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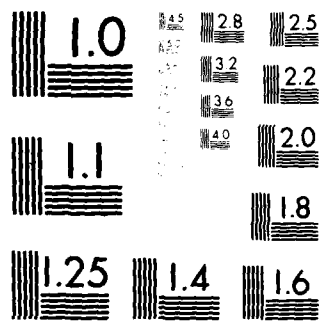
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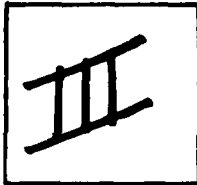


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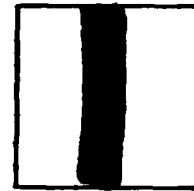
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DEVELOPMENT AND APPLICATION OF A TENDON PROSTHESIS
FOR EARLY FUNCTIONAL RESTORATION OF THE HAND

ANNUAL REPORT

by

James M. Hunter, M.D.

September 1975

(For the period 1 July 1973 to 30 June 1974)

Supported by

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20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Previous studies on prosthetic end attachment to bone indicate that porous metal tapes showed a fall-off in tensile strength after 12 weeks. During this period folded 316 L stainless steel screens were implanted (#58 mesh - 325 micro pore size, #80 mesh, 180 micro pore size, #120 mesh, 150 micro pore size) into the metacarpal bones of canine shepard dogs. Tensile testing on 96 specimens was carried out at 4, 8, 12 and 16 weeks. Pull-out strengths were approximately double those done with metal tapes.		

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It was concluded that this method introduced a feasible technique for tendon implant distal end attachment study in the future. Preliminary implants of dacron valore and stainless steel screens in dog muscles did not yield reproducible or significant results. Further study is necessary.

The vascular injection study - This was continued in fresh cadavers neonatal and adult extremities. Special injection techniques using latex and india ink continued to be developed and techniques of illumination see-through photography is being organized. The two basic tendon intrinsic vascularization patterns (1) the pre-sheath tendon pattern lies in a intrafascicular connective tissue bed. In the sheath the tendon pattern is determined to be segmental relating vessel communication from the vinculum in short, long and mixed vinculum forms. In part, the superficialis tendon bed becomes critical to flexor profundus blood supply.

New tendon implants for textile using a mixture of dacron and Fiber B metal loop end attachment was designed for fixation of tendon to bone. Basic strengths have been calculated and new directions in tendon prosthetic construction were established.

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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: During the past year, the investigation continued in the study of three distinct areas, each contributing to the overall goal of the development of a permanent flexor tendon prosthesis.

The major activity during 1972-1974 was the investigation to define the optimum method for distal end attachment. Other areas of concentration concerning the refinement of the tendon prosthesis design and the basic healing process of the tendon.

A. Distal End Attachment

As described in the Quarterly Report of 29 March, 1973 and, in greater detail, in a paper entitled, "Development of a Single Stage Active Tendon Prosthesis, 1. Distal End Attachment," presented at the 1974 Meeting of the Orthopaedic Research Society in Dallas, Texas, the concept of deriving a viable distal end attachment in which cellular and tissue infiltration into a woven, porous metallic ribbon has been convincingly demonstrated.

The results of these studies indicated that sufficient bonding strength in tension results after about 12 weeks in situ. Tensile testing conducted on the metallic tape/metacarpal bone system revealed a decrease in pull-out strength at time periods greater than 12 weeks. Hypothesizing on the reason for this fall off of strength, it was suggested that the end of the metallic tape should be firmly fixed so as to not permit the unraveling of the wire fibrils when the tape is cut to size. Secondly, the fibrous ingrowth after 12 weeks in situ may be so profuse as to spread apart the metal fibrils so that the cross linkage of the basic weaving process (the woof) becomes ineffectual, thus lowering the overall structural integrity of the tape. In addition, this could decrease the interfascial bond between the metal tape and the newly laid down connective tissue.

