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DEVELOPMENT OF A DYNAMIC INTERNAL SPLINT FOR MILITARY INJURIES --ETC(U)
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TITLE: Development of a Dynamic Internal Splint for Military Injuries to the Hand and Fingers

Final Comprehensive Report

by
Jonathan Cohen, M.D.

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Tufts University Medical School
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Dynamic Internal Splint Military Injuries Hand Fingers

20. ABSTRACT (Continue on reverse side if necessary and identify by block number)

A device for use in military injuries to the hand was developed. It applies to cases of complex open trauma to fingers and metacarpals in which flexibility of the joints should be maintained. It consists of an intramedullary rod capable of repeated bending at the sites of the traumatized joint.

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Summary

The purpose of the work was to devise an internal metal splint which would be suitable to use for patients who have severe injuries of the hand in which bones are fractured and the metacarpal phalangeal and/or inter phalangeal joints are destroyed, and severe damage to soft tissues also is evident. The splints devised are titanium aluminum vanadium rods with pointed ends and a reduced midsection which allows cyclic bending to 45-60°. The bending feature allows mono planar flexion and extension of the (destroyed) joint so that the mobility of all the soft tissues can be retained while the surface heals, thus allowing a reconstruction regimen to be instituted then. The methods used to plan the device were: 1) A survey of the metals which would be tolerated by the tissues and could meet the physical requirements of cyclic bending. 2) Survey of 100 hands (roentgenograms) to decide the overall dimensions. 3) Trial of numerous geometries of the mid-section to find proper dimensions of the hinge section. 4) Mock-up of several models. 5) Insertion of models into cadaver hands, with mock injuries. Conclusion: Specifications for a metal splint for severe injuries of the fingers, metacarpals and adjacent joints are now available. The splint can be used for military injuries to the hand.

List of tables and illustrations

Development of a Dynamic Internal Splint for Military Injuries to the Hand and Fingers

The feasibility study with reference to possible metals to be used for this internal splint began with studies of four alloys all of which are currently being used for long-term implantation applications in humans. Table 1. Those alloys did not require further testing as to corrosion resistance. In the proposal as submitted, it was contemplated that new metals, nitinol, etc., would be tested for corrosion resistance in saline and in acids according to tests that were devised in the laboratories of the present investigators. Those new alloys presented us with severe fabricational problems both as regards corrosion testing and as regards the dimensional requirements of the wires needed for the application under consideration. The over-riding problem was that we could not undertake the fabrication of rods of the shape needed for the application (see below) and for the corrosion testing coupons. Rods presently available in the alloy are 1/4" in diameter and are fabricated by Dr. Shepard at the Watertown Arsenal Laboratory.

Our need for rods about 1/8" in diameter with a center 1 mm. in thickness could not be machined from available rods. (Machining removes that property of the alloy considered essential to the application - the "memory" spring-like action of the rod). We therefore abandoned the idea of using this metal for the dynamic splint, and turned to consideration of other alloys as follows: H.S. 21; H.S. 25; Stainless Steel type 316; titanium 6 Al 4 Va; and Hastelloy. The main ones are listed in Table 1. All of these alloys would meet the needed specifications for corrosion resistance, and also those for tensile strength and other physical properties as listed, but a decision had to be reached as to the exact design of the implant in order to select the optimal alloy. The choice of design had to be between a spring of appropriate dimensions, an articulated assembly, or a one piece wire with a reduced center zone that could withstand multiple cyclic bends. The spring concept had to be abandoned because none of the materials had, or could be made to have the requisite hardness and elasticity. All were either too deformable or too brittle. The articulated wire design was discarded because of its complexity, wear problems, and lack of flexibility in application. We chose to develop the wire with reduced center section because it was simple to make and use and because the application of the concepts of dynamic force and cyclic force application could be incorporated into the proposed application relatively easily.

The several alloys in table 1 were reconsidered for their suitability to withstand multiple cycles of bending to 30°, 40°, 60° and 90° with return to neutral.

Adequate fatigue strength and elongation had to be achievable and the alloy that seemed best was annealed Ti 6 Al 4 Va. We therefore chose it for further development.

Our next problem was design. To learn the dimensional parameters of the bones of the hand pertinent to the application, measurements were made of 100 adult hands from normal males. The measurements were made on roentgenograms taken from the files of the Massachusetts General Hospital and derived from patients who had had injuries to the hand. The following measurements were made on all metacarpals, and proximal phalanges: length, diameter of medullary cavity at the mid point or at the narrowest point of the diaphysis diameter of the bone at the narrowest part of the diaphysis. A computer program was elaborated for the Hewlett Pachard 9820A calculator to give the mean value, standard deviation and standard error of the mean for all the above parameters. These figures are provided in Table 2.

