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MEDICAL SCHOOL
Department of Physical Medicine and Rehabilitation

Orthetics Research Project

Technical Report No. 1

ANALYSIS OF DESIGN BASES FOR UPPER-EXTREMITY ORTHESES

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I. Introduction

The present report pertains specifically to the development of devices which would permit a person having flail arms to feed himself. A complete statement of Task Plan D. D. 1 (Design and Development Task No. 1), as assigned to the Device Design and Development Group by the Systems Committee, is contained in Appendix A. As a result of the initial study by the Group and consultation with the Systems Committee, the task was expanded to include the following:

A. The formulation of a statement of design objectives. The purpose of this statement is to: (1) make explicit and specific design objectives implicit in the task assignment, (2) provide a framework for methodical analysis of the problems inherent in the task assignment, and (3) permit agreement on the degree of sophistication desired at this time in the design of any system accomplishing the objectives. The detailed objectives selected are stated in Section II.

B. A survey of the current "state of the art" in fields bearing directly on the design and development of orthetic devices. A report of this survey is contained in Section III.

C. An analysis of function lost as a result of upper-extremity flaccid paralysis, followed by an identification of the different classes of orthetic systems which might be used to restore the loss. These studies are treated in Sections IV and V, respectively.

D. A survey and analysis of the engineering factors involved in the actual design of orthetic systems meeting the task objectives. This was done to help identify areas of future research and development important to the Project as a whole, and to introduce concepts of design for a specific prototype system. Sections VI through IX are concerned with this phase of the work.

E. A list of questions pertaining to the design of the various possible types of ortheses considered, and recommendations for specific areas of future engineering effort. These are contained in Section X and XI.

The report is arranged as an essentially chronological account of the work done. All phases of the study were not treated in equal detail because of differences in their relative importance, the special backgrounds of the Committee members, and the availability of information on several phases from other centers where related work is being carried out.

Although the present report pertains to the treatment of a specific disability, an effort was made, where possible, to make it applicable to orthetic devices in general.

II. Design Objectives

A survey of general objectives of orthetic systems is outlined in Appendix B. These objectives have been modified, for the purposes of this report, to meet the requirements of the present task. They are described in terms of ideal and minimum levels of attainment, and are arranged in the four categories of function, comfort, cosmesis, and practicality.

A. FUNCTION

Since the hypothetical disability for which the system is being designed consists of a flail arm and a functional hand, the basic objective of the device must be to provide the hand positions and orientations necessary to the activity of eating (see Appendix B). The ideal capability of the system would be one of providing all hand positions and orientations involved in feeding, plus those for any other high-priority activities which could be provided (grooming, toiletting, dressing, typing, telephoning, etc.).

The minimally acceptable capability has been considered, arbitrarily, as one of providing the hand positions and orientations necessary for a four-phase cycle of eating (while using a standard table, chair, and service). The eating cycle is defined as including:

1. "loading," with the hand at table-top level, picking up food with a spoon, fork, or fingers, and picking up a cup or glass;
2. "transporting" the food and utensil to the mouth;
3. "unloading" the food into the mouth; and
4. "returning" the hand to the food area.

Preliminary to "loading" is frequently a "preparing" operation which consists of cutting food, adding sugar or cream to a beverage, stirring, use of a salt shaker, spreading butter, etc. Except for the cutting of soft foods, preparing functions are not included as minimum functional requirements. "Serving" functions are also excluded from the minimum requirements.

To perform this cycle, the system must provide the necessary constraints, power and control required by the activity (see Appendix B).

1. Constraints

As a minimum, the device must provide the constraints necessary for acceptable alignment, stability, and guidance of movement of upper extremity segments in carrying out the cycle.

2. Power and Control

As a minimum, the device must provide the power necessary to effect movement of upper extremities (and eating utensils) throughout the cycle, and to control (under the direction of the will) the amount, rate, duration, direction, and point of application of the power in the manner required by the cycle.

B. COMFORT

Ideally, the device when used throughout the day would cause the patient no significant discomfort due to skin irritation, pressure, excessive weight, faulty joint alignment, fatigue resulting from operational requirements, etc.

As a minimum, the device must not cause undue discomfort during the course of eating a complete meal.

C. COSMESIS

Ideally, the device should be hardly detectable when worn under loose fitting, long-sleeved clothing. The motions produced by and required to operate the device should fall within the range of motions commonly used by nonhandicapped persons in performing the same activity.

As a minimum, the cosmetic aspect of the device must be at least tolerable to a substantial number of eligible patients. A moderate amount of unnatural trunk (but not head) movement to power and control certain upper extremity movements will be considered acceptable in the first experimental systems.

D. PRACTICALITY

Ideally, the device should (1) be marketable at a cost within a range reasonable for purchase by individuals and agencies, (2) be easily adapted to fit a wide variety of patients, (3) require a minimum of maintenance, with no servicing skills or equipment needed beyond those normally available, and (4) permit convenient renewal of the power source (if used) at low cost.

As a minimum, none of these items should preclude the use of a device by at least a significant percentage of eligible patients.

III. A Review of Previous Developments

The available literature was searched and abstracted, with emphasis on engineering aspects. A listing and brief description of some of the more significant references are given as Appendix G. Among the particularly pertinent references were those dealing with externally powered prostheses, such as the IBM electric arm (Refs. 1, 2, and 5) and the Heidelberg pneumatic arm (Refs. 26 and 27).

In searching for additional information relative to the Heidelberg development, attention was called to work being done at the American Institute for Prosthetic Research. After testing the Heidelberg arm, the AIPR undertook the development of their own device. The AIPR arm employs a pneumatic system using CO_2 as a source of energy, and appears to represent a significant advance over the original Heidelberg design. Two members of the Committee, Prof. J. R. Pearson and Mr. R. F. Timm, visited the AIPR laboratories. A report of Mr. Timm's visit is included as Appendix C.

Another subject of particular interest is bioelectric control. Material pertaining to such controls may be found in Refs. 10, 15, and 29.

To familiarize the Committee with some of the current orthetic research efforts, conferences were held with several visiting representatives of groups working in related areas.

IV. Basic Analysis of the Disability

Although the primary design objective is to restore function of the organism as a whole, it is best achieved by replacing the functions lost in the individual body parts. An understanding is necessary, then, of the effects of the disease process on the function of the various body tissues.

A systematic inventory of such effects can be made by listing the consequences of impaired cell function to the organ and system containing the impaired cells, and to cells and organs of other systems. The tissue functions altered directly by the disease process can be called the "first-order effects" (or losses); their effects, in turn, on tissue function in other systems can be called "second-order effects" (or impairments); and so on. For

each type of tissue involved, the effects are different at the cellular, organ, and system levels because of the different functional roles of each level.

If the first-order losses could be replaced in their entirety at each level, the second- and third- , etc., order impairments that were reversible would automatically be corrected, and the function of the organism as a whole would be restored towards normal. Even though attainment of such an objective might be impossible at present, it is still the goal of the project to replace as many of the first-order losses as feasible, or, failing this, the functional impairment as close to the first-order losses as possible.

The problem of flaccid paralysis resulting from destruction of the lower motor neuron has been analyzed to categorize the possible orthetic solutions, and to permit judgment of the feasibility and requirements of each solution. Some of the effects of LMN (lower motor neuron) destruction are listed below.

First-order effects

A. Cell level (neuron)
   Loss of: (1) pick up; (2) transmission; (3) application of signals from control centers to muscle fibers.
B. Organ level (nerve)
   Loss or reduction in signals controlling: (1) time of contraction; (2) tension developed by a muscle.
C. System level (motor portion of peripheral nervous system)
   Loss or reduction in signals controlling the relative: (1) time of contraction; (2) tension developed by different body muscles, and thus controlling coordinated movement.

Second-order effects, i.e., effects on muscle as a result of loss of LMN function

A. Cell level (muscle fiber)
   (1) Loss of activation by the nervous system; (2) impairment of metabolism and function of the contractile mechanism (atrophy of denervation and disuse) with ultimate irreversible changes; (3) reduction in distensibility; (4) reduction in heat production.
B. Organ level (muscle)
   Loss or impairment of ability to apply force at its origin and insertion.
C. System level (all muscle)
   Impairment of: (1) agonistic, antagonistic, fixating, synergistic, etc., functions of muscle groups; (2) dynamic joint-constraining functions of tendons.

Third-order effects, i.e., effects on other tissues as a result of impaired muscle function

1. Skeletal system and its associated connective tissue
   A. Cell level
      (i) impairment of bone metabolism (osteoporosis)
      (ii) alteration of physical properties of periarticular fibers (lengthening, shortening, etc.) secondary to abnormal stresses or reduced movement.
   B. Organ level
      (i) impairment of movement and application of forces by skeletal parts.
      (ii) alteration of joint alignment or range of motion (secondary to muscle shortening, periarticular changes, abnormal stresses, etc.).
   C. System level
      Impairment of interrelated movements and applications of forces by the skeletal framework.
   D. Organism level
      The abnormal function of all three systems, nervous, muscular, and skeletal, combine to impair ability of the individual to carry out purposeful physical activity (self care, vocation, etc.).
2. Other body systems
   Venous and lymph return, muscle arterial supply, respiratory function, heat regulation, etc., may be affected by impaired muscle function.

Fourth- , etc., order effects

Edema formation, reduced skin thickness, the consequences of impaired respiratory function, etc., can result from the third-order effects.

Associated losses

Some disease processes acting on the lower motor neuron exert simultaneous first-order effects on other tissues, e.g., sectioning of a peripheral nerve destroys sensory as well as motor fibers. The type of tissue involved in these associated losses depends, of course, on the nature of the diesease process, but may include:

A. Sensory nerve and fusimotor fibers, causing loss or impairment of tactile and pain sensation, proprioception, muscle spindle control, etc.
B. Upper motor neurons, causing spasticity, etc.
C. Autonomic nerve fibers, causing impaired vasomotor control, trophic skin changes, etc.

V. Classes of Possible Solutions

To assist in the interpretation of the classes of possible solutions, Fig. 1. has been prepared as a simplified diagrammatical representation of a feedback control system which is analogous to the normal physical system.

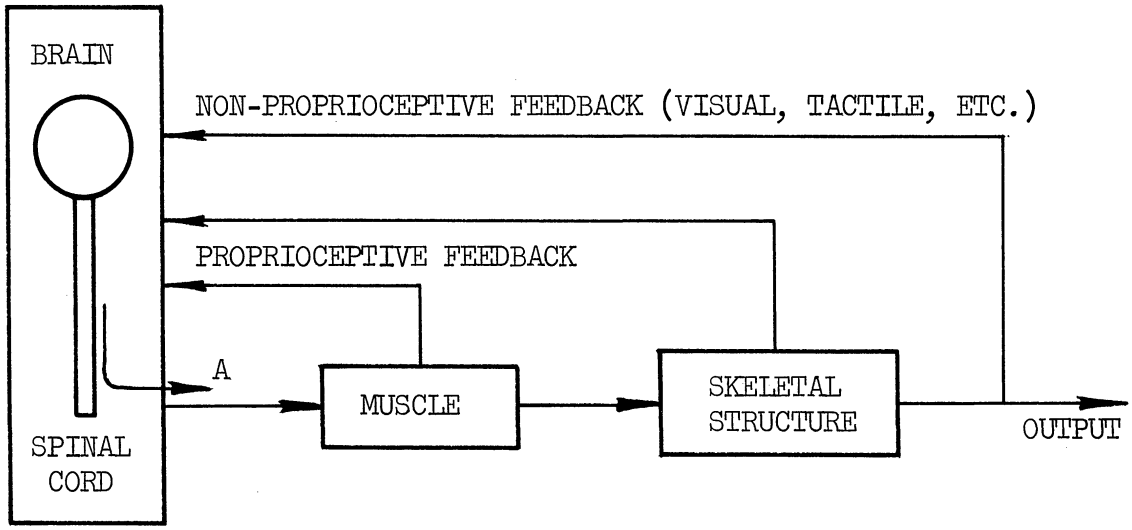


Fig. 1. Diagram of normal system.