As a result of these findings, a second series of implant studies were initiated using type 316L stainless steel screens. These basic screening materials are more readily available than the woven tapes, are cheaper, and are constructed in such a manner as to relieve the problem of unraveling noted above with the tapes.

Three screen sizes were used

- No. 58 mesh @ 325 μ pore size
- No. 80 mesh @ 180 μ pore size
- No.120 mesh @ 150 μ pore size

The implant specimen was made by cutting a strip of screen 18 mm x 75 mm long and folding it to a 10 mm width. This was then refolded to the final width dimension of 5 mm. The folding was done for two purposes:
a) increase the tensile strength to reach a value of at least 35 kg and
b) decrease the pore size of the specimen from the stated size by overlapping.

The implant protocol varied somewhat from our previous technique as follows:

- a. 20 kg German shepherds were used instead of the beagle.
- b. An osteotomy was made to produce a 6 mm trough into the medullary canal of the mid-shaft of the 3rd & 4th metatarsal bones.
- c. 10 mm of the screen specimen was placed in the trough.
- d. The implant was impacted to the bone using a wedge shaped bone graft obtained from the osteotomy site.
- e. Longitudinal movement was restricted by the placement of small K-wire.
- f. The procedure was repeated on the adjacent metatarsal.

The limbs were cast using Merck, Sharp and Dohme Lite Cast II fiber glass netting for 4, 8, 12 and 16 weeks.

This procedure resulted in two implants/limb. Using 12 dogs, 96 specimens for each time period of 4, 8, 12 and 16 weeks.

It should be pointed out that this protocol resulted in a complete lack of foreign body granuloma formations in the interfascial zone.

Pull testing was conducted at a laboratory of the Philadelphia College of Textiles in Philadelphia, as before, at a cross head speed of 12.5 cm/min. using their Thwing-Albert Electrotensiometer.

Results are shown on Table I

Table I

Results of 5 mm. Folded Screen Implant Studies

Type Screen Mesh/Pore	Control Strength Kg/cm	Max. Pull out Strength Kg/cm	Time at Max. Pull-out strength Weeks	Final Pull Out Strength @ 16 wks. Kg/cm
58/352	38	36	12	35
80/180	55	45	8	40
120/150	20	17	4	15

Figure I presents this information in a plotted form.