From the data it was decided to use, as a model, a rod 78 mm. in length and 3.5 mm. in diameter. Such a rod would be adaptable to every metacarpo-phalangeal joint in all subjects, and to get the proximal interphalangeal joint in the vast majority as well.

We next had to determine the dimensional characteristics of the center reduced section which would allow the requisite numbers and ranges of cyclic bends. First we devised a cyclic bending testing apparatus consisting of a 3" square wooden holder 1/4" thick mounted on the shaft of a motor. The corners of the square were rounded, and each side was hollowed to receive a rod. On one side of the square we mounted a rod with its end projecting beyond the corner of the rod and with the midpoint of the center reduced section at the corner. When the motor turned, the rod could be bent to any angle desired by placing posts at the appropriate spots, where they would encounter the turning free end of the rod, bending it over the corner of the square. See Figure 1. The motor was made to turn slowly so that the rod would recover from the maximal deformation and the extent of recovery was noted. If necessary recovery was enhanced by use of an oscillating motor.

Turning our attention to the design of the rods, we first tried reducing the center section to a strip which was 0.3 mm. thick, by machining the center down on both sides with a circular grinding stone. Three mm. proved to be too thick to allow a 45° bend. Further reduction to 0.2 mm. allowed 45° of bend, but after just a few cycles, the center section broke. Further reduction to 0.15 mm. allowed 90° of bend, but there was considerable deformation with cyclic bends, and breakage occurred after relatively few cycles. We then instituted a grinding program designed to create a flat strip several mm. (not less than 1/4") in length at the middle of the reduced section. This flat section had a thickened (1/4" radius) transition zone on either side (see Figure 1b). This design proved more durable and rods were tested with thicknesses of center section ranging down to .05mm. We then tested several rods varying in center section thickness from 0.2 to 0.005 mm. These rods either were cold worked or heat treated for 20 minutes at 935° and kept at 525° for 2 hours thereafter. The cold worked specimens all showed no permanent deformation if bent 45-60° or less but they had about 5 degrees of deformation when they were bent 90°. No heat treated rod showed good recovery (no deformation) when bent 45 degrees or more. Cold worked and heated specimens at 25-35 degrees bends survived 100,000 cycles, and they also survived 15,000 cycles at 45 degrees without breakage. At 48° of bend there was failure of the cold worked specimen after $5/10^6$ bends and at 90° the specimen failed after 6000 bends. All the specimens so tested were 0.1 mm. thick in the center section.

We next turned our attention to a trial application of the rod to a simulated injury. The hands of 4 cadavers were obtained from the anatomy department, Tufts University Medical School. Rods 78 mm. long with center sections 0.1 mm. thick were sharpened at both ends. The first metacarpal of the index finger and then of each of the other fingers was exposed surgically and the distal segment was excised. The same was done for the adjacent proximal end of the proximal phalanx. We then were able to insert the ends of the rod successively into both bones, although some difficulty was encountered in the process owing to the rigidity of the soft tissues. We did not have to dissect away any soft tissue however, and, if the simulation were to be closer to actual clinical injuries, the soft tissues surely would be extensively torn, allowing easier insertion of the rod. After insertion of rods across several joints, we manipulated the joints into 60° and 90° of flexion repeatedly, and after 1000 such manipulations x-rays were taken (Figure 2).

Conclusion

We have established the feasibility of applying a dynamic internal splint as a temporary prosthetic replacement of a metacarpophalangeal or inter phalangeal joint. Such a splint will allow cyclic flexion and extension of the joint and can also be used to retain the remaining bone of the metacarpal and phalanx in proper position relative to each other.

Metal	(N/m^2) Tensile	% Elongation	(N/m^2) Yield Strength	(Diamond point #) Hardness*	($N/m^2 \times 10^8$) Fatigue Strength
Steel #316	6.5×10^8	45	2.8×10^8	19	2.8
H.S. 21	6.9×10^8	8	4.9×10^8	300	3.0
H.S. 25	15.4×10^8	9	10.5×10^8	450	4.9
Ti 6 Al 4 Va	10.0×10^8	12	9.7×10^8	150	3.0

Table 1

TABLE 2

Length of the metacarpals (Measured in the axes of bones)

I.		II.		III.		IV.		V.	
N1=	100.0000	N2=	100.0000	N1=	100.0000	N2=	100.0000	N1=	100.0000
M1=	45.7000	M2=	68.4800	M1=	65.7400	M2=	59.6800	M1=	53.3300
SD1=	3.4275	SD2=	4.8273	SD1=	4.3243	SD2=	6.7970	SD1=	3.6956
SE1=	.3427	SE2=	.4827	SE1=	.4324	SE2=	.6797	SE1=	.3696

