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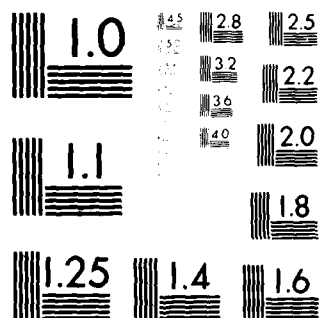
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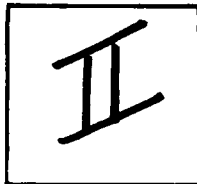


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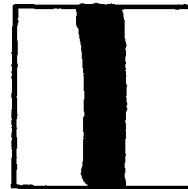
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DEVELOPMENT AND APPLICATION OF A TENDON PROSTHESIS
FOR EARLY FUNCTIONAL RESTORATION OF THE HAND

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**DEVELOPMENT AND APPLICATION OF A TENDON PROSTHESIS
FOR EARLY FUNCTIONAL RESTORATION OF THE HAND**

ANNUAL REPORT

by

James M. Hunter, M.D.

September 1975

(For the period 1 July 1971 to 30 June 1972)

Supported by

**U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
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20. ABSTRACT (Continue on reverse side if necessary and identify by block number) The basic Hunter tendon, a dacron silicone mold prosthesis has been prepared in four sizes and shapes. The function of the prosthesis is being studied in the dog and primate with reference to gliding pseudo sheath form- ation, fluid formation and distal and proximal juncture attachments. A new tendon prosthesis design using the 304 and 316 L stainless steel yarn was designed. The yarn was covered with high pressure mold silicone process and its services are inert and smooth for implantation. The porous metal yarn,		

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250 micra, is exposed at the prosthetic end for end attachment investigation. Distal end attachment was studied using the porous tape. Forty-eight samples were placed into the metacarpal and forearm bones of the dog for periods of 4, 8, 12 and 16 weeks. Bone specimens were tensile tested. Tape shears were irregular and new weave techniques will be developed. It was determined from this study that 304 stainless steel tape was not acceptable for implantation due to tissue reactions. Strength union of 316 L metal tapes approached 50% of the initial strength of the 5 mm. tape. Cross tissue was studied using 160 gauge steel mesh screens in the vastus lateralis muscles of dogs. The evaluation of tensile testing was inconsistent and will be made available at a later date. Tenosynovial fluid in the canine tendon implants was studied and preliminary antibody titers will be established. The studies will continue using dacron tape and woven stainless steel tapes for the shaft of the flexible implant. Each study of end device fixation will include plates, screws, loop designs as well as mesh material to permit tissue ingrowth.

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**The Restoration of Early Hand Function, Following Traumatic Injury
by the Use of an Active Gliding Tendon Prosthesis**

Title: Development and Application of a Tendon Prosthesis for Early Functional Restoration of the Injured Hand.

1. Type of Project: Definitive Study
2. Technical Objective: The technical objective of this proposed research study is to extend the development and application of the "Hunter Tendon" so that this implant may be used as an early and permanent active tendon prosthesis following injury to the flexor tendon system in the hand.
3. Hypothesis: The working hypothesis germane to this program is that an acceptable permanent prosthesis can be developed using the fundamental approach afforded by the "Hunter Tendon," a gliding artificial tendon.

In order that this technique becomes capable of earlier application following injury and long-term tendon replacement, it is recognized that design changes may be required in these areas relating to materials of construction and methods of attachment to bone, tendon and muscle. In addition, the basic knowledge of tissue growth, response and acceptance to a tendon prosthesis should be augmented by further laboratory study.

4. Background:

Basis and Previous Work: The work covered by the first year of investigation consisted of several entities as follows:

- a) Animal Orientation Program and Exploratory Studies
- b) Tendon Repair Investigation
- c) Design Refinements of the Prosthesis
- d) End Attachment Investigations

The results are discussed below in separate sections.

