High failure rate of cementless threaded acetabular cups

A radiographic and histologic study in the goat

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We studied the fixation of the Mecron cementless titanium screw cup radiographically and histologically in 20 dwarf-goats after periods of 0, 6, 26 and 52 weeks. In only 3 goats did histology show good bone-implant contact, whereas in the other 17 goats a fibrous membrane interface was seen. This high failure rate is caused by the poor primary fixation and should be a warning against the use of this implant.

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Our 7-year follow-up study on the Mecring cementless threaded acetabular cup showed an alarming rate of radiographic loosening (Bruijn et al. 1995).

In order to investigate further the process of fixation and loosening of cementless threaded acetabular cups, we studied this method of fixation in goats.

Material and methods

Prosthesis

The implant system consisted of a straight, cemented femoral stem, with a cobalt-chrome head and a threaded acetabular component (Mecring, Mecron, Berlin) made of titanium alloy (Ti6Al4V) with a matt surface, containing a snapfit polyethylene liner. The threaded cup has a hemispherical shape and a central hole, which enables visualization of the fit; the outer surface contains 5 screw threads. The component is similar to the types commercially available for use in humans, except that the polyethylene liner does not allow direct contact with the acetabular bone. A standard 17 mm diameter body with a 1 mm thread was used.

Animals

20 young, fully-grown, dwarf-goats, with a body weight of approximately 30 kg, were used. This animal model is considered relevant to the human situation (Schreurs et al. 1994).

Surgery

The operations were performed under general anesthesia, using standard aseptic techniques. Amoxicillin was administered for 7 days postoperatively.

An anterolateral approach to the right hip was used. The acetabulum was carefully reamed by manual force to prevent heat necrosis up to a diameter equal to that of the base of the threads on the Mecring body.

One cup-diameter was appropriate for all goats. Insertion of the self-tapping threaded component was done with a torque wrench (tested torsion: 12 Nm). The fit was checked through the central hole.

Postoperative treatment

During the first 24 hours following operation, the goat was nursed in a hammock with its legs clear of the ground. Then full weight-bearing was allowed in a cage and 1 week postoperatively the goat was brought back to the meadow for unrestricted activity. Loading patterns were scored weekly, using visual grading of function.

Preparation and analysis of the hips

The goats were killed by an overdose of pentobarbital sodium in 3 groups: the first (n 8) after 6 weeks, the second (n 6) after 6 months and the third group (n 6) after 12 months. Three goats received a Mecring on the contralateral side, just before the end of the experiment, as a control (0-week group).

Anteroposterior and axial radiographs were taken of the pelvis and operated hip.

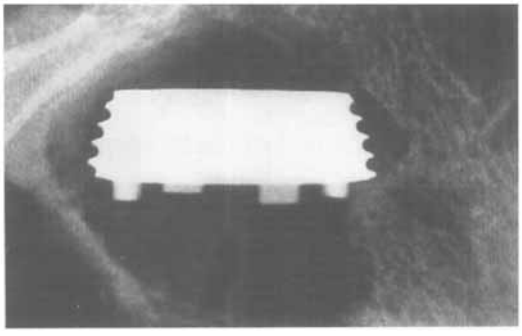

Figure 2. Extended demarcation; the demarcation zone is complete and covers the entire ring.

Figure 1. Limited demarcation, not covering the entire ring. On the left, there is no radiographic demarcation.

The entire acetabulum was resected en bloc from the pelvis and immersed in Karnovsky's fixative (4% formaldehyde, 5% glutaraldehyde), dehydrated in graded series of ethanol, and embedded in methylmethacrylate.

The samples were hemisectioned perpendicular to the threads of the Mecring. One half was sputter-coated with carbon and examined and photographed with back-scatter electron microscopy (Philips 525M). The other half was submitted for radiographic and histological evaluations. Contact-radiographs were taken of the bone-implant contact area. The postmortem and contact-radiographs were assessed for bone-densification (Huiskes 1987) (as compared to the contralateral side), bone-implant contact (Tooke et al. 1988) and evidence of loosening in terms of demarcation and migration (Mjöberg 1986, Kwong et al. 1992, Seelen et al. 1992). Demarcation around the implant was defined as a radiolucent zone with a sclerotic margin (Kwong et al. 1992) and was graded as none, limited or extended.

No demarcation: no lucent zone with a sclerotic margin (Figure 1).

Limited demarcation: a thin line of demarcation, that does not cover the entire ring (Figure 1).

Extended demarcation: the demarcation zone surrounds the entire ring (Figure 2).

Sections, that were not decalcified, with a thickness of 50 micrometers were cut, using a diamond sawing microtome. Sections were also taken from the synovium. They were routinely stained with hematoxylin-eosin, and methylene blue and basic fuchsin.

