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CONSTRUCTION OF ORTHOPAEDIC IMPLANTS

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**EVALUATION OF NITINOL FOR USE AS A MATERIAL IN
THE CONSTRUCTION OF ORTHOPAEDIC IMPLANTS**

**Final Scientific Report Covering the Period from
December 1, 1973 to December 31, 1976.**

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(10) Author: James L. Hughes, M.D.

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School of Medicine
CMSC 9
600 N. Wolfe Street
Baltimore, Maryland 21205
35400 7/10/80 15

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Continuation of block 20. (Abstract)

when nitinol alloys are plastically deformed below the TTR, they are capable of reversible and forceful total recovery of shape when heated to temperatures exceeding the TTR. This study investigated the bio-compatibility of nitinol alloys and the ability of these alloys to display their "shape memory" properties in vivo.

All tests concerned with the biologic acceptability of the nitinol alloys showed no adverse tissue reaction to the nitinol alloy when compared to titanium and 316-L stainless steel. These studies included the effect of nitinol alloy powder on human fibroblast cultured in Leighton tubes, the effect of nitinol alloy filings on collagen synthesis in fetal rat calvaria tissue, and the tissue response to nitinol implants placed in the subcutaneous tissue of standard laboratory mice.

Nitinol bone plates containing a strain gauge were manufactured. These plates were pre-stressed below the TTR and held in a pre-stressed manner until applied to the femora of sheep, after which the restraining device was removed allowing the alloy to return to its original shape. The force transmitted through the plate to the bone was documented by monitoring the strain gauges at periodic intervals. Data obtained in this fashion revealed that the nitinol alloy retained the "mechanical memory" in vivo.

A hip prosthesis and intermedullary rod were constructed using internal fixation components produced of nitinol. These were placed into a human femur with the temperature of the units below the TTR. Firm fixation of the metallic components within the bone by changes in shape of the nitinol components as the temperature exceeded the TTR demonstrated the feasibility of utilizing nitinol alloy in the production of certain Orthopaedic implants.

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EVALUATION OF NITINOL FOR USE AS A MATERIAL IN THE
CONSTRUCTION OF ORTHOPAEDIC IMPLANTS
Army Contract, DAMD contract 17-74-C-4041

PHASE I, 1 December 1973-28 February 1975

BACKGROUND AND DISCUSSION

The near equiatomic alloys of titanium and nickel with their unique "shape memory" displayed future potential as superior materials for orthopaedic implants. It was the purpose of phase I of this project to investigate and evaluate the in vivo biologic acceptance of such materials, given the generic name NITINOL (Ni-Ti-Naval Ordnance Laboratory). Previous studies by Buehler¹ have shown that each of these alloys possesses a critical transition temperature range (TTR) over which the alloys undergoes a highly unique electronic change and atomic repositioning. This TTR can be varied through alloy composition changes in excess of 100⁰C down through the liquid nitrogen temperature (-196⁰C). Certain mechanical properties such as elastic modulus and yield strength, also vary drastically as the alloys are moved through the TTR. Furthermore, when NITINOL alloys are plastically deformed below the TTR (up to 8%), they are capable of reversible and forceful total recovery when heated to temperatures exceeding the TTR. The greater the amount of strain, up to 8%, the larger is the recovery stress on force produced.

OBJECTIVES

1. Investigate the corrosion resistance of NITINOL alloys of varying composition when exposed to biologic fluids for different time periods based on earlier work by Castleman, et al. (personal communication) that revealed that NITINOL was, in fact, biologically acceptable.

¹Results of this work may be found in Appendix A.

2. Demonstrate that these alloys continued to display their "shape memory" properties in vivo.

MATERIALS

To study the biocompatibility of NITINOL, it was necessary to look at several alloy compositions. Because various potential medical devices require certain design characteristics, representative alloys spanning the temperatures and recovery stresses were investigated in order to provide for a broad spectrum of future applications (see Table I). The primary difference between each alloy was in the nickel-cobalt relationship. Such changes altered the heat recovery range. The immediate wrought configuration and ultimate use of each alloy may be found in Table II. The following four NITINOL materials were prepared for this investigation:

1. Filings and powder. Fine filings and powder required for fibroblast tissue studies were produced by filing a 4.5mm diameter alloy rod with a tungsten carbide file.
2. Implant specimens (see fig. 1). NITINOL alloys were machined into implant specimens whose axis was the same as the principal axis of the original hot swaged rod. The dumbbell configuration allowed for ingrowth of tissue which could then effectively resist wandering of the implant in the tissue.
3. Washers. Washers were prepared, but were not used until phase II of this project and will be described further at that point.
4. Bone plates. Contracting bone plates were designed and machined as outlined in Appendix A to determine whether or not NITINOL alloys would continue to exhibit memory recovery when heated through the recovery range in vivo.

METHOD AND RESULTS

The following studies were performed in order to determine tissue response to various NITINOL alloys.

1. The first study utilized NITINOL powder alloys I, IV, and V in human fibroblasts cultured in Leighton tubes with McCoy's culture medium plus calf serum. Titanium and 316-L stainless steel were used as controls. In this short-term experiment, morphology and cell counts were checked as gross barometers of tissue toxicity. At 20 and 26 days, no significant differences in morphology or cell counts among the three metals were revealed (see fig.2)

2. The second study was carried out by Dr. Gerald Finerman and his staff at UCLA. Filings from each of the 5 alloys as well as from titanium and stainless steel were placed in buffered fetal rat calvaria tissue in order to determine their effects both on general protein and on collagen synthesis (see fig.3). With over a hundredfold concentration range for each of the substances, no statistically significant differences from the controls were found. Shaded areas on the graph in fig.3 indicate the range for control values, and in all cases, experimental values fell within these ranges.

3. The third portion of phase I utilized the small dumbbell-shaped implants beneath the skin of standard laboratory mice (fig.4). Each of the five alloys was tested on 27 mice, nine implants left for one week, nine for three weeks, and nine for nine weeks. The animals were fed a standard diet and watered ad libitum. Activity was not restricted. For surgery, the mice were anesthetized with ether. A small incision over the sacral area was made with a hemostat subcutaneously approaching the scapular area

posteriorly. The chromic suture material was passed from the sacrum cephalad and emerged with the needle superior to the scapula. The implant was then pulled from the sacrum into the scapular area and locked with a chromic suture. Implants were not left over the sacrum as originally planned because of the animals' ability to get to this area and disturb the implants. At one, three, and nine weeks, the mice were sacrificed and the implant was removed in toto. Specimens were observed for gross irritation and discoloration. The metal was not explanted from the surrounding tissue in order to preserve the interface.

The metal, together with the surrounding tissue, was then embedded in methylmethacrylate. The extreme hardness of the metal, however, prevented the microtome from cutting sections. It was therefore necessary to place the entire block in an acid solution and to pass a current through the metal. The NITINOL implant then popped out, allowing sections to be cut with the microtome. Although small bits of the fibrous layer in contact with the metal were lost, representative sections in most of the preparations were obtained (fig. 5)

No gross necrosis and/or color changes were observed by macroscopic examination of the tissue samples in the NITINOL, stainless steel, or titanium tests. Microscopic tissue response was evaluated by studying the fibrous membrane immediately adjacent to stainless steel, titanium or alloy implants, by observing the cellular activity of the connective tissues around the membrane, and by checking the muscle around the implant for signs of degeneration and/or abnormal cellular infiltrates. An early fibroblastic response in the formation of a membrane around the implant was revealed in all cases. At nine weeks, vasculature and blood vessels surrounding the area appeared normal. There were no giant cells present or

degeneration of the muscle layers or loose connective tissue. No significant differences between the control and the NITINOL implant tissue sections were noted.

4. The final step in phase I was to study NITINOL plates as designed and machined in App. A. The plates were instrumented using strain gauge cells glued into the plate (fig. 6). Two small wedges were drawn into the straining cavity during cooling of the plate. Because the outside diameter of the wedges was larger than the entrance diameter, the straining cavity was effectively elongated. With the straining device in place, the plate was then dipped into 90% alcohol at -150°C . This temperature was monitored by probe thermometer during plate cooling. As the plate and the straining device were cooled, a wrench was used to apply active forces to the straining device. Once this device was sufficiently elongated, and the wedges were in place, the plates were allowed to warm to room temperature and were standardized with a hep strain gauge cell.

Following standardization, the plates were gas sterilized for implantation in sheep femora. The hind legs of the sheep were prepped and draped for a lateral incision. Either the dorsal or lateral aspect of the femur was selected, dependent upon how well the plate mated itself to the bone. Standard placement of the screws was achieved using a torque of 40 kiloponds of force. The straining device was then removed, and the pressure was recorded in kilopounds (fig. 7).

Measurements of the strain gauge cells were taken at weekly intervals (fig. 8). The sheep were fed standard diets with water ad libitum. No restrictions were placed on activity. The plates were left on for 1-2 months. Radiographs of the femora were taken at two-week intervals (fig. 9).

Eight sheep underwent surgery. A total of eight different plates were applied at this time. Control plates were the A-O DCP type made of stainless steel. Microradiographs were taken and normal staining of bone tissue was carried out (fig. 10). No grossly abnormal proliferation or discoloration of tissue surrounding the plates were observed. On all histological specimens including controls, absorption cavities could be seen beneath the plate indicative of stress being borne by the plate rather than by the bone. The strength of the forces at work within the plates was evidenced by a plate that fractured after being warmed to room temperature with the constraining device in place, sending portions of the constraining device several meters from the original site (fig. 11). Two other plates were rendered inaccurate when the strain gauge wires were broken by the sheep. Points in fig. 12 represent the initial measurement of force taken with the plate in place on the sheep femora. The range extended from 8-108 kiloponds. Tests revealed a standard bone response to the stresses applied, whether by NITINOL or by stainless steel.

CONCLUSIONS

1. NITINOL appears to be as biocompatible as presently accepted materials.
2. Unique properties of NITINOL are not altered by a biologic environment.
3. NITINOL continues to show promise in several specific problem areas of orthopaedic surgery, as further supported by the data obtained in phase II of this project.

PHASE II, Ending January 31, 1976

Phase I revealed that:

1. NITINOL appeared to be biologically acceptable in vivo.
2. The distinct and unusual characteristics of NITINOL would indeed function in a biological environment.

Based upon the findings in phase I, phase II combined the efforts of the Johns Hopkins University School of Medicine, Division of Orthopaedic Surgery and the Naval Surface Weapons Center in White Oak, Md. to produce a new implant technology. Under primary consideration were the problems surrounding fixation of prostheses to the hip and the possibilities of using a NITINOL intramedullary rod (App. B).

Mr. Dave Goldstein and Mr. John Tidings of the Naval Surface Weapons Center designed and manufactured both a prototype hip prosthesis and an intramedullary rod (fig. 13) The prototype hip prosthesis was fabricated with heat-activated self-deploying NITINOL tabs (fig. 14) This prosthesis was inserted in a cadaver femur at a temperature of 0°F. Upon warming to 70°F, the tabs deployed and formed a structurally rigid assembly with the femur (fig. 15) This was considered to be a strong indicator of feasibility of a self-deploying NITINOL prosthesis. Removal of the prosthesis was achieved after recooling the femur to 0°F and then pulling at opposite ends of the assembly. The insertion and removal process was videotaped through an image intensifier at the University of Mississippi. A copy of this tape is available through Mr. David Goldstein at the Naval Surface Weapons Laboratory.

An intramedullary rod was also designed using a bulbous NITINOL assembly which would fix internally and cause increased stability (fig. 16)

This prototype was also tested by inserting it in a reamed hole in a femur after flattening of the NITINOL elements at 0°C. As with the hip prosthesis, withdrawal was possible by re-chilling the bone/rod assembly. The embedded device in the expanded mode was impossible to withdraw, thus indicating that exceptional stability was achieved in the femur. Radiography illustrated both the deployed and non-deployed position of the NITINOL elements in relationship to the bone (fig. 17).

One added experiment to investigate use of NITINOL in orthopaedic biomaterials tested NITINOL washers that were implanted into sheep femora with alternating stainless steel and titanium screws. These were implanted in two sheep in 1975 and remain in place. Stress reactions around the screws can be observed in fig. 18, but there was no evidence of toxicity related to the interaction of the different metals. On physical examination, no lymph adenopathy or reaction in the soft tissue surrounding the implant were present. The sheep have continued to graze and perform the usual duties of sheep without any alteration of their normal lifestyle. The sheep will be sacrificed at a later time and studies of the histological compatibility of NITINOL, stainless steel, and titanium will be undertaken at that time.

Problems encountered with the above project were primarily centered around the difficulties in: 1.) standardization of the titanium-nickel ratio into an appropriate temperature mode for use in the body, and 2.) attempting to work with an extremely hard material. Despite these technical problems, it appears that NITINOL can be successfully utilized in the manufacture of properly designed orthopaedic implants and will deploy in the body as expected. The positive findings in both phases of this project merit further attention in the future.

Appendix A

Dr. S. M. Perren
Laboratorium für Experimentelle Chirurgie
Schweizerisches Forschungsinstitut
CH-7270 DAVOS-PLATZ
Switzerland

Dear Dr. Perren:

I have received a copy of your letter addressed to Dr. Lee H. Riley, M.D., dated 10 November 1972. I have made a very careful study of the letter's contents in order to respond in a thorough and proper manner.

I feel the first response correspondence should deal primarily with design considerations. This would consider such aspects as the strain-heat-recovery of the Nitinol, contracting force and the effects of varied strain as a function of temperature and time, selection of an optimum alloy "transition temperature range" (TTR) and various miscellaneous required data in order to make your measurements meaningful.

Also, in light of the following discussions, we should jointly consider whether the present proposed bone plate design is optimum for experiments with the Nitinol alloys. While these thought processes may appear somewhat time consuming, I feel that fewer experiments may be needed to conclusively test the value of a contracting Nitinol bone plate system.

To preface what follows, I definitely feel a contracting Nitinol bone plate is a novel approach and it could add a

new dimension to healing fractured bones. However, my initial concern lies in the area of the contracting force. With the contracting force potential of the Nitinol, means may be required to lessen or moderate this force. I have devoted a section of my following write-up to this aspect.

The In Vivo Compatibility of Nitinol

During the discussions following a recent talk that I gave in San Francisco, California, U.S.A., a Dr. Alan A. Johnson, Ph.D., Department Head, Department of Materials Science and Engineering, Washington State University, reported that he had tested binary TiNi-base alloys (Nitinols) in vivo on beagle dogs. His study was only to determine the biocompatibility. His tests centered around plates that were merely fastened to the front leg bones of the beagle. Some plates had been embedded for as much as 18 months. He summarized his results by stating that there had been no evidence of irritation or inflammation in the plate area and that a thin fibrous sheath had formed over the plate.

It would appear, based upon these data and our own successful crevice corrosion results on cobalt-modified Nitinol in seawater, that this aspect will present no problem and may be set aside at this time.

Important Design Considerations

The Nitinol materials undergo what is commonly termed a "martensitic transition" (transformation). This transition is in part described in the literature; see references A, B, C and D, enclosed. The term "martensitic transition" is used

here only to denote an atom "shear" movement associated with the application of a "shear force." A second feature of the Nitinol alloy system is the unique electron bonding change that occurs as a function of heating and cooling through the transition temperature range (TTR). The combination of atomic shearing and electron bonding change provide the strain-heat-recovery behavior and the unusual force that accompanies this recovery.