Width of the marrow cavities (Measured at the isthmi)

I.		II.		III.		IV.		V.	
N1=	100.0000	N2=	100.0000	N1=	100.0000	N2=	100.0000	N1=	100.0000
M1=	6.7020	M2=	4.1760	M1=	4.1400	M2=	3.4460	M1=	4.7030
SD1=	.9359	SD2=	1.2218	SD1=	1.0579	SD2=	.9300	SD1=	1.0811
S E1=	.0936	SE2=	.1222	SE1=	.1058	SE2=	.0930	SE1=	.1081

TABLE 2 Continued

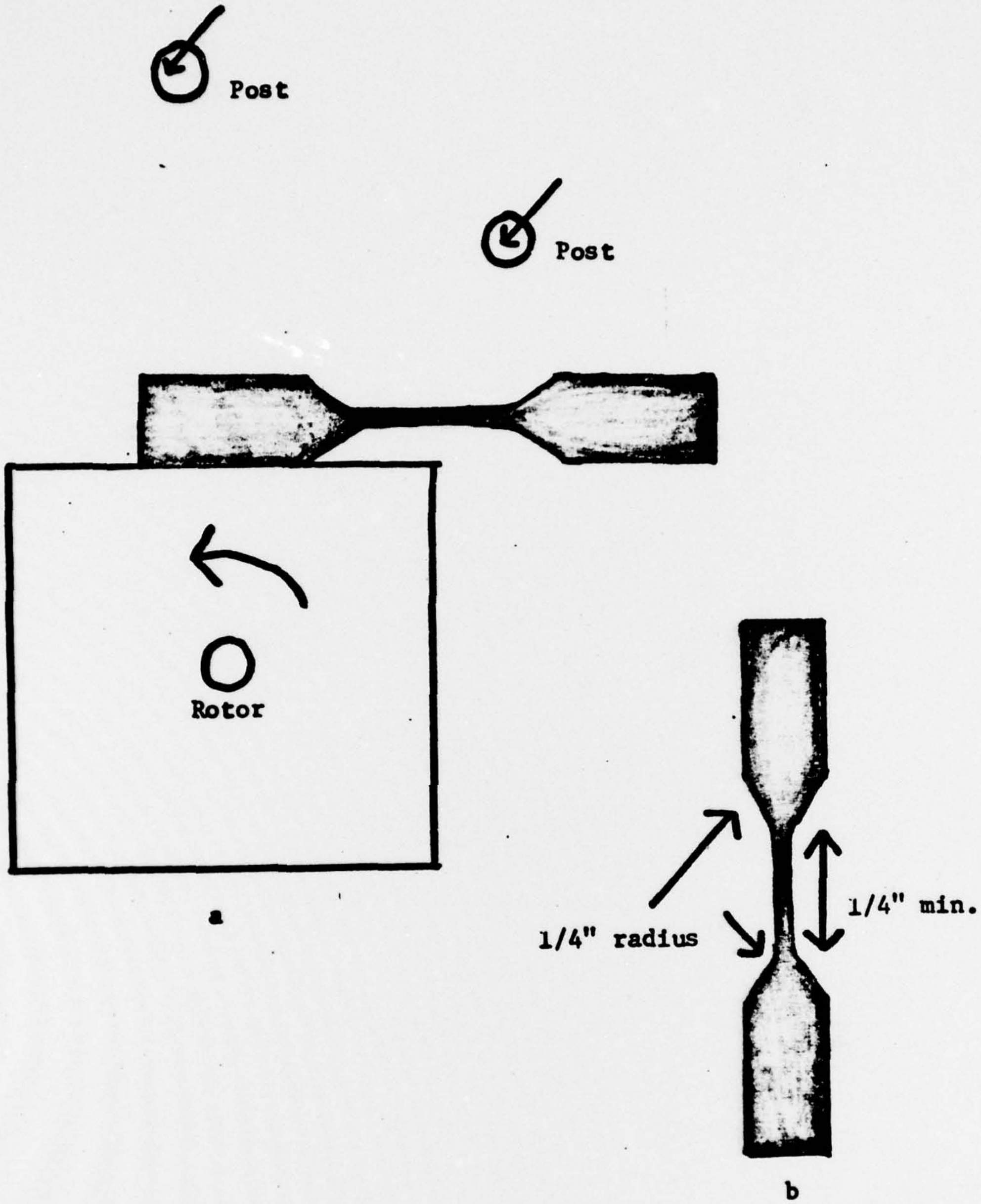
Length of the mid-phalanges

	II.		III.		IV.		V.
N1=	59.0000	N2=	58.0000	N1=	58.0000	N2=	58.0000
M1=	21.5593	M2=	26.2069	M1=	25.1207	M2=	18.4483
SD1=	2.5816	SD2=	2.6475	SD1=	2.6825	SD2=	2.1939
SE1=	.3361	SE2=	.3476	SE1=	.3522	SE2=	.2881