Sections were also taken from the bony threads of the acetabulum of the control group goats.

The surface of the Mecrings was studied through a ×10 objective for damage and signs of wear.

Results (Table 1)

All goats tolerated the surgical procedure well. 3 out of 8 goats in the 6-week implantation group and all goats in the 26- and 52-week implantation groups regained normal weight bearing and gait within the first week postoperatively and had no complications at the end of the experiment.

Complications

5 goats in the 6-week implantation group dislocated their operated hip immediately after operation; 3 of them had a fractured femur and 1 had a deep infection. 3 of those goats limped and 2 were unable to use their operated hip. They were not excluded from the study, because these complications did not interfere with the aim of investigating the primary fixation of the acetabular component and correlating the radiographic characteristics with the interface response.

Radiographic evaluation

Bone-densification of the whole acetabulum was seen in 12 of the 20 goats, more or less equally distributed in the 3 groups with different implantation periods.

A radiographic bone-implant contact of more than 75% was seen in 4 goats only, with no clear preference for different implantation periods.

Only 3 goats showed no demarcation, 1 in the 6-week and 2 in the 26-week implantation group. Limit-

Table 1. View data

A	B	C	D	E	F	G	H	I
1	6	1	1	2	0	1+2	2	2
2	6	0	4	0	0		1	0
3	6	1	1	2	1		1	3
4	6	0	1	2	0	1+3	2	3
5	6	1	3	1	0		1	1
6	6	1	3	1	0	1+2	4	1
7	6	0	2	2	0	1+2	2	2
8	6	0	1	2	0	1	4	2
9	26	0	5	0	0		1	0
10	26	1	0	2	1		1	3
11	26	0	1	2	1		1	3
12	26	1	0	2	1		1	3
13	26	1	0	2	1		1	3
14	26	1	5	0	0		1	0
15	52	0	0	2	1		1	3
16	52	1	5	1	0		1	1
17	52	1	0	2	1		1	3
18	52	1	0	2	1		1	3
19	52	1	2	1	0		1	1
20	52	0	2	2	1		1	3
5	0	0	4	0	0	4	–	4
6	0	0	3	0	0	4	–	4
11	0	0	4	0	0	4	–	4

A Goat
B Weeks implanted
C Bone-densification
  0 no
  1 yes
D Percent bone-implant contact (radiographic)
  0 < 10%
  1 10–25%
  2 25–50%
  3 50–75%
  4 75–90%
  5 90–100%
E Demarcation
  0 no
  1 limited
  2 extended
F Migration
  0 no
  1 yes
G Special remarks
  1 hip dislocation
  2 fractured femur
  3 infection
  4 control hip
H Gait
  1 good
  2 slight limp
  3 serious limp
  4 not using operated hip
I Interface (histologically)
  0 good bone-implant contact
  1 thin dense collagenous membrane
  2 mixture of dense collagenous and collagen-poor membrane
  3 thick collagen-poor membrane
  4 bone thread of poor quality

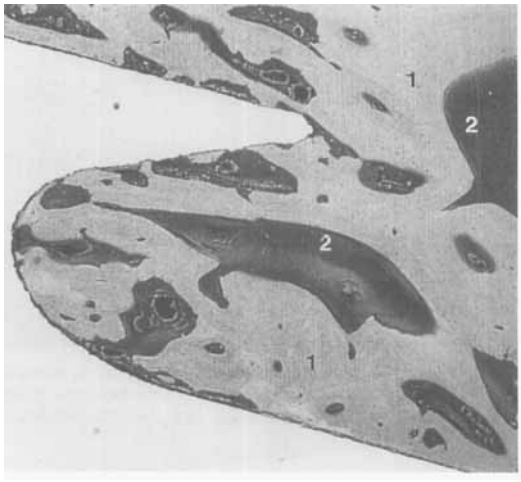

Figure 3. Good implant fixation; normal bone structure (1) with only a few foci of fibrous tissue (2) is present between the threads (backscatter electron microscopy, ×60).

Figure 4. Dense fibrous membrane with collagen bundles organized parallel to the surface of the Mecring. Only a few fibrocytes and hardly any vessels are visible. The thickness of this membrane varied between 0.3–0.8 mm (hematoxylin-eosin, ×250).

ed demarcation was seen in 4 goats. The remaining 13 goats showed an extended demarcation.

Migration was seen in all cases of extended demarcation, except for those unable to fully load their hip because of dislocation. Migration was not seen in cases with little, if any, demarcation.

The 3 left-sided acetabuli receiving a Mecring just before the goats were killed, as a control group, showed an incomplete bone-implant contact on the radiographs.

Histologic evaluation

3 goats, 1 in the 6-week and 2 in the 26-week groups, showed generally good osseous trabecular contact with the implant. Normal bone structure was present between the threads, with only a few foci of fibrous tissue. This was confirmed by electron microscopic examination (Figure 3).

