

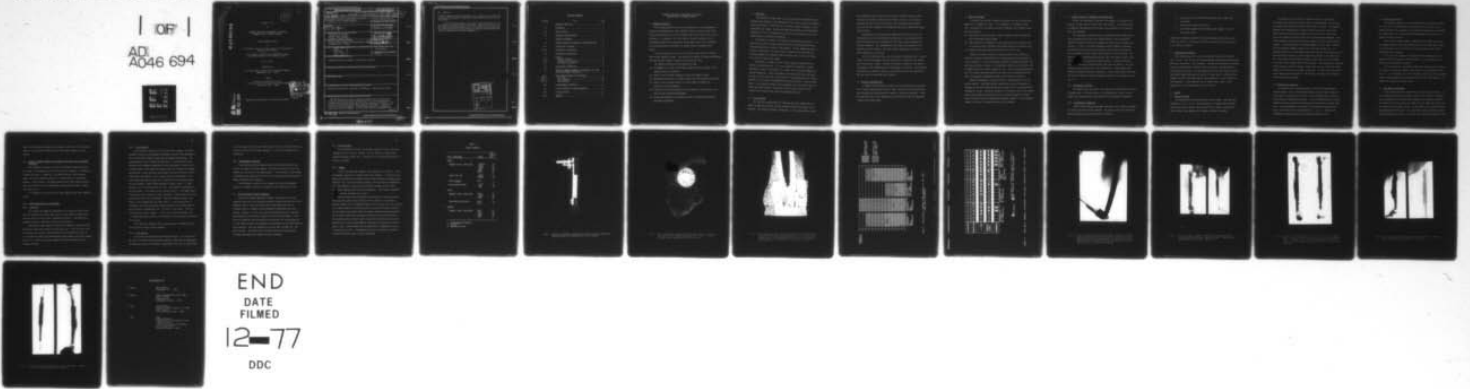
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ILLINOIS UNIV AT CHICAGO CIRCLE
INTERNAL PROSTHETIC REPLACEMENT OF SKELETAL SEGMENTS LOST IN CO--ETC(U)
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on

INTERNAL PROSTHETIC REPLACEMENT OF SKELETAL
SEGMENTS LOST IN COMBAT INJURIES

Annual Summary Report

by

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residual fragments and the prosthesis into a single unit of calcified tissue which is capable of load bearing and function for the life of the patient.

It has been demonstrated in the model that these objectives can be attained by proper design of prosthesis, combined with the use of bone grafting and proper compression. With proper clinical procedure the porous prosthesis becomes invested by growing calcified bone and union is achieved with the bone fragments.

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INTERNAL PROSTHETIC REPLACEMENT OF SKELETAL
SEGMENTS LOST IN COMBAT INJURIES

I. TECHNICAL OBJECTIVE

The continuing objective of this investigation is the development of artificial replacements for large segments of bone or bones and the intervening joints which are lost due to trauma such as that which occurs in war casualties. In addition, it is felt that a civilian by-product of this investigation would be an application of the same system to the reconstruction following massive resections for certain types of malignant bone tumors.

The basic principle is the use of a special porous metallic material which allows ingrowth of bone. This permits the implant to become incorporated into the patients skeletal structure with functional union.

The specific objectives of the program include:

- (a) Development of a series of biological models that are relevant to the eventual clinical situations.
- (b) Study of the biological response of local and remote tissues.
- (c) Evaluation of the bone in intimate contact with the prosthetic materials.
- (d) Study of the long-term toxicity in animal models including the possibility of carcinogenesis.
- (e) Evaluation of specific properties of the materials used from the viewpoint of their long-term performance.
- (f) Design and evaluation of prosthetic devices including design studies for human implantation.

II. HYPOTHESIS

The prosthesis designs make use of a porous material manufactured by molding short lengths of fine titanium wire into precise shapes and bonding the wires (fibers) to each other by a sintering thermal treatment at high temperatures in vacuum. We have developed and perfected the manufacturing techniques in our own laboratories such that the technology may be transferred readily to industrial production.

The product is unique in its physical and mechanical properties. It possesses about 50% by volume of pores which are interconnecting and have inscribed diameters in excess of 100 microns. We have demonstrated over a period of eight years in a wide variety of animal models that bone and vascular elements will rapidly invade the pores and in a matter of months will invest the whole pore volume.

The material is highly elastic; having compliance characteristics similar to cancellous bone. It is also capable of permanent or plastic deformability which is necessary for clinical fit to end bone fragments by applied compression. While the product can be made from almost any metal available in fine wire form, we have chosen to work primarily with titanium because of its excellent biocompatibility and availability in high strength forms. The prosthesis designs involve composites of solid pieces which are strong and load bearing in conjunction with the porous material which carries little load but hosts the bony regrowth and union.

III. BASIC DESIGNS

The cortical configuration of a long bone has been synthesized by a tubular design whose profile and wall thickness matches the segment to be replaced. The cortical prosthesis component is a thin-walled tube of solid

high strength titanium sleeved with the porous titanium special product. The overlay of porous titanium for the baboon is about 1.5 mm thick and overhangs the solid tube at either end. The overhand permits complete fit up to the bone fragments by deformation under axial compression (using the AO device).