- a) Animal Orientation Program and Exploratory Studies

As pointed out in the basic proposal of May, 1971, the animal model of choice is the chimpanzee. Accordingly, two male chimpanzees were procured along with the required cages and transfer systems. These animals are adults weighing about 98 pounds each. In addition, two young chimps, weighing about eighteen pounds each have been obtained. A colony of beagle hounds have also been acquired and are housed in the animal facility of the University. Orientation of the mature chimpanzees has taken several months and the task of having an acceptable cast applied to their arms has proved extremely difficult. The usual behavior of both animals was to begin the destruction of the plaster of Paris casts soon after recovery from the anesthetic used to knock them down so that the casts could be reapplied. The successful method that has been evolved incorporates a wire mesh shaped basket into the plaster. The cast is an above-elbow application with the elbow in 90 degrees of flexion and the wrists in approximately 40 degrees of flexion. The casts must be carefully applied and be comfortable, else the animals will destroy them within one to three days. Standardized dosage of Sernolyn have been evolved for reference as to sleep time versus dosage. Several x-ray studies have been conducted on the hands of these animals in order that the anatomy and structure of the extremity is well known and understood.

b) Tendon Repair Investigation

A basic problem that has aroused some controversy concerns the healing of a repaired tendon with its sheath. The question is whether tendon ends have the capacity to heal. One school of thought suggests that supportive fibrous tissue growth from the surrounding sheath tissue triggers healing across the joined tendon junction. The opposing forces postulate that slow healing occurs from end to end. The resolution of this question is of great importance in the early management of acute injury and bears investigation. To this end, an experiment was designed in which the sublimis tendon was retracted laterally after the tendon sheath was exposed through an incision made over the left distal palmar crease over the third metacarpal. The chimpanzee had been administered 7.0 mg. of Sernolyn intramuscularly followed by IV solutions of lactated Ringers (10 cc/min). The sheath was lacerated at the approximate level of the distal palmar crease. This area was selected since it is the middle 1/3 of the tendon and, physiologically and anatomically, is the poorest zone of intrinsic blood supply and nutrition. The tendon suture repair method of Bunnell was utilized. The sheath was then repaired followed by the skin closure. A long-arm cast was applied incorporating the fingers completely. This same procedure was applied to the second chimp. Unfortunately, in both cases, the animals destroyed the casts and the tendon anastomosis failed because of tendon disruption.

New tendon prostheses of the Dacron-silicone type were fabricated in the correct length and implanted in the hands of the two chimpanzees, replacing the profundus tendons. The procedure was carried out under

aseptic conditions and the hands were cast in the manner described earlier. After six weeks of well-tolerated results, it was discovered that an infection had started in one animal. Cultures revealed that staphylococcus aureus penicillianse resistant organism had invaded the zone of repair. As a consequence, that arm was re-operated and the prosthetic device removed and the infection treated. The animal has responded well to treatment and is presently recovered. The other chimpanzee has accepted the passive gliding tendon prosthesis well.

c) Design Refinements of the Prosthesis

a) Dacron Silicone Prosthesis

As stated earlier, the published works and research to this point have resulted in four (4) new tendon prostheses that are now available for clinical application designated as "Hunter Tendons" in four different sizes. These prostheses are used for passive gliding new sheath-buildings programs. The tensile results are included in this report.

b) Metal Tape - High Pressure Mold Silicone Prosthesis

Considerable effort is being devoted to the development of stainless steel metal silicone surface type prosthesis. The stainless steel yarn is currently being supplied to the Brunsmet Co., Chicago, Ill. through a research and development arrangement between Dr. Hunter, the Bally Ribbon Mill and the Holter Co.. The Bally Ribbon Mill of Bally, Pa. is currently responsible for design and weaving of a metal experimental fabric for animal implant studies. 304 stainless steel yarn was acquired from the Brunsmet Co. at the expense of the Bally Ribbon Mill. This has been turned into tape and tensile testing results are included herewith.

