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Short Communication

Intramedullary Fixation with Screwed, Conical Stems—Unsolicited Results from Animal Experiments

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Abstract: For the purpose of studying bone remodeling around prostheses, a segmental replacement for the goat tibia was designed, using a conical, screw-threaded, hydroxyapatite-coated stem for fixation. Eight goats were provided with the implant, seven of which loosened within 10 days post-operatively, displaying progressive radiolucency and gross rotational motion. The eighth one also loosened radiographically, but developed a stabilizing callus bridge to prevent motion. A second design of similar shape and coating, but lacking the screw threads, was designed and also applied in eight animals. In this case, no loosening occurred in the first 6 weeks post-operatively. It is concluded that the application of screwed intramedullary stems for prosthetic fixation is not a viable concept, because the threads prevent the stem from subsiding and restabilizing when minor initial interface stress-relaxation and remodeling has occurred.

INTRODUCTION

There is no consensus about the optimal shape and fixation mode of uncemented hip stems and other intramedullary fixated prostheses. Of the methods proposed in recent years, the screwed cone is not the most popular one, but it is used nevertheless.[1,2] From a technological point of view such a fixation is attractive, because it apparently provides adequate initial stability of the prosthesis, using a mechanism by which the stem is tightly fixed by prestressing the bone. The results of the animal experiments reported here, however, do not support this fixation concept.

These results are the effects of serendipity. Testing the feasibility of screwed intramedullary fixation was by no means the initial object of this study. For the purpose of verifying theoretical predictions relative to stress-shielding and strain-adaptive bone remodeling around intramedullary prostheses,[3] we needed an animal model in which a stem of variable stiffness could be fixed in a relatively straight and circular bone. We chose the tibia of the goat and an upper-mid diaphyseal, segmental prosthesis, with a tapered distal component, screw threads, and coated with hydroxyapatite.

The results, which were disastrous, are reported here, and compared to those of a second series with tapered, hydroxyapatite-coated, but smooth stems.

METHODS AND MATERIALS

Two series of implants were used, types I and II (Fig. 1). Both consist of two parts, together forming a segmental replacement in the goat tibia. The proximal parts of both types consist of stainless steel sleeves to fit over the entire diaphyseal rim, and intramedullary pins, which are fixed using acrylic cement. The distal parts consist of metal (stainless steel) trays with conical, circular stems.

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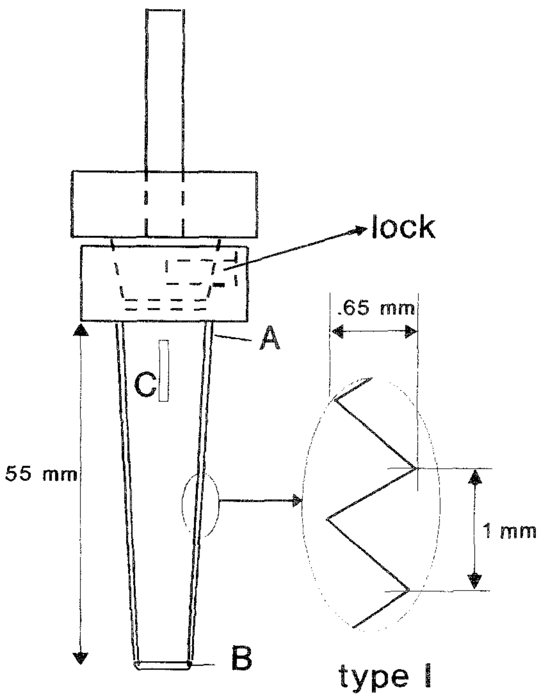

Fig. 1. Schematic of the implant used. The distal stems of the type I and type II implants differ with regard to their surfaces and methods of fixation. The conical stem of type I is provided with screw threads on its entire length (insert). The type II implant has a smooth surface. To prevent rotation of type II, a 1·6 mm Kirschner wire is inserted through a rectangular slotted hole and fixed in the cortex through a drill hole.

All have the same conical index of 1:50. Three different diameters were available: 10·2, 9·0 and 8·2 mm at section A in Fig. 1, and 9·2, 8·0 and 7·2 mm at section B in Fig. 1. These dimensions are based on a geometrical *in vitro* study, so a proper selection can be made for a particular goat during the operation. The proximal and distal parts are connected with a conical fit, after implantation. The stems were coated with hydroxyapatite with a plasma-spraying technique.[4] The thickness of the coating was 50 ± 20 μm.

The type II stems were smooth before the coating was applied, but the type I stems were first provided with screw threads. The type II stems were provided with a slotted hole at the proximal side (C in Fig. 1). A small steel pin (1·6 mm K-wire), positioned distally in this hole through drill holes in the cortex, provided resistance against torsion, but did not prevent axial subsidence.

The type I and type II prostheses were each implanted in eight goats. After a segmental diaphyseal tibial resection of 1·6 cm, the proximal prosthetic part was cemented. The distal diaphysis was reamed with a conical drill, using Ringer's solution for cooling.

In the case of a type I implant, screw threads were tapped, and the stem was screwed in place, applying the highest torsion considered possible without failing the bone. Right-handed screw threads were used in left tibiae. The stems were then tested manually and could not be unscrewed.

In the case of a type II implant, the stem was pushed in place with the highest possible force considered safe. A hole was drilled through the proximal diaphysis and the anti-rotation fail-safe pin was positioned through the slotted hole in the stem.