I have enclosed reference E in an effort to have the basic design principles better understood. The information and data in reference E were extracted from a "Nitinol Characterization Study" performed at Goodyear Aerospace Corporation for the NASA organization. In this study three alloy compositions were used, which were labeled A, B and C. Information on the three alloys is given in Table II (Ref. E). Figure 5 (Ref. E) graphically illustrates (as a function of resistivity) the key critical temperatures as they relate to the martensitic transition in the Nitinol materials. The symbol definitions are given in the upper right-hand corner of Figure 5 (Ref. E).

It should be emphasized that heat-recoverable straining must be performed below the M_D temperature. Further, the A_S temperature must be reached (on heating) before the onset of dimensional recovery can occur. Also, the precise temperatures of A_S and M_D can be varied considerably by altering the alloy composition. This latter point is described in some detail on

pages 111 and 112 (Ref. A). In a practical sense recovery temperatures (A_S) may be established by alloying as low as liquid N_2 ($-196^\circ C$) or at various levels up to about $+100^\circ C$. This A_S temperature flexibility is a most important design consideration and will be discussed in more detail below.

Following along in reference E it can be seen in Figure 6 that there is a definite relation between strain-heat-recovery (bend in this case) and the electrical resistance (resistivity)-temperature profile. The optimum recovery occurs in a material with proper cold working (below M_D temperature) coupled with a proper final anneal; see Figure 6 (Ref. E), upper right panel.

Typical engineering stress-elongation curves (in tension) are presented in Figures 14 and 15 (Ref. E). Note the change in curve shape both below and above the transition temperature range (TTR). This may be seen more clearly in my general curves given in reference F. The vast differences in curve shape are directly attributable to the electron bonding changes that occur between the A_S temperature on heating (M_S on cooling) and the M_D temperature. These bonding changes are most evident in the elastic modulus (E) and the yield strength (Y.S.), and the change is summarized graphically in Figure 16 (Ref. E). Stated in simple terms the Hittinol materials are very ductile and flexible ($E \approx 3.5 \times 10^6$ psi) and possess low strength (Y.S. $\approx 10 \times 10^3$ psi) below the A_S (on heating). The application of heat causes a change to predominantly covalent bonding to take place above the A_S , which sharply changes the E to about 12×10^6 psi and the Y.S. to about 80×10^3 psi. The resultant alloy,

above its transition temperature range ($\gg A_S$) is thus quite strong and rigid. Certainly, above A_S it represents an engineering type material that one can work with in a design sense. Therefore, in designing a suitable bone plate alloy one must be certain to have body temperature definitely above the A_S - M_D range (Fig. 16, Ref. E) of the alloy. Such an alloy will provide, at body temperature, a suitable immobilizing bone plate structure and yet will receive sufficient heat from the body to contract with great force.

To be an effective means of forcing together or impacting the fractured bone sections the "mechanical memory" must be capable of exerting an adequate force--yet not too large a force. Figure 28 (Ref. E) shows typical tensile recovery stress versus temperature curves at various prestrain levels (when straining is done below the M_D - A_S range). One can immediately note certain key points; for example, the maximum recovery stress appears to be associated with a tensile strain of 8%. Also, the recovery stress increases as a function of strain up to the 8% strain level. Another important fact is the temperature change (ΔT) that is required to reach the maximum recovery stress. In each strain level up to 8% the ΔT from onset of thermal recovery to the "knee" of the curve is increasing with increasing prestrain. To best illustrate these points I have extracted the curves of three prestrain conditions (2, 4 and 8%) and these are shown in reference G. In brief these curves are obtained by prestraining a Nitinol wire sample

a given amount (for example, 2, 4, 8, etc.) , then resistance heating the strained wire to increasingly higher temperatures while providing the necessary force (arrows, Ref. G) to maintain the prestrained length. Knowing the sample cross section area, curves of recovery stress versus temperature are attained.

It has been previously established that the initiation of recovery (A_g) is a variable of the alloy composition. Since body temperature is fairly constant (about 37°C), some interesting design possibilities arise.

Assume the above 2, 4 and 8% recovery stress-temperature curves and further assume that through alloying these curves can be moved sidewise in position with respect to the temperature axis. With these assumptions established now position body temperature vertically across the curves, as shown in reference II by the dashed lines. Body temperature is 37°C; however, it is shown at four different locations. This graphical representation is simpler than moving the curves sidewise and provides an equivalent result.

Now one may observe the following: if body temperature is at position A the 4% strain will produce the greatest recovery stress followed by 2% and least by 8%. In position B, the 4% strain gives greatest recovery stress while the 2% and 8% are equivalent. In position C the 4% and 8% are equivalent while 2% lags behind. At position D the 8% strain is providing much the largest recovery stress with the 4% and 2% dropping down in order.

From the representation given in reference H the importance of alloy design (composition) can be seen. Where should the A_s temperature (onset of recovery) be with respect to a fixed body temperature? How much temperature change (ΔT) is required to provide the proper bone impacting force? Further, how much impacting stress is desired or can be tolerated by the bones? Or, will the bone screws be stripped from the bone threads if the load becomes excessive? A still further consideration is: what might the curve of impacting force as a function of time look like--particularly if the bone mending is accompanied by contraction and thus strain reduction? I have conjectured graphically in reference I on this aspect. No effort has been made to put these curves in any proportionate scale. The curves are merely given to graphically show the relationship of impacting force, the A_s to body temperature change and the possible effects of reduced strain during bone mending.

In summary, it would appear that situation D (Ref. H and I) is least complex. Maximum impacting force occurs immediately on heating the 8% prestrained plate to body temperature. Then any lowering of the strain will be accompanied by modest lowering of the impacting force. The other representations (body temperature at A, C in Ref. H and I) merely show what might occur with very careful A_s to body temperature control. However, these latter possibilities would probably require a very careful alloying study in order to be able to place body

temperature in either position A or C (Ref. 7H).

Now let us address the design considerations dealing with the contracting force (recovery stress) associated with the Nitinol material. Figure 28 (Ref. E) shows the magnitude of the "recovery stress" for an annealed uniaxial-strained 0.1 inch diameter wire (rod). To assure continued pressure at the fracture interface during healing one would probably tend to use a strain (stretch) approaching that which will provide nearly complete heat-induced recovery. Further study of Figures 29 through 31 would set that strain (stretch) level somewhere in the 6% to 8% range. Also using a 6% to 8% strain will provide a significant amount of plate "stretch" even in rather short bone plates. A stretch of 0.060 inch to 0.080 inch per inch of stretched bone plate would allow adequate tolerance during initial bone mating, healing accommodation, etc. Further, as was indicated earlier, if this initial accommodation causes a moderate drop in strain (stretch) the load (force) associated with the lower strain values will still be quite high (see Figures 29-31, Ref. E).

Assuming the use of strain levels of 6% to 8%, one must be concerned with the kind of recovery stress or force this will produce. Using Figure 30 (Ref. E) data for a 0.1 inch diameter wire (rod), one is able to derive the data given in Table I. These data show the relative magnitude of recovery stress one might expect from a 12 mm x 4mm Nitinol bone plate cross section when strained (stretched) to various levels. On a 1.0 square

Table I. Impacting Force Potential of Nitinol Strained to Various Levels

Strain (%)	Maximum Recovery Stress* (lb/in ²)	Impacting stress (force) produced by the subject 12 mm x 4 mm bone plate**		
		1.0 in. ² cf bone interface	2.0 in. ² cf bone interface	2.0 in. ² cf bone interface
8	80,000	5920 psi (5920 lbs)		2960 psi (5920 lbs)
6	62,000	4590 psi (4590 lbs)		2295 psi (4590 lbs)
4	45,000	3330 psi (3330 lbs)		1665 psi (3330 lbs)
2	27,000	1995 psi (1995 lbs)		998 psi (1995 lbs)

* Based on an annealed 0.1 inch diameter wire (rod), NASA Report CR-1433.

** Bone plate--approximate cross section dimensions 12 mm x 4 mm $\approx$ 48 mm² $\approx$ 0.074 in.².

inch of bone interface the impacting stress varies from 1995 psi to 5920 psi. While a 2.0 square inch interface varies from 998 psi to 2960 psi. Observing the generally lower recovery stress trend for larger diameter wire and sheet (Figures 29-31, Ref. E) might indicate some general lowering in a wrought bone plate section. How much lower the recovery stress values (at various strains) might be in the proposed 12 mm x 4 mm bone plate section is unknown. Since the recovery stress (force) is a function of the orientation and degree of microtwinning, one would have to actually determine the recovery stress at various strains in the 12 mm x 4 mm bone plate experimentally.

Now one has to ask the question, "What level of impacting force is optimum to expedite bone mending?" Is that impacting force attained, or exceeded in the proposed bone plates and experiments?

The maximum impacting forces (recovery stresses) shown in Table I cannot be exceeded in the 12 mm x 4 mm proposed bone plate. Higher impacting forces could only result from larger bone plate section size. Chances are very good that the values given in Table I are higher than can be expected in the more massive wrought bone plate section.

How then does one reduce the impacting force while employing a fairly large strain or stretch in the plate? Below are listed some suggested techniques:

1. Use a lower prestrain (stretch) but somehow extend the length of the strained zone. For example, 8% strain over

2 inches = 0.160 inch of stretch. While the same 0.160 inch stretch is possible using a 4% strain over 4 inches. While the stretch is similar the recovery stress for 4% strain is considerably lower than in the 8% situation.

2. Reduce the cross sectional area of the portion of the bone plate that is strained (stretched). This will lessen the recovery stress proportional to the area of the stretched portion; however, it will also reduce the stiffness of the bone plate in the thinned section. The latter limitation may affect the ability of the plate to immobilize bending or lateral movement in the fractured area.

3. Establish the TTR, through alloying, so that body temperature (37°C) falls on the sloping portion of the recovery stress-temperature curve (see Fig. 28, Ref. E and Ref. H, lines A, B and C). However, observing Ref. H, lines A and B and referring to my prior discussion--one can see potential problems when the strain level lessens (contraction) the impacting stress can actually increase.

4. Use overstraining as a means of forcing the maximum recovery stress down to a lower level. One can observe this trend in Figures 28 (10% curve), 29 through 31. However, to employ this scheme one would have to know more about the recovery stress vs temperature profile for overstraining sections like those utilized in bone plates.

5. Employ a two-piece bone plate that is designed to telescope or slide one piece within another but yet maintain

rigid alignment of the fractured bone sections. This scheme, if at all suitable, would allow initial fastening of the plate(s) to the fractured bone sections followed by the attachment of a stretched Nitinol element(s). In this case the contracting (impacting) force could be accurately controlled based on the straining and cross-sectional area of the contracting Nitinol element(s).

6. Another possible method of reducing the contracting force might utilize the bucking action of a spring component built into the bone plate proper. A crude attempt at a design is offered in reference J. Here one could use one or more stretched and contracting Nitinol wire or rod elements that would produce a force moderated by the compressive straining (bending) of a designated portion of the plate. Reference J shows a typical proposed middle section. If this middle section were designed properly it seems that elastic bending could be made to occur sidewise as illustrated while minimizing upward bending. Perhaps to accomplish this a considerably different Nitinol element mounting cut-out webbing design would be necessary. The illustrations in reference J are merely employed to suggest the use of the bone plate itself to control more accurately the impacting force. Whether or not a multicomponent contracting bone plate is feasible still remains a question.

In summary, six "techniques" have been suggested as possible means of controlling or moderating the impacting force produced by the uniaxial contracting force of the Nitinol. This is not to imply that the above are the only means of controlling the impacting force. The major intent of this exercise is to show

that some means are available by which the impacting force can be adjusted. Further variations are definitely possible and it is hoped the above will encourage original thoughts and techniques that may prove more desirable.

Potential Biaxial Strain-Heat-Recovery

The Nitinol material always exhibits a heat-recovery which is in opposition to the prestrain direction. This suggests the possibility for multiaxial straining and complex bone plate performance. How much recoverable straining is possible in two or more directions simultaneously is unknown. Perhaps it bears some relation to the 8% level of uniaxial prestrain. This point is made merely to suggest that multiaxial movement is probably available from Nitinol. If this could add a highly useful aspect to bone healing, some experimentation should be initiated to better understand the complex strain-heat-recovery as a prelude to bone plate design.

Nitinol Bone Plate Mounting Technique

Assume the use of a Nitinol composition that has a TTR significantly below body temperature (see point D, Ref. H). Now, then, does one mount such a plate without triggering contraction during the mounting process?

In principle, if one can believe fully the data in reference K, it is apparently possible to suppress the heat-actuated recovery. In reference K the bent Nitinol wire was allowed to recover elastically, then it was constrained in position while it was heated well above its normal unstrained TTR ($A_g \sim 100^\circ\text{F}$).

At about 280°F the constrained wire was released and allowed to freely recover. The data in reference K indicate about 96% recovery under these conditions. From these data one might assume a similar behavior when constrained following stretching and heating well above the TTR. This latter point should be checked experimentally before considering it for bone plate use. If the constrained recovery is permissible then the following bone plate mounting steps are suggested.

1. The carefully machined plate is immersed in a suitable sterile refrigerated bath to lower its temperature well below the M_D - A_S range for the alloy used. Partial chilling of the strained area only may be employed if there are attendant advantages.
2. Strain the chilled bone plate using a suitable mechanical or hydraulic straining device. Some predesigned gripping holes, lugs, etc., will have to be provided in the plate to assure uniform straining.
3. Use the straining device or other device placed in the gripping holes, lugs, etc., to constrain recovery on subsequent heating above the A_S temperature range.
4. Conventionally mount the bone plate using the screwing action to provide initial impacting load.
5. With the plate(s) screw-fastened in position re-chill the stretched (strained) Nitinol plate section that has been constrained from contracting during the initial warming during screw mounting. When the plate is chilled the constraining device is removed.

6. The Nitinol plate is then warmed causing it to contract and load the fracture interface. The load-level profile as a function of time was discussed earlier.

7. Later removal of the plate may be accomplished by once again chilling the contracting section of the plate. This should relieve the contracting load long enough to allow easy load-free removal of the screws.

An alternative to step 3 above would be to maintain the temperature of the stretched portion below the A_s during installation. While this ^{is} possible, it is felt the method described in 3 is preferable.

Steps to be Taken

It is suggested that the addressee and others receiving this letter review it and submit their suggestions directly to me. I will combine those suggestions into a second open letter and in the same letter respond to the various suggestions.

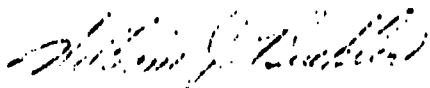
The most pressing design questions appear to be in the area of strain (stretch) and the associated impacting force. You have stated a level of load for impacting sheep tibia of about 200 pounds. My immediate question centers on whether or not this force level is optimum for healing, or whether it is based on experiences with compression produced by conical screw holes.

From my prior discussions you can appreciate the intricacies of the strain-recovery stress of the Nitinol materials as well as the relative levels of inherent recovery stress. This then

points up the important question of whether the 200 pounds is an optimum value, or would significantly higher impacting forces be desired if they can readily be attained? An answer to this question probably constitutes a primary step in the design of a contracting Nitinol bone plate.

If this consideration can be adequately addressed, then other steps should follow. For example, a suitable alloy with proper TTR should be designed; the stress-strain curve (at 37°C and above the TTR) should be determined for this alloy and the chill + constrain + release + recovery behavior determined. If these results prove satisfactory, then actual bone plates, with the necessary stretching provision, would be produced for evaluation.