The prosthesis is provided with immediate fixation by the use of a intramedullary rod of high strength titanium which is also sleeved with porous titanium and by a titanium plate with screws applied diametral to the bone diaphysis. The intramedullary rod becomes incorporated in the long bone by bony invasion. The plate becomes submerged in callous but may be removed at a later date.

As will be described later, we have begun to experiment with a simpler design in which the segment and the intramedullary components are integral. This "rolling pin" design is sleeved with porous titanium over the whole of the segment; with overhand and over the medullary projections. The medullary projections are limited in length by the problems of clinical implantation but they should be sufficient for fixation.

IV. RELEVANT PUBLISHED WORK

A complete review of work by others on related subjects was presented in the annual summary report of 1974. Many investigators have demonstrated bone ingrowth into porous materials (metallic, ceramic and polymer). There has been relatively little application to prosthesis design and supporting research with animal models.

V. SURGICAL PROCEDURE

A detailed description of surgical procedures was given in Quarterly Report No. 12 (August 31, 1974). It is important to re-emphasize here that, in addition to the standard surgical techniques, the surgical principles used include:

- (a) Preparation of the bone ends to ensure intimate contact between bone and the deformable porous metal.
- (b) Good compression of fragments to add stability and to deform the ends of the porous metal prosthesis for optimum contact and ultimate union.
- (c) Adequate bone graft where the protocol calls for its use.

Surgical procedure consisted of resecting 50% of the diaphysis of the bone in question subperiosteally or extraperiostally and replacing it with a prosthesis. Some of the animals received autologous bone graft laid around the prosthetic segment. The prosthesis affords rigid stability, and no immobilization or external support is used. By the sixth post-operative day, all animals functioned normally and could not be distinguished from their non-operated counterparts except by their surgical incisions.

Monthly radiographic evaluation reveals a rapid progression in the grafted animals. Bone graft quickly consolidates around the prosthesis; bridging the gap and restoring continuity between the two remaining lengths (fragments) of bone. Within an average of 4 1/2 months, most of the grafted animals show complete reconstitution of the resected diaphysis by mature bone with normal cortex enveloping the prosthetic segment. The non-grafted animals all failed to reconstitute their lost diaphyses.

VI. POROUS FIBER-METAL SEGMENTAL REPLACEMENT PLAN

We have now implanted 52 segmental replacements in 42 baboons with resection of more than one half of the shaft length. In 20 baboons with 22 segmental replacements the histologic and postmortem X-ray evaluation have been completed.

The experimental design called for comparison between subperiosteal versus extraperiosteal resection, grafted implants versus nongrafted implants and plate fixation with compression versus fixation without compression. A total of 10 femurs underwent radical segmental replacement with follow-up between four and 33 months, eight tibias with follow-up six to 23 months and four humerus with follow-up six and 12 months. Six femurs underwent subperiosteal resection, four other femurs, eight tibias and four humerus were resected extraperiosteally. Thirteen resections were done without utilizing bone grafts and nine were grafted. Our first attempt to apply compression was not satisfactory. Three animals were operated accordingly with poor compression. The AO tension device was used for six plate fixations and the compression obtained was satisfactory (see Fig. 1).

VII. EVALUATION IN AUTOPSY

The baboons were sacrificed. The stability of the implants was tested by manual force. The entire bone, its surrounding soft tissue, and all organs were examined grossly and processed for histological examination.

VIII. RADIOLOGICAL EVALUATION

Contact X-rays from each specimen were taken after autopsy and graded for union and extent of bone ingrowth. The proximal and distal bone/fiber metal interfaces were rated separately as follows:

- 0 = non-union at the interface between fiber metal segment and bone shaft
- 1 = partial bone union in this area
- 2 = solid bone ingrowth into the fiber-metal segment in the AP and lateral views

Large callus formation around the fiber-metal segment (with union or non-union) was rated 2, a thin layer of callus or partial callus was rated as 1, no callus was rated 0.

IX. HISTOLOGICAL EVALUATION

Each specimen was cut in 5 to 10 horizontal slices with the fiber metal in situ. One vertical cut was done through the middle of the proximal and distal fiber-metal - bone interface. Non-union with ingrowth of fibrous tissue or interposition of fibrous tissue was rated 0, limited amount of bone ingrowth was rated 1, and bone ingrowth from the shaft cortex into the fiber-metal segment extending at least 0.5 cm was rated 2. Endosteal bone ingrowth into the fiber-metal rod was rated separately. Zero (0) means no bone ingrowth, 1 = bone ingrowth only at single levels, and 2 = bone ingrowth up to the solid center core at all levels.

X. RESULTS

X.1 Autopsy Findings

The baboons were sacrificed between 4 and 33 months. One femur was obtained at 4, 5, 8, 12, 14, 18 and 33 months, two femurs after 6 months; three tibias after 6 months, three tibias after 12 months, one after 18 and 23 months; three humeri after 6 months, one after 12 months.