d) End Attachment Investigations

During the preceding year studies were initiated to investigate the means whereby the prosthesis may be anchored to the musculoskeletal system. This area of study is of prime importance to the development of a permanently implanted prosthetic device. The problems are of two magnitudes, one relating the anastomosis of the end attachment to bone. The other concerns attaching the device to soft tissue, i.e., muscle. The latter is more difficult and requires greater involvement for resolution. The obvious answer to each end attachment, distal (bone) and proximal (muscle), is by tissue ingrowth. However, several unknowns, both medical and physical, must be resolved prior to a satisfactory solution is made available. The design of the end plates are of great importance as regards tissue ingrowth. The surface area, configuration,

method of physiology of wound repair, primary attachment, material, exercise regimen, surgical skill, physiology of wound repair, et al, are all major contributors to the eventual solution. Several new end designs are in process of fabrication and trial. Two study programs were undertaken this year to define tissue ingrowth as a function of material porosity as applicable to the distal anastomosis. Stainless steel wire screens of different mesh sizes were implanted, under aseptic conditions, in the spinous processes of beagle hounds. The stainless steel gauzes, 60, 100, and 200 mesh, were inserted and permitted to remain for time periods of 3, 6, 9, and 12 weeks. They were then removed and subjected to tensile testing in a tensiometer.

The second study program concerned the tissue ingrowth into the stainless steel tapes, 5 mm. wide, implanted into each of six beagles. The tapes are of two porosities resulting from different weaving techniques that were necessitated by the fact that the 316 SS is more difficult to handle than the 304 SS. As explained in our Progress Report of February 14, 1972, the use of the 304 SS for these experiments is considered satisfactory even though the material is subject to corrosion in the physiological environment since the life of the experiment is relatively short. The ribbons were surgically implanted into the fore-paw metacarpals of one paw. It runs proximally and is anastomosed to the extensor carpi ulnaris. The dogs were re-operated on the 3rd, 6th and 8th weeks and the experiment will be concluded after the 12th week. Data obtained to date are presented on the following tables.

Implanted Speciment	Tensile Strength, Kg/cm ²	
	After 7 Weeks	After 13 Weeks
60 mesh, 304 SS Collandered	27.5	55.0
100 mesh, 304 SS	13.7	27.5
200 mesh, 304 SS	Mesh Tore	Mesh Tore
Ribbon, 316 SS	Bone Fractured	Bone Fractured

Results of Tensile Testing
of Bone-Ribbon Bone

(Done on Dillon Universal Testing Machine 0-100 lb. cap.@20 inches/min.)

Week After Implantation	3	6	8	10
Tensile Test 304 SS	9.2	12.4	24.5	0 ^{#2}
Kg/cm ² 316 SS	15.3	24.4	13.0 ^{#1}	5.5 ^{#2}

#1 - Foreign body granuloma

#2 - Ribbon pulled from bone soon after implantation due to failure of external immobilization

The aborted experiments will be repeated

5. Methods: As stated previously, the long-term goal of the present research program is to develop the "Hunter Tendon" for direct application to a permanent prosthesis for the early restoration of the injured hand. To accomplish this goal it is estimated that perhaps four years or basic and clinical research will be required. The first year's study has resulted in the delineation of the major areas requiring resolution. These are:

- A. Distal and proximal end attachment
- B. Tendon Prosthesis Design Refinement
- C. Elucidation of the healing process as it affects the acceptance of the prosthesis.

During the next year it is proposed to investigate items A and B above in order that a definitive design will be evolved that will permit maximum hand function withing the minimum time following surgical repair. Selected topics in item C above will of course be studied in order that the knowledge will be forthcoming to apply to the solution of the problems encountered in the first two items.

In the sections that follow, we will describe the specific research studies that will be undertaken to achieve the stated goal.

A. Distal and Proximal End Attachments

Because of the difference in complexities and approaches, these attachment studies will be discussed separately.