A signal originating in the brain is transmitted along neural path A to the muscle. Muscular motion actuates the skeletal frame so as to produce the desired force or motion in the upper-extremity. Proprioceptive feedback from the muscle and skeletal structure, plus non-proprioceptive feedback (visual, tactile, etc.) completes the control loop by supplying information to the control center relative to the exact nature of the output achieved. If this output does not correspond precisely to that desired, corrective signals are issued by the central nervous system to compensate for the perceived error.

The diagrammatical representation of Fig. 1, together with the analysis of disability contained in the previous section, provide a basis for listing the classes of possible solutions. The following listing begins with direct replacement of the first-order loss. Although not feasible at the present time, this solution would appear to be the ultimate in an orthetic device. The classes of solutions which follow treat progressively lower orders of loss. Hence, they represent solutions having progressively less potential functional merit, but also less probable difficulty of achievement.

Each of the classes of solutions is illustrated by a figure having (a) a solid-line portion exactly like Fig. 1 except that the damaged neural path A is shown as a dashed line, and (b) a dotted portion representing the device.

Class 1 - Replacement of the original connection between control center and motor (Fig. 2).

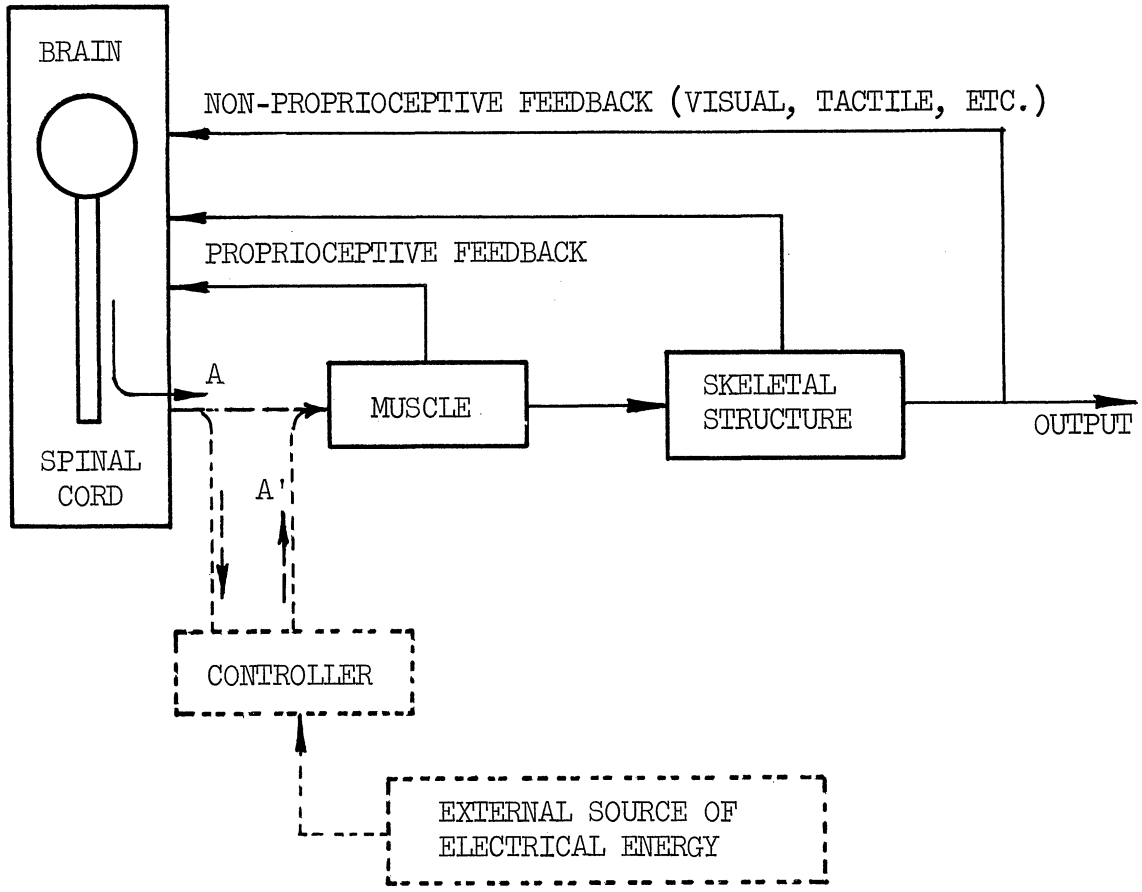


Fig. 2

Although solutions of this class which attempt to replace the entire first-order loss could potentially restore a maximum degree of normal neuromuscular function, they are not feasible at the present time. The possibility of their use depends upon the success of future research efforts related to the following phenomena.

a. Prior to development of irreversible changes, a denervated muscle is capable of contraction, assuming a suitable stimulus can be provided. In Fig. 2, electrical energy is supplied to the muscle from an external source through path A'. The subject of artificial stimulation of denervated muscle fibers is considered in detail in Appendix F.

b. Provided original nerve path A is not totally destroyed, the patient's attempts to actuate the muscle will result in a small fraction of the normal electrical impulses in nerve path A. This ENG (electro-neurographic) signal

is used to regulate the flow of electrical energy from the external source, using the control unit shown. Unfortunately, not enough is yet known about ENG signals to predict whether or not this approach will ultimately prove to be practical. An even more difficult approach would be to detect appropriate signals directly from the spinal cord.

Class 2 - Substitution of an alternate connection path between control center and motor (Fig. 3).

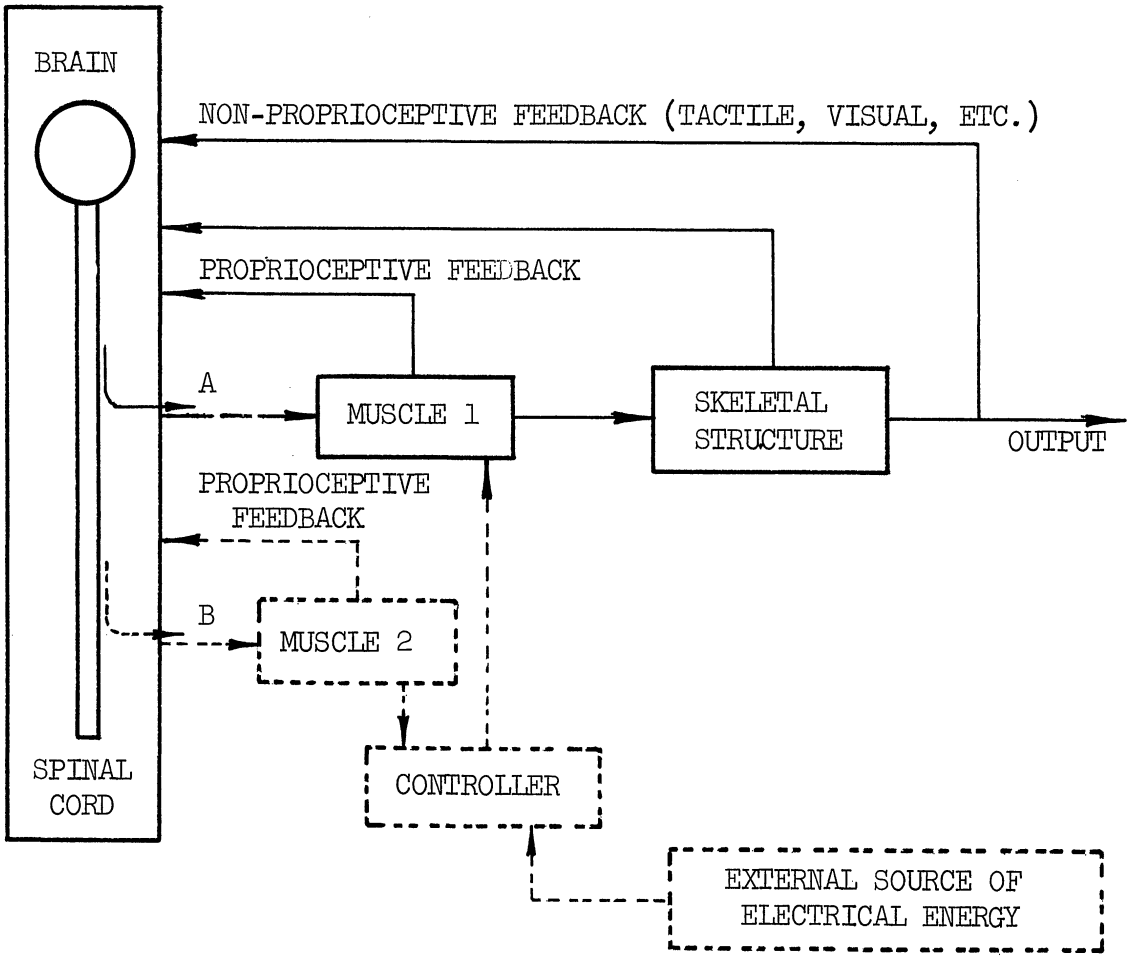


Fig. 3

This solution strives to replace only part of the first-order loss, i.e., transmission and application of signal to the muscle. The signals are derived indirectly from the control centers. In Fig. 3, the denervated muscle (muscle 1) is artificially stimulated to a degree controlled by an available normal muscle (muscle 2) in the finger, foot, truck, etc.

Class 3 - Use of an externally powered linkage, attached to the extremity, and controlled by the remnant of the original signal (Fig. 4).

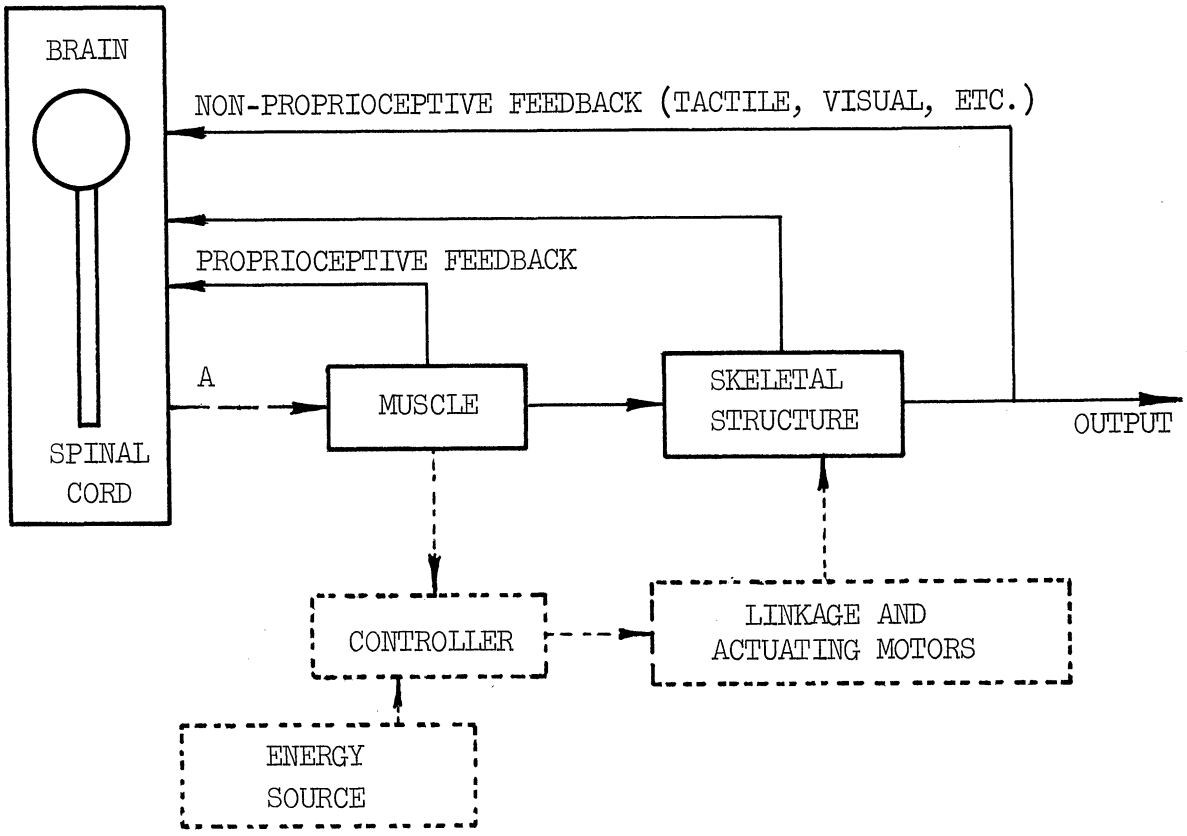


Fig. 4

This solution, by substituting an external motor for the denervated muscle, is directed at the second-order loss, and although more conventional, restores less function. Figure 4 is a diagrammatic illustration of an orthesis incorporating a linkage, suitably attached to the skeletal structure, and powered by an external energy source, probably pneumatic, electric or hydraulic. The supply of energy to the motor units which actuate this linkage is regulated in this case by EMG (electro-myographic) signals which emanate from the partially denervated muscle. ENG signals could also serve this purpose. The study of EMG signals for this purpose is still in the first stages. Also, it should be noted that neither EMG nor ENG signals are present in a 100% flail neuro-muscular system.