Sincerely yours,


WILLIAM J. BUEHLER

Copy to:

- (1) Major David Eddy, M.D.
- (2) Dr. Lee Riley, M.D.
- (3) Dr. Toby Hayes

NAVAL ORDNANCE LABORATORY
WHITE OAK

SILVER SPRING, MARYLAND 20910

IN REPLY REFER TO:
211:WJB:ej

5 June 1974

Dr. James L. Hughes, M.D.
Assistant Professor of Orthopedic Surgery
Department of Orthopaedic Surgery
The Johns Hopkins Hospital
Baltimore, Maryland 21205

Dear Jim:

I am in hopes with this summary letter to convey many of the details pertaining to the modified-Nitinol alloy bone plates for use under Army Contract DAMD-17-74-C-4041.

METALLURGICAL HISTORY

Alloy Composition. The bone plates were made from an alloy with the composition $Ti_{.5}Ni_{.45}Co_{.05}$ with a transition temperature range (or recovery temperature range) measured to be about $-52^{\circ}C$ to $-18^{\circ}C$ (see letter of 4 Feb 1974 to J. L. Hughes).

Alloying and Casting. Eighteen 150-gram melts were weighed with the wt % composition as follows: Ti = 67.38 grams, Ni = 74.32 grams, Co = 8.30 grams (or $Ti_{.5}Ni_{.45}Co_{.05}$). Each 150-gram charge was melted multiple times on a water-cooled copper hearth using a nonconsumable arc technique.* All melting is performed in a partial atmosphere of purified argon to avoid alloy contamination. Repeated alloy melting is done to insure composition homogeneity. The final product is a 150-gram "button" about 2 inches in diameter by 3/8 inch thick.

Three of these alloyed "buttons" are then remelted together to form a bar. The finished 450-gram bar measures about 1 inch thick x 1-3/8 inches wide x 4-1/4 inches long. Using this procedure 18 alloy buttons were made and these were then remelted into 6 rectangular bars.

Metallurgical Processing. The arc cast bars, as described above, were then given the following processing operations.

*Considerable delay was encountered in this operation due to atmospheric humidity and its adsorption on the internal components in the arc-melting chamber.

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1. The arc-cast bars were hot rolled to the rough thickness of 3/8". Initial rolling passes were performed at 850°C and the temperature was lowered gradually to a final rolling temperature of 600° to 650°C. The reason for the lower finishing temperature was to induce a finely textured micro-twinning in the bone plate stock to enhance the strain-heat-recovery behavior.

2. The hot rolled plates were press-flattened using a heating temperature in the 600° to 650°C range.

3. On cooling to room temperature the hot rolled plates were cut longitudinally using an abrasive cut-off wheel. The cut plates are shown in Fig. 1(A), attached.

4. The cut plate sections from 3 above are then surface ground to a width of 0.550 $\pm$ ^{0.020}/_{0.000} inch.

5. The cut-and-ground bars from 4 above are heated to the 600° to 650°C range and press forged to form the strain gage cavity section off line with the bar ends.

PLATE MACHINING

Machining. The following machining steps were taken to obtain the finished bone plate.

1. The upset forged bars were reground on their side surfaces to a width of about 0.550 inch.

2. The bottom surfaces of the end sections were surface ground in-line and flat.

3. The rough ends were abrasively cut to length and mill finished* to insure accuracy.

4. The remaining unmachined surfaces were sanded or ground to remove any surface oxide left from the "hot" processing operations. Clean oxide-free surfaces were necessary for trouble-free EDM (electrical discharge machining) of the holes, cavities, etc.† The bars as delivered to the Main NOL shop for EDM are shown in Fig. 1(b), attached.

5. Upon return from EDM each bar was hand ground on a specially contoured SiC grinding wheel. This grinding operation provided the

*All milling, turning, etc., required use of tungsten carbide tooling.

†EDM was difficult until the surface oxide was removed and an adequate electrical path to the work piece was obtained.

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reduced sections on either side of the strain gage cell (see Fig. 2, attached).

6. The next operation was to hand grind or sand the approximately 2-inch radius on the upper portion of the end sections of the bone plate. Considerable care was exercised to avoid uneven grinding of the parallel side sections of the straining cavity (see Fig. 2, attached). Uneven, cross-sectional areas in these straining sections could lead to nonuniform straining and highly unpredictable heat-recovery. The upper and lower views of a plate, at this stage, are shown in Fig. 1(c).

7. Tungsten carbide end and ball mills were then employed to finish machine the screw holes, screw slots, screw countersinks, inner wall of the strain cavity and the strain gage cell.

8. As of this writing the concave undersurfaces of the plate ends have not been finish machined. This will be accomplished by either ball milling using a 1-inch radius ball mill or making a series of longitudinal passes with a contoured surface-grinding wheel.

9. Finally, hand grinding and sanding using various abrasive grits will be employed to remove all sharp edges and roughness.

Post-Machining Treatment. The finish machined bars will be washed carefully in trichlorethylene to thoroughly degrease them. Then they will be heated for several minutes in boiling water to remove any possible surface contamination due to absorption of hydrogen into the metallic surface, the possible hydrogen contamination coming from the EDM operation.

ALLOY CONTROLS

Very few controls or checks were possible during the plate preparation to assure a uniform composition from plate to plate. Most of the assurance comes from the following:

1. Careful alloy component weighing prior to melting.
2. Care in melting, both in handling the weighed charges and in preventing gaseous and interstitial contamination (e.g., the formation of Ti_4Ni_2O , Ti_4Ni_2N , TiC , etc.).
3. Qualitative damping to crudely determine the approximate transition temperature range and be certain that the dry ice temperature is below this critical temperature.
4. A thin "tang" was abrasively cut from the edge of one of the hot rolled plates (see Fig. 1(A)). This tang was sanded to reduce a short section to ~ 0.057 inch thick. The test piece was cooled in dry ice until its temperature had equilibrated to that of the dry ice. It was then

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quickly bent into a tight U-bend with an approximate bend radius of 0.4 inch. The bent section was then warmed by a human hand to cause recovery. The recovery from this approximately 6.5% outer fiber strain was rapid and efficient. The ground tang virtually recovered its original shape. This test tang has been included along with this letter report and bone plates.

BONE PLATE VARIATIONS

The finished bone plates as received by Drs. Riley, Hughes and Perren will be totally ready for deployment. However, there may be a desire on the part of the above doctors to slightly modify the "as received" plate(s). As a result, the following suggestions are made:

1. A reduction in the cross sections of the contracting walls of the straining cavity. This may be accomplished two ways: (a) Surface grind the same amount from the total length of the plate side surfaces. This way both the straining members would be reduced in cross section while simultaneously reducing the width of the total plate, (b) Locally surface grind the same amount from each straining wall and leave the bulk of the plate the original width. Surface grinding, as described above, should be done with a proper grinding wheel and appropriate coolant. The latter will be important to avoid possible "walking" or movement of the thinned-down straining walls. If this should happen, a nonuniform straining wall could result. Finally, heating in boiling water may be a desirable precautionary step to eliminate any possible contamination from the grinding-coolant combination.

2. A further reduction in the thinned-down sections on either end of the strain gage cell may be desired. This can be accomplished by either carefully hand grinding these zones using a contoured grinding wheel, or, alternatively, it can be done by milling using tungsten carbide mill cutters.

3. Any other variations may logically be accomplished through the careful use of grinding, sanding or cutting using appropriate tungsten carbide tooling. Coolants used during grinding and/or sanding appear helpful; also, cutting lubricants used during carbide milling, drilling, etc., are recommended.

BONE PLATE OPERATION

The current contracting bone plates are designed to operate by the contraction of the side sections of the straining cavity. The principal mode of strain is parallel to length of the plate. Two tools are provided to render the plate contracting. One is a modified vice-grip pliers and the other is a tool for constraining contraction during deployment of the plate. In addition to these tools, dry ice is the only other item required. The suggested steps for plate operation are as follows:

Dr. James L. Hughes, M.D.

1. Chill bone plate, straining pliers and constraining fixture in crushed dry ice.

2. When the plate, pliers and fixture have reached the dry ice temperature, insert the two 3/8" diameter stretching lugs on the pliers into the bone plate.

3. Slowly (possibly by steps) elongate the straining cavity. Monitor the amount of strain by constantly checking the length of the plate. For example, the straining legs on the straining cavity are ~ 0.625 inch long. Therefore, a 4% strain would be $.04 \times .625 = .025$ inch. Check the unstrained (initial) length of the plate when cooled to dry ice temperature. This length plus the 0.025 inch would represent the length of a 4% strained plate. NOTE: DO NOT ATTEMPT TO STRAIN THE PLATE UNLESS IT IS AT A TEMPERATURE NEAR THE DRY ICE TEMPERATURE. The latter could result in permanent deformation and/or fracture of the wall of the straining cavity.

4. Once the plate is strained to the desired level the chilled constraining fixture is inserted and adjusted so that its lugs will prevent any contraction during the installation of the plate.

5. Following installation the screw in the constraining fixture is backed off allowing the plate to contract. This contraction should follow previous measurements as shown in Fig. 3, attached. The force of contraction against the screw at 37°C may be large enough that pliers or a wrench will be required to hold the side of the constraining fixture while the set screw is backed off allowing contraction of the bone plate.

It is suggested that the above steps be practiced on simulated bones, at room temperature, in order to master the manipulation of the Nitinol bone plate.

PLATE STRAINING VARIATION

In accordance with an indirect communication from Dr. S. Perren it was suggested that the straining cavity could be given a "bent" or "bowed out" memory configuration. This is shown in Fig. 4(B). Then on cooling to dry ice temperature the side walls of the bowed cavity could be bent back straight (see Fig. 4(C)). Warming to body temperature would cause the straight walls (Fig. 4(C)) to revert back to the bowed configuration (Fig. 4(B)). If the bone screws are fastened while the strain walls are maintained straight, then when bowing was allowed to occur the fracture interface would be loaded.

While this scheme appears to be a suitable alternative to tensile straining there may be certain drawbacks. These are:

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1. The recovery force, from a bending mode, may be quite low.
2. Considerable bowing is required to derive much axial contraction. Further, this bowing is somewhat limited by the maximum outer fiber straining that can completely recover.
3. Considerable care must be exercised in the bowing operation. This probably should be done in the 550° to 650°C range. This is a temperature range of larger plasticity. Some early experiments to deform (bow) a bone plate at room temperature, when the TTR was -52°C to -18°C, resulted in early low strain fracture. This can be seen by observing the small experimental plate attached.
4. If bowing the side walls is to be attempted, in addition to the 550° to 650°C temperature, special plate holding fixtures and heated spreading mandrel will probably be needed in order to symmetrically accomplish the task.
5. Assuming now that a suitable bowed memory configuration is obtained then it would require certain specific steps to deploy this plate. These are:
 - a. Chill the plate, suitable pliers and the constraining fixture in dry ice.
 - b. Bend bowed strain cavity walls straight--probably with pliers.
 - c. Insert constraining fixture and adjust to prevent bowing on heating.
 - d. Fasten plate to fractured bone sections.
 - e. Back off on set screw in the constraining fixture allowing the walls to bow and load the fracture interface.

Additional questions will probably arise in the use of these plates. However, the above writeup should serve to address and answer many of the obvious questions.

Sincerely yours,

William J. Buehler
WILLIAM J. BUEHLER
Magnetism & Metallurgy Division

FIG 1



A

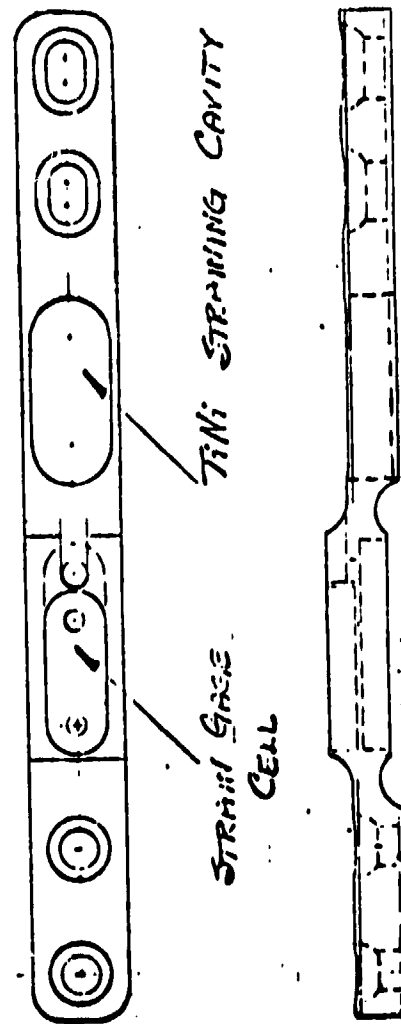


B



C

FIG. 2



SOLID TiNi BONE
PLATE WITH STRAIN
GAGE CELL

SCALE 1:1



FIG. 3 Percent Recovery After Axial Straining
 a Co-Modified Nitinol Bone Plate (TTC:
 -52°C to -18°C), Restraining Recovery
 (37°C), Chilling to -78°C , Removing
 Restraint and Reheating to 37°C .