No drainage or other signs of infection occurred in this series. The animals with subperiosteal bone resection showed abundant callus formation around the fiber-metal implant, except under the plate. The ungrafted segments with extraperiosteal resection showed very poor or no new bone formation and the fiber-metal segment was covered by a thin soft tissue layer with ingrowth of fibrous tissue into the fiber-metal framework. Good callus formation covering the fiber-metal segment was found in the grafted segments. Marked instability to bending movements was not found. Several of the non-grafted segments showed little rotational instability. All implants, however, were functionally successful and the bone between proximal and distal bone occurred at least through bone ingrowth in the fiber-metal rod. Two animals with instability showed a small amount of black staining in the soft tissue between fiber metal and plate. This staining was explained as wear products from the titanium. Three small cortical screws were found broken in two tibias due to primary instability. All rods, plates and fiber-metal segments were found intact. The findings in autopsy were correlated to the histological findings.

X.2 Radiological Evaluation

The contact X-rays showed non-union in two of the subperiosteally resected femurs, twice in the extraperiosteally resected bones without the use of graft or compression and in one of the extraperiosteally resected tibias with poor compression and graft. All the extraperiosteally resected segments with good compression and bone graft showed success on both interfaces. Each intramedullary rod seemed to be penetrated from cancellous bone (see histology of the intramedullary rod - Fig. 2). There was no radiolucency around the fiber-metal coated intramedullary rod.

X.3 Histology Evaluation

The osteogenic property of the periosteum gave a good bone envelope in all of the six subperiosteally resected bones; but only two of six showed successful bone ingrowth at both interfaces between bone and segment. Of 12 interfaces, six only demonstrated histologically confirmed bone ingrowth and solid fixation.

In the series without adequate compression and without bone graft, one segment showed histologically bone fixation to the fiber-metal segment. In 14 interfaces, only four interfaces (in three animals) were solidly stabilized by bone ingrowth.

The series with inadequate compression but bone grafting had one segment with bone ingrowth at both interfaces. In six interfaces, only three were histologically successful.

The last group with satisfactory compression and bone graft showed in five of the six replaced segments solid fixation on both interfaces (see Fig. 3). In 12 interfaces, 10 were successful, and five of the six grafted animals showed complete bone envelope around the fiber-metal segment. The results are summarized in Figs. 4 and 5.

XI. WAR CASUALTY SIMULATION

Three animals have been operated on with the war casualty model. As in the quarterly report, war casualty animal #1 (PA 1813) died 15 months after implantation of the fiber-metal segment from a pulmonary embolism. War casualty #2 (PA 2421) and #3 (PA 2199) are still doing well and no sign of infection is clinically visible. PA 2421 shows a very prominent plate edge palpable under the skin. It is planned to remove the plate to avoid secondary opening of the skin. The X-ray shows good bone ingrowth at both

ends of the fiber-metal segment and no signs of instability in both animals. There is no visible bone bridge over the fiber-metal segment in either animals.

XII. COMBINED FEMORAL SEGMENTAL REPLACEMENT WITH KNEE JOINT REPLACEMENT PROSTHESIS

This prosthesis includes one third of the femoral diaphysis and the knee joint. Two animals are alive with this kind of implant. PA #638 has a 24 month follow-up. PA #989 has a six month follow-up. Both implants appear to be well attached to the bone. The knee motion is restricted, however, in both animals. The baboon develops very easily flexion contractures of his knees due to the predominant sitting position that he adopts (see X-ray Fig. 6).

It is planned to do two or more of these implants, but with a modified design.

XIII. OTHER MODIFICATIONS OF THE SEGMENT

XIII.1 Solid Rod

Four animals had segmental replacement on the femur with solid rods. All four segments were shorter than usual to avoid technical difficulties. This was the first step to make a removable prostheses. Two animals are already sacrificed. Both were stable at each interface.

From the two other animals the plates were removed in January of 1975. Both animals with plate removal are doing very well. The X-ray shows still an excellent bone envelope and stability at both interfaces (see Fig. 7). It is planned to repeat the same experiment using segments with usual lengths from 7.6 cm, because the shorter segments show better tendencies to be bridged with bone.

XIII.2 Solid Segments

To evaluate the superiority of the fiber-metal segment, two femurs underwent titanium solid segmental replacement using the same technique as for the fiber-metal segments (bone graft and compression-plating). The intramedullary rod was coated with fiber metal. PA #2757 and PA #2059 underwent solid segmental replacement on the right femur in October 1975. A larger amount of bone graft was placed around the titanium solid segment and excellent initial stability was obtained using the AO tension device. Surprisingly both animals did well during the first three months. The X-ray showed good bone envelope, but a radiolucent line developed around the solid segment. Baboon #2059 underwent a stroke on April 11, 1976, and had to be sacrificed on April 12, 1975. The autopsy was performed in the usual manner. The contact X-ray is shown in Fig. 8. The femur showed slight rotational instability at both interfaces. Fibrous tissue was interposed between bone and solid segment. Good bone ingrowth, however, was found at the intramedullary rod (fiber metal). It was not possible to disassemble the femur after plate removal because of the holding power of the fiber-metal intramedullary rod. PA #2757 is still alive. The X-ray follow-up shows similar changes. It has also a good bone envelope, but not enough functional stability of the implant to allow further observation of the animal.