Class 4 - Use of an externally powered linkage, attached to the extremity, and controlled by an available normal muscle (Fig. 5).

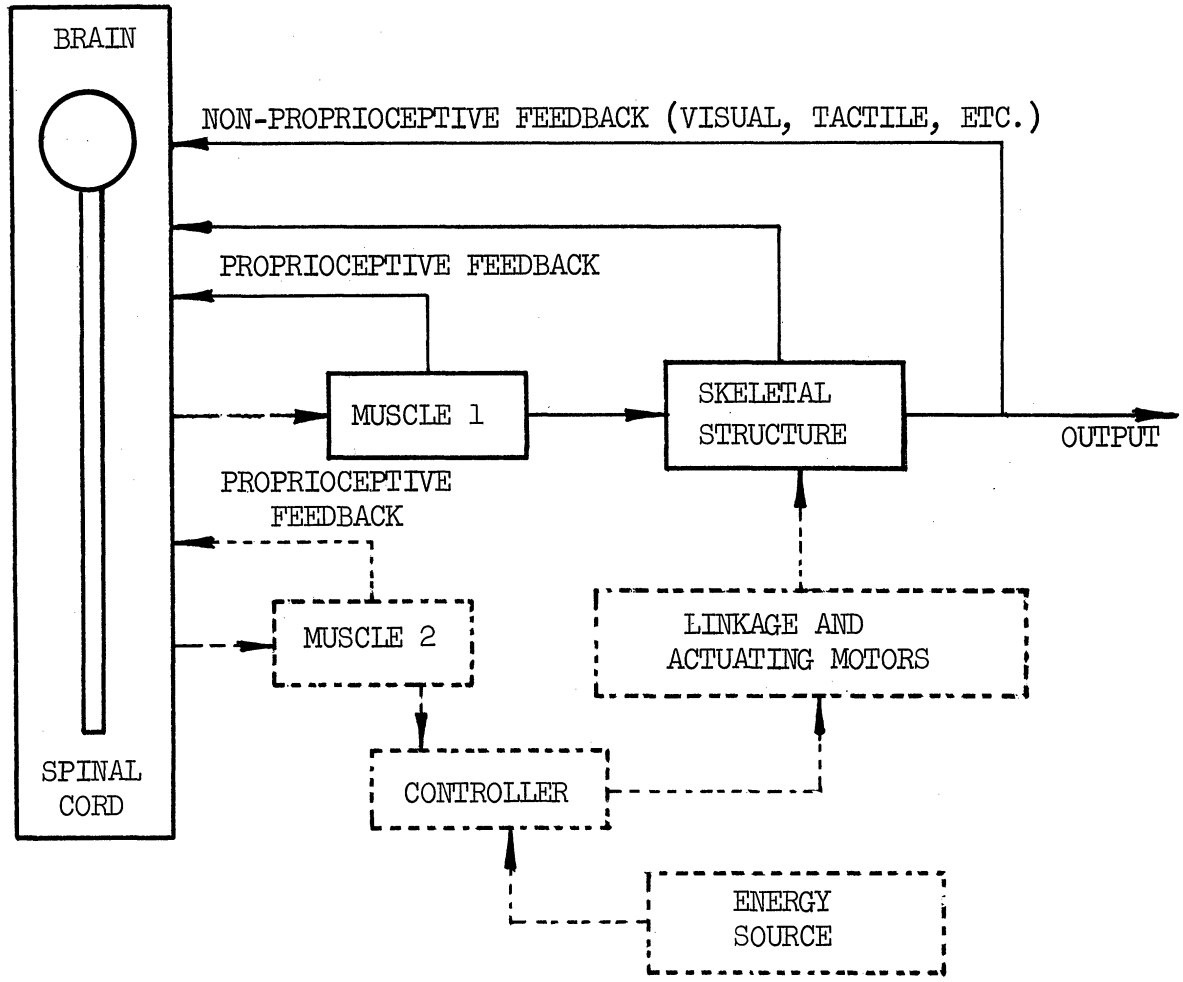


Fig. 5

This class of solution, also aimed at the second-order loss, represents the combination of the more conservative components of classes 2 and 3. An external linkage powered by external motors is employed, as in Fig. 4, and the external motors are controlled through the use of some other muscle (muscle 2), as in Fig. 3. This is the type of orthesis normally visualized in connection with this study, whereas the first 3 types represent tremendously more ambitious undertakings.

Class 5 - The same as class 4 except that the linkage is powered by one of the patient's usable muscles (Fig. 6).

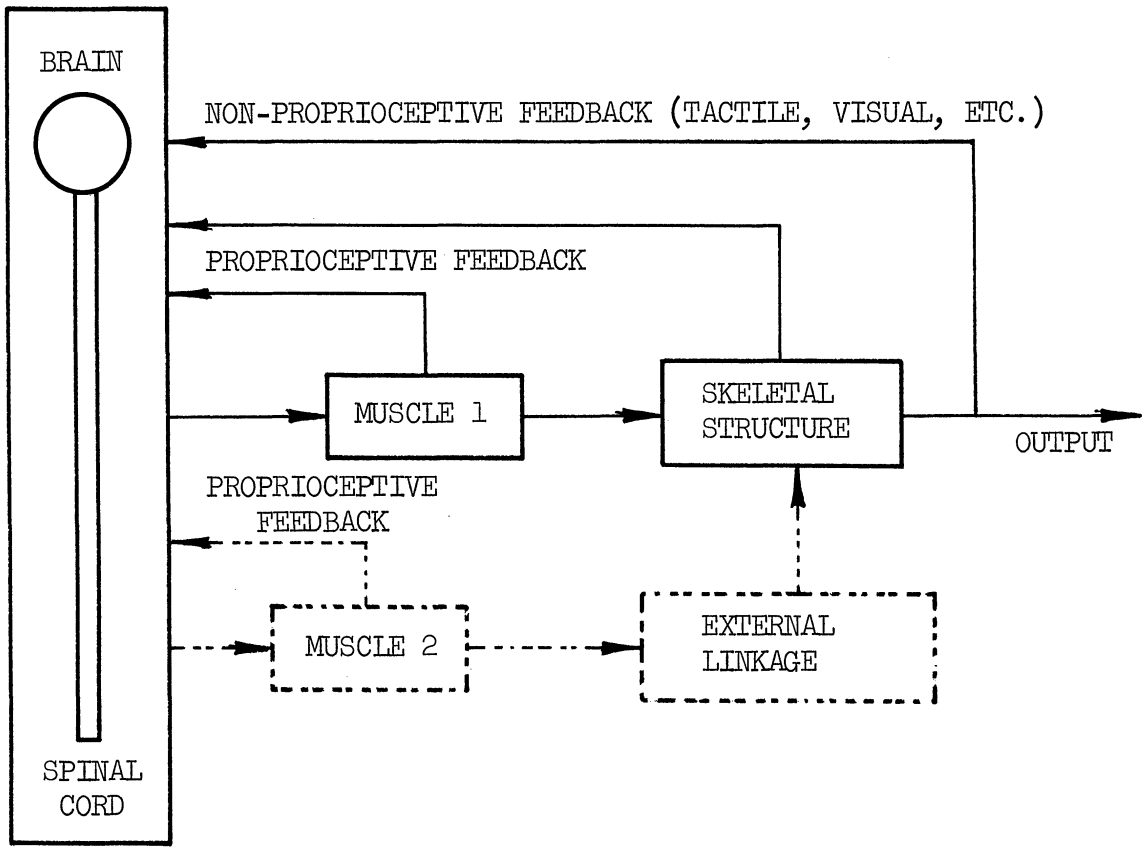


Fig. 6

No additional control apparatus is required in this case, as the patient uses his natural control system in operating muscle 2.

Class 6 - Unpowered devices (not illustrated).

A vastly simpler type of orthesis than any of the above is the group of devices, including the conventional feeder, which brings no additional source of power to the flail extremity. These devices serve primarily to carry the gravity weight of the extremity, and to enable the patient to obtain maximum benefit from any residual muscle power in the extremity, or from trunk motion. A study of the operation of feeder-type devices will be reported in connection with project I.I. (Immediate Improvement) No. 1.

Class 7 - Devices not involving the extremity (not illustrated).

A final classification of orthetic devices might be those concerned with replacing loss of function at the organism level, i.e., the loss of the ability to accomplish activities such as feeding. These devices would be designed solely to accomplish a particular activity and need not even be concerned with bringing the patient's upper extremities into play in the process.

This classification is obviously of no concern to this investigation; its inclusion serves merely to complete the listing of possible classes of solutions.

All classes of solutions would be concerned to some degree with such third- and fourth-order losses as altered joint alignment, edema formation, reduced skin thickness, impaired respiratory function, etc., insofar as they affected the performance or utilization of the orthetic system.

VI. Size, Motion, and Force Considerations

In undertaking the design of an orthetic system concerned with manipulation, certain basic physical parameters of the upper extremities must be considered. These include the dimensions, weight, and weight distribution of the upper extremity segments, the range of displacements, velocities, and accelerations required, and the forces to which the device will be subjected. This section of the report contains a summary of information which is currently available concerning these parameters.

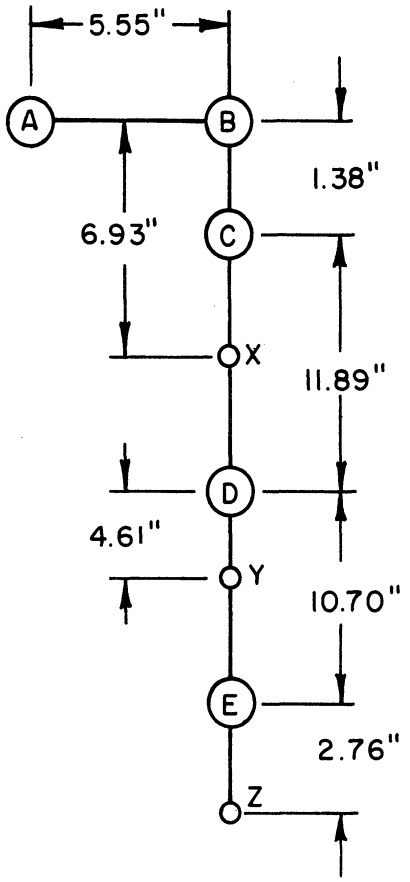
A. DIMENSIONS, WEIGHT, AND WEIGHT DISTRIBUTION

The most complete dimensional data were found in Ref. 8, and the most useful information regarding weights of the upper extremity segments, in Ref. 14. The latter contained regression equations which related segment weights to total body weight empirically. Data from these sources, pertaining to a 5' 10", 170-lb adult male, are summarized in Table I, and illustrated in Fig. 7. These values correspond to the 50th percentile of U. S. Air Force personnel.