In the other 17 goats, the bone-implant interface consisted of a fibrous membrane of 2 different types or a mixture of them.

The first type of fibrous membrane (Figure 4), seen in 4 goats, consisted of collagen bundles organized parallel to the surface of the Mecring, with few fibrocytes and hardly any vessels. The thickness of this layer varied between 0.3–0.8 mm. Spots of limited bone absorption were present, close to the polyethylene liner as well as the titanium Mecring.

Figure 5. Fibrous membrane with many fibrocytes and vessels, but without massive collagen production. The thickness of this membrane varied between 1.2–2.2 mm (hematoxylin-eosin, ×60).

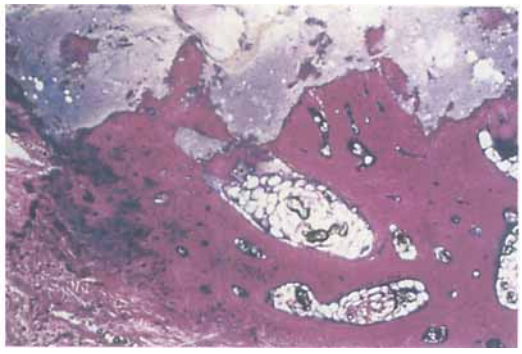

Figure 6. A section taken from the bony threads in the acetabulum of a control group goat showing damaged bone; small areas with good trabecular bone changing into areas with compressed and destroyed bone are visible (hematoxylin-eosin, ×15).

The second type of fibrous membrane (Figure 5), seen in 10 goats, consisted of connective tissue, with many fibrocytes and vessels, but without collagen bundles.

Foci of histiocytes containing iron pigment were present as remnants of bleedings. The thickness of this fibrous membrane was generally 1.2–2.2 mm. Bone absorption was seen on a larger scale and was more pronounced adjacent to the polyethylene liner than the titanium Mecring. Another 3 goats, all in the 6-week group, showed a mixture of type 1 and type 2 interface.

Sections taken from the synovium showed scattered areas with giant cells and polyethylene particles in all animals, except those of the 6-week implantation period. However, no polyethylene particles or signs suggesting a foreign-body reaction were detected in any of the interface membranes.

Sections taken from the bony threads in the acetabulum of the control group goats showed damaged bone and small areas with good trabecular bone changing into larger areas with compressed and destroyed bone (Figure 6).

The surface of the Mecring showed some damaged and bowed thread-tips and superficial scratches in the titanium. Such signs of wear were mostly found in goats lacking good bone-implant fixation.

Discussion

The quality of primary fixation determines the quality of secondary fixation (Perren 1984, Pilliar et al. 1986, Albrektsson and Albrektsson 1987, Favard et al. 1992, Seelen et al. 1992). Threaded acetabular components are of interest because of their rigid mechanical interlock, initially achieved at surgery. However, the primary fixation of the Mecring in our present study was usually inadequate: only 1 of 8 goats in the 6-week implantation period showed good bone-implant contact histologically.

The inserted component, self-tapping according to the manufacturer's manual, instead of cutting a proper thread in the acetabular bone, destroys it, as was revealed by examination of the acetabuli in the control group (Figure 6). Aiming at good bone-interdigitation between the threads and bone-implant press-fit, the screw-in maneuver forces bone and bone-debris deeper into the diminished volume of the threads. As a consequence, high stress develops locally in the bone at the interface, resulting in (micro)fractures and pressure necrosis, leading to resorption of the bone, its replacement by fibrous tissue and early loosening (Kody et al. 1990). This fibrous tissue formation, radiographically characterized by demarcation (Kwong et al. 1992, Seelen et al. 1992), can occur in a relatively short time after implantation, as was seen in our goats.

Demarcations are easy to demonstrate in the goat. As Engh et al. (1989) stated, demarcations can be difficult to demonstrate around unstable cementless acetabular components in human beings and the true incidence of loosening in this way is underestimated.

Migration was not seen in goats with a thin dense collagen membrane interface on histological examination (Table 1). Apparently this provides a more stable anchorage of the implant with less loss of bone, which is consistent with the findings of Søballe et al. (1992).

Loosening of acetabular components may be accelerated by the presence of polyethylene particles (Goldring et al. 1983, Agins et al. 1988, Nasser et al. 1990, Santavirta et al. 1991, Bruijn et al. 1995). We detected polyethylene particles in the synovium, but

none in the interfaces. This may be explained by the relatively short implantation period and by the implant design preventing direct polyethylene-bone contact, contrary to the type commercially available for use in humans (Bruijn et al. 1995).

Our study demonstrates a high failure rate of threaded acetabular components in goats, which calls for a warning against the use of this device.

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