Table 3

Bend Tests: Ti 4 Al 6 Va Rods

Heat treatment	Angle of Bend	# Cycles	Final deformation	Breakage
No	28	10×10^5	0	0
Yes	28	10×10^5	5 - 10°	0
No	35	10×10^4	0	0
Yes	35	10×10^4	10°	0
No	40	12×10^4	0	0
Yes	40	12×10^4	10°	0
No	45	15×10^4	0	0
Yes	45	15×10^4	10°	0
No	48	5×10^6	-	+
Yes	48	5×10^6	-	+
No	90	cyclic 6000	0	0



a

b

Figure 1

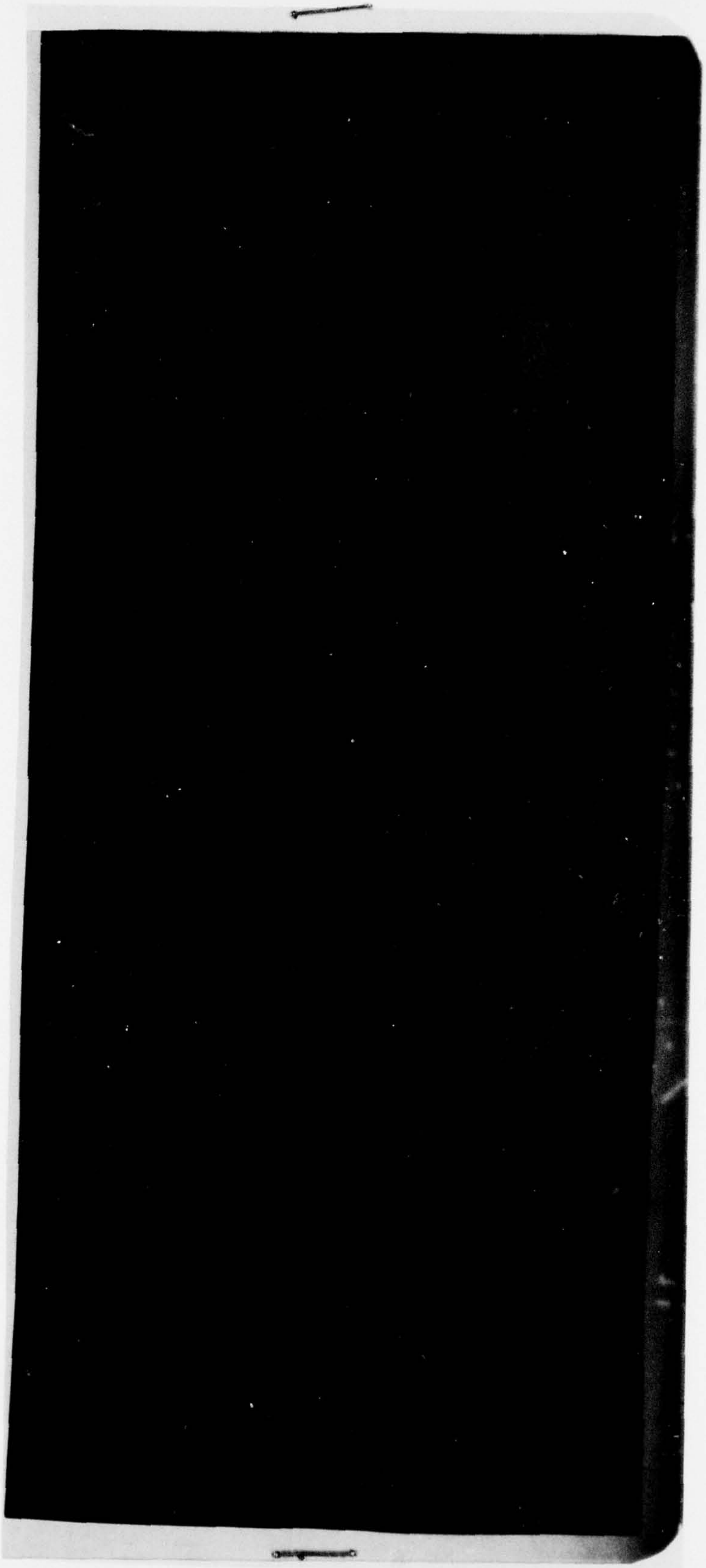


Figure 2

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