TABLE I

UPPER-EXTREMITY WEIGHTS OF NORMAL 170-LB ADULT MALE

Body Segment	Regression Equation	Weight of body segment for 170-lb body weight, lb
Upper arm	$\frac{1}{2}$(.08 x Body Wt. - 2.9)	5.4
Forearm	$\frac{1}{2}$(.04 x Body Wt. - .5)	3.1
Hand	$\frac{1}{2}$(.01 x Body Wt. + .7)	1.2
Total weight of arm		9.7



A Sternoclavicular Joint

B Claviscapular Joint

C Humeroscapular Joint
D Elbow Joint

E Wrist Joint

X Upper Arm c.g.
Y Lower Arm c.g.

Z Hand c.g.

Fig. 7. Upper-extremity weight distribution for normal 170-lb adult male.

These figures are obviously high for the average patient whose muscles are partially atrophied. It seems likely, however, that they might be fairly representative of the heaviest upper extremities for which the device need be designed. A study of mass data pertaining to atrophic arms is currently being undertaken by Dr. W. T. Dempster. No previously collected data were found on the moments of inertia of the segments.

B. MOTION

Reference 31 contains a report of Ruth Miller, O.T.R., and Beverly Israel, R.P.T., pertaining to their study of the motions and excursion ranges of eating in normal adults.

An analysis of velocities and accelerations is currently being made by Dr. W. T. Dempster and Prof. J. R. Pearson. This study is being handled in three phases:

1. A kinematic and kinetic study of planar motions of the upper extremity, to determine elbow and shoulder force and torque reactions. These are voluntary, vigorous motions of magnitudes exceeding those involved in connection with this particular task.

2. A study of positions, paths, and hand orientations in self-feeding. This study does not include velocity, accelerations, or kinetics. It should be of value in determining the ranges and types of complex motions performed by "normals," from which the frequency of component motions for "low" order losses might be deduced.

3. An effort to determine moments of inertia of limb segments and to set up a method by which these may be determined quickly with simple clinical methods and reasonable accuracy.

C. FORCES

The maximum static load normally encountered in transporting food to the mouth is that associated with a glass of liquid. Calculations contained in Appendix D show that the elbow torque required to maintain the forearm in a horizontal position with the hand holding a 10-ounce glass filled with 12 ounces of liquid is of the order of 52 inch-pounds.

To obtain a comparison of orders of magnitude of static loading and inertia loading, Appendix D contains a rough approximation of the maximum elbow torque required to flex or extend the elbow through an excursion of 90° in a time interval of 1 second. For this calculation, it was assumed that the forearm started at rest and accelerated harmonically throughout the 90° excursion. The maximum calculated torque was approximately 2 inch-pounds. Since this is of the order of 5% of the maximum calculated static torque, it is concluded that as far as device design loads are concerned, inertia forces are relatively unimportant. Inertia torques at the shoulder appear to be of even lesser importance. It is possible, however, that inertia forces will assume more significance in connection with control system refinements.

VII. Survey of Power and Control Types

Power sources for orthetic devices can be classed as either internal (intrinsic) or external (extrinsic), where the latter includes all sources other than the muscles within the body of the patient.

Intrinsically powered devices can be further divided into (1) those involving a direct connection between the source of power and the extremity being powered, and (2) those which use energy-storage units (such as batteries or compressed gas tanks) which are recharged periodically by a manually operated unit. Units of the first type are common in prosthetic practice, and normally employ a bowden cable for the direct connection. Other types of connection are also possible. In particular, hydraulic connection appears worthy of consideration. Intrinsically powered units of the second type embody a complete externally powered system plus an additional component which provides for manual recharging. Appendix E contains a summary of advantages and disadvantages associated with various possible types of intrinsically powered designs. While the use of intrinsic power at some point in an externally powered system may possibly be desirable, it is felt that harnessed muscular energy alone is not sufficient for powering orthetic devices which are to meet the specifications presently being considered. This is particularly true in view of the fact that most potential users of these devices are not as strong as individuals using prosthetic devices (where intrinsic power finds its greatest application).

Externally powered systems incorporate three major components:

1. Energy-storage unit (battery, tank of compressed gas, etc.). The type of energy selected for use in an orthetic system must be capable of storage in quantities sufficient to operate the system for a reasonable period of time, yet having the small volume and weight which are vital to portability. The ease with which the energy supply can be replenished is another important factor.

2. Actuator (electric motor, solenoid, nylon muscle, cylinder and piston, bellows, etc.), including any mechanism (involving gears, clutches, linkages, cables, etc.) necessary for suitably connecting the actuator to the skeletal or device links. The actuator itself should be small and lightweight to permit installation close to the point at which the motion is required. Preferably, it should produce directly the low speed linear or angular motions needed at the extremity, thereby obviating the necessity for speed reduction units and extra linkage.

3. Control system (elements which secure a command from the patient and regulate the flow of energy to produce a desired effect). In addition to other considerations, the control system should enable the signal to be derived from a body motion which is as naturally associated with the desired arm movement as possible. This is important for facilitating the learning of control as well as for cosmesis. Present indications are that the control system will likely involve more difficult problems than either the power source or the prime mover.

The present "state of the art" suggests three possible types of externally powered systems: electric, pneumatic, and hydraulic. The following paragraphs summarize some of the characteristics and considerations associated with these types.

A. ELECTRIC

Small, rechargeable batteries have been developed which provide reasonably compact and light-weight energy storage. Possible battery types include lead-acid, nickel-iron, nickel-cadmium, silver-cadmium, and silver-zinc. The lead-acid and nickel-iron types are relatively heavy. The silver-zinc type has a relatively short life and is the most costly. The silver-cadmium and nickel-cadmium types appear most promising at the present time.

Miniature high-speed d-c motors, such as those used with the IBM electric arm, appear to be the most promising electric actuators. However, these require the use of speed reduction units, and possibly clutches and brakes which add complexity. The powering of multiple motions would require multiple power units, or a multiple clutching system adapted to a single power unit.

Other electrical devices, such as the Leden rotary solenoid, appear to have desirable characteristics for orthetic devices where locking, gear shifting, or other low-duty-cycle situations arise.

The electrical control system itself appears to be ideal. Wires and electrical circuits can presently be miniaturized to a much higher degree than comparable pneumatic or hydraulic units. Also, in the event that ENG or EMG signals prove useful for orthesis control purposes, these could feed directly into an electrical control system.

B. PNEUMATIC

High-pressure cylinders provide compact energy storage for pneumatic systems. By far the most common medium presently used is carbon dioxide, which is stored at pressures approaching 1000 pounds per square inch. The potential hazard associated with storing high-pressure gas has been minimized by the development of high-pressure cylinders equipped with safety devices, such as pressure-relief valves and blow-off diaphragms. Freon is a medium which can be stored at lower pressures than carbon dioxide, thereby possibly eliminating the need for a pressure-reducing valve, and improving safety. On the other hand, freon is more costly. A more detailed study will be required to establish definitely the best medium for a particular pneumatic system.

Probably the chief advantage of the pneumatic system for the present application is the availability of extremely simple actuators which are also light, compact, and inexpensive, and which directly produce linear motions

within the speed range desired. These actuators include the nylon muscle, bellows, piston, and "bellofram" (trade name for a spring-opposed cylinder which incorporates a special diaphragm to eliminate leakage at the piston).

Any of the pneumatic actuators can be used with "on-off-hold" controls or with proportioning control valves. Although no proportioning controls are commercially available which have the desired characteristics together with a sufficiently compact design, it appears likely that these could be developed.

It is the opinion of the group making this study that the pneumatic system holds the greatest promise for providing a satisfactory solution to the present problem within the next few years.

C. HYDRAULIC

Hydraulic systems differ from pneumatic systems in that they deal with an essentially noncompressible medium. Although hydraulic energy storage units and hydraulic control systems do not appear to be well suited to the present problem, the modification of an otherwise pneumatic system by using a noncompressible fluid between the control valve and the actuator appears to have merit. A specific proposal along this line is stated in Section XI.

VIII. Device Attachments

It is recognized that the consideration of device attachment is an important phase of the over-all problem of orthetic design. Some of the principles of attachment design are listed below.

1. Consideration should be given to the substantial variation in pressure tolerance of different body surfaces, taking advantage, wherever feasible, of areas permitting pressures which are relatively high.

2. Careful fitting must be provided to obtain the desired distribution of pressure over the contact area involved. This will include judicious use of suitable padding in some instances, and possibly no padding in others.

3. The device should be so designed that no unnecessary forces are applied to the body. When flexing the elbow, for example, it is desirable that pressure be exerted as distally as is feasible, and in a direction perpendicular to a plane containing the forearm axis and the elbow joint axis.

IX. Linkages

The design of a suitable linkage appears to involve a considerable measure of ingenuity combined with experimental testing. Also, the linkage system must be considered in relationship to the total patient-device system.

X. Questions Indicating Areas for Research and Development

A major purpose of the present investigation is the determination of questions which may arise in connection with the actual development of an orthetic device. The questions listed herein are those which, in the Committee's judgment, indicate appropriate areas to be considered for research and development. They are organized with reference to the types of devices discussed in Section V and illustrated in Figs. 2-6.

The first group of questions pertains to devices of all types; the second group arises from a consideration of the ultimate solution, represented by Fig. 2, and involves both utilization of denervated muscle and signal pick-up from the remnant of the original control path; the third group of questions pertain to the "conventional" type of solution illustrated by Fig. 5, which incorporates external motors and which utilizes control signals derived from available body movements; the final group of questions relates only to the type of solution found in Fig. 6, a solution which makes use of intrinsic power. Device types illustrated by Figs. 3 and 4 involve combinations of the features shown in Figs. 2 and 5 and thus involve combinations of these questions.

A. GROUP I. QUESTIONS RELATING TO ALL TYPES

1. What are the minimal upper-extremity motions (i.e., independent joint motions and excursions) needed to provide the hand orientations and placements necessary for performing basic self-care activities, particularly feeding?

2. What is the relative order of importance of adding other motions (on the basis of restoring additional function and of performing the basic activities more satisfactorily)?

3. To what extent can normal activity be restored by providing two-, three-, and four-degree-of-freedom systems, having specific excursion limitations?

In connection with the above questions, it should be noted that, unless the denervated muscles are utilized for power, the motions provided by the device need not necessarily correspond to anatomical motions. The hand could be positioned by the device with the upper and lower arm merely "going along for the ride."

B. GROUP II. QUESTIONS RELATING TO FIG. 2

1. Can denervated muscles be artificially stimulated, so as to function usefully? If so, how? As developed in Appendix F, this question appears to indicate an important area for research which has heretofore received little attention.

2. Can a usable signal be obtained from the remnant of the original control path leading to the denervated muscle? If so, how? The importance of this question has been widely recognized (see Refs. 15, 7, 10, 28), and other groups are already engaged in research in this area.

3. What is the most suitable type of external power supply and of controller for use with the system illustrated in Fig. 2? An answer to this question must depend on the answer to questions 1 and 2; and satisfactory answers to these questions will probably come, if at all, as a result of relatively extensive research efforts.

C. GROUP III. QUESTIONS RELATING TO FIG. 5*

1. What is the best form of stored energy for use in powering the device? On the basis of the discussion in Section VII, the tentative answer to this question is pneumatic power. Many of the following questions in this group are therefore related to the use of pneumatic power.

2. What is the most suitable medium for use in a pneumatic orthetic system (CO_2 versus freon, etc.)?

3. What type of pneumatic motors are most suitable for the various joint powering applications involved (nylon muscle, cylinder, bellows, etc.)?

4. From what body locations can satisfactory control signals be derived?

5. Can the average patient learn to operate proportional controls to advantage?

6. Given suitable multiple controls, can the average patient operate them simultaneously to his advantage? If so, how many and what sort?