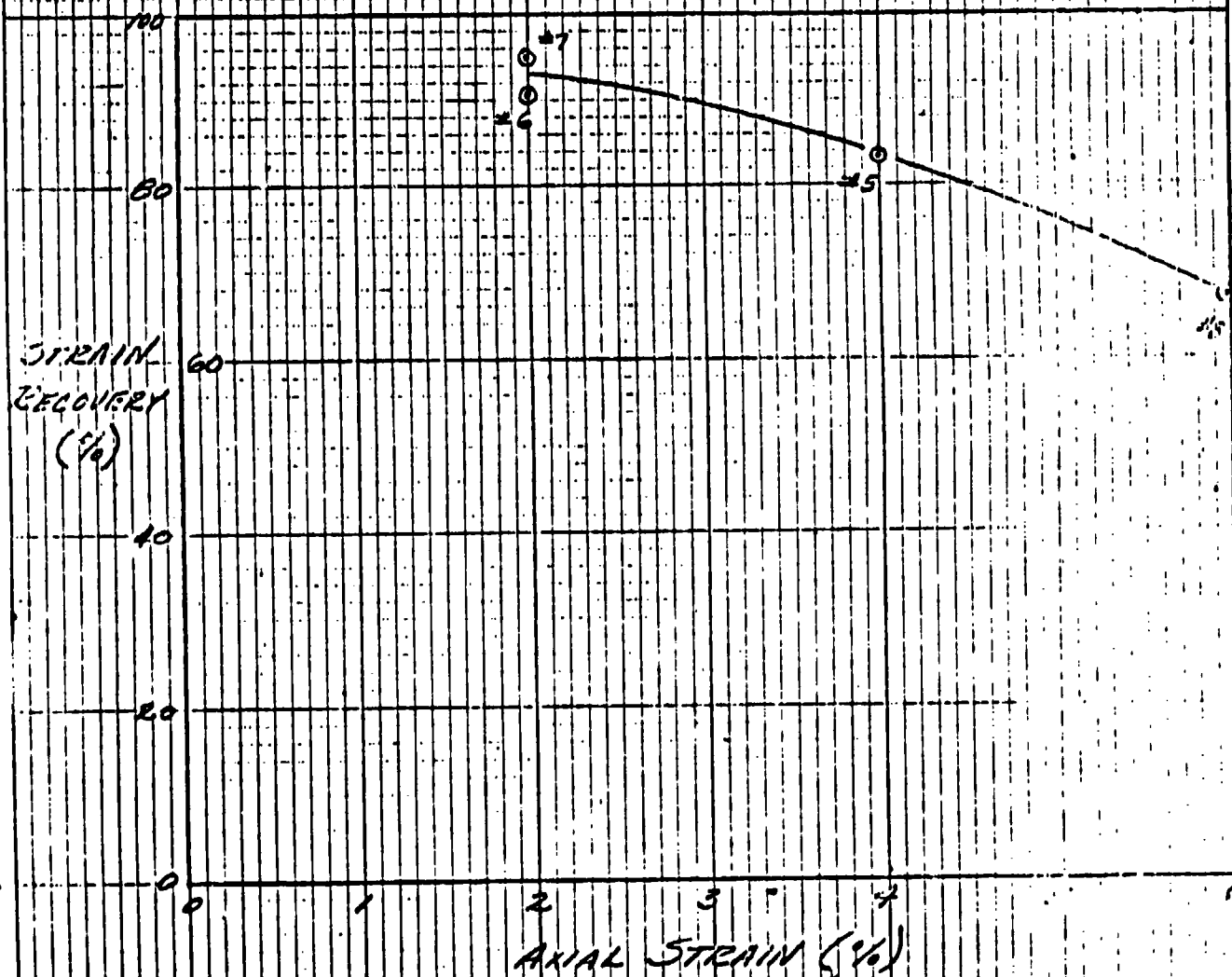
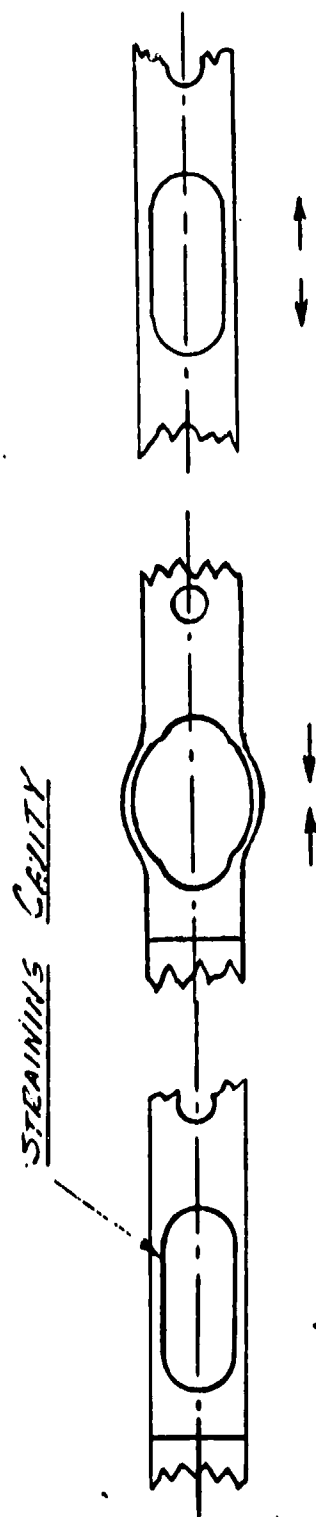


FIG. 4



A - As Formed

B - MENDEL CONFIGURATION

C - COOLED & STRAIGHTENED

Added Notes on the Bone Plate Design

The attached drawing is the design consensus of John Tydings and myself. Initially we are discounting the Nitinol section joined (probably by hammer swaging) to a titanium-base alloy to form the end sections of the plate. In the overall view, the harder machining of Nitinol may be more than outweighed by mechanical joining problems, sterilization, etc. In addition to the mechanical drawing, I have also made a three-dimensional sketch showing more realistically the proposed plate.

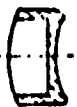
Observing the drawing(s) (Figure 1 and/or 2) it can be seen how we plan to chill and stretch the "TiNi Straining Cavity." The locking wedge will have a taper that will not allow it to "back out" under the contracting load of the warming bone plate. If this should be a problem then we have alternative schemes that can be used and are almost equally as simple. Further, if the wedge technique works, wedges of varying thickness can be employed to provide variable initial strain, e.g., 2%, 4%, 6% etc.

The design of the bone plate is based upon its use as shown schematically in Figure 3 (A-D). The section called the "TiNi Straining Cavity" would be chilled and strained below the MTR of the alloy (Figure 3-B). Recovery would be constrained during installation and warming, by the use of the locking wedge. This is shown schematically in Figure 3-C. Then the wedge could be carefully ejected allowing contraction and loading of the fracture (Figure 3-D). The graph given in Figure 3 shows the extent of recovery when one first constrains recovery and then removes the constraint and allows free recovery.

PROPOSED NITINOL BONE PLATE

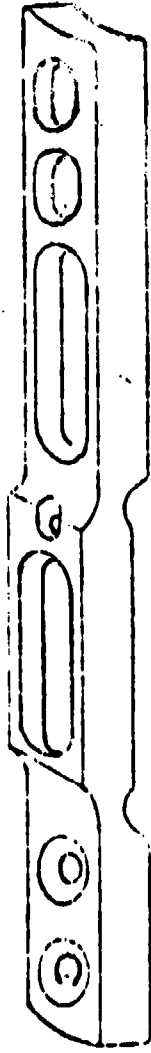


A-A

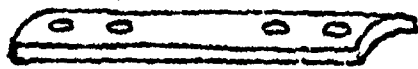


B-B

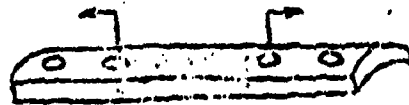
100A



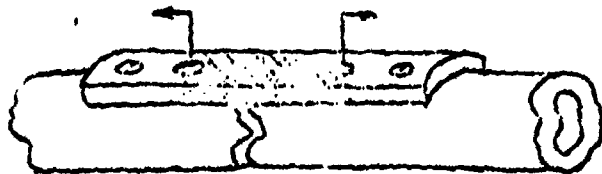
100B



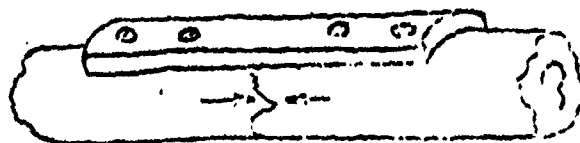
(A)



(B)



(C)



(D)

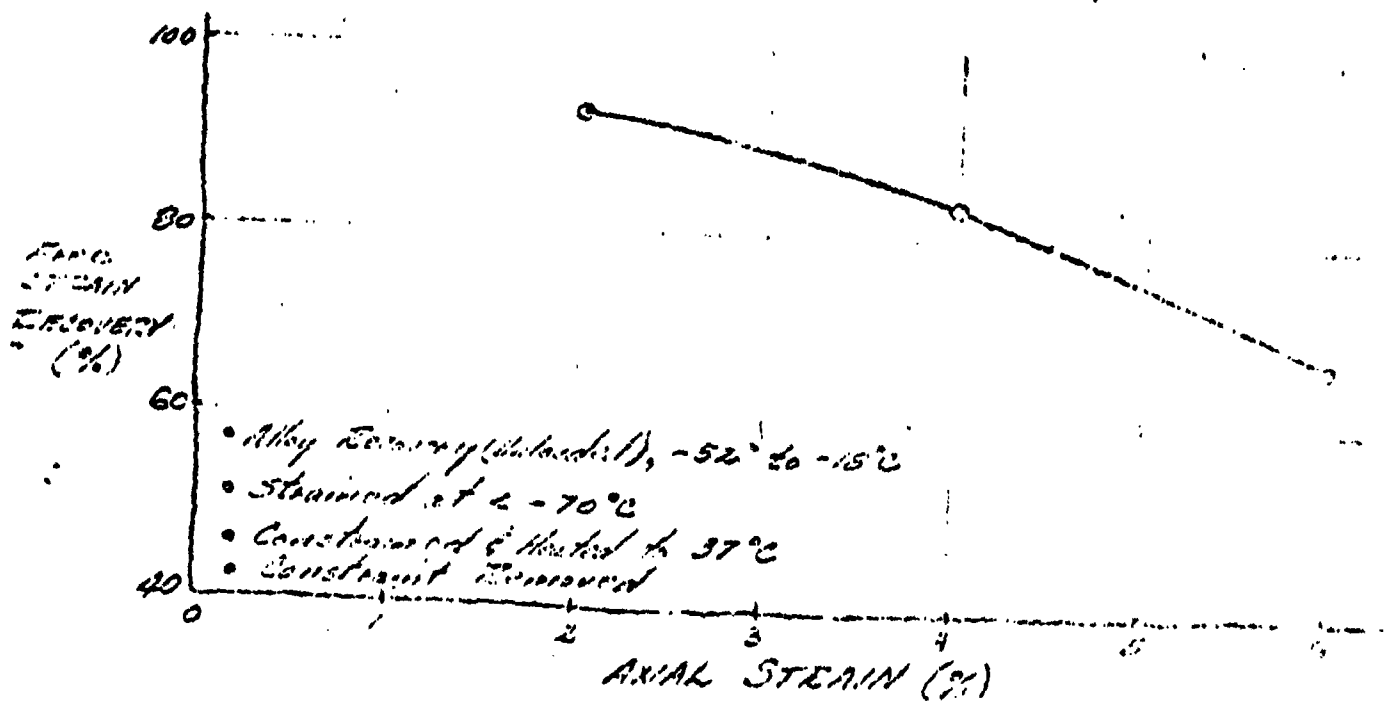


Fig. 4

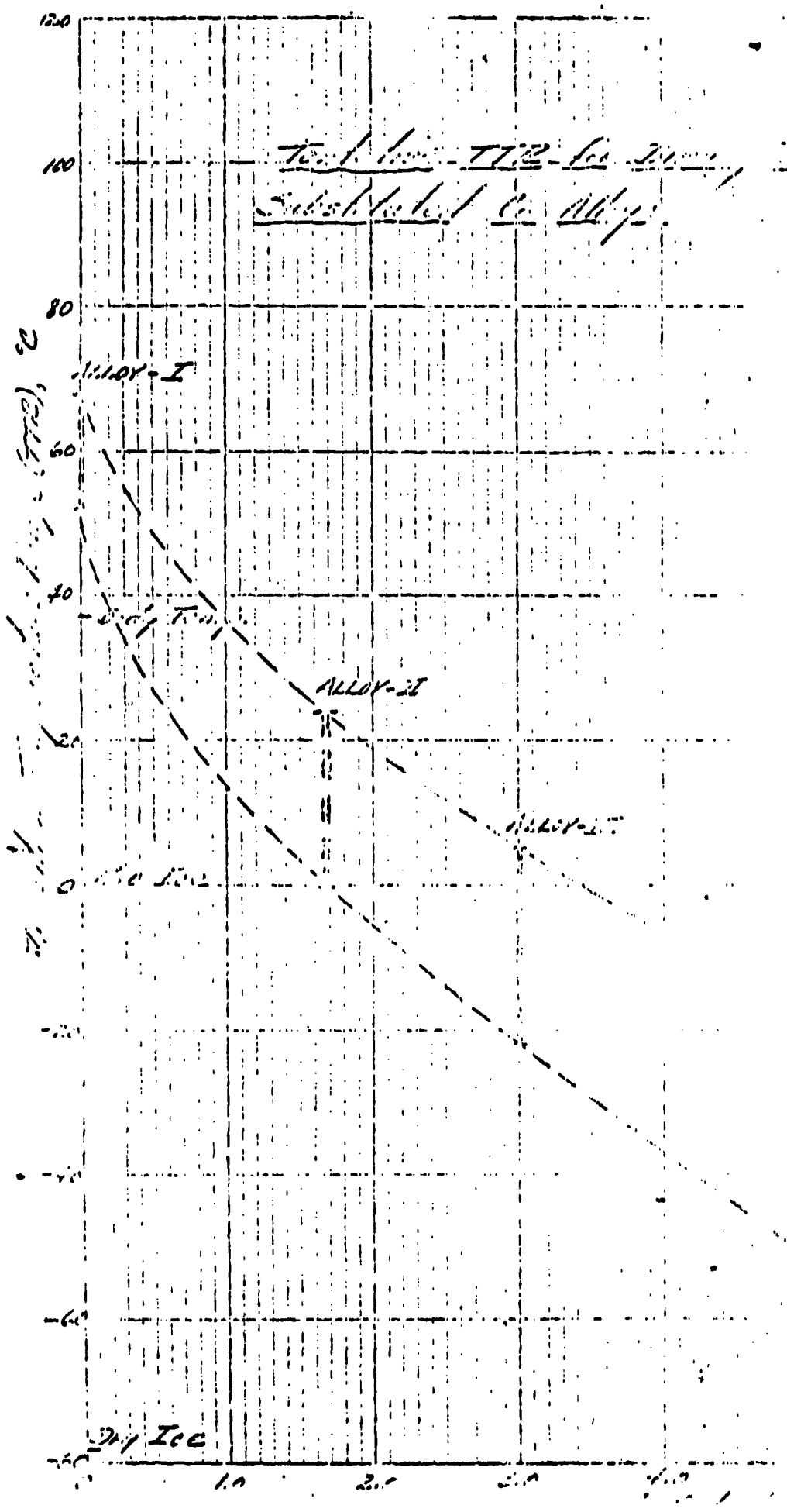
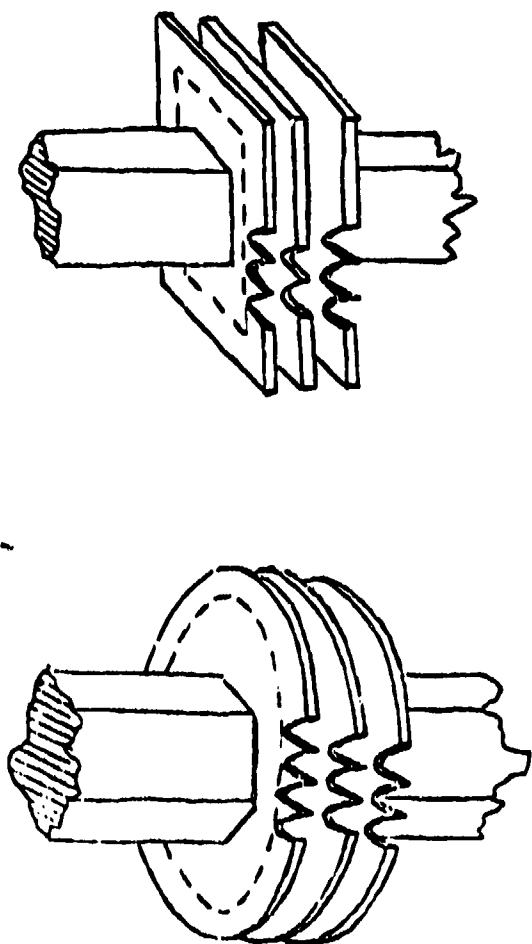