1. Distal Attachment: Previous in-house experience, coupled with published results, have indicated that this aspect of the overall problem is closest to resolution. Anchoring looped ends to bone by means of screws, rivets, wire sutures passed through drilled bone, are a few of the techniques that have met with partial success. Improvements to the mechanical anchor design will form an approach to the long-term solution. A specially designed staple, taking into consideration the woven characteristics of the stainless steel ribbon tapes presently being examined as a replacement for the Dacron tape will be designed and produced in experimental quantities for implant studies. Revised weaving procedures may present a more compatible looped end (less bulk) for screw or suture anchoring. Tissue ingrowth studies will form a major portion of this phase of the program since reasonably good results have already been achieved from the past year's work. These results indicate that this technique has a high potential for ultimate success. Variables to be examined include porosity of the ribbon, surface area of the end piece and material, including sintered end plugs. The implant studies will be conducted initially in dogs. A minimum of three implants will be conducted for each time test in order that sufficient data are made available to evaluate. The various design variables will be in place for specific time periods (3, 6, 9 & 12 weeks) prior to surgical removal for histological and strength determinations. Sections will be made and examined under magnification to determine the types of cells that have invaded the site of implantation. Particular attention will be placed on the involvement of collagenous material at the ingrowth site since this will signal an increase of tensile strength. The tensile strength will be obtained from pull tests conducted on a Dillon Universal Testor. The ribbons will be run proximally and anastomosed to either the extensor carpi ulnaris or radialis tendon of the forepaw metacarpals of the beagle hounds. As results warrant, the investigation will be transferred to the chimpanzee.

It is anticipated that this portion of the study will require about six months for completion. This is contingent on the delivery of the several different end attachment techniques which include variations in the ribbon weave to alter porosity, Geometric configuration, looping and the delivery of the newly-designed staples.

2. Proximal Attachment: Little experimental evidence is available in this aspect of the problems attendant with the development of a permanent tendon prosthesis to direct attention to a specific approach leading to its resolution. The Hunter Gliding Tendon technique secured the distal end of the prosthesis and permitted the proximal end the freedom of movement so that sheath formation was evolved. The prosthetic device was then removed and replaced by a tendon graft and fixed proximally and distally. The repair at the proximal site was enhanced by virtue of the fact that autogenous material was present at the anastomosis and, in time, repair was affected. Implanting non-biologic material and anastomosing it to musculature or other relatively soft connective tissue requires a new approach to result in a successful procedure. Obviously, the key to success here is a deep understanding of the repair process in the body. Tissue ingrowth is all important and in order that this may be maximized, it would appear that at least the following conditions must be met:

Maximum surface area presented for cellular invasion, consistent with anatomical locus.

Minimal surgical trauma consistent with the procedure.

Aseptic conditions maintained

Proper regimen of exercises

The design of the proximal end attachment of the prosthesis will receive considerable attention. Geometric configurations in the form of rolled cylindrical coils, fish-tailed fans, variations in mesh sizes (derived by altering the weave pattern of the ribbon) and other candidate materials (discussed later) will be tested both before and after implantation. The testing in the tensiometer will help rank the designs from a tensile strength point of view and relate the potential strength of the end plate to that value of strength required for a successful anastomosis. The possibility of enhancing the tissue ingrowth into the lattice work or grid of material forming the proximal end device offers a potential solution to this vexing problem. Studies will be directed toward defining the role that weak electric potentials may play in: a) the alignment of the collagen fibrils (for increased strength); b) the movement of the various cells necessary to affect wound repair, and; c) the electrophoretic and electroosmotic transport of the nutrients contained in the ground substance to the site of the anastomosis. This particular aspect of the study will rely upon the results of the investigation presently underway as a supplemental study under the present Contract No. DADA17-71-C1112.

These studies will also use the beagle hound as the experimental model. Surgical procedures will be as before and the results will be derived as before. The implants will be removed on a timed basis, histologically examined and subjected to pull testing to derive values of tensile strength as a function of time and configuration. The experiments utilizing the weak electric potentials will also be subjected to the same protocol. Of course, this portion of the study will be eliminated should the results of the supplemental study investigation the electric potentials prove valueless.