This experiment indicates that a porous implant is mandatory to get solid fixation by means of bone ingrowth.

XIII.3 Plate Removal

Four plates were removed from successful implants: two on the tibia and two on the femur (with fiber-metal segmental replacement and solid rod). One femur has now had a follow-up at eight months, one tibia at eight months

(see X-ray Figs. 9 and 10), one femur and one tibia at two months follow-up. All the X-rays show no secondary changes, i.e., no bone re-absorption or instability.

XIV. CARCINOGENESIS POTENTIAL

Albino inbred rats were implanted with seven different metals and Silastic as shown in previous reports. With the exception of 50 rats, all animals are sacrificed or died spontaneously. The surviving 50 rats belong to different test groups and will have to be sacrificed during the next two months according to the schedule.

The histologic evaluation of the implant site and the determined organs is in progress and will be reported in the second half of 1976.

XV. IN VIVO STUDIES OF COUPLE CORROSION

The need to combine mechanical strength, resistance to wear and unusually high levels of corrosion resistance requires often the use of two different alloys. There has always been serious doubts that this is advisable from the viewpoint of electrochemical mechanisms which could operate. However, in vitro tests which we performed previously indicated that titanium, cast Co-Cr-Mo, wrought Co-Cr-Ni-W and "multiphase" - Co-Ni-Cr-Mo are compatible and corrosion was not observed. We have designed an in vivo couple corrosion test specimen and permutations of the four materials were assembled. They were implanted in one dog some 18 months ago. The dog is healthy. We would plan to sacrifice the animal within the next 12 months and examine the "couple" corrosion specimens.

XVI. FATIGUE STUDIES

We had planned to evaluate the fatigue strength of some of the high strength alloys to be used. However, the test machine has broken down repeatedly during the past year. We believe it is now functioning and will proceed as planned.

XVII. SUMMARY

In toto, 52 fiber-metal implants were implanted in 42 baboons. Forty-one implants consisted in standard fiber-metal segments. In addition, four femurs were implanted with modified fiber titanium segments and solid intramedullary rods, two solid titanium segments with fiber-metal intramedullary rod were implanted in femurs and two animals underwent partial femur replacement combined with total knee replacement. Three animals underwent the casualty procedure on the tibia.

From 20 animals with 22 implants the histology is already evaluated. From eight more animals the histology from 10 implants is in progress. Fourteen animals with 19 different implants are still kept alive (see Table 1). All of these animals are doing fine and are using the extremities normally. The two animals with partial femur replacement combined with knee prosthesis do not seem to suffer from the flexion contracture of the operated knees. The evaluation of the results shows clearly that an excellent result may be obtained in over 80% provided adequate technique with compression and bone graft is used. Bone ingrowth into the fiber-metal intramedullary rod may be obtained very easily. Intramedullary fixation of implants by means of titanium fiber metal seems to be very promising.

TABLE I
CURRENT BABOONS

SITE & PROCEDURE	ANIMAL	TIME POST OP (Mo.)
Femur:		
Segment & rod, fiber metal	638R ^{1,2}	49
	964R ²	41
	964L ³	25
	1645R	24
	2589	23
Solid I.M. rod	963R ³	15
	1812R ³	15
Solid Segment	2757	5
Knee & Distal Shaft	638L ²	25
	989	6
Tibia:		
Segment & rod, fiber metal	1645L	29
	963L ³	25
	1812L	22
Simulated war casualty	2421	13
	2199	6
Humerus:		
Segment & rod, fiber metal	2547	24
	902	24
	2545 ²	24
	2588	25

