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Hoffman, E.; Buma, P.; Huiskes, H.W.J.; Versleyen, H.

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The In-vivo Effects of an Intramedullary Implant Evoking a Constant Radial Stress to Bone. An Animal Study in the Tibia of the Goat

E. Hoffman, a P. Buma, b* R. Huiskes b & H. Versleyen b

a Department of Orthopaedic Surgery, St Franciscus Hospital, Boerhaavelaan 25, 4708 AE Roosendaal, The Netherlands
b Institute of Orthopaedics, Laboratory for Experimental Orthopaedics, Academic Hospital Nijmegen, P.O. Box 9101, 6500 HB Nijmegen, The Netherlands

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Abstract: Initial stability is essential for successful bone ingrowth into non-cemented prostheses. An entire new concept to increase the initial stability directly after implantation of intramedullary stems was developed (the tension rod prosthesis). The concept is based on a tension rod made out of memory metal that pulls a proximal stem of a prosthesis towards a distal anchor with a constant force. The stress generated along the long axis of the bone produces a radial stress around the prosthesis in the proximal femur. The main goal of this design is to increase the primary stability of the prosthesis during the ingrowth phase and to prevent stress shielding and bone resorption, as realized by the radial force applied to the proximal endosteum of the bone.

To assess the efficacy of this concept and to collect data for the anchor design, an implant was developed for implantation into the tibia of the goat. Analyses of push-out strength and bone reactions were performed postoperatively.

After 48 weeks the push-out strength of this implant was increased and the histological evaluation showed almost complete osseousintegration. Histomorphometrical analysis showed pronounced, permanent periosteal reactions, located around the anchor of the implant, which generates the radial stress.

These first results showed that the bone can withstand the radial stress provoked by the anchor of the tension rod. It is concluded that the concept of a tension rod prosthesis is viable.

INTRODUCTION

Ten percent of cemented arthroplasties have to be revised within 10 years postoperatively.1 Aseptic loosening is the major long-term reason for revision. The mechanisms of the loosening process are still poorly understood, but various factors of mechanical and biological nature probably play an important role.

In search for improved long-term fixation of prostheses, and to avoid the major biological problems associated with cement, prostheses are implanted without cement, using a ‘press-fit’ fixation instead. To improve long-term anchoring to living haversian or trabecular bone (osseousintegration), the prostheses may be coated proximally with either a porous metal or hydroxyapatite (HA).2-6 Although the short-term results of cementless prostheses are good,7-9 they can also loosen,10 probably by comparable mechanisms as involved in the loosening of cemented prostheses.

For successful bone ingrowth into the HA or porous coating, the initial stability of the prosthesis should be adequate. The maximally allowed relative motion between prosthesis and bone may not surpass 28–40 μm.11,12 Since the process of bone
ingrowth into the prosthesis is rather slow,\textsuperscript{13,14} it is thus of utmost importance that the interface between the bone and the prosthesis is stable, particularly during the ingrowth phase, without significant micromovements.\textsuperscript{15}

In order to obtain an uncemented prosthesis which combines immediate postoperative stability and avoids stress shielding, an entirely new fixation concept was developed. This concept involves three features: a relatively short proximal stem, connected to a distal anchor by a tension rod, made out of memory metal (Nitinol; 80% titanium and 20% nickel). Because memory metal has a flat stress–strain relationship within a certain range (superalastic properties) the force applied by the tension rod is predictable and constant, even in the case of postoperative subsidence (Fig. 1). The result is a prosthesis with optimal initial postoperative stability and a stem which permanently loads the proximal femur, thereby preventing stress shielding to occur.

The purpose of the present study was to test the viability of the anchoring principle of the tension rod. In particular, it was investigated if the postoperative strength of the anchor remains intact and if the radial stress of the anchor applied to the endosteal bone induces undesirable bone remodeling effects. Animal experiments in the tibia of the Dutch milk goat were performed. The effects of such an anchor on the bone were analysed with push-out tests and histology, at various time periods after implantation of the device.

**MATERIALS AND METHODS**

The experimental implant anchor consisted of a tapered core, surrounded by conical sleeve segments, arranged in a cylinder and connected to a tension rod (Fig. 2). The tension rod was made of 80% titanium and 20% nickel (Nitinol). The constant force applied by the tension rod moves the tapered core towards the rod. The sleeves spread out and the effective diameter of the cylinder increases, thereby loading the endosteal bone.