FIG. 1



Top View

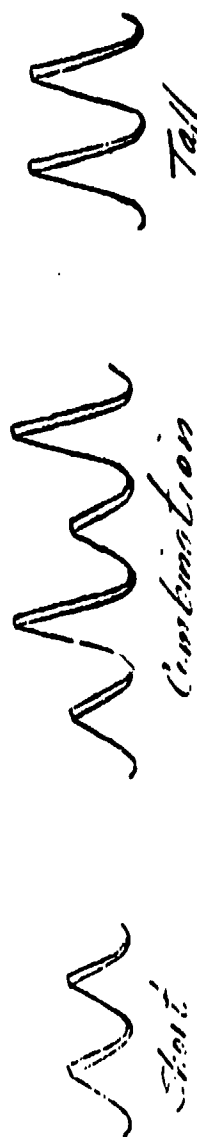


FIG. 2

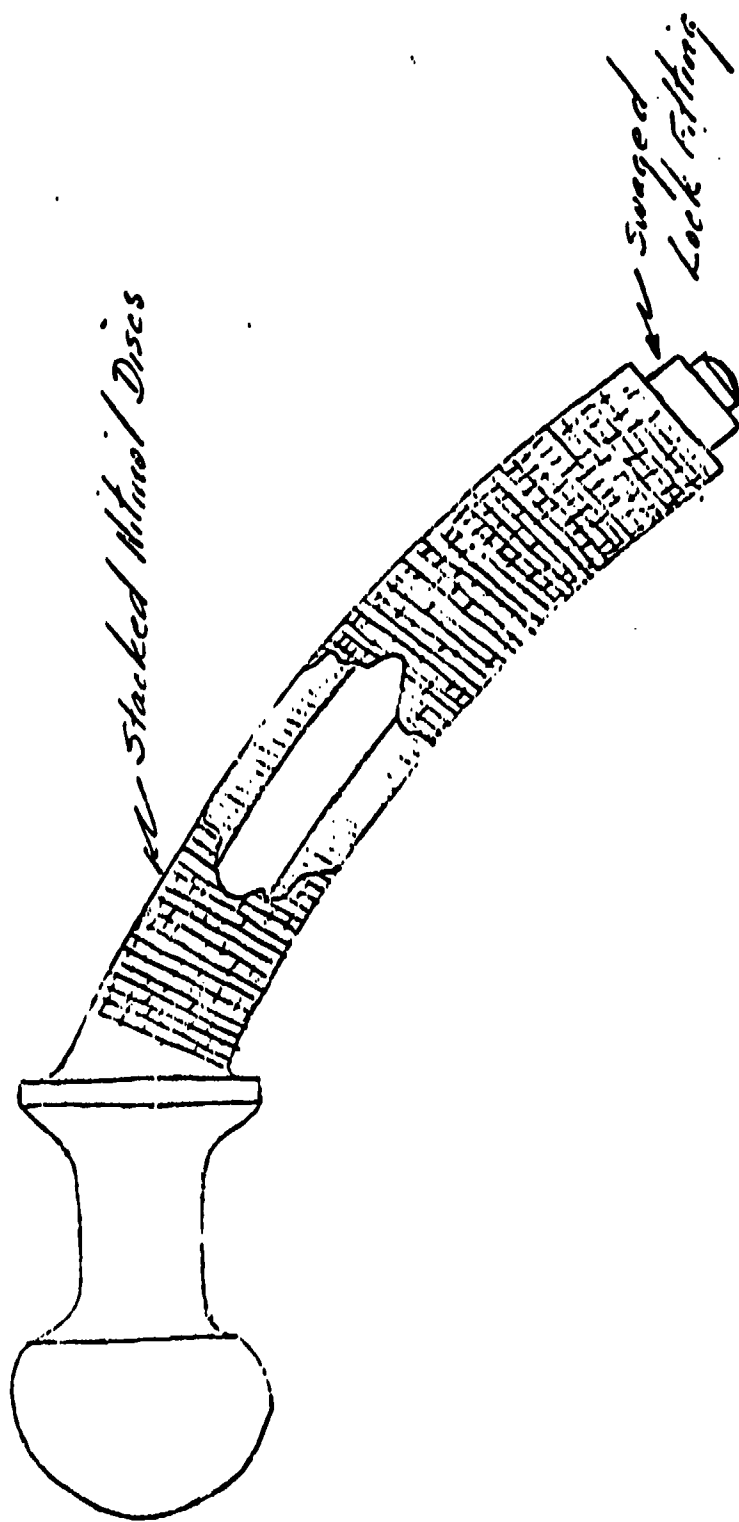


FIG. 3

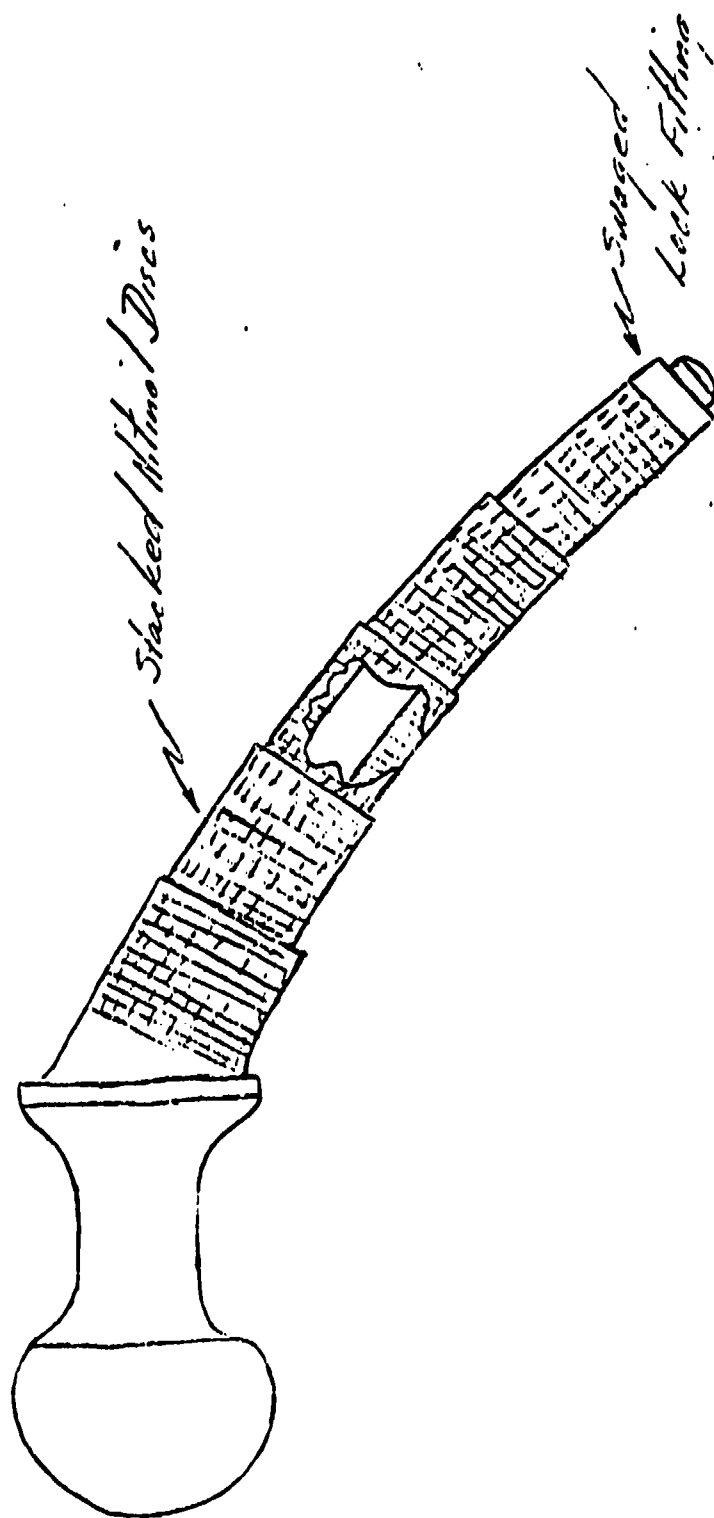


FIG. 4

Bone Cavity Preparation

1. Insert curved drift pin into soft bone
2. Drive out cavity using progressively larger cutters which follow curved drift pin

Options:

- a. Flexible broach may be used to cut a shaped cavity (e.g., square, hexagonal, etc.). Broach would be guided by a curved drift pin and powered by low cycle vibrator.
- b. Use flexible broach to cut a square-to-round tapered cavity.
- c. Use flexible broach to cut keyway(s) to prevent twisting of the metallic pin.

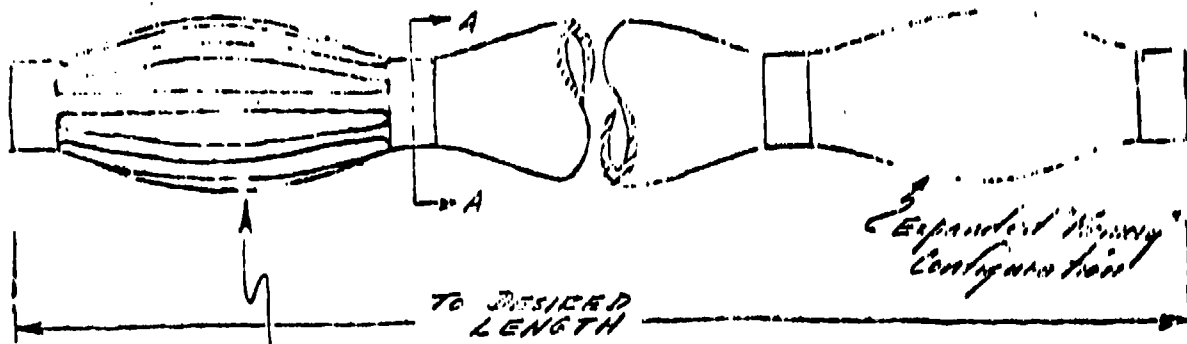
Active Nitinol Pin

1. Prepare a structure which is composed of stacked nitinol sheet discs. See Figures 1, 2, 3 and 4 attached.
2. Deform teeth upward after shifting structure below TTR of Nitinol.
3. Insert pin quickly into prepared cavity.
4. On warming to body temperature teeth

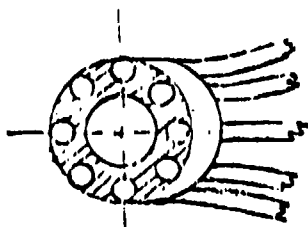
will deploy radially outward and dig into wall of bone cavity. An interference fit is provided by making the bare bone cavity smaller than the deployed nitinol disc.

Advantages

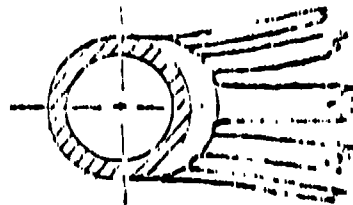
1. Use of standard orthodontic type pins adapted to accept "active" nitinol elements
2. Fine teeth will promote structure for ingrowth of tissue.
3. No plastic required
4. Maximum nitinol recovery performance associated with the highly uniaxial stress material.
5. Mechanism costs associated with nitinol will be minimized.



6 1/2 strain & bend radii of 1 inch
for 0.094 inch diameter wire

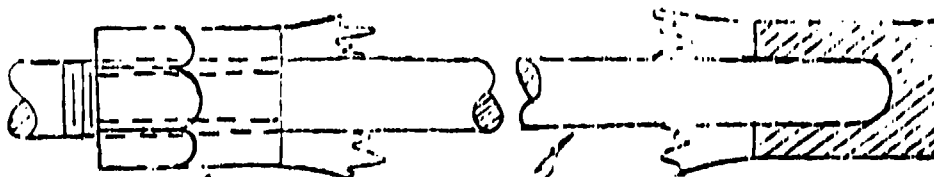


Nitinol Wire & Stainless
Steel Rings



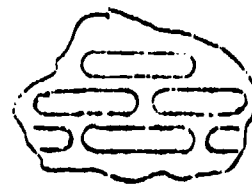
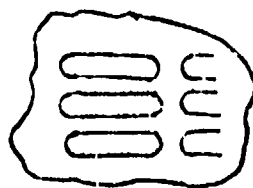
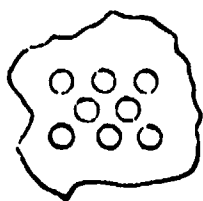
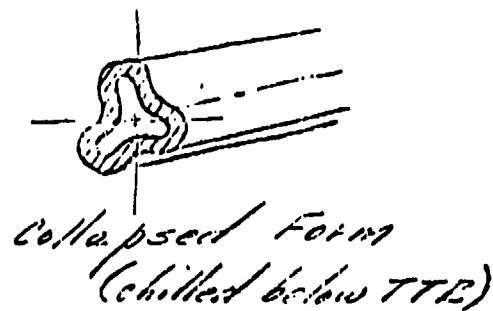
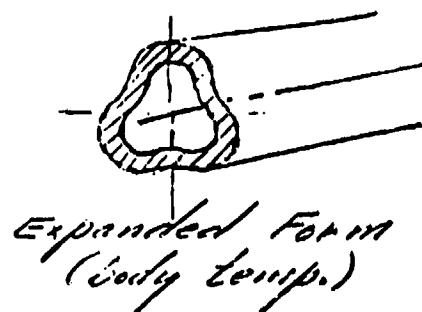
Nitinol Tubular
Construction

SECTION A-A



End Pieces Either
Stainless Steel or Nitinol
Depending upon Design Above

INTRAMEDULLARY ROD

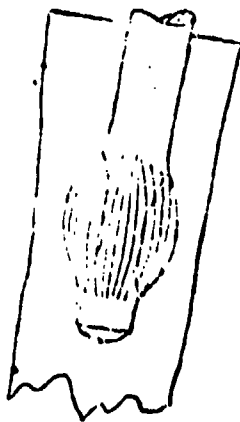
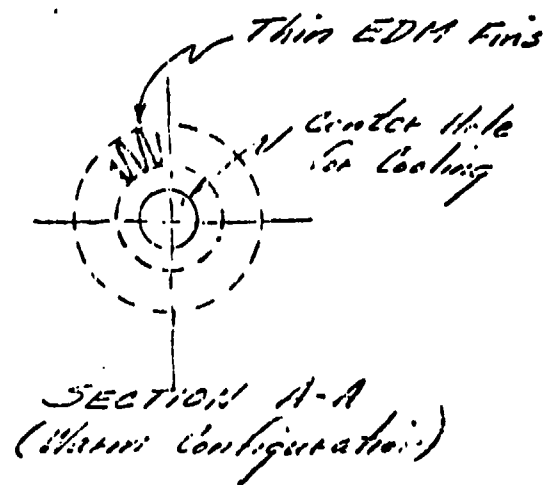
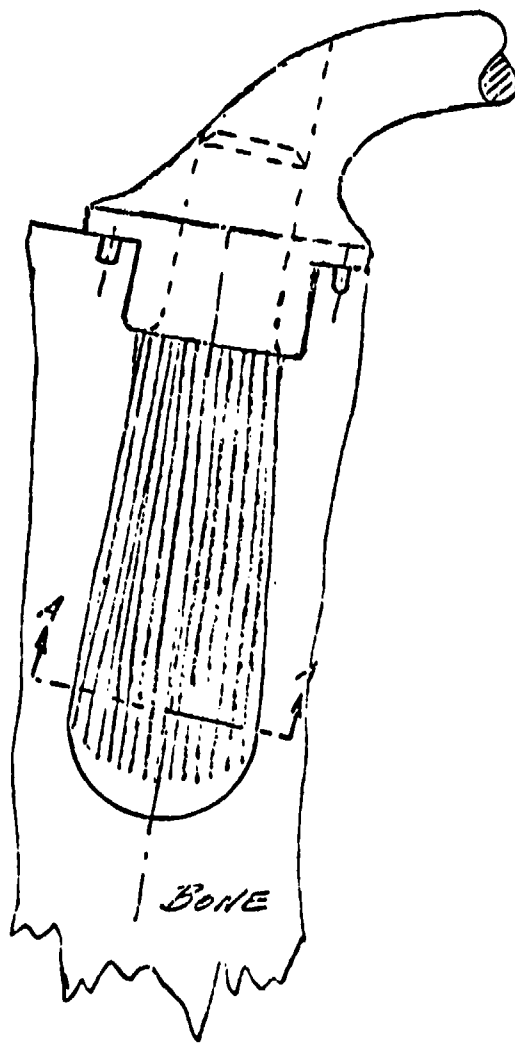


Possible Variations in Density

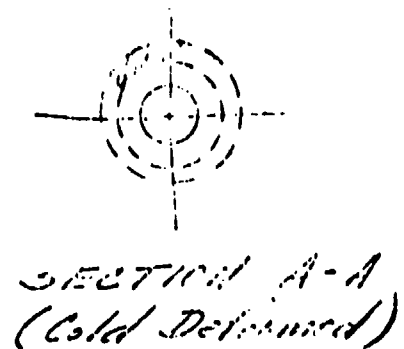
Constructive Details:-

- Tube, if porous, would be punched from sheet
- Next, roll into tubular form
- Electron beam weld (if needed)
- Hot-form to "expanded form" shape

INTRAMEDULLARY ROD



Shape
Variation



INVERTED-TAPER HIP PROSTHESIS

Table I

NITINOL Alloy Compositions Chosen for Experimental Studies*

<u>Alloy No.</u>	<u>Charge Composition</u>	<u>Approximate Heat Recovery range (°C)⁺</u>
I	TiNi	52 to 68
II	Ti _{.5} Ni _{.483} Co _{.017}	0 to 24
III	Ti _{.5} Ni _{.47} Co _{.03}	-22 to 5
IV	Ti _{.5} Ni _{.45} Co _{.05}	-52 to -18
V	Ti _{.5} Ni _{.43} Co _{.07}	-80 to -40

*Charge Materials were: Ti, commercial purity sponge
Ni, Mond carbonyl nickel
Co, High purity grade (MRC)

+Based upon bending wrought sheet specimens below transition range followed by heating to induce recovery under no load.