1. Subperiosteal resection
2. No graft
3. Removal of plate

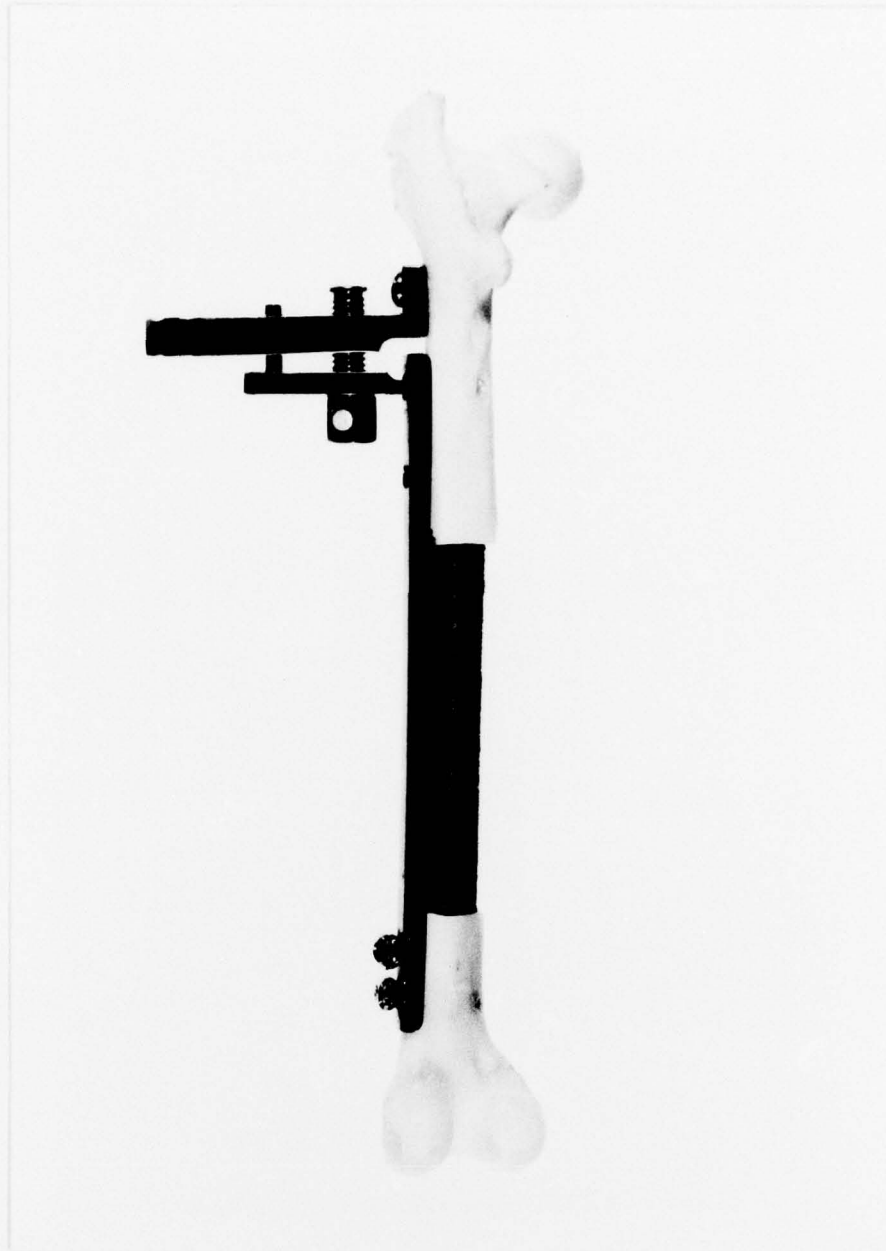


Fig. 1 Fiber-metal segmental replacement in femur utilizing compression plating showing AO-tension device in situ (model).

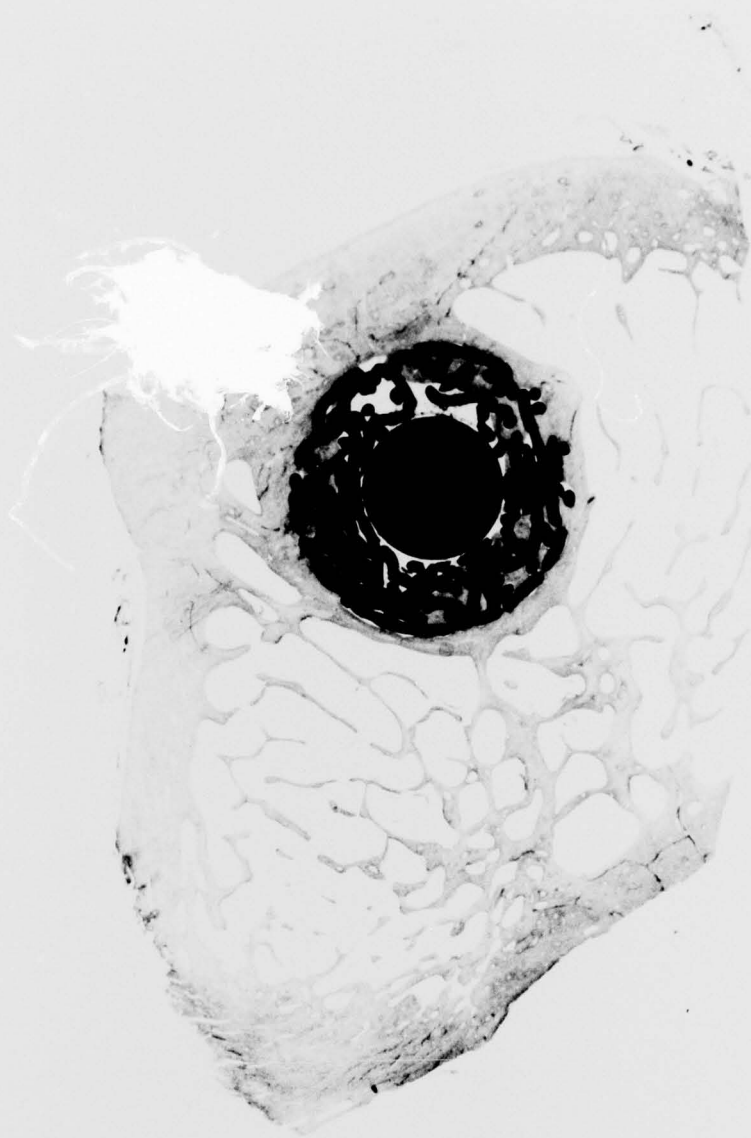


Fig. 2 Bone ingrowth into intramedullary rod (fiber metal). Transverse histologic section through intertrochanteric region. PA #617 33 months after implantation (long-term result).