*Some of these also relate to Figs. 3, 4, and 6.

7. Should consideration be given to providing programmed control in which a single control signal activates a preselected sequence of motions?

8. What is the best type of control device? Is it possible that electrical controls could be justified because of weight and bulk considerations, even though the system is pneumatically powered?

9. Can an otherwise suitable proportional pneumatic control be developed which does not involve bleed loss?

10. What are the best techniques for locating the joint axes (as will undoubtedly be required in connection with the fitting of any device involving a linkage to be attached to the upper extremity skeletal structure)?

11. What design features should be incorporated into the members which attach the device to the body? What materials are most compatible for skin contact? What unit pressures are permitted, and what is the relative pressure tolerance of various surface areas in probable regions of attachment (hips, trunk, elbow, wrist, shoulder)? Under what conditions is padding desired?

12. What loading can be tolerated by the joints of a flail extremity?

13. What linkage arrangements are most suitable?

D. GROUP IV. QUESTIONS RELATING TO FIG. 6

1. Can the constructions and materials of bowden cables be altered so as to reduce friction materially?

2. Can the principle of conventional hydraulic remote controls be adapted as a superior substitute for the bowden cables?

3. What are the most satisfactory muscles for intrinsically powering a flail upper extremity?

4. How does the patient's control ability of intrinsically powered multiple upper-extremity motions compare with the control ability using a stored energy source?

5. How much of the energy normally dissipated in walking could be harnessed for recharging a stored energy supply? (For example, could significant energy be derived from a bellows type pump in the heel of each shoe without requiring the patient to expend noticeable additional energy when walking?)

XI. Recommended Areas of Engineering Development

A. PROPORTIONING PNEUMATIC CONTROL

Pneumatically operated devices presently in use in orthetics and prosthetics employ comparatively simple valve mechanisms which enable the operator to add, exhaust, or hold gas in a pneumatic motor. Since normal arm function permits continuously variable movement, it seems desirable to aim for fully proportioning control in externally powered ortheses as well. Adequate provision of such control would require a proportioning pneumatic control valve.

Various types of pneumatic control devices with an output which varies in proportion to a continuously variable input signal have been employed in industry for years. The principles of their operation are described in Ref. 30. Several of these controls of the type used in diverse industrial processes were donated by the Johnson Control Company, and our laboratory bench tests (not involving a patient) have demonstrated that their performance in positioning of nylon muscle at an intermediate pressure is definitely superior to that of the conventional on-off-hold valve.

The most important factor in our consideration of proportioning controls is, of course, whether or not the patient can operate them.

To answer this question, a device is being constructed which will incorporate two valves being donated by Johnson Controls. A brief description of their principle of operation follows.

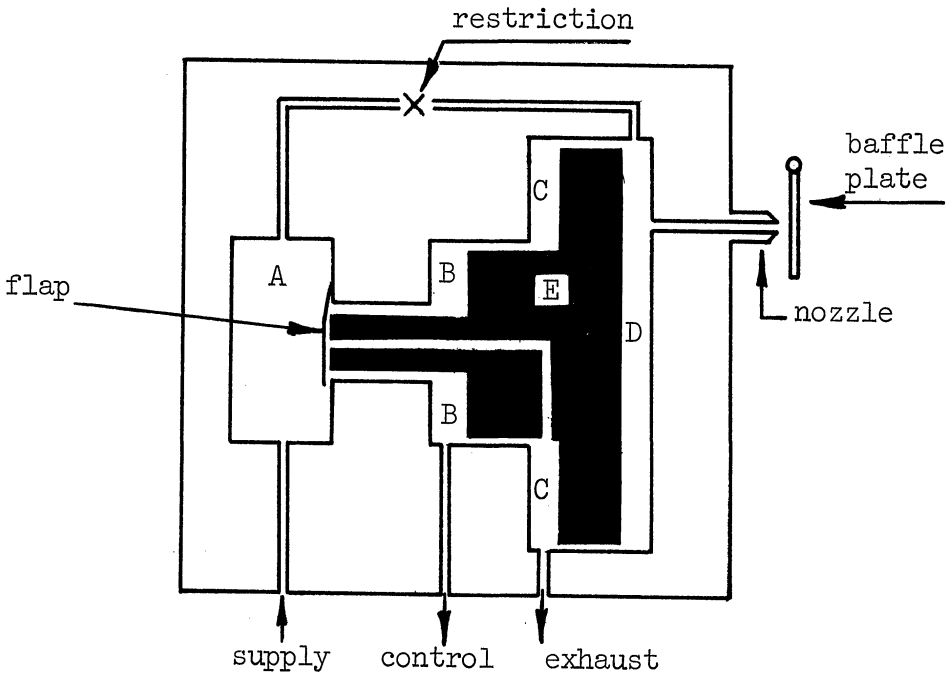


Fig. 8

In Fig. 8, gas is supplied to chamber (A) and bleeds through a restriction into chamber (D). To increase the "control" pressure, the baffle plate is moved toward the nozzle, a pressure build-up in chamber (D). This causes piston (E) to move to the left, and the flap seals the port at the left extremity of (E). At the same time, the flap is moved to permit gas to enter chamber (B) from chamber (A). Gas pressure thus builds up in chamber (B) and in the control line to the actuating device until that pressure is sufficient to move piston (E) to the right. As (E) moves in this direction, the flap seals off chamber (B) from chamber (A). The forces on E, due to pressures in chambers B and D, are now in equilibrium. If the baffle plate is moved to the right, the pressure in D decreases, and E moves to the right, unseating the flap from the port at the left extremity of E. Gas is thus permitted to escape from chamber (B) into chamber (C), where it is exhausted into the atmosphere. This exhaust continues until the forces on E are in equilibrium (corresponding to the originally selected position of the baffle plate).

Although this type of controller is relatively inexpensive, gives excellent and dependable response, and requires very little force to actuate, the valve is not, in its present form, applicable to an orthetic device for ambulatory patients. It can, however, be used on prototypes to determine the feasibility of proportioning controls as such.

The main objection to the conventional proportioning control valves just described is the bleeding of gas at the nozzle. At a relatively low supply pressure (20 psi gage), gas bleeds through the nozzle at a rate of approximately 20 cubic inches per minute. This means greater consumption than tolerable with the necessarily small supply of gas available to the ambulatory patient.

If experimentation with these valves indicates that proportioning controls are desirable, it will be necessary to develop a proportioning valve along the lines of our particular needs. Consideration should also be given to the possibility of actuating a pneumatic valve by an electrical signal such as the EMG.

B. A MODEL OF THE UPPER EXTREMITY

A model of the upper extremity is currently being constructed, so as to correspond generally with drawings contained in Ref. 8, which will incorporate the following additional features:

1. Provision for lock-out of any motion, or combination of motions which might result from the stabilization of a portion of the arm in predetermined position.

2. Provision for varying the mass and mass distribution of the arm and forearms.

3. Provisions for varying the length of the upper- and lower-arm segments.

4. Calibrated dials indicating the angular position of various joints.

C. HYDRAULIC TRANSMISSION BETWEEN CONTROL VALVE AND ACTUATOR

A device which might be used to conserve gas in a pneumatically powered system is currently being investigated. The principle involves filling the connecting lines and motor devices with an incompressible fluid and coupling these to a pneumatic valve using a diaphragm to separate the compressible from the incompressible fluid. This would save the gas otherwise needed to build up pressures in the air lines and in the "dead" spaces in the actuators. The diaphragm element which serves as a hydro-pneumatic converter is shown in Fig. 9.

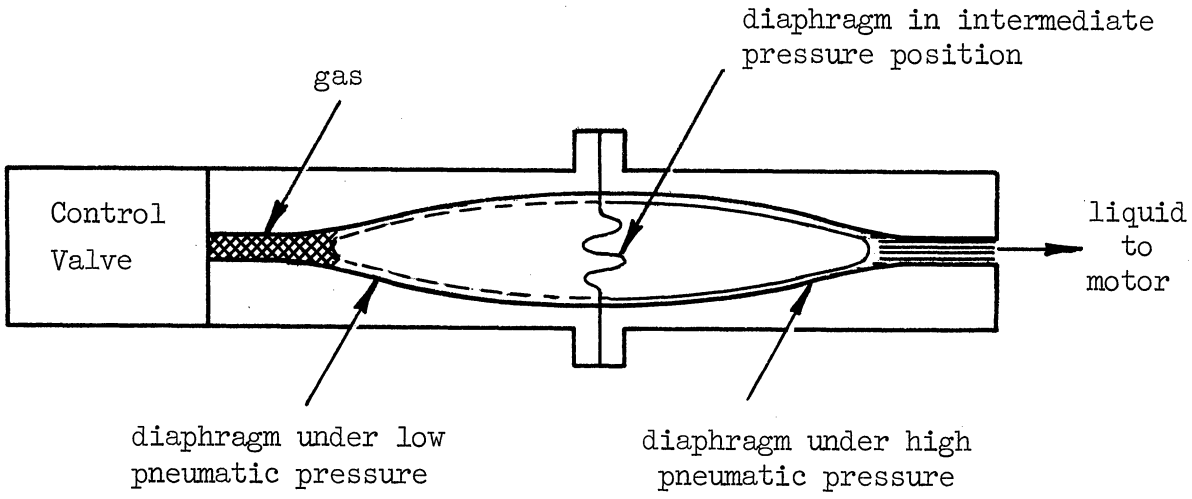


Fig. 9

D. A SELECTED DEVICE FOR FUTURE DESIGN STUDY

Figure 10 illustrates one possible embodiment of the general type of device which appears to merit study. Further consideration will undoubtedly result in substantial deviations from any device now envisaged.

The illustrated device would be supported at the hips in a manner generally similar to that used in the attachment of a brace.

The principle of this preliminary drawing involves support of the arms and shoulders at the forearm in spring suspension. The spring is enclosed in link (B), which is supported by link (A). Link (A) is rigidly attached to the hip brace and contains a pneumatic motor (piston or nylon muscle) which causes link (B) to rotate about pivot (X), giving humeral adduction or abduc-