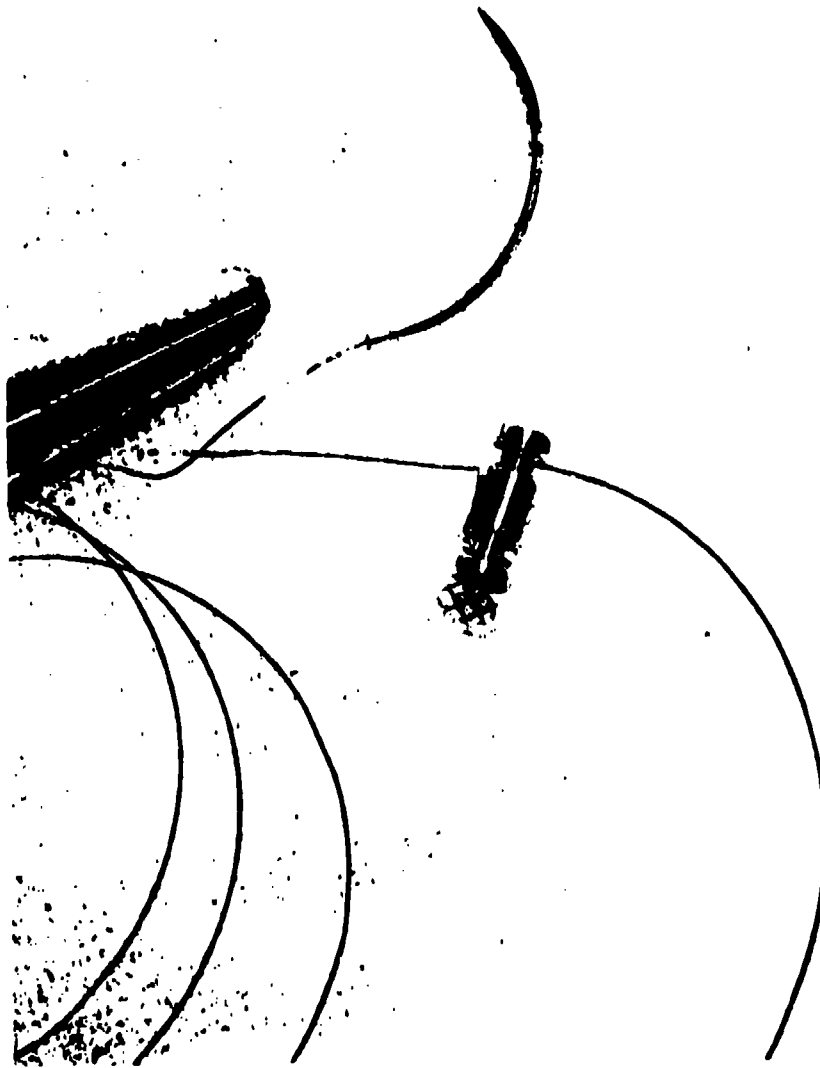
Table II

Summary of the Arc-Melted Alloys Produced and Their Ultimate Use

<u>Alloy No.*</u>	<u>Arc-Melted Buttons-150gr.</u>	<u>Arc-Melted Bars (150gr), Bars (450gr)</u>	<u>Hot Wrought Shape</u>	<u>Component Produced</u>
I	2	2 (150gr)	Hot swaged (dia) 13mm, 4.5 mm	● filings ● implant specimens ● washers (4)
II	2	2 (150gr)	hot swaged (dia) 13mm, 4.5mm	● filings ● implant specimens ● washers (4)
III	2	2 (150gr)	hot swaged (dia) 13mm, 4.5mm	● filings ● implant specimens ● washers (4)
IV	2	2 (150gr)	hot swaged (dia) 13mm, 4.5mm	● filings ● implant specimens ● washers (4)
V	2	2 (150gr)	hot swaged (dia) 13mm 4.5mm	● filings ● implant specimens ● washers (4)
V	12	4 (450gr)	hot rolled into plate 9.6mm thick	● contracting bone plates (8)

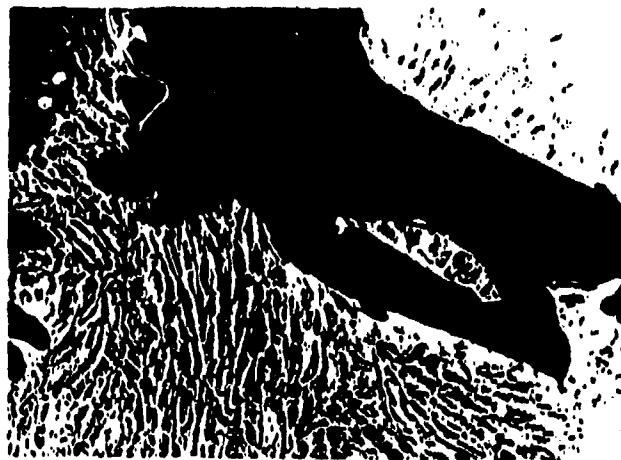
*See Table I for information on the compositions and heat recovery ranges of the five alloys listed.

FIGURE 1
NITINOL IMPLANT SPECIMEN





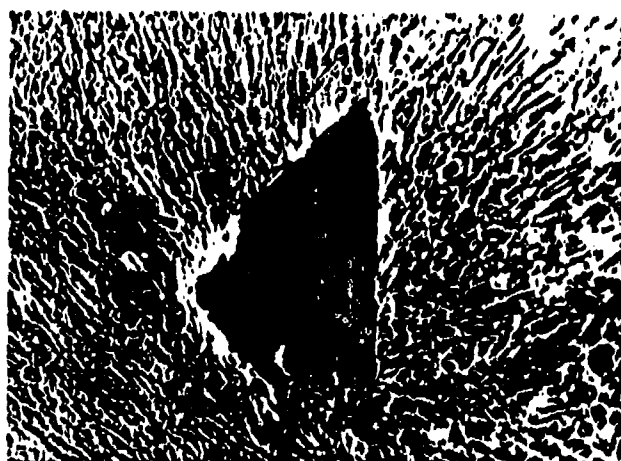
ALLOY IV
DAY 5



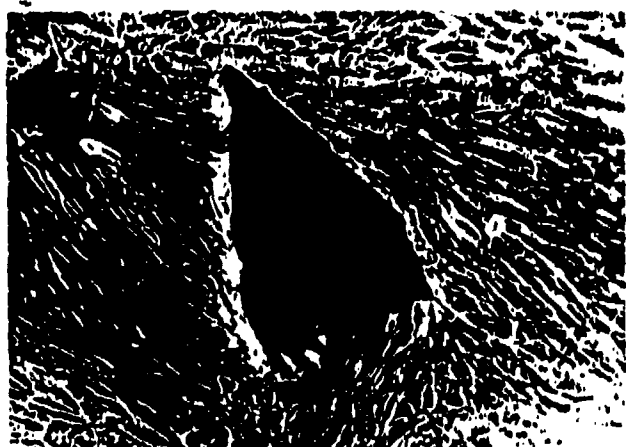
ALLOY IV
DAY 7



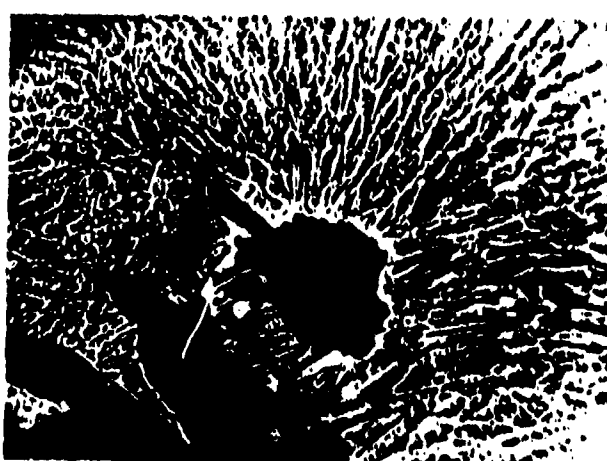
ALLOY I
DAY 9



ALLOY I
DAY 11



ALLOY V
DAY 13



ALLOY V
DAY 15

FIGURE 2a

LEIGHTON TUBE SLIDES IN THE PRESENCE OF NITINOL POWDER

Lab. 12: 304



DAY 10

DAY 10

DAY 11

DAY 11

DAY 12



DAY 13

DAY 13

DAY 14

DAY 15

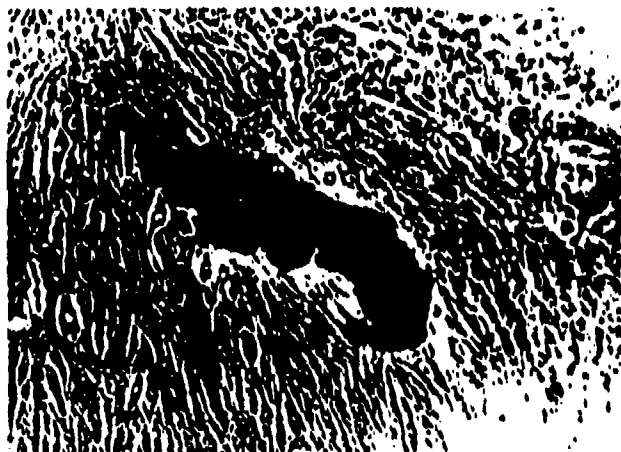
STAINLESS STEEL

TITANIUM

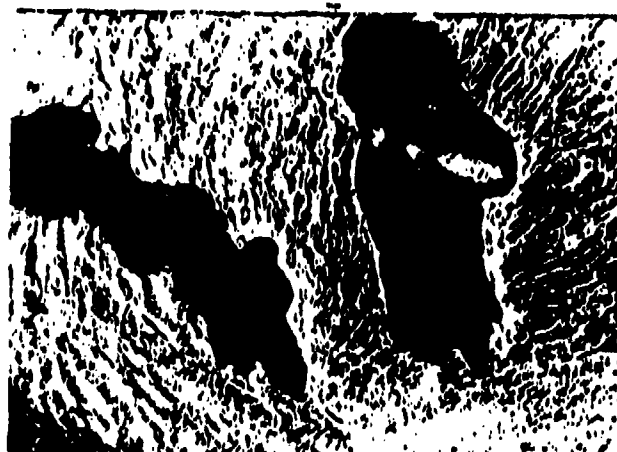
FIGURE 2b

LEIGHTON SLIDE TISSUE CONTROLS

Slide No.	Section	Staining	Examination	Remarks
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
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39				
40				
41				
42				
43				
44				
45				
46				
47				
48				
49				
50				



TITANIUM
DAY 17



TITANIUM
DAY 20



STAINLESS STEEL
DAY 21

FIGURE 2b (cont.)

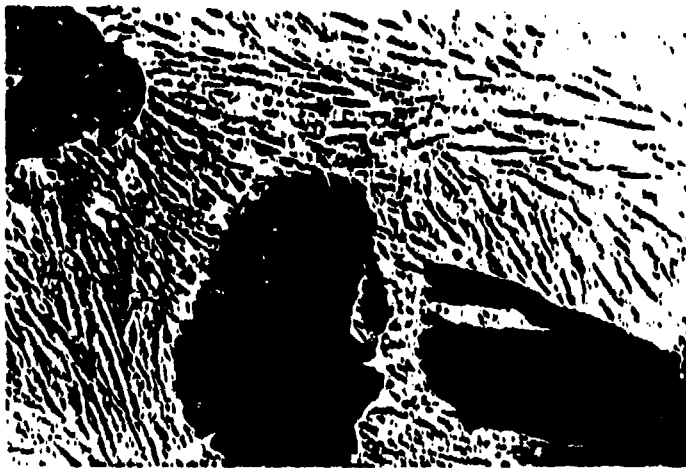
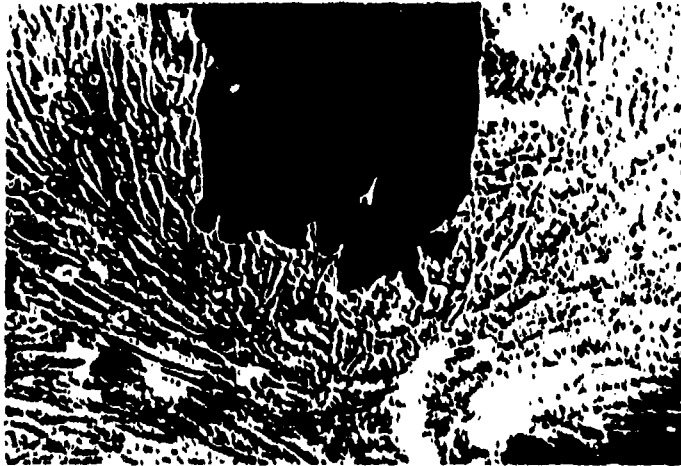


