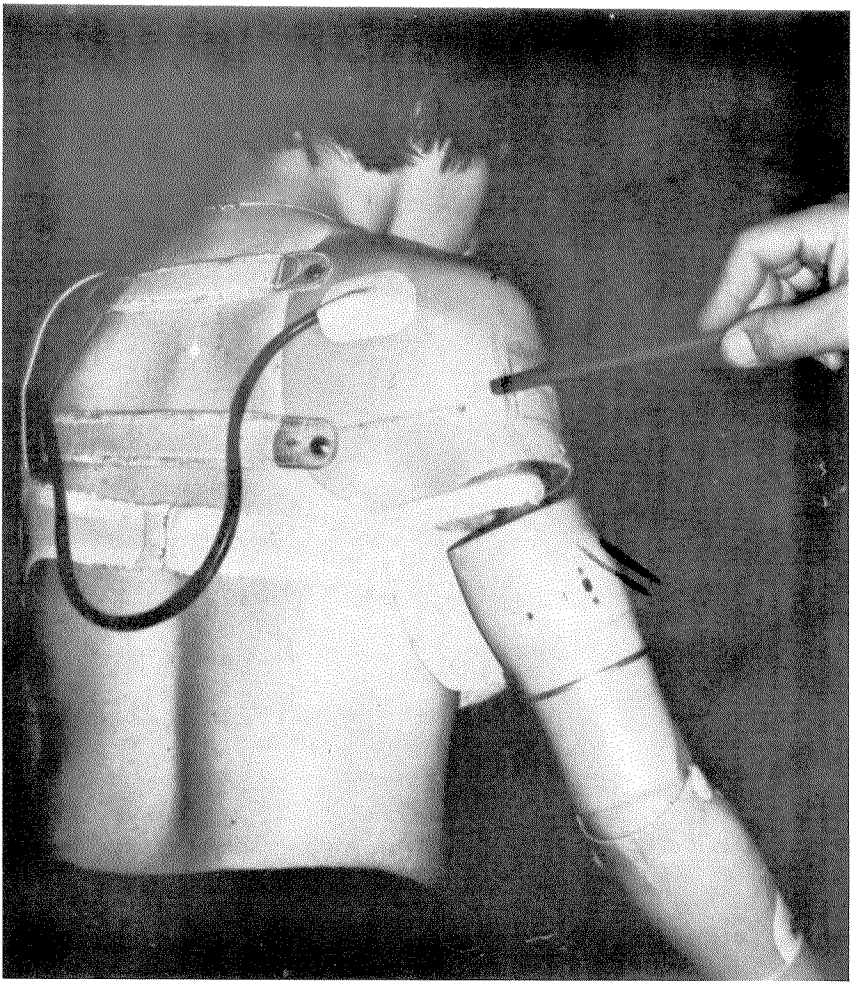


FIGURE 23.—Traction (pull) switch or microswitch which makes possible the voluntary elimination of certain functions of the prosthesis (such as the elbow or the wrist).

In the application of such complex prostheses, it must never be forgotten that the patients we treat are human beings, handicapped as a result of their malformations with the loss of dexterity, manipulative ability, and proprioceptive feedback. To compensate for their restriction of movement they have developed a sensibility that is more acute than that of physically normal people. They will give their cooperation as long as they feel the effectiveness and the benefits of the prosthetic restoration. They react adversely if they are disappointed with the device—and we must strive to see that this does not occur.