Fiber Titanium: Animal Studies and Clinical Trials

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Introduction

Since 1968, Galante and Rostoker have been using a meshwork of sintered titanium fibers for bone replacement and for the cementless attachment of implants to bone. The material has undergone a lengthy series of mechanical and biomechanical tests. Animal studies have been conducted in rabbits, dogs and baboons, and 10-year implants are currently being evaluated in the baboons. "Fiber titanium" has also been in use since 1976 for bone replacement in tumor patients. Following thorough evaluation of the experimental results, a total hip prosthesis was developed which featured a fiber titanium coating. At this writing, uncemented total hip and knee prostheses have been used in human patients for more than 15 months. The first clinical results are now available.

For production of the fiber titanium, the titanium wires are first kinked, cut into short lengths, and then pressed into the desired shape. The pressed wires are sintered together in a vacuum annealing furnace at over 1000°C. This produces a stable meshwork with an interconnecting pore size of 200–300 μ that is not unlike the trabecular structure of bone. The elasticity of the sintered body can be controlled by varying the sintering temperature. Fiber titanium is intended as a surface coating for uncemented implants, providing a network of interconnecting pores that are receptive to bone ingrowth. Titanium is well known for its excellent compatibility with tissues. Because the surface area available for bone contact is very large in porous bodies (about 5 times larger than in smooth bodies), it is essential that the material used be as nontoxic as possible. The excellent biocompatibility of titanium makes it decidedly superior to vitallium, for example, which contains relatively toxic substances such as cobalt, chromium and molybdenum.

The compatibility studies, in which the release of various substances (including titanium) into the tissues was investigated, were followed by various experiments to determine the optimum pore size. It was found that the rate of bone ingrowth was best with a pore size of 200–300 μ. Segmental bone replacement operations with fiber titanium implants were performed in more than 150 long bones of adult baboons. As a supplement to many previous publications [1–9], we shall present a yet-unpublished series of experiments designed to explore the possibilities of fiber titanium bone replacement.

Method

At operation, a segment was excised from the femur, tibia or humerus of the baboon and replaced with a fiber titanium cylinder (see Fig. 1). The replacement segment was stabilized by means of a central intramedullary rod. Fixation was provided by two flanges at each end of the replacement segment, which were fitted into corresponding notches in the proximal and distal cortices of the remaining bone. To achieve optimum stability, a semitubular titanium plate was then attached to both cortices, using the compression device of the ASIF (Association for the Study of Internal Fixation). This enabled postoperative care to be administered without the need for plaster or other external fixation. The animals were placed in large cages so that they could ambulate with little restriction.

A total of 22 segmental bone replacements were performed in 10 femora, 8 tibiae and 4 humeri. One baboon received 3 different implants, and the others received 1 implant each. The length of the replacement segment was 5 cm for the humerus, 6.3 cm for the tibia, and 7.6 cm for the femur. The segments for the tibia
and femur had a circular cross-section, while the humeral segments had a triangular cross-section. Each segment consisted of a Ti6% Al4% V cylinder onto which the fiber titanium was sintered. To improve rotational stability, two flanges were placed on each end of the cylinder to be fitted into the remaining cortices. An intramedullary rod, also with a fiber titanium coating, was inserted for additional stability. Temporary fixation was provided by a semitubular plate attached with four steel screws from the small-fragment set of the ASIF. The bone segment was resected subperiosteally (s.p.) in 6 femora and extraperiosteally (e.p.) in 4 femora, 8 tibiae and 4 humeri. In 7 of the e.p. resections, no bone grafts were used. In the remaining 9, autologous grafts from the resected bone segment were applied. The grafts were grouped around the prosthetic segment and were also placed at the junction between the segment and bone. The compression instruments of the ASIF were additionally used in 6 cases. Standard sterile technique and antibiotic prophylaxis were employed for the implantation. The femoral segments were implanted through a lateral approach, and the tibial and humeral segments through an anterior approach. No external fixation was used, and the baboons were free to move about in their relatively large cages. The animals were killed between 4 and 32 months following implantation. The implants were tested manually for stability. The entire bone and surrounding soft tissues, as well as all internal organs, were removed for histologic study. In addition, a contact radiograph was made of each implant. The specimens were embedded in PMMA and sectioned (< 50 microns). Besides the 5–10 horizontal sections, one vertical section was obtained through the interfacial zone between the titanium, cylinder and bone. The following point system was used:

0 = pseudarthrosis,
1 = less than 0.5 cm bone ingrowth into implant,
2 = bone ingrowth of 0.5 cm or more.

Bone ingrowth into the coated intramedullary rods was evaluated separately:

0 = no ingrowth,
1 = ingrowth limited to a few layers,
2 = ingrowth permeates coating and reaches central core.

Results of Segmental Replacement

Macroscopic evaluation showed no gross evidence of intraoperative infection. The animals with a s.p. resection showed extensive bone formation around the implant, except for the area below the plate. In the e.p. resections without bone grafting, a thin, adherent layer of connective tissue formed around the shaft. Some of these implants showed rotational instability. Two of the unstable specimens showed black discolorations between the plate and cylinder that were interpreted as corrosion or wear. In one humerus there was a fracture of the intramedullary rod, and one of the distal screws...