It is anticipated that this phase of the study will require at least one year and, quite likely, two years. The initial work, as mentioned above, will be conducted on the dog. As meaningful results are obtained, the experimental model will shift to the chimpanzee.

B. Tendon Prosthesis Design Refinement

This area of the investigation is subdivided into two major portions as follows:

1. Material Selection: A continual search is underway to derive the optimum material of construction for the shaft, end device and coating of the tendon prosthesis. To date, Dacron-coated with a medical grade of silicone rubber has proved compatible with the physiological environment. The major difficulty with this system is that the proximal attachment techniques require end devices that may not be compatible with the Dacron tape. Preliminary results with a ribbon made of Type 316L continuous filament yarn woven into a 5 mm tape and coated with medical grade Silastic is also well accepted by the organism and does not have the problems exhibited by the Dacron as regards the attachment of the end devices. In fact, a greater flexibility is apparent when using the stainless steel since the methods for attachment of end pieces are enhanced since one can use the various methods of welding, i.e., heat, sonic, spot, and ion beam. Other materials offering promise to end device attachment, compatibility, strength and long life include pyrolitic graphite, collagen, bioceramics and bioglass. The availability of samples of these and other materials having desirable characteristics will determine their testing schedule within this year's work.

All materials presently in use or in contemplated use will undergo standardizing tensile and fatigue testing prior to in vivo studies in order that they may be ranked. Each material will be subjected to fatigue testing in a specially adapted apparatus which will maintain the material in a physiologic saline solution. A minimum of ten million cycles will be considered the normal usage trials. Prestress testing new or revised material and designs will also be subjected to these tests.

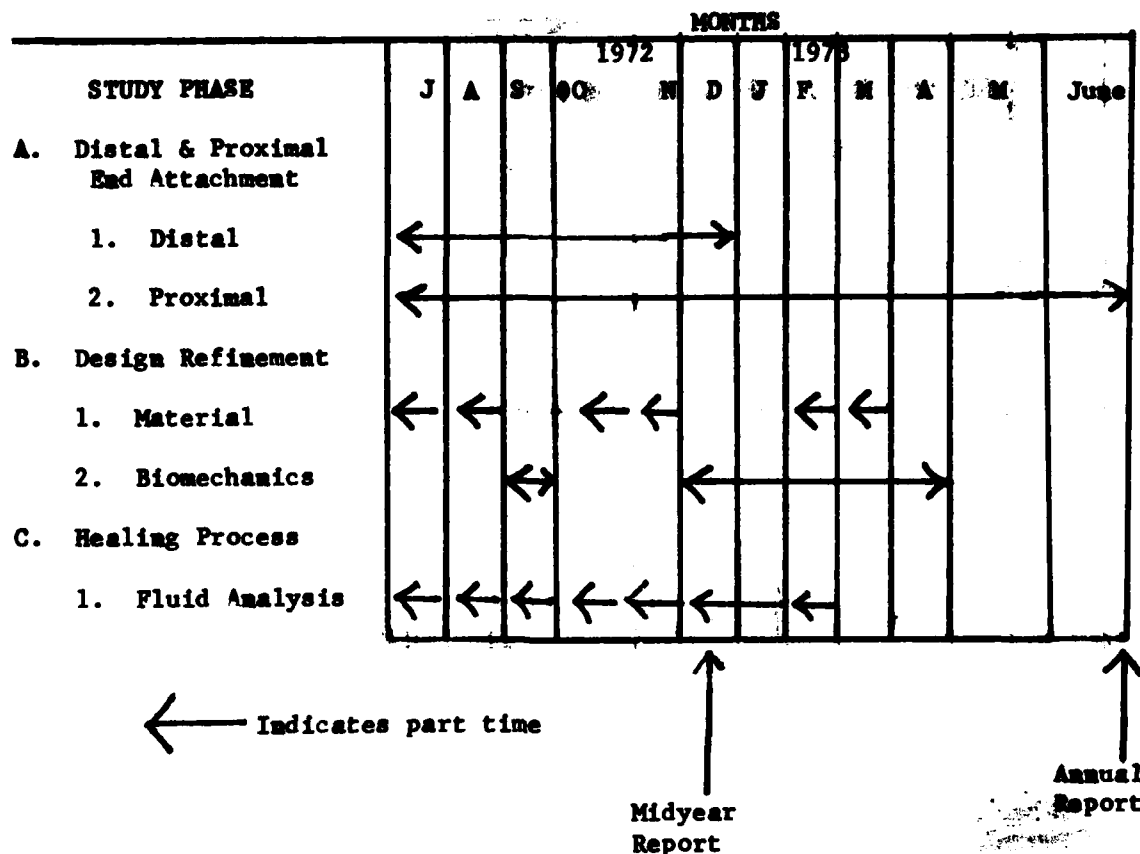
Another selection criterion for each material is its ability to be shaped, looped, mandril rolled and/or woven into ribbons or tapes of known porosity and otherwise handled for ease of manufacturing. The overall time required to accomplish this phase of the work is estimated to be about three months. However, the studies portion of the program is considered to be relatively small and not all materials will be available at the same time. The presently used materials, Dacron and stainless steel, will undergo the above testing when the testing machines are ready.