Fig. 3 Bone ingrowth at bone - fiber-metal interface. PA #1646, humerus. Segmental fiber-metal implant applied with bone graft and compression plate. (Compression plate and core of the fiber-metal intramedullary rod are removed in this histologic section.)

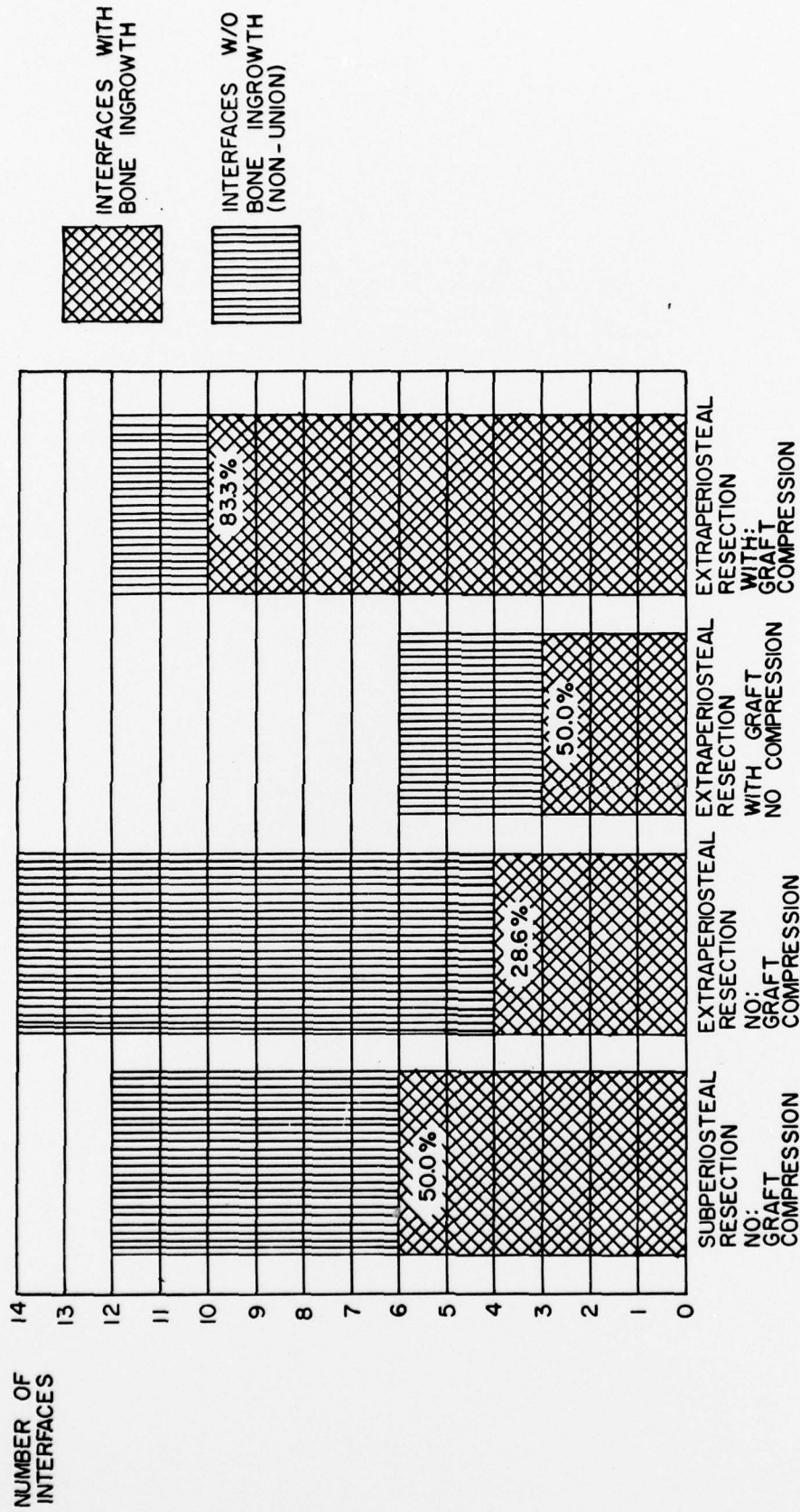


FIGURE 4. HISTOLOGICALLY VERIFIED BONE INGROWTH AT THE BONE - FIBER METAL INTERFACES

LOCATION	F	F	F	F	F	F	F	F	H	F	T	T	T	T	T	T	H	H	H	F	F	T	
DURATION	4	5	8	12	14	33	6	6	18	6	12	18	23	6	12	12	6	12	6	6	6	6	6
x-RAY	N	N	●	●	●	●	N	N	●	●	●	●	●	N	●	●	●	●	●	●	●	●	●
HISTO- LOGY	N	N	N	●	●	N	N	N	N	N	N	N	N	N	N	N	N	●	●	●	●	●	●
COMBINED																							
	SUBPERIOSTEAL R. NO GRAFT NO COMPRESSION			EXTRAPERIOSTEAL R. NO GRAFT NO COMPRESSION			EXTRAPERIO- STEAL GRAFT NO COMPRES- SION			EXTRAPERIOSTEAL WITH GRAFT WITH COMPRESSION													