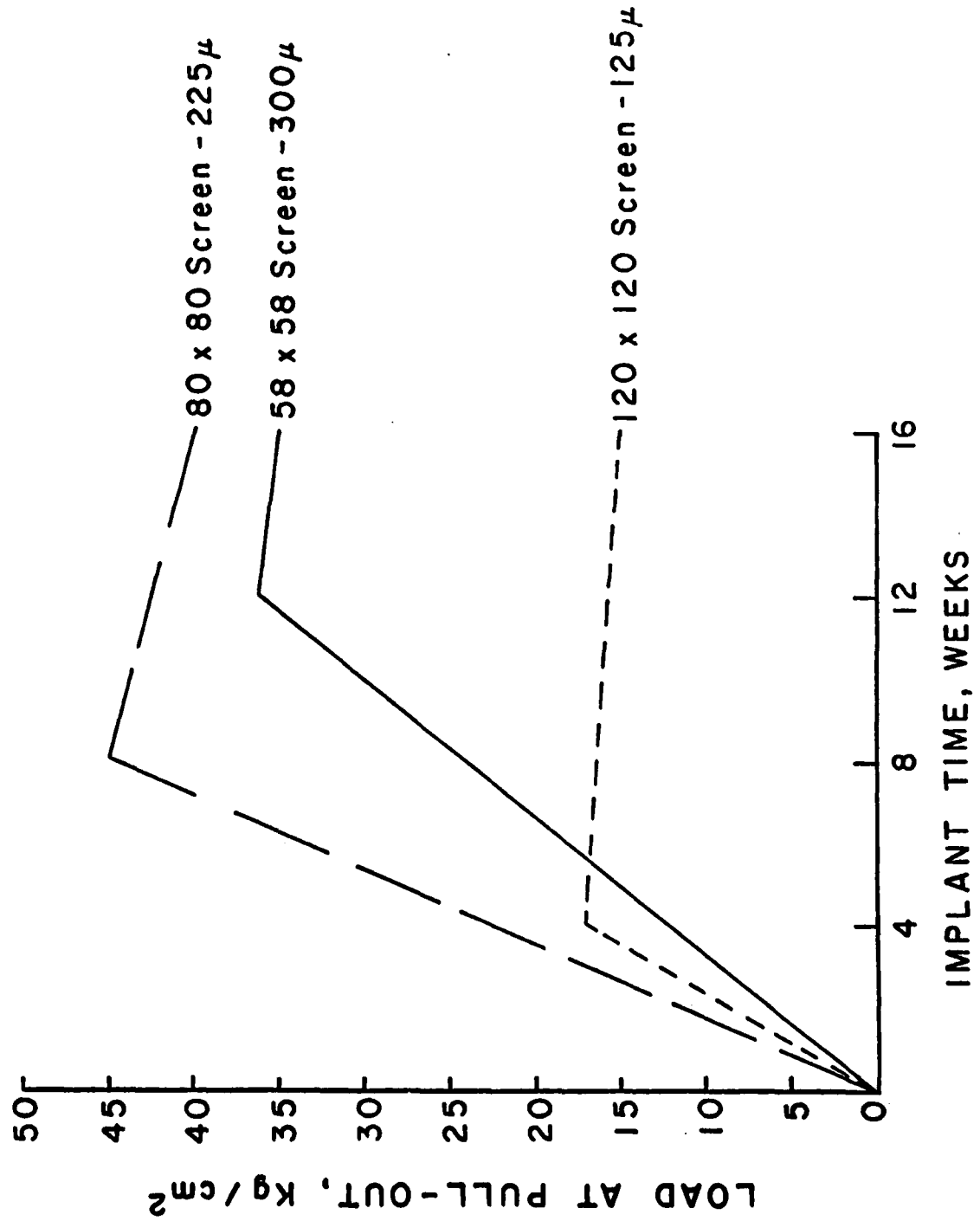
Evaluating these data, it may be stated that the rate of increase in pull-out strength is approximately the same for each pore size tested. The optimum pore size from the viewpoint of maximizing pull-out strength is in the 150 to 180 μ diameter. However, the actual measurement of the pore diameters has not been measured. The values cited are estimated from the geometrical relationship resulting from the folding of the basic 20 mm. wide screen.

No reason can be ascribed to the differing time to achieve maximum strength. Speculating, one might relate this parameter to the pore size since the peak time increases with the pore size. Another possibility may be due to the "K" wire fixation, causing uneven stress concentration in the screen which could result in a fatigue failure.

No unravelling or loosened wires were encountered in the pull testing which allowed for the increased strength measured in these trials when compared with the values obtained with the implanted woven metallic tapes. The actual increase is approximately 2 X. This is also the result of having approximately twice as much surface area in contact with the cortex in these tests when compared with the earlier studies.

FIGURE I--

PULL - OUT STRENGTH - FOLDED SCREENS



The major conclusion drawn from these studies is that this method presents another feasible approach for the distal attachment of the tendon prosthesis.

A. Detailed paper is in process and will be submitted when completed.

B. Proximal End Attachment

The preliminary implant studies in which velour and stainless steel screens were placed in the vastus laterali muscles in the dog did not yield reproducible results. Some ingrowth was noted in each case, however, little significance can be extracted since the population sample was small and no physical or histological studies were conducted.

C. Basic Healing Studies

As indicated in last year's report, work was begun using a refined injection technique to derive visible pathways of the vascular supply to the tendons. During the current year our study of the flexor tendons may play in the early vs. delayed repair and the one vs. two tendon repair in "no man's land."