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**Fig. 1.** The stretch–strain relationship of a memory metal rod. Note that the stress remains constant in a range of approximately 6% of the original length.

**Fig. 2.** (A) The experimental implant with a calculated radial force of 15 MPa: 1, the tension rod; 2, the tapered core of the rod; and 3, the sleeves of the tension rod. (B) Enlargement of (A).

**Fig. 3.** Prosthesis (P) in the tibia (T) of the goat after (A) 12 and (B) 60 weeks postoperatively. Note extensive periosteal reaction (arrows) at the location where the radial force is applied. (C) Large periosteal reaction (P) 6 weeks after the implantation. In the cortical bone (C) creeping substitution (arrowheads) starts at the interface between living haversian bone and endosteal necrotic bone, original magnification × 30. (D) Bone prosthesis interface 12 weeks after implantation showing very characteristic indentations of the bone, original magnification × 60. (E) and (F) Cortical bone 60 weeks after implantation. The arrowheads point at a completely remodeled fracture that was intraoperatively induced by the applied stress to the bone. The boundary of the original peristeum is indicated by the dotted line. The periostal reaction (P) is completely remodeled into new haversian bone, original magnification × 40. (G) and (H) Detail of fracture that was completely remodeled after 12 weeks, original magnification × 100.
Tension rod based prosthesis
Table 1. The push-out forces of the experimental implant obtained after 3, 6, 12 and 60 weeks of implantation

<table>
<thead>
<tr>
<th>Duration of implantation (weeks)</th>
<th>Push-out force (Newton)</th>
<th>S.E.M.</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>814</td>
<td>± 60</td>
</tr>
<tr>
<td>12</td>
<td>958</td>
<td>± 221</td>
</tr>
<tr>
<td>60</td>
<td>3525</td>
<td>± 605</td>
</tr>
</tbody>
</table>

Table 2. Surface area of cross-sections of operated and non-operated tibiae

<table>
<thead>
<tr>
<th>Total surface area and S.E.M. of control tibia in cm²</th>
<th>Total surface area and S.E.M. of operated tibia in cm²</th>
<th>Total surface area and S.E.M. of periosteal reaction in cm²</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 weeks 1.79±0.19</td>
<td>1.91±0.23</td>
<td>0.30±0.24</td>
</tr>
<tr>
<td>12 weeks 1.89±0.08</td>
<td>2.19±0.15</td>
<td>0.34±0.23</td>
</tr>
<tr>
<td>60 weeks 1.78±0.15</td>
<td>2.12±0.01</td>
<td>0.37±0.16</td>
</tr>
</tbody>
</table>

radially, creating holding power. The dimensions of the design, particularly the cone angle, were based on a theoretical mechanical analysis. The most important criterion was to create a hoop stress in the bone of not more than 15 MPa, well below the cortical transverse strength of 50 MPa. The tension rod was assumed to generate 100 MPa stress in the axial diameter under an initial strain of 8%. The calculations were verified with a finite element analysis. The rod was made out of memory metal, the other parts out of stainless steel. The device was implanted in the left tibia of nine goats. After the implantation, X-rays were made in order to confirm its correct implantation (Fig. 3(A) and (B)). The goats were killed in three groups of three goats at, respectively, 6, 12 and 60 weeks postoperatively. The left and right tibiae were freshly harvested, radiographed and stored at -80°C until testing. Both the right and left tibiae were prepared for further study, whereby the right tibia served as control.

Before mechanical testing, the bones were thawed at room temperature. The tibiae were sectioned just distal from the implant, whereafter the distal surfaces of the cone and sleeves were carefully exposed. Then the proximal part of the prosthesis was dissected. The bones were embedded in polymethylmethacrylate (PMMA) in such a way that it allowed the prosthesis to be pushed out in the distal direction on a MTS machine. After mechanical testing the specimens were fixed in 0.1 M, pH 7.4 paraformaldehyde for 2 weeks. Slices were cut of 3 mm thick with a water cooled saw. For routine histology, half of the sections were decalcified in 25% EDTA, embedded in PMMA, thin sectioned (7 μm) and stained with hematoxiline eosine. The alternative slices were stained with 2.5% basic fuchsin in 70% ethanol during 3 h, dehydrated and embedded in PMMA, after which 20–30 μm thick sections were cut with a rotating water cooled diamond saw (Leitz 1600; for details of the method see Ref. 17). Camera lucida drawings were made of the sections and subsequently the surface area of cortical bone and periostial reactions were quantified with a Zeiss Contron Videoplan.