SUCCESSFUL
 SUCCESSFUL IN HISTOLOGIC EVALUATION
 NOT SUCCESSFUL (NON-UNION)

FIGURE 5: FIBER METAL SEGMENTAL REPLACEMENT: HISTOLOGICAL EVALUATION VERSUS X-RAY EVALUATION



Fig. 6 X-ray: lateral view left knee (PA #638). Total knee replacement combined with fiber-metal segmental replacement on distal femur (25 months after implantation). The knee prosthesis is attached to the residual femur across the fiber-metal segment, and to the tibia by means of bone cement.

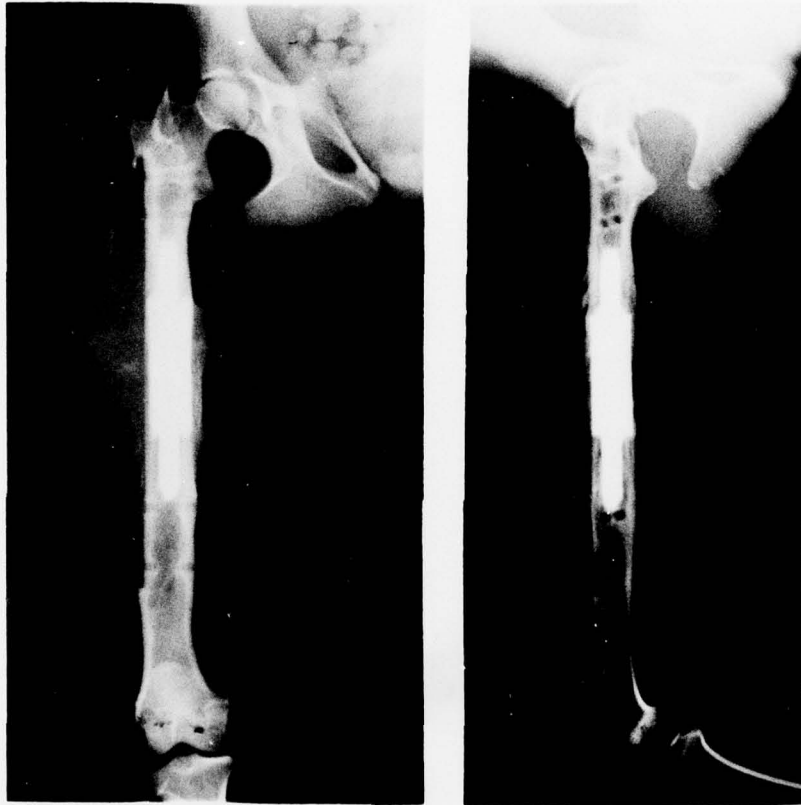


Fig. 7 Short fiber-metal segment in femur with solid intramedullary rod eight months after plate removal (PA #963). Implantation: January 1975, plate removal: March 1976.