The prosthetic parts were then connected. The animals were allowed to bear weight directly post-operatively.

RESULTS

All implants appeared well-fixed and stable on initial post-operative radiograms in both groups (Fig. 2). Of the eight type I implants, six were obviously loose after 3 days and one after 10 days post-operatively. Each of these seven goats displayed an exorotated lower leg (the direction in

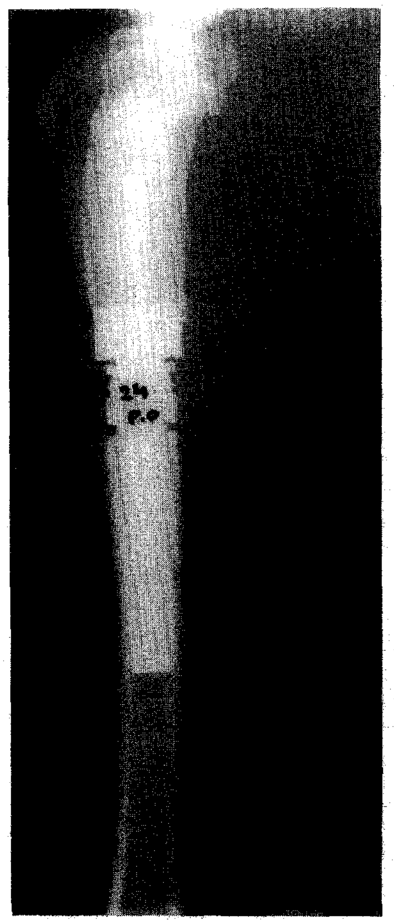

Fig. 2. Radiograph taken in the lateral-medial direction directly after implantation of a type I prosthesis. Proximal cement is visible. The distal, screwed fixation appears firm.

Fig. 3. Radiograph taken in the lateral-medial direction at the time of harvesting a type I implant at 11 weeks. Clinically the implant was loose 3 days post-operatively. A limp was apparent, but the animal was functioning quite well, maybe because of callus formation. The gross rotational instability present in the first weeks after loosening diminished to a few degrees at the end. At harvesting there were no signs of infection and cultures were negative.

which the stem is 'unscrewed') in walking; all could be rotated manually. Serial radiographs taken at 3-week intervals showed increasing lysis at the stem/bone interface, and periosteal bone appositioning at the distal side in particular (Fig. 3). The seven animals were killed between 2 and 12 weeks post-operatively. A fibrous tissue was found at the interface, of which the thickness appeared proportional to the post-operative time period. On histological analysis, metal particles embedded in macrophages and hydroxyapatite particles without related cellular reactions were found in the fibrous tissue.

The one goat in series I without clinical loosening developed a bridge 'callus' shortly post-operatively, which appeared to stabilize the prosthesis, although also in this tibia, radiolucency around the implant was seen.

The eight goats with the type II implants were weight-bearing normally and functioning well to at least 6 weeks after the operation. Although the stems have obviously subsided somewhat in the immediate post-operation phase, no signs of loosening were seen in a period of time equal to group I, and radiographically the implants seemed to be osseointegrated until at least the 6 weeks post-operative control. Two out of eight implants became loose after that period, one because of infection, the other peracute, probably due to the impact of a jump.

DISCUSSION

Obviously, the study of implant-loosening mechanisms was not the purpose of this project. Osseointegration of the implants was a prerogative, rather than a subject of investigation. As a consequence, a rigorous prospective protocol for post-operative analysis of the failed cases was neither planned nor carried out. However, in view of the obvious failure mechanism of the screwed implants, and its prohibitive consequences for implant designs in general, the publication of our observations was considered important.

Both the smooth and the screwed tapered stems are initially held in the bone by pre-stresses and friction. Their stability depends on the interface stresses generated during the fixation procedure, and on the roughness (coefficient of friction) of the connecting materials. Because the interfaces can be more highly stressed with the screwed, type I implants, as compared to the smooth, type II implants, it was assumed that the former would provide better initial stability than the latter. However, this assumption is a purely technological one, and neglects the biological reactions of the bone.

Apparently, the stresses generated within the bone during the fixation procedure disappear post-operatively, either through a viscoelastic mechanism, or, more likely, as a result of some bone resorption at the interface. When this occurs, the screwed stems become effectively loose, after which relative motions, predominantly in torsion, will cause more bone to resorb and fibrous tissue to be formed. The smooth stems, however, have no resistance against subsidence, hence secondary stability can be provided by the axial force component.

It can be argued, of course, that bone screws have been used in orthopaedic surgery and traumatology with great success. However, in that case more stress can be generated because of the wider screw threads and the smooth (non-coated) surface, and in addition, bone screws are not normally loaded in torsion.

A similar observation was reported by Miller & Kelebay,[5] who noted in an abstract describing a similar segmental replacement in dogs: 'All failed within days or weeks of surgery with loosening occurring in torsion'.

It can be concluded that we unintentionally demonstrated that the application of screwed intramedullary stems for prosthetic fixation is not a viable concept. It is also evident that hydroxyapatite coatings, however beneficial their osteo-inductive effects, will not prevent an inferior prosthetic design from loosening. For non-cemented prosthetic designs in general our experience implicates that a prosthesis must be given the opportunity to re-set by the axial force component, after some interface resorption has occurred, as is bound to happen.

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