Thirty neonatal upper extremities and ten adult hands were studied. Injections of varying dilutions of India ink and latex were made via the largest available artery with the end point being return of the injected material from the venous system. Specimens were then dissected, dehydrated, and cleared in a tricresyl phosphatetriethyl phosphate solution. Cleared specimens were then examined with a dissecting microscope, or sectioned serially and examined microscopically.

It was found that the intrinsic vascularization of flexor tendons follows two patterns. From the area of the musculotendinous junction to the DPC (distal palmar crease) the intrinsic blood vessels lie in the interfascicular connective tissue in an even distribution. In the fibro-osseous canal, the pattern is totally different. A second repeatable observation made is that the blood supply to the flexor digitorum profundus was intricately related to the flexor digitorum sublimis in the fibro-osseous canal. Excision of the flexor digitorum sublimis at varying levels would thus leave a large segment of the flexor digitorum profundus avascular.

These data are being prepared in a formal report for presentation and publication.

D. Tendon Prosthesis Design Refinement

Tendon implants have been manufactured using the Dupont Fiber B admixed with polyester (Dacron) to achieve the desired stiffness. A pressure molded coating of silicone rubber (Silastic, Medical Grade) was applied and implant studies begun. A metal wire loop has been appended to each end of the shaft of the implant and held in place by crimping a sleeve over the

loop/shaft interface. The loop adds a considerable strength factor to the implant since it is used to hold the passive or active gliding tendon implant firmly against the distal phalanx. Wire sutures are placed around the loop and through holes bored into the metacarpal bone. On the proximal end, the loop has been used to anchor the active implant by wrapping the remaining natural tendon through it and knotting.

The basic design of the implant plus loop is meritorious and continued studies will be made.

Inquiries have been made concerning the availability of other metals for weaving, in particular, Titanium.

5. Methods:

Studies in the past year have permitted a clear picture to emerge as regards the design of a tendon prosthesis implant. The methods for distal end attachment has been elucidated and a revised implant is presently in the design stage.

Proximal attachment methods have also been narrowed since some information obtained in the distal studies are applicable as are the experimental looped implant studies. Indeed, it appears desirable to include loops on either end of the implant regardless of the modes for distal and proximal attachments.

Excellent resolution has been achieved in the pursuit of the vascular supply to tendons and now the work is being extended to studies of adult hand systems.

Consequently, it is believed that good progress has been made in our overall goal to achieve a tendon prosthesis for early functional restoration of the injured hand. The next series of studies should result in a still clearer picture of the vascularization of the tendons of the hand, a projected design of our experimentally derived artificial tendon having unique design features to permit its use as an active tendon implant.

A. Design Studies

1. The results of the earlier studies result in the following judgements that, in effect, form a set of specifications describing the configuration of the tendon implant.

- a. Stainless steel of titanium wire fibrils woven into a tape 5 mm wide x about 1 mm thick (for adult use) and 2 mm x 1 mm for children having the two ends sealed, either by a weaving technique or physically (welding, cementing, etc.).
- b. This woven shaft is then coated with silicone rubber (medical grade Silastic) leaving approximately 1.5 cm uncoated at the distal end and perhaps 1.0 cm or less proximally.

- c. A loop is attached on each end of the shaft, about 1.5 cm from the distal end and 1.0 cm on the proximal end.
- d. A fish-tailed shape of screening or velour 5 mm wide at its base and tapering to a width of perhaps 10-15 mm over a length of 2 cm or more attached at the proximal end.

2. Units meeting those general design specifications (a and b above) are fabricated and implant studies will be conducted in the stump, tail monkey presently on hand. A loop will be added distally. It is anticipated that a 2 mm width implant will be required because of the size of the hands and feet of this primate. These will be passive gliding studies of a metallic tendon implant, anchored distally.

The implant studies will be conducted for a time period ranging from 4 to 6 maximum of 12 weeks at which time the experimental systems will be removed and the evaluation of their effectiveness determined. This will be done as follows:

- 1) Strength of hand distally.
- 2) Maturity and integrity of neosheaths formed around implanted silicone coated active tendons.
- 3) Evaluation of finger motion during implant period.
- 4) X-Radiological studies during implant.