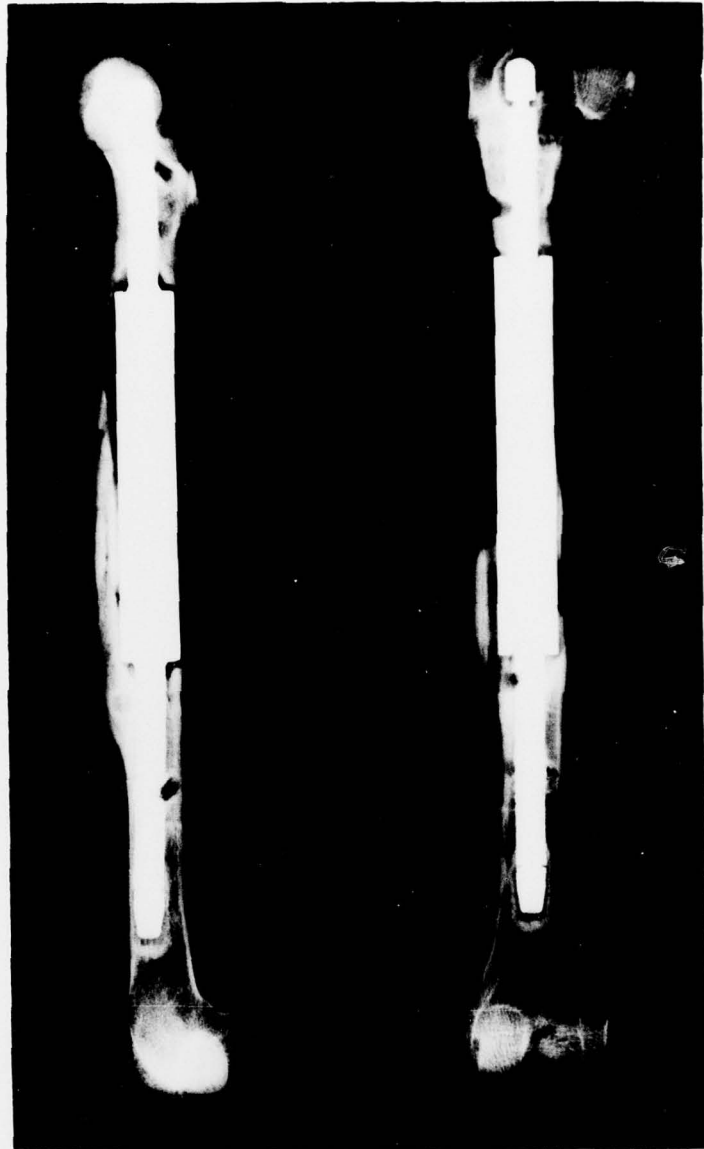


Fig. 8 Contact X-ray obtained from right femur 22 weeks after implantation of a solid titanium segment with fiber-metal intramedullary rod. X-ray shows in this autopsy specimen a radiolucent line around the solid segment, but good bone ingrowth into the fiber-metal rod.



Fig. 9 Left femur eight months after plate removal (PA #964). Implantation: March 1974, plate removal: August 1975.

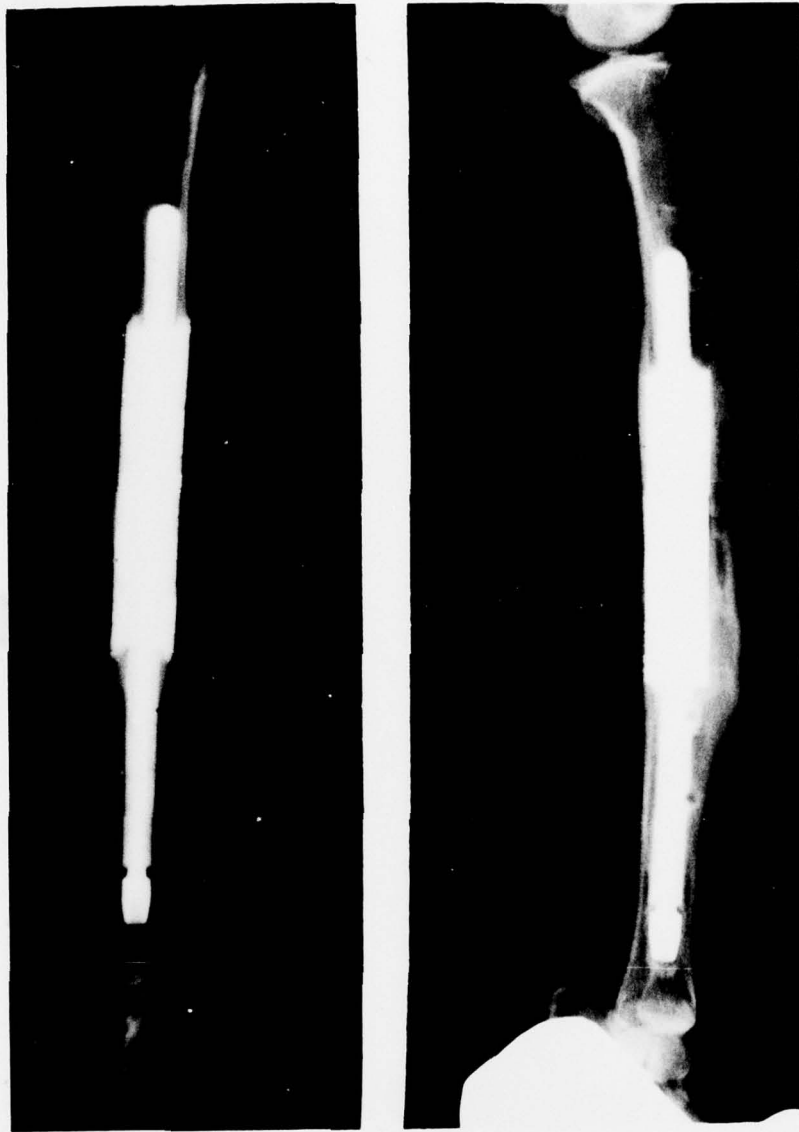


Fig. 10 Left tibia two months after plate removal (PA #1812). Implantation: June 1974, plate removal: March 1976.

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