RESULTS

The biomechanical results of the push-out test are represented in Table 1. The mean push-out force was 814 N 6 weeks after the implantation and increased over time to 3525 N after 60 weeks. This considerable increase in resistance of the anchor against a push-out force suggested a well established osseointegration of the anchor, which was confirmed by the histological results.

No adversive tissue reactions to the implanted materials were found. Initially the implant was in contact with necrotic bone. Very characteristic undulating indentations into the cortical bone, resembling the outer surface of the anchor, showed that direct bone–sleeve contact was present (Fig. 3(D)). At locations where gaps were present between anchor and bone a fibrin cloth was found. Cortical necrosis induced by the destruction of the endosteal blood supply was restored by creeping substitution of the dead necrotic bone (Fig. 3(C)). After 6 weeks this process of creeping substitution started to reach the prosthesis and new bone was formed in the gaps (if present), and at the bone–prosthesis interface. The microfractures that were initially formed in the cortex of some of the tibiae by the radial force applied by the sleeves, showed complete repair and remodeling after 12 weeks (Fig. 3(E)–(H)). There were periostal reactions at the site of the sleeves of the implant (Fig. 3(B),(C),(E) and (F)). Initially, these reactions produced callous bone formation (Fig. 3(C)), but after 60 weeks this was remodeled into normal cortical bone, and was no longer recognizable as a periostal reaction, as evident when the bones were investigated with polarized light (Fig. 3(E) and...
Fig. 4. (A) and (B) Microradiographs of 100 μm thick sections at the level of the sleeves and at a level proximal to the sleeves, indicated by the arrowhead in Fig. 2(A). Note very intimate contact between the prosthesis and bone in (B). The arrowheads point at bony ingrowth into the space between the different parts of the anchor. The arrows point at a stress fracture that was a result of the push-out procedure, original magnification × 3. (C) Bone prosthesis interface 60 weeks after the implantation. Note the characteristic indentations into the bone, original magnification × 12. (D) Thin sawing section (20 μm) of bone prosthesis interface. Note areas of complete osseointegration (arrows) between the implant (removed during push-out procedures) and the bone, original magnification × 70.

(F)). Quantitative measurements showed that this reaction caused considerable permanent increases of the total surface area of the cortex after the implantation (Fig. 3(B), Table 2).

After 60 weeks, the push-out force revealed that the anchor was firmly connected to the cortical bone (Table 1). Histology indeed showed almost complete osseousintegration of the anchor and the bone. The entire surface of the anchor was connected with newly formed bone, without a soft tissue interface (Fig. 4(A)–(D)). Bone ingrowth was also present in between the different parts of the anchor (Fig. 3(B)). In general, cortical remodeling was complete after 60 weeks. Only in the direct environment of the contact area between cortical bone and anchor, were remodeling phenomena still seen, which indicated accelerated bone turnover at the bone–anchor interface (Fig. 4(D)).

DISCUSSION

This experiment clearly demonstrates that an intramedullary implant evoking radial stress to the endos- stem, thus hoop stresses to the cortical bone, is accepted in the tibia of the goat. Theoretically, the material of the tension rod, that consists of 80% titanium and 20% nickel, could have a cytotoxic potential. However in the present study no adverse tissue reactions or signs of corrosion between the tension rod and the stainless steel components were seen. Some aspects of the experiment may be of particular importance while developing a prosthesis based on the same principle for clinical application. First, it appeared that the microfractures caused by the implantation or by the subsequent forces evoked by the implant were completely repaired after 12 weeks. After 60 weeks excellent
integration had developed between the bone and the implant. The bone around the sleeves had remodeled itself to such an extent that the metal was embedded in a shell of new cortical bone. At the very site of the sleeves of the implant, intimate contact was gradually formed between metal and bone up to nearly 100% of the interface after 60 weeks.

Second an interesting phenomenon was noticed: the extensive subperiostal bone apposition, which was remodeled into normal bone, resulted in a permanent increase of the total surface area of the cortical bone. Although the precise mechanism of this periostal reaction is still unknown, similar results were found in animal experiments in the tibia of rabbits, in which a radial force was induced by an inflated balloon. This strongly suggests that the radial stresses are the main factors in the extensive periosteal reaction and that the cortical area enlargement is mediated by strain-adapted remodeling mechanisms.

CONCLUSIONS

The results showed that an intramedullary device evoking constant radial and transversal stresses in the bone is very well accepted and shows both excellent integration with the cortical bone and a thickening of the cortex.

REFERENCES