FIGURE 2c
COMPARISON OF TISSUE CULTURE
SLIDES AT 20 DAYS

ALLOY IV
DAY 20



ALLOY V
DAY 20



STAINLESS STEEL
DAY 20



TITANIUM
DAY 20



ALLOY 1
DAY 20

1001

1001

1001

1001

1001

FIGURE 3

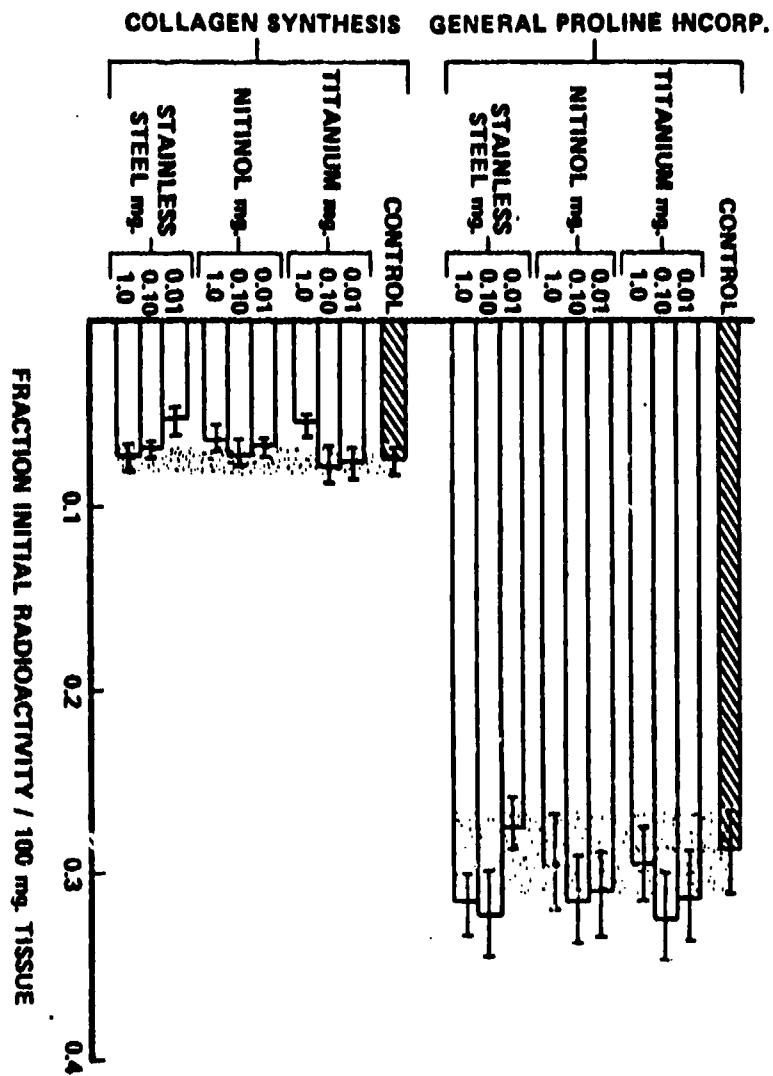


FIGURE 4a

INSERTION OF IMPLANT SPECIMEN IN MOUSE

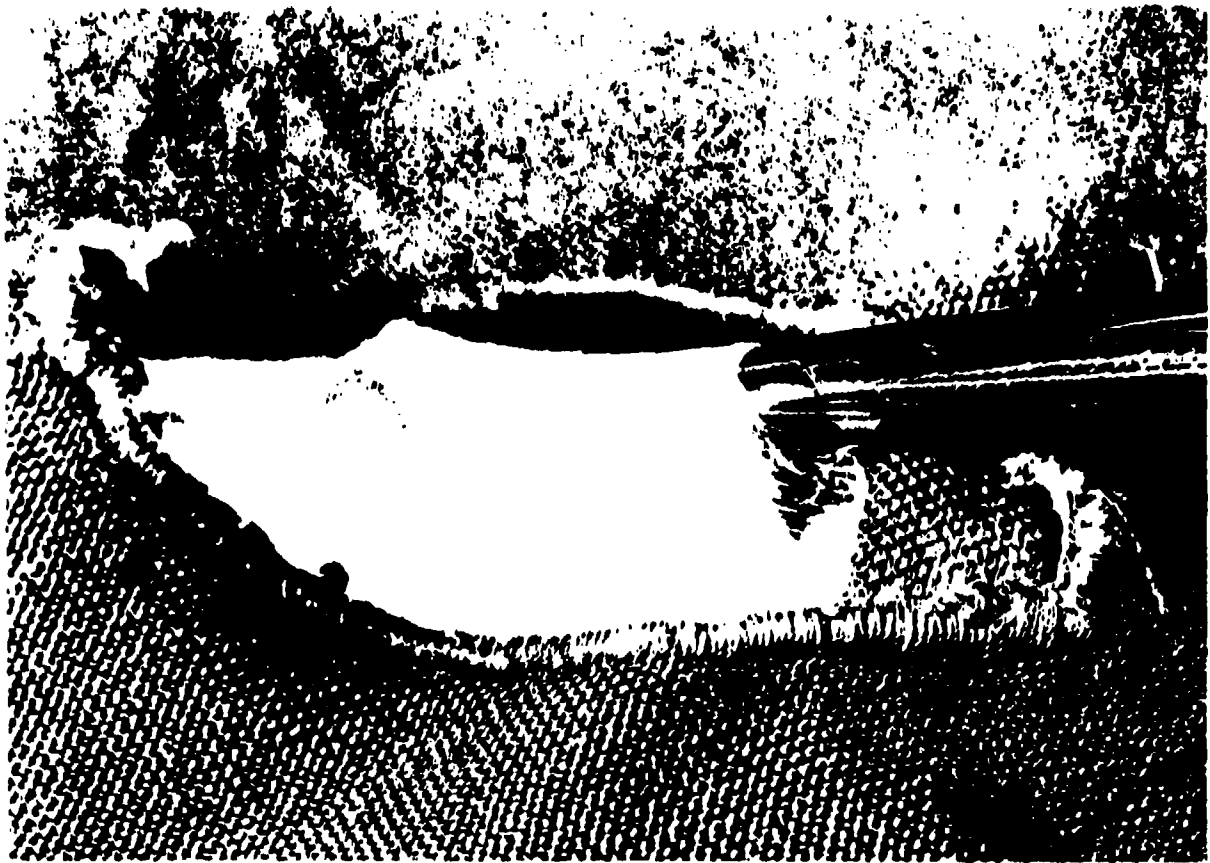


FIGURE 4b

IMPLANT SPECIMEN IN PLACE ABOVE THE SCAPULAR AREA



FIGURE 4c
IMPLANT SPECIMENT EMBEDDED IN TISSUE



FIGURE 5

PREPARATION OF TISSUE SECTIONS FOLLOWING REMOVAL OF IMPLANT SPECIMEN
NINE WEEKS POST-SURGERY

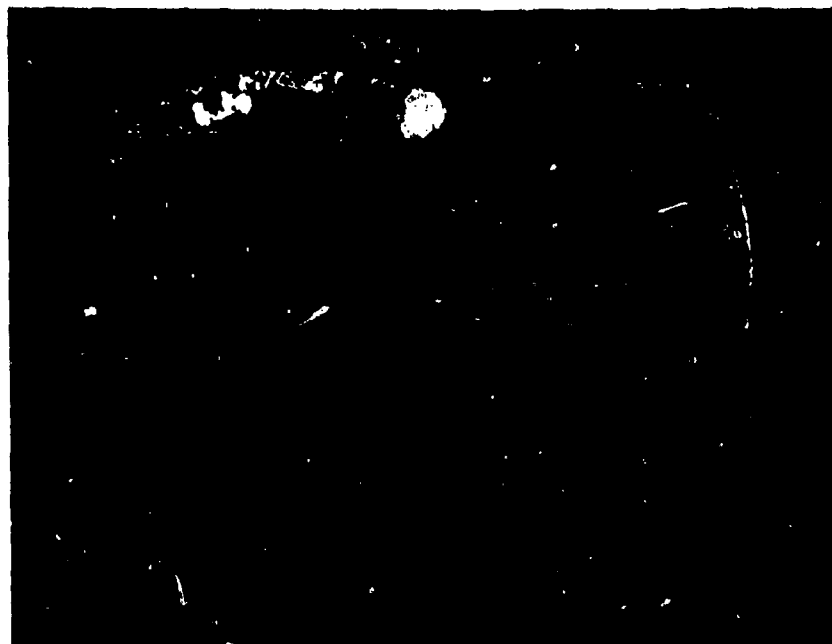


FIGURE 5a

TISSUE AND IMPLANT EMBEDDED IN METHYMETHACRYLATE

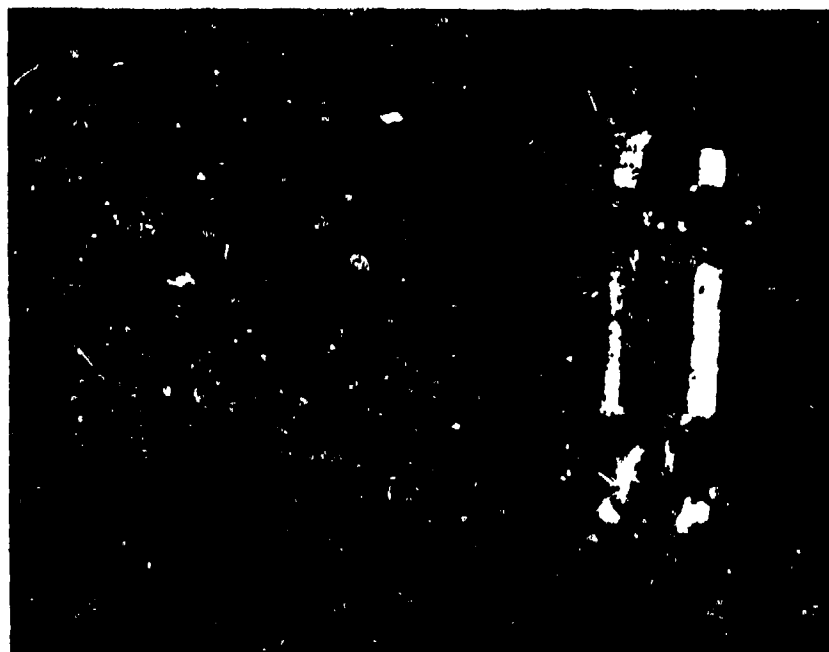


FIGURE 5b

REMOVAL OF IMPLANT FROM TISSUE BLOCK



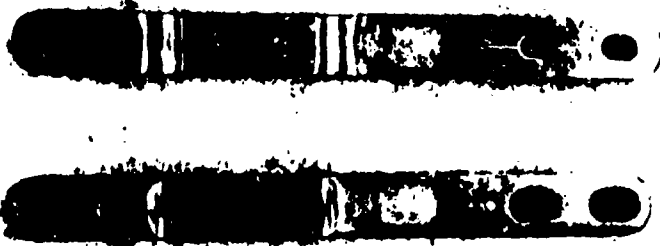
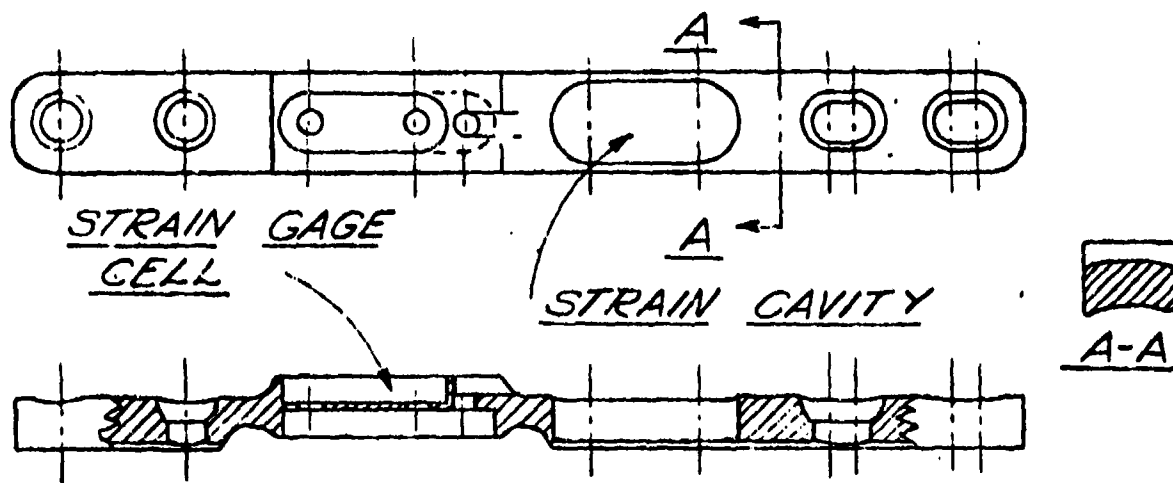
FIGURE 5c
TISSUE SECTIONING



FIGURE 5d
NORMAL TISSUE SURROUNDING IMPLANT

FIGURE 6

NITINOL PLATE WITH STRAIN GAUGE CELL



NITINOL bone
plate with both a
"strain gauge cell,"
a "strain cavity,"
and slotted screw
holes on one end
for adjustment. Drawing
above shows
major details. Bone
plate length ~12.9
cm. Photographs
at left show two
finished commercial
bone plates.