3. Concurrent with these studies we will be examine several materials in the geometric configuration noted in specification d. above. These will be implanted on and in various muscle sites in the same monkeys having the experimental passive gliding tendon implants.

4. Composite materials will also be examined for possible application as the shaft material. A possible combination includes stainless steel and polyester of fiber B.

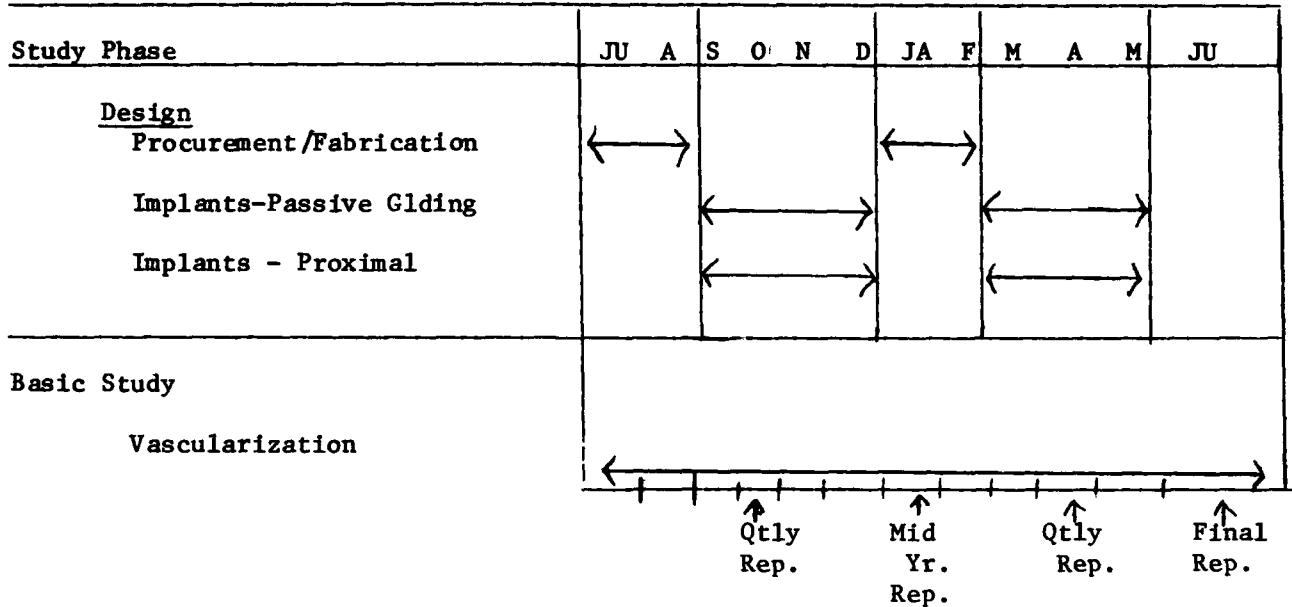
5. Through the good graces of the Extracorporeal Co., King of Prussia, Pa., we are receiving, at no charge, a fatigue tester designed to subject the tendon implant to million of cycles of flex testing in a saline environment. This apparatus will be applied to investigating the fatigue properties of the artificial tendon systems evolved during this study.

B. Visualization of the Tendon Vascular System

India Ink/latex injections will be continued and expanded to include the adult and, when possible, the adolescent population. The number of cadavers available for this study is of course limited. However, through the cooperation of the Robert J. Merklin, Ph.D. of the Dept. of Anatomy, we will receive limbs of the proper decade when they become available.

C. Estimated Time Breakdown

The following bar graphs illustrate the estimated time to complete various studies described above.



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 Hnads" and muscle atrophy that result in part from edema and distuse 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 on 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 hand and forearm.

Based on our experience over the past nine (9) years as Hand Consultant to Valley Forge General Hospital, and background in tendon research, we believe this proposal is a forward step in the better early care of the military injury.

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