2. Biomechanical Analysis: An analytical study will be conducted to determine the magnitude of the forces expected under the several modes of finger loading in the normal hand. Concurrently, tests will be conducted to derive the values of tensile strength of the natural tendon/pulley system; the bond/tendon connection; the tendon/muscle connection on animals and; as possible, in cadavers prior to their preservation. A literature search/review will also be conducted to determine which of these values is already known in order that duplications will not be made (unless the data are not considered reliable). This basic study will be conducted in order that a firm, sound specification may be derived as to the required strength of the artificial tendon and the anastomosis and will require an estimated six months for completion.

C. Flucidation of the Healing Process

1. Synovial Fluid Characterization: A technique has been defined that is capable of extracting small micro quantities of fluids from joints, sheaths, bursae and other difficult to reach anatomic sites in vivo. This method, derived by Howell, D.S., et al, J. Clin. Invest. 47: 1121, 1960, will be adapted to our studies in order that we may learn more about the development of the pseudosheath formed around the Hunter Clidia Tendon. The pseudosynovial fluid will be extracted from this site, analyzed and compared with normal synovia. By this means, a timed record may be obtained regarding the development of the pseudosheath around the prosthesis. Another use of this extraction technique may be to determine the rate of healing at the anastomosis of the muscle and prosthesis by analysis of the cellular content of the fluids including the ground substance taken from the site of the repair. Assembly of the apparatus and the required instrumentation will take about four months and the experiment will take an additional three months. The probability of success of all the applications of this technique is perhaps 0.5. However, the possible payoff is such as to warrant its application.

The following bar graph illustrates the estimated time to complete the various phases of the proposed program.



6. Military Significance: Surgery of the hand had its beginning in the Army during World War II under Surgeon General Kirk and Sterling Bunnell. Today in special military treatment centers, surgeons with specific training in Hand Surgery give expert care to the war wounded. Despite these programs aimed at restoring optimum hand function, time loss from injury and a high incidence of permanent disability remain as major problems.

Significant causes of this problem are "Stiff Hands" and muscle atrophy that result in part from edema and disuse of the upper extremity following severe injury.

If this vicious cycle of deterioration could be reversed early after injury, many able bodied soldiers could be returned to active duty sooner and permanent disability could be significantly reduced.

We propose a common denominator to the return of early hand function a tendon prosthesis that will link the silent muscles of the forearm to the resting skeleton of the hand early after injury.

This concept has become a realistic probability because of improved techniques in the early care of the injured hand; namely, 1) Stabilization of hand fractures by internal fixation and 2) the recent successful military programs of delayed primary closure of severe wounds in the hands and forearm.

Based on my experience over the past eight (3) years as Hand Consultant to Valley Forge General Hospital, and my background in tendon research, I believe this proposal is a forward step in the better early care of the military injury.

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