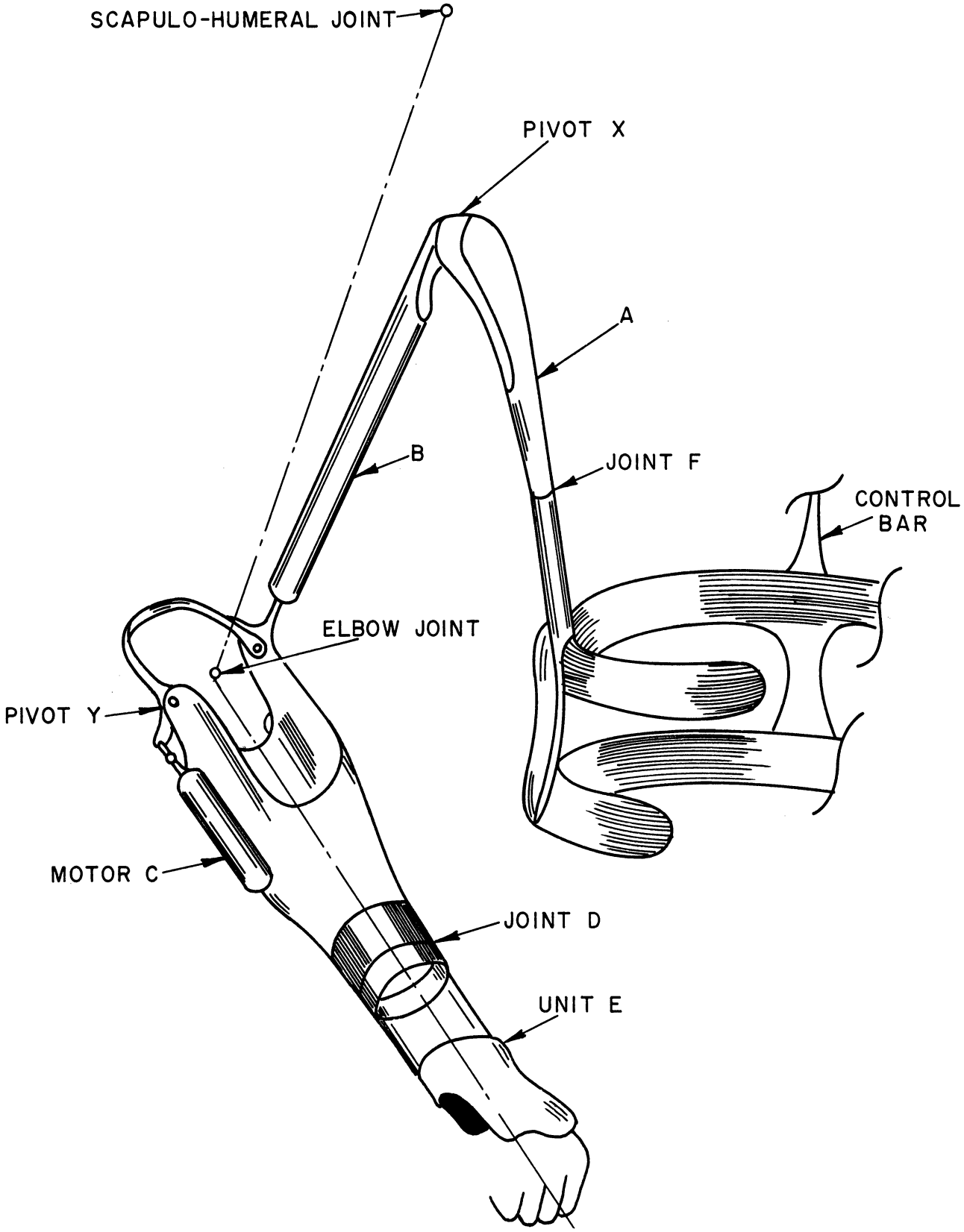

SCAPULO-HUMERAL JOINT
PIVOT X
A
B
JOINT F
CONTROL BAR
ELBOW JOINT
PIVOT Y
MOTOR C
JOINT D
UNIT E

Fig. 10

tion with gravity return.

Limited humeral rotation could be achieved by providing a powered, friction, or ratchet turntable at joint (F).

The unit for the left side (for right-handed bilateral cases) could be similar in appearance but would contain no external power elements. It is suggested that this unit might use spring force to support the arm and shoulder in a predetermined position. The patient would then use trunk motion to position the arm as is done in the ordinary chairback brace. This positioning of the left side would have to be accomplished with all active components in the right side de-energized.

E. CONTROLS

As indicated previously, an attempt will be made to generate control signals from trunk motion.

Figure 11 shows a T-bar made up of three links (B, C, and D). This T-bar is attached to hip support (A) at pivot (O); link (C) is attached to (B) at (O_2); and, link (D) is attached to (C) at (O_3). The control signals are to be derived from relative motions between the links, resulting from movements of the trunk relative to the pelvis.

Motion at (O_1), (O_2), and (O_3) might be as follows: at (O_1), a control signal is generated by rotating B about the X-axis, and another by rotating (B) about the Y-axis; at (O_2), (C) slides in and out of (B) along the Z-axis; and at (O_3), (D) rotates about the Z-axis.

Control signals resulting from these motions might be used as follows:

1. proportional control of elbow flexion and extension by rotation about the X-axis at (O_1);

2. proportional control of humeral rotation by rotation about the Z-axis at pivot (O_3);

3. humeral abduction and adduction by slide on the Z-axis at (O_2) with an on-off-hold control (hold in the relaxed position);

4. proportional control of pronation and supination by rotation about the Y-axis at (O_1).

The selection of a control signal for a particular motion would ultimately be determined by the patient's success with various combinations.

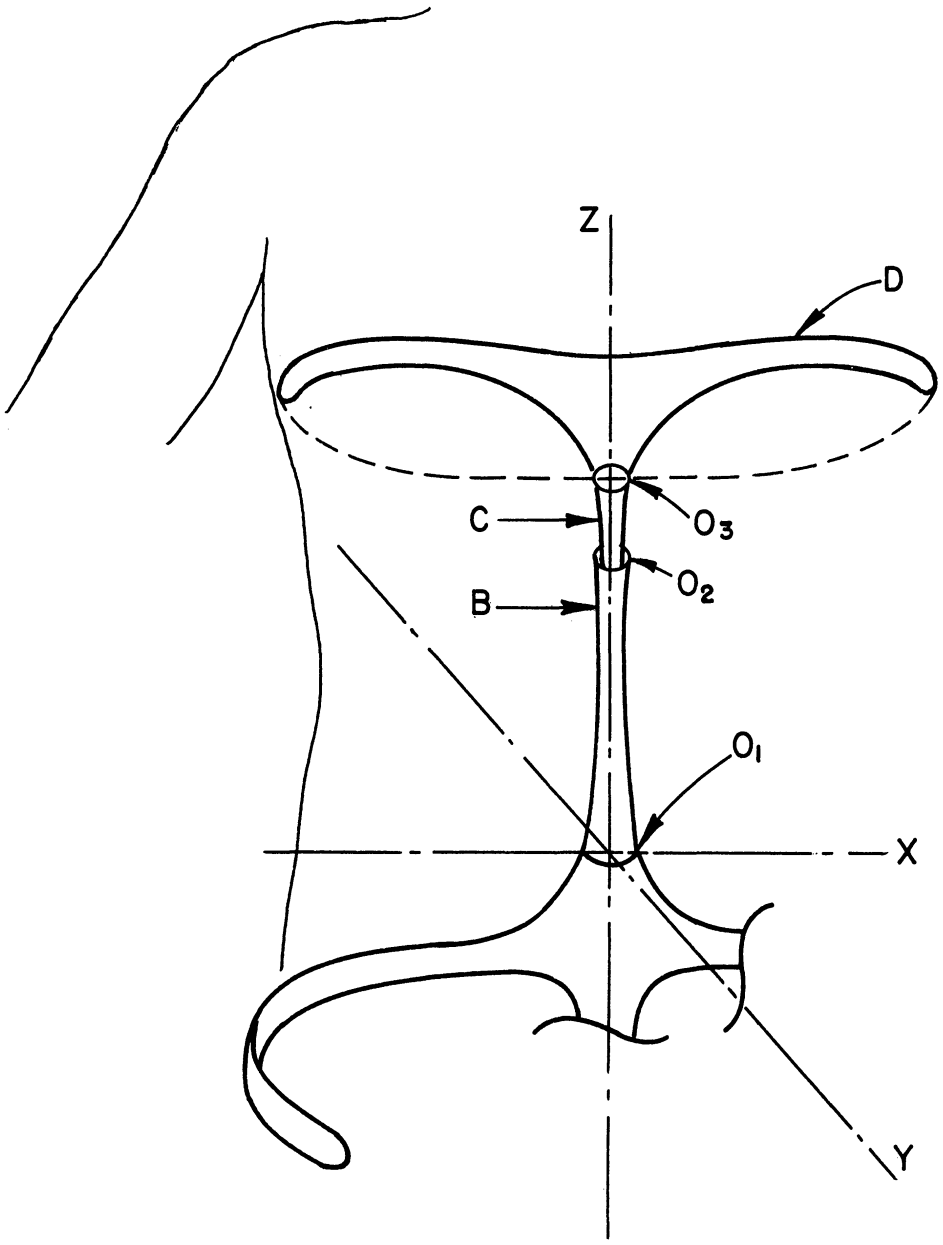


Fig. 11

APPENDIX A

DEVICE DESIGN AND DEVELOPMENT

Task Plan: D.D. 1 Approved 12-15-59

Purpose:

1. To accumulate questions which will indicate what the designer needs to know for the development of a design for orthetic systems by preliminary design effort or studies on a specific case.

2. To develop a proposal for the detailed design and development of a selected device.

Problem: To provide the activity of feeding for a patient, observing the following conditions:

1. Patient has bilateral flaccid paralysis of the upper extremities.
2. Scapular complex is included in the paralysis.
3. Patient has bilateral hand function. Wrist stabilized in some "optimum" position.
4. Patient is an adult of average size and weight.
5. Patient is ambulatory.
6. System should be designed for the dominant arm (right).

Assumptions:

1. Activity will be performed with the U.E.
2. Subject will be seated while performing the activity.

Suggested Procedure:

1. Determine size and weights of U.E. elements.
2. Describe the motions of the U.E. involved in performing the activity.
3. Describe the range of loading cycles.
4. Consider all possible human-device systems to perform functions of (2) and (3).
5. Select the best one of the possibilities of (4).
6. Drawing board illustrations of system(s).

Schedule:

Starting date: December 15, 1959.
Finish: June 1 (sooner if possible), 1960.

Personnel:

Prof. R. C. Juvinall, Chairman; Dr. Smith, Mr. Timm, and Mr. Czap.

Consultants - Prof. J. E. Pearson
Dr. James W. Rae, Jr.
Mr. Hal Schulte, Jr.

APPENDIX B

GENERAL OBJECTIVES OF ORTHETIC SYSTEMS

E. Smith

(Based on the Granger report: "Criteria for Acceptance of a Device," UMORP 5-2-60)

The objectives of any orthetic system can be conveniently classified into four groups: (1) to restore function, (2) to avoid undesirable side effects, (3) to be acceptable to the patient, and (4) to be feasible economically. The specific objectives listed will be influenced by the nature of the disability and the requirements of activities, but each should be carefully considered, nevertheless, during the design of any type of orthetic system.

A. RESTORATION OF FUNCTION

Upper extremity function can be broken down into two components: (1) hand-manipulative function and (2) hand-placement function (which includes positioning and orientation). The upper extremity performs these functions through the proper combination of power, control, and constraints. Thus the primary objectives of an orthetic system restoring function should be to provide, as indicated, one or more of the following:

1. Constraints, necessary to:

   a. Align upper extremity segments
   b. Stabilize segments
   c. Guide movement of segments

2. Power, necessary to effect useful movement of segments.

3. Control (under the influence of the will) of the amount, rate, duration, direction, and point of application of power.

4. Integration of the power, control, and constraints necessary for the hand manipulative and/or placement functions making up performance of activity.

B. AVOIDANCE OF UNDESIRABLE SIDE EFFECTS

In achieving functional objectives, effort should be made to minimize such undesirable side effects on the patient as:

1. Interference with function otherwise available to the patient
2. Adverse effects on skin (excessive pressure, irritation, sensitization, etc.)
3. Adverse effects on circulation (hyperemia, ischemia, etc.)
4. Adverse sensory stimulation (pain, etc.)
5. Excessive energy demands
6. Adverse effects on joint constraints

C. ACCEPTABILITY TO THE PATIENT

Objectives in this area include:

1. Simplicity of operation, adjustment, application, removal
2. Comfort
3. Cosmetic acceptability
4. Durability
5. Ease of maintenance

D. ECONOMIC FEASIBILITY

Objectives in this area include:

1. Reasonable construction costs
2. Reasonable adaptability of parts to different individuals
3. Reasonable fitting time requirements
4. Reasonable training time requirements
5. Reasonable maintenance costs

APPENDIX C

AIPR VISIT MEMO

Visit to: American Institute for Prosthetics Research

By: Robert F. Timm

Date: June 16, 1960

Contacts: Mr. Willis C. Gorthy, Director
Mr. Keisling, Consulting Engineer
Mr. Bartho, Engineer

The visit lasted approximately four hours. A one-hour tour of the Institute was made with Mr. Gorthy and the remaining time was spent with Mr. Keisling and Mr. Bartho discussing and examining the Heidelberg prosthesis and the prosthesis developed at the Institute.

The Heidelberg prosthesis was judged not acceptable. The major reasons for this are listed as follows:

1. Parts are not interchangeable.
2. The hand is not acceptable cosmetically and does not have sufficient strength.
3. The aluminum CO_2 cylinders were judged unsafe.
4. Pressure relief valves are unreliable.