FIGURE 7



FIGURE 7a
PLATE APPLICATION

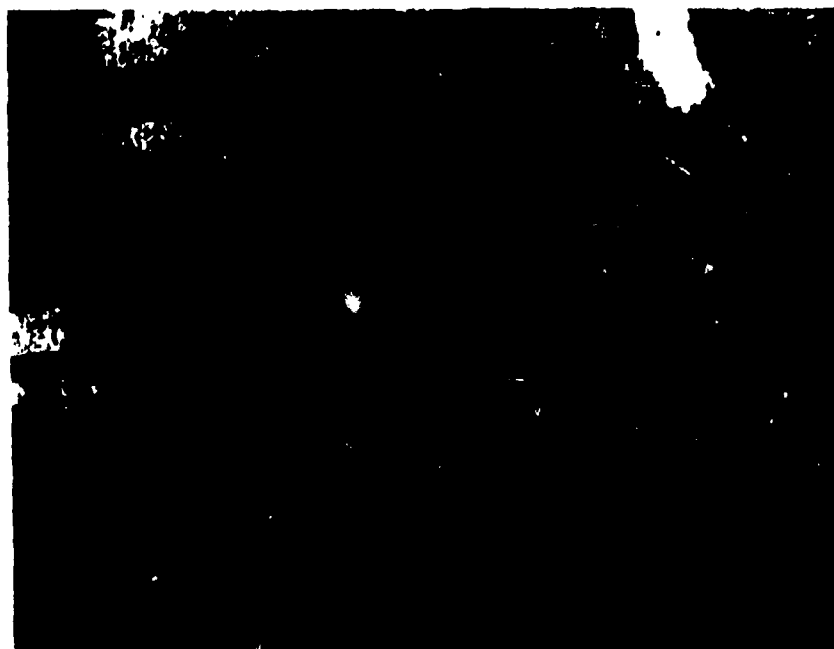


FIGURE 7b
PLATE IN PLACE ON SHEEP FEMUR

FIGURE 8

MEASUREMENTS OF THE STRAIN GAUGE CELLS TAKEN AT WEEKLY INTERVALS

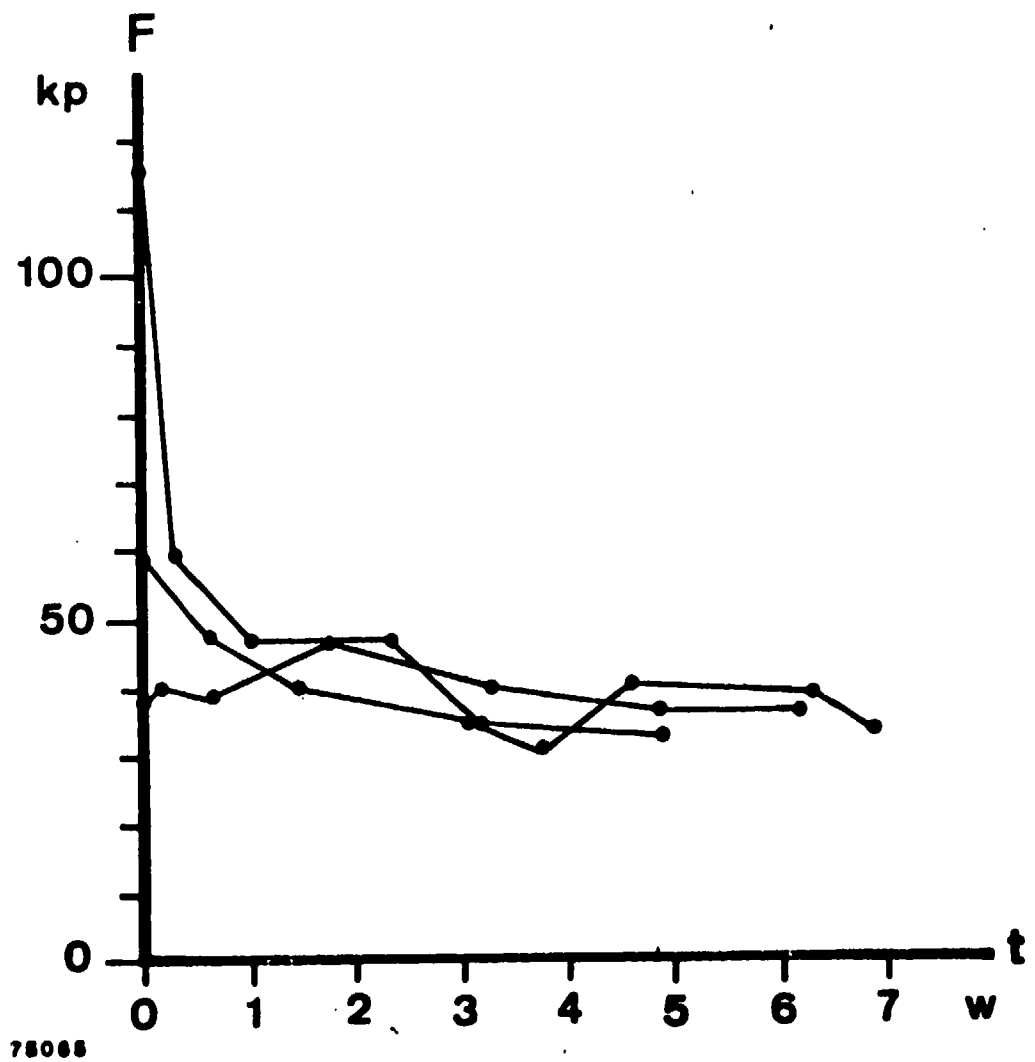


FIGURE 9
NITINOL PLATES ON SHEEP FEMORA

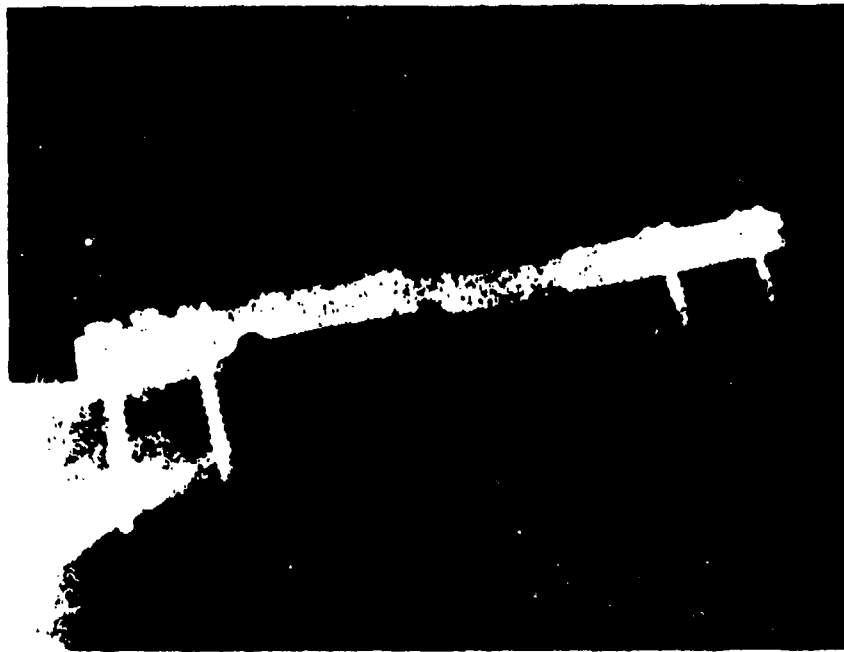


FIGURE 9a

EARLY RADIOGRAPH FOLLOWING PLATE APPLICATION

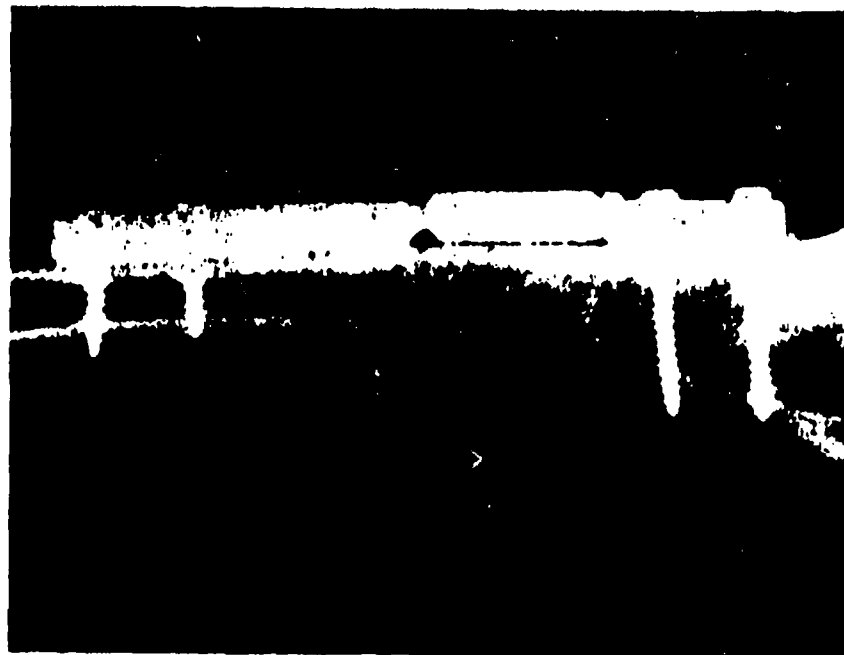


FIGURE 9b

LATER RADIOGRAPH REVEALING EARLY BONE FORMATION

FIGURE 10a

NORMAL BONE FORMATION AT THE EDGE OF THE PLATE



FIGURE 10b

EDGE OF BONE AFTER REMOVAL OF NITINOL PLATE
BONE IS ALIVE AND NORMAL

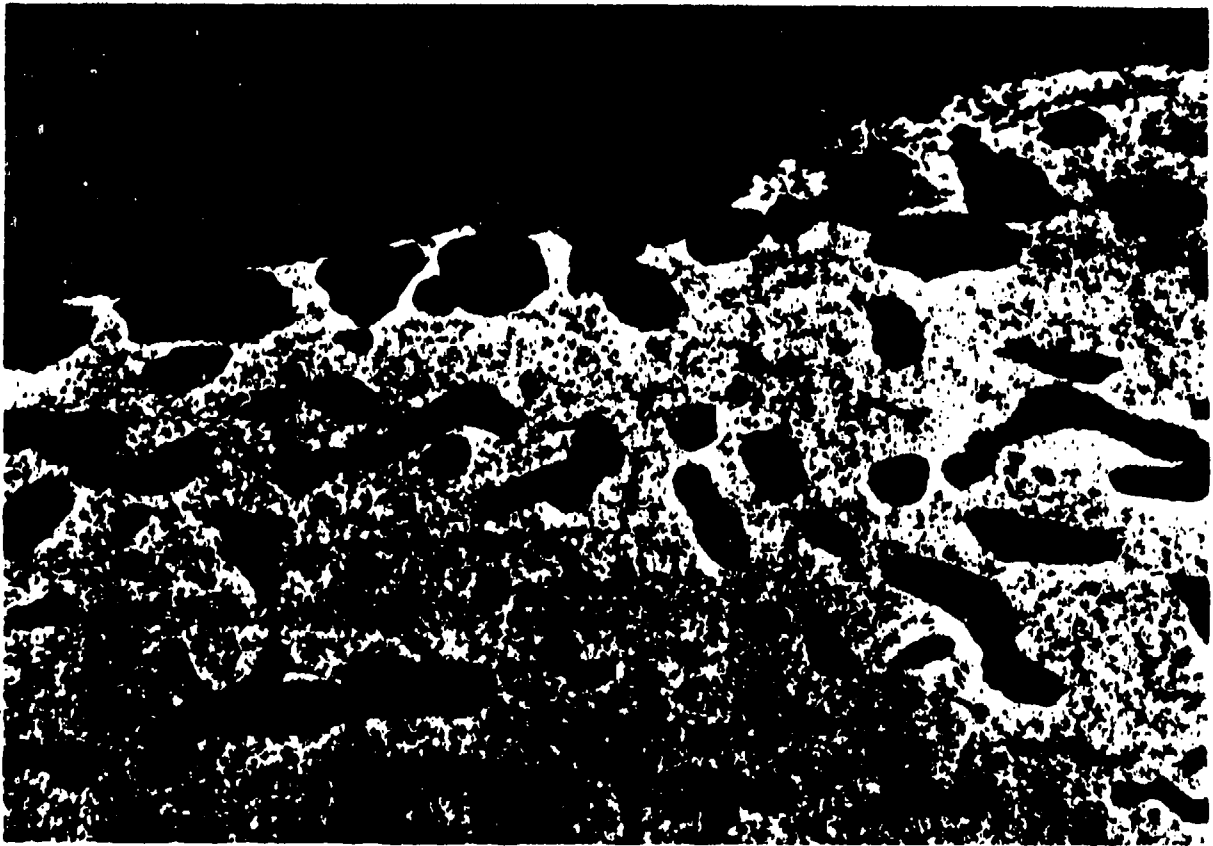


FIGURE 11
PLATE FRACTURED AFTER STRESS



FIGURE 12

INITIAL MEASUREMENT OF FORCE TAKEN WITH THE PLATE IN PLACE
ON SHEEP FEMORA

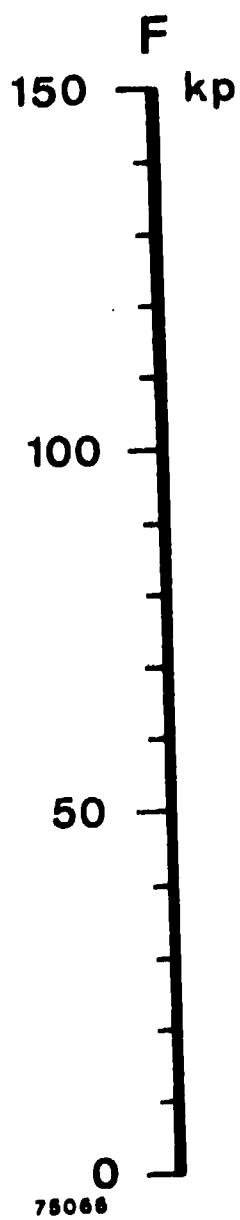


FIGURE 13

PROTOTYPES OF HIP PROSTHESIS AND INTRAMEDULLARY ROD



FIGURE 14

NITINOL HIP PROSTHESIS WITH SELF-DEPLOYING TABS



FIGURE 15

HIP PROSTHESIS IN PLACE IN SHEEP FEMUR



FIGURE 16

NITINOL INTRAMEDULLARY ROD



FIGURE 17
INTRAMEDULLARY ROD IN CADAVER FEMUR

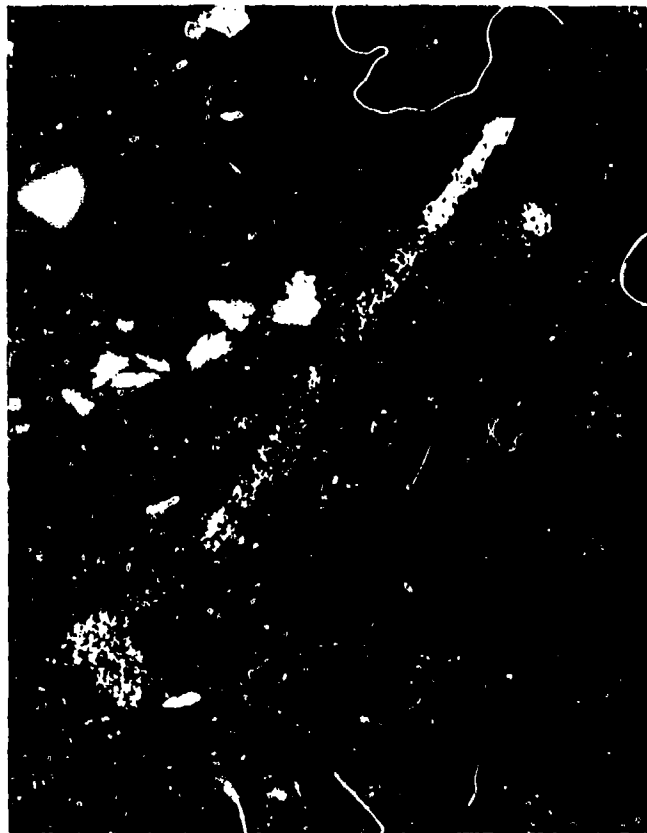


FIGURE 17a
DEPLOYED POSITION

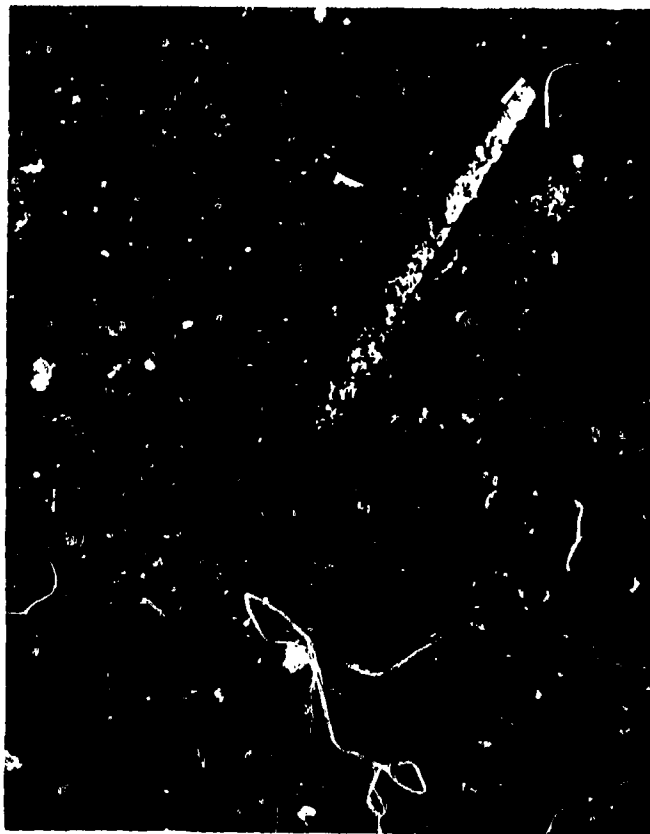


FIGURE 17b
NON-DEPLOYED POSITION

FIGURE 18

NITINOL WASHERS WITH ALTERNATING SCREWS OF STAINLESS STEEL
AND TITANIUM