In spite of these inadequacies, patients were able to use the device and the Institute undertook the development of an entirely new pneumatically powered prosthesis.

Complete details of the new arm are not discussed here. The features of the arm are described as follows:

The arm operates on CO_2 at 80 lb/in.^{2} which is available from a pair of stainless steel cylinders which are connected by an aluminum manifold. The two-cylinder manifold arrangement was adopted to obtain a more compact unit which is better suited to being worn by the patient. This unit also incorporates the pressure relief valve and the pressure reducing valve.

The control valve is a very compact device which is actuated to fill, hold, or exhaust cylinders.

Double-acting cylinders with O-ring seals are used to provide the following motions:

1. humeral abduction and adduction
2. elbow flexion and extension
3. pronation and supination of the forearm
4. hand prehension and extension

The model which was examined by the writer was designed for use by a congenital quadriplegic. It was indicated that the patient was using the prosthesis and that this was the first device that he was able to operate successfully.

Mr. Keisling has consented to send plans for components and will provide information on metallurgical developments which he feels makes the pneumatic cylinders preferable for this application. He also indicated that he wants to continue to exchange ideas with the UMORP.

It is recommended that one of their cylinder units be purchased for our use. Mr. Gorthy is sending prices in this regard.

APPENDIX D

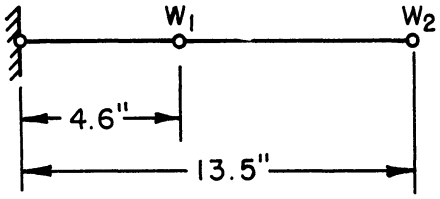
FORCE CALCULATIONS

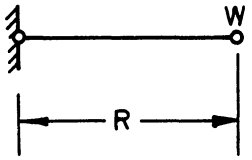
DYNAMIC FORCES

...Flexing the elbow thru 90° in 1 second with the angle of rotation varying sinusoidally.

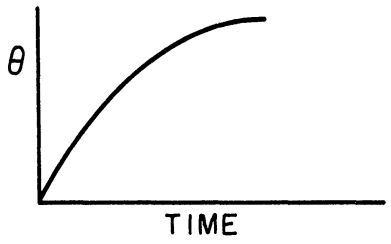
...Forearm and hand are approximated by a point mass.

ELBOW

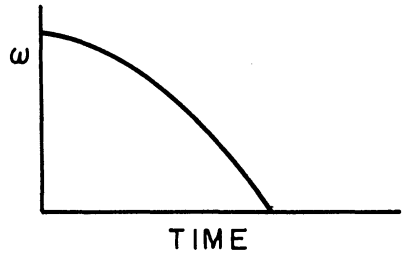




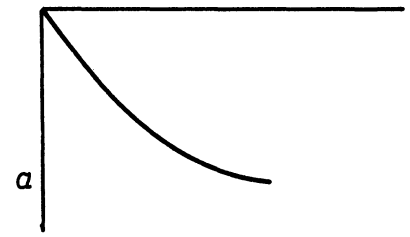
ANGULAR DISPLACEMENT



ANGULAR VELOCITY



ANGULAR ACCELERATION



W_1 = weight of forearm
W_2 = weight of hand
W = 3.1 + 1.2 = 4.3 lb
ΣM, (3.1)(4.6) + (1.2)(13.5) = 4.3R
R = 7.1"
W = total weight
R = equivalent torque radius

$$\theta = \frac{\pi}{2} \sin \frac{\pi}{2} t \qquad A^n = R\omega^2 \qquad A^t = R\alpha$$

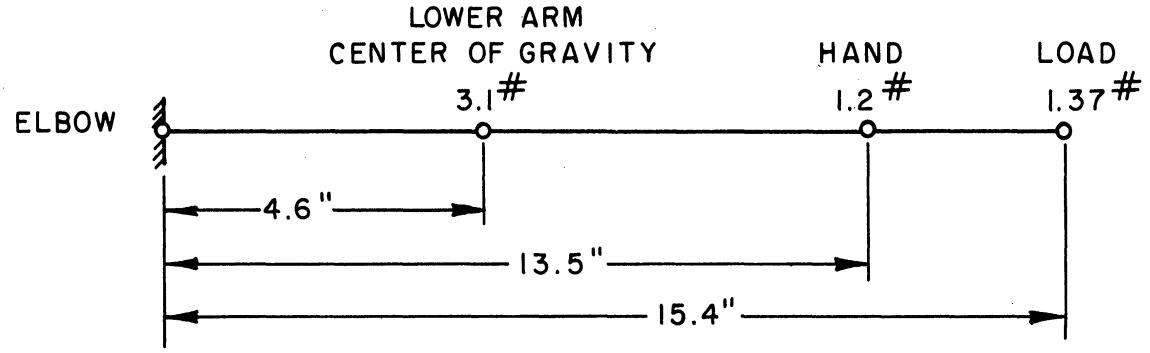
$$\omega = \frac{\pi^2}{4} \cos \frac{\pi}{2} t \qquad A = \sqrt{A^{n2} + A^{t2}}$$

$$\alpha = -\frac{\pi^3}{8} \sin \frac{\pi}{2} t \qquad F = \frac{W}{386} A$$

θ (degrees)	t (sec)	A^n in./sec^2	A^t in./sec^2	A in./sec^2	F lb.	$T_i = W/386\ A^t R$ in.-lb.
0	0	43.1	0	43.1	.48	0
45°	1/3	32.3	-13.9	35.1	.39	1.10
78°	2/3	10.8	-23.8	26.3	.29	1.88
90°	1	0	-27.5	27.5	.31	2.17

θ = degrees rotation
A^n = normal acceleration
A^t = tangential acceleration
A = $A^t + A^n$ (vector sum)
F = total acceleration force
T_i = inertia torque (due to tangential acceleration only)

STATIC FORCES



Torque due to 1.37 lb load at 15.4 inches

$$T = 1.37 \times 15.4 = 21.2 \text{ in.-lb}$$

Torque due to weight of lower arm and hand

$$T = (3.1 \times 4.6) + (1.2 \times 13.5)$$
$$= 14.2 + 16.2$$
$$= 30.4 \text{ in.-lb}$$

Total = 51.6 in.-lb = max. static gravity load with a 1.37-lb external load in the hand.

APPENDIX E

ADVANTAGES AND DISADVANTAGES-INTRINSICALLY POWERED SYSTEMS

A. POINTS PERTAINING TO ALL INTRINSICALLY POWERED SYSTEMS

Advantages

(1) Power source already available
   (a) no added weight for an external source of power
   (b) no added bulk
   (c) no added cost
(2) Power supply lasts "indefinitely"; hence no recharging problems
(3) Possible psychological advantage in using the patient's own muscle power
(4) Possible therapeutic value of exercising the driving muscles

Disadvantages

(1) Limitation of power available
   (a) may overload the muscles of the patient
   (b) severely involved patients could not use it at all (hence not a universal solution)
(2) Restricts the normal function of driving muscles
(3) Cosmetic disadvantage of requiring conspicuous motions not required of nonhandicapped persons
(4) Muscles best for power may not be those most naturally suited for control

B. POINTS PERTAINING TO DIRECT CONNECTION TYPES ONLY

Advantages

(1) No controls required. Patient's inherent control of the driving muscle provides automatically proportional control at the upper extremity
(2) Potentially quite efficient (the only inherent loss is transmission friction)
(3) Potentially simple
(4) Potentially light in weight
(5) Potentially inexpensive

Disadvantages

(1) Requires either
   (a) large excursions at driving muscle, or
   (b) magnified forces, plus magnified control errors at the driving muscle
(2) Limits the number of independent motions to number of power sources available; hence the difficulty of powering multiple motions simultaneously may even exceed the difficulty of controlling multiple motions
(3) Probably awkward to use in a standing position (and patients able to use intrinsic power are very often ambulatory)

C. COMPARISON OF VARIOUS MEANS FOR PROVIDING DIRECT CONNECTION

(1) Mechanical (solid connection)

(a) Bowden Cable

Advantages	Disadvantages
(i) simple	(i) high friction losses
(ii) lightweight	
(iii) inexpensive	
(iv) compact	

(b) Links, Belts, Chains, etc.

Advantages	Disadvantages
(i) potentially low friction	(i) complicated
	(ii) housing problems
	(iii) bulk problems

(2) Hydraulic (noncompressible fluid connection; similar to remote controls for engine testing, requiring only one line between the transmitter and receiver)

Advantages	Disadvantages
(a) low friction (seal friction in sending unit piston; possibility of using nylon muscle for receiving unit, or as sending unit as well)	(a) weight, bulk, cost problem of transmission and receiver units
(b) flexibility and low bulk of transmission line	

(3) Pneumatic (compressible fluid connection)

Disadvantages
(a) compressibility of the medium precludes its use

(4) Electrical

Disadvantages
(a) no known types meriting consideration

D. POINTS PERTAINING TO SYSTEMS EMPLOYING MEANS FOR MANUALLY RECHARGING AN ENERGY STORAGE UNIT

Advantages	Disadvantages
(1) spreads muscular energy requirement over a longer time period	(1) requires all components of an extrinsic power system plus a charging device

APPENDIX F

USE OF DENERVATED MUSCLE AS A SOURCE OF POWER IN ORTHETIC SYSTEMS

Edwin M. Smith, M.D.

INTRODUCTION

In lower motor neuron disease, the primary function lost is transmission of signal from control centers to motors. In keeping with the Project's policy of striving to replace the most basic functional loss possible, an assessment has been made of the feasibility of using an orthetic system to substitute for this loss of signal transmission. Such a system would, conceivably, permit purposeful utilization of all remaining functional tissue, especially muscle tissue.

The function of such a system, then, would be to gather appropriate information from the central nervous system and apply it to denervated muscle in a way causing it to contract and power purposeful movement. The first part of this function, e.g., obtaining appropriate signals from the central nervous system, has been proven feasible (although crude) in the variety of current orthetic and prosthetic devices under the control of the will, and is not considered further in this report. The other function of the system, e.g., applying stimulus to denervated muscle fibers to power movement, has received little attention in the field of orthetics, even though it potentially has many advantages over other sources of power.

POSSIBLE ADVANTAGES OF A SYSTEM USING DENERVATED MUSCLES AS MOTORS

It seems clear that any orthetic system which could use denervated muscles as motors would provide several important benefits, including those resulting from:

1. The application of forces to the skeletal framework in a manner closely approximating normal application.
2. The availability of as many motors as there are usable muscles.
3. The elimination of need for external motors, with their bulk, power sources, complexity, etc.
4. The restoration of more normal homeostasis and the benefits resulting from active contraction of muscle.

POSSIBLE PROBLEMS ASSOCIATED WITH USE OF DENERVATED MUSCLE AS A POWER SOURCE

An attempt has been made to determine the basic categories of obstacles which might be encountered, and to consider possible solutions. It is assumed that if no insurmountable problems are foreseen, both the feasibility and the direction of further investigation should be indicated.

It appears that any problems presently foreseeable fall into three categories:

1. Those related to initiation of muscle contraction.
2. Those related to transmission and localization of signals to muscle fibers.
3. Those related to maintenance of the physiologic integrity of muscle and associated tissue.

I. Initiation of Muscle Contraction

Current knowledge indicates that there are four possible types of stimuli capable of effecting contraction of a muscle fiber: (1) electrical, (2) chemical, (3) thermal, and (4) mechanical.[1] Each is believed to initiate contraction by causing elimination of the electrical potential across the cell membrane or by direct action on the contractile element.

It would be expected, however, that mechanical or thermal stimuli sufficient to produce repetitive contractions would result in serious damage to the muscle fiber. Although all possible forms of these stimuli probably have not been investigated in this regard, there appear to be formidable obstacles to their use in an orthetic system.

Chemical stimuli also seem to present serious difficulties, particularly in their transmission, activation, localization, confinement, control, speed of reversal, effect on other tissues, etc. For these reasons a search for a satisfactory chemical stimulus would be uncertain of success despite the many possibilities among this group. Nevertheless, a literature search, at least, in this area might be indicated, particularly to look into a possible combination of chemical and electrical stimuli.

Electrical stimulation, of course, is the form used most extensively to initiate contraction of denervated muscle. Considerable knowledge regarding its physiologic effects and its requisites for producing contraction is available. In all probability it is the form most closely approximating the normal nerve impulse, and it is possible, under some circumstances, to use it repeatedly without harming tissue. Despite these advantages it has not been used successfully to produce useful extremity movements, primarily because of difficulties encountered in stimulating enough muscle fibers without causing

adverse effects in intervening tissues, and in localizing current to desired fibers with precision and without spread. Although these problems are serious, possible solutions can be envisioned, and for this reason, and because of its other advantages, electrical stimulation is the form considered in this report.

II. Transmission and Localization of Electrical Stimuli

Two types of transmission of electrical stimuli from skin to muscle are possible: (1) percutaneous stimulation, whereby intervening tissue serves as a volume conductor, and (2) direct stimulation, without interaction with intervening tissue. The first type is the standard clinical method.

A. Percutaneous Stimulation.—Although small amounts of current applied directly to muscle fibers will cause useful contraction, relatively huge quantities must be applied to the skin over the muscle before a similar contraction occurs. The most likely reason for this phenomenon is the presence of low resistance paths between electrodes in tissues other than muscle causing an electrical shunt around the muscle.[2] The blood stream, for example, offers very low ohmic resistance, while fascial tissue (which encases muscle) is high in resistance. Very likely, the only current reaching denervated muscle in any quantity is carried there through blood vessels penetrating the fascial barrier.

When a high-intensity stimulus is required to initiate useful contraction, undesirable stimulation of adjacent sensory nerve endings occurs, and if the stimulus is strong enough, actual damage to other low-resistance tissues may result. The amount of percutaneous stimulation tolerated by a patient is usually too low to produce a contraction sufficient to move an anatomical part against resistance. Also, current thus applied tends to spread to other muscles, causing unwanted contractions.

Because of the relative simplicity of applying percutaneous stimulation, however, this method would be desirable if its disadvantages could be overcome. Several possible means of increasing strength of contractions without intensifying the side effects have been proposed. One means would be to reduce the intensity of side effects per unit of current, thus permitting use of a stronger stimulus. Another would be to increase the number of fibers stimulated per unit of current. If both could be accomplished, their beneficial effects should be complementary.

One method of reducing side effects per unit of current would be through use of a stimulus affecting muscle but not sensory nerve endings. That such a solution might be possible is suggested by the fact that the characteristics of an electrical stimulus necessary to activate denervated muscle are somewhat different from characteristics of stimuli necessary to activate sensory nerve endings. The difference known to result in the greatest discrimination

is the time constant of the stimulus; and it has been shown that stimuli with longer time constants are less painful but equally effective in producing contraction of denervated muscle.[3] It is not known how much additional current (and thus increased strength of contraction) the use of this type of stimulus permits, or, for that matter, what the precise characteristics of such a stimulus necessary to produce maximum discrimination might be.

A preliminary experiment has been carried out on denervated muscle to find whether stimuli with prolonged time constants might permit use of additional current without causing more pain. In this experiment it was noted that such stimuli did allow the use of more current, but not nearly enough to activate useful movement. This suggests again that most of the extra current never reaches muscle but is shunted around it through low-resistance tissue.

The problem of adverse sensory stimulation might also be tackled by eliminating the sensory nerve endings or paths in the area. This could be done by destroying the nerve supply or by introducing a local anesthetic, possibly by iontophoresis. This more drastic solution has not been investigated as yet, but percutaneous stimulation in a patient who has already lost sensation is planned.

Problems associated with percutaneous stimulation have also been approached by seeking a way to increase the number of fibers stimulated per unit of current. To this end it was postulated that if all fibers in the path of a unit of current were stimulated, and if the number of fibers encountered varied among different paths, the strength of contraction would depend on which path (or paths) the current took. The best path might then be selected through proper electrode placement.

A simple test was made of this hypothesis by varying both the location and number of electrodes over a muscle belly. Very little variation in strength of contraction was noted with this test, however, and the strongest contraction did not produce useful motion. At the same time, altering the placement of electrodes did not seem to affect the spread of stimulus to adjacent muscles. Once again, it was presumed that most of the current traveled through the vascular subcutaneous tissue, and that it spread to adjacent muscles through the blood stream.

Thus it would seem that the inherent problem of percutaneous stimulation is one of "having to use a cannon to do the job of a slingshot." To date, no clear way of obtaining useful extremity movement against resistance with this method is visible. It might, however, have promise in systems requiring relatively little power to produce useful movement, such as the "feeder," and the theoretical advantages of intrinsic over extrinsic sources of power would warrant its further investigation.

B. Direct Stimulation.—This method of electrical stimulation avoids using intervening tissue as a volume conductor, but rather transmits the electrical energy directly to desired muscle fibers without interaction with in-

tervening tissue. Preliminary testing of direct stimulation of normal muscle with needle electrodes has shown that strong contractions can be obtained with less than one-third of the current required with percutaneous stimulation. Furthermore, by the crude method of varying electrode placements in the muscle belly, the pain of electrical stimulation could be reduced to a level tolerable to the two subjects used in the experiment.

Although direct stimulation theoretically minimizes the problems of current shunting and undesirable sensory stimulation, it raises other problems associated with getting the stimulus to the muscle. That these problems are not insurmountable, however, has been shown in the field of heart disease where electrical "pacemakers" employing direct cardiac stimulation have been used clinically.[4] Problems have been encountered with this application, but it has been successful enough, seemingly, to justify consideration in the field of orthetics.

A system of direct stimulation would require two basic components: (1) a method for transferring the stimulus to the area of the muscle, and (2) a mechanism for applying the stimulus to muscle so as to initiate useful contraction.

1. Stimulus Transfer.—There are two apparent ways for transmitting electrical stimuli to muscle without affecting intervening tissue: use of an insulated conductor, and use of a form of energy not interacting with tissue.

Insulated conductors, in turn, could be composed of either a physiologically inert material introduced between skin surface and muscle, or of body tissue modified to serve as an insulated conductor. Wires with plastic insulation have been used in cardiac pacemakers, and plastic fluid-carrying tubes have been inserted into tissues for prolonged periods, testifying to the possibility of their use in orthetics.

Several kinds of tissue might also serve as insulated conductors. Degenerated nerve fibers, for example, might be used if electrically conducting materials could be introduced into them all the way to their point of contact with muscle. Conceivably, application of a signal to this treated nerve would cause stimulation of all muscle fibers supplied by the nerve. Even vascular tissue might serve as a specific, semi-insulated conductor of stimulus throughout a muscle belly, providing the appropriate vessel could be brought to the stimulus or vice-versa. Still another possibility might be the use of high-resistance tissues, such as fascia, in constructing electrolyte-enclosing tubes between skin and muscles. Simple percutaneous stimulation might even be made more feasible if the electrical barrier of fascia around muscle could be reduced, as, for instance, by cutting "windows" in it.

There are also interesting possibilities in using a form of energy which does not seriously interact with intervening tissue to serve as a carrier of signal to muscle. Transducers would then be located in muscle to convert this energy to appropriate electrical stimuli. Electromagnetic, accoustic, or even mechanical energy conceivably could serve as such signal carriers.

In this regard, a cardiac pacemaker has been developed which employs modulated, high-frequency energy as a carrier of stimulus to a transducer embedded in subcutaneous tissue. The "detected" signal is then led to cardiac muscle by an insulated wire.[5] Use of carrier energy in one of these forms could bypass the possibility of infection and discomfort resulting from skin penetration by wire or other foreign material.

2. Stimulus Application to Muscle.—With some of these proposed methods for direct conduction of a stimulus, the problem still remains of applying the signal to muscle fibers in a satisfactory way. Again two classes of solutions are suggested: use of physiologically inert electrodes implanted in muscle, or use of modified anatomical structures already in existence. In the first instance, the electrodes might serve either as a device for applying stimulus directly to muscle or also as a transducer converting "carrier" energy to stimulus. In either case considerable knowledge regarding the optimum structure, composition, number, placement, etc., of such electrodes would be necessary in order to obtain the most usable contraction without causing tissue damage.

Modified anatomical structures or tissues might also serve as intromuscular electrodes. If blood vessels or degenerated nerves were used as conductors, their terminations would represent ready-made "electrodes." It might also be possible to bring other conductors into muscle and tie them into terminations of one of these tissues, or even to construct artificial electrodes of appropriate tissue.

III. Maintenance of Physiologic Integrity of Denervated Muscle and Associated Tissue

With either system of muscle stimulation, percutaneous or direct, the problem remains of maintaining the denervated muscle fiber as an effective contractile element. It has been shown that, even with repeated percutaneous stimulation for a long period of time, atrophy will progress.[6] It is not known, however, whether this atrophy is the result of failure to provide the muscle fibers enough "exercise" even with the repeated stimulation, or whether some other factor is involved. There is evidence, for example, to suggest that nerves normally exert a "trophic" effect on muscle metabolism, indepen-

dent of the effect produced by stimulation of contraction, and that loss of this trophic effect may be one cause of atrophy.[7] Along another line, it has been shown that fibrillations usually disappear from completely denervated muscle within a year (indicating complete loss of function of the denervated muscle), while in partially denervated muscle, fibrillations may remain indefinitely.[8] The difference may be one of vascular supply, with loss of function of fibers in the completely denervated muscle the result of a "drying up" of its circulation due to lack of demand.[9] The best way to minimize atrophy may well be to use direct muscle stimulation, since such stimulation should activate large numbers of fibers as often as the muscle is used and should, at the same time, increase the demands on the local circulation. Present clinical use of percutaneous stimulation to reduce atrophy probably does not come close to accomplishing this level of muscular activity.

Another problem associated with electrical stimulation is the accumulation of adverse chemical effects resulting from current flow. The "electrolysis principle" probably underlies many of these effects in that destructive ions accumulate at electrodes when direct current is being used. Periodic reversal of polarity might reduce this problem considerably, but whether it would eliminate the problem when using electrodes embedded permanently in muscle is not known. The other destructive effects of electricity, such as those resulting from generation of heat, are usually the result of high current intensities. This problem might be controlled by proper electrode size, number, and placement so as to avoid high local concentrations of current.

The problem of foreign-body reaction must also be considered when introducing any material into tissue. A variety of relatively inert materials has been found recently which might be used in direct stimulation, but use of these materials over a period of many years has not been fully evaluated.

In the final analysis, the problem of adverse tissue reactions to current flow, ion accumulation, and the presence of foreign materials may be the biggest obstacle to the use of direct stimulation. In using cardiac "pacemakers," for example, difficulty is frequently encountered after a few weeks from scar tissue development around implanted electrodes.[10] This reaction, however, may be resulting, in part at least, from the use of d-c impulses, with their "electrolysis effect."

CONCLUSIONS

From the foregoing, it appears possible that denervated muscle could serve as a practical source of power in orthetic systems. Direct stimulation is theoretically superior to percutaneous stimulation in that it seems to offer better localization of stimuli, less pain, and more useful movement against resistance. It may also result in better preservation of metabolic

function of denervated muscle. Percutaneous stimulation, on the other hand, might be of value in systems requiring minimal power, such as the feeder.

The most serious problem recognized at this time is the one of tissue reaction to prolonged electrical stimulation and electrode implantation. It is proposed, therefore, that before undertaking intensive study of use of denervated muscle in general, the problem of tissue reaction be investigated. If solutions are found, studies would then be indicated in such other areas as:

1. Maintenance of metabolic function of denervated muscle.
2. Elimination of pain with electrical stimulation.
3. Transmission of stimulus to muscle without puncturing skin.
4. Optimization of stimulus characteristics.
5. Selection of muscles for use as motors.
6. Instrumentation.

APPENDIX G

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