Crack Revision Improves Fixation of Uncemented HA-coated Implants Compared with Reaming

An Experiment in Dogs

Jorgen Baas MD, PhD, Brian Elmengaard MD, PhD,
Thomas Jakobsen MD, Joan Bechtold PhD,
Kjeld Soballe MD, DMSc

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Abstract The crack procedure is a surgical technique for preparing the implant cavity at revision of loose joint replacement components. It disrupts the neocortical bone shell that typically forms around the cavity. Using an animal model, we compared the crack technique with reaming. Twenty micromotion implants were inserted bilaterally into the knees of 10 dogs according to our revision protocol, allowing formation of a standardized revision cavity (loose implant, fibrous tissue, and sclerotic bone rim). Eight weeks later we performed revision surgery. On the control side, in which the neocortex was removed, the cavity was reamed. On the intervention side, in which the neocortex was perforated but left in situ, the cavity was cracked. For revision we used non-motioning hydroxyapatite (HA)-coated, plasma-sprayed titanium implants. Observation after revision was 4 weeks. The implants revised by the crack

technique had better mechanical fixation in all mechanical parameters by the push-out test. The crack revisions also provided more new bone formation around the implants compared with the reamed revisions but had no effect on new bone ongrowth. The data suggest using this bone-sparing technique may be superior to reaming in terms of achieving improved early implant fixation of uncemented HA-coated revision implants.

Introduction

Initial stable fixation of a joint replacement is critical for its long-term survival [6, 11]. This can be a challenge in revision arthroplasties, in which the bone bed often is insufficient. At revision, the loose implant often is encapsulated in fibrous tissue and surrounded by a sclerotic bone shell [9, 13]. This endosteal neocortex potentially is an obstacle for cellular recruitment, bone ingrowth, and osseointegration of the revision implant, regardless of whether it is inserted uncemented, cemented, or by impaction allografting. At revision, it usually is reamed away, and the neocortex is removed to expose a well-vascularized bone surface. Although the neocortex may inhibit implant osseointegration, its complete removal by reaming may cause unnecessary bone loss.

Kold et al. described a surgical technique that systematically disrupts (cracks) the neocortical bone shell [7]. The procedure is presumed to improve access of marrow cells, blood, and growth factors to the revision implant. It also leaves the cracked neocortex in situ where it may provide scaffold for new bone ingrowth. Kold et al. suggested the crack technique provided increased early mechanical fixation of porous titanium implants compared with leaving the neocortex completely undisturbed [7].

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J. Baas (✉), B. Elmengaard, T. Jakobsen, K. Soballe
Orthopaedic Research Laboratory, Department of Orthopedics,
Aarhus University Hospital, Norrebrogade 44, Build.1A, 8000
Aarhus C, Denmark
e-mail: baas@ki.au.dk

J. Bechtold
Midwest Orthopaedic and Minneapolis Medical Research
Foundations, Minneapolis, MN, USA

We hypothesized that the crack revision technique would augment early implant fixation and osseointegration compared with revision by reaming as evidenced by improved mechanical fixation, more new bone formation around and on the implants, and reduced presence of fibrous tissue.

Materials and Methods

This study was designed as a paired animal experiment in the knees of 10 female American Foxhounds with a mean weight of 22.7 kg (range, 20.3–25.3 kg). We determined the number of animals based on a power analysis to detect relative group differences of the mechanical and histomorphometric variables of at least 30% assuming a coefficient of variance of the paired differences of 30% (CVDIFF). This CVDIFF was based on previous data from the same experimental model. We assumed a level of alpha of 0.05 and a beta of 0.80. Our revision protocol was followed to create the environment representative of implant loosening [3, 4]. After 8 weeks, we revised the primary implants. The type of revision procedure (crack or ream) was alternated systematically between sides with random start. The observation after revision was 4 weeks. All procedures in this study were approved by the Animal Care and Use Committee of the Minneapolis Medical Research Foundation.

The revision protocol reproduces a periprosthetic tissue reaction characteristic for implants undergoing revision (dense fibrous tissue, macrophages with intracellular particulate polyethylene, and a sclerotic bone rim) [3, 4]. The revision environment is ensured with the use of a micromotion device [3] implanted into the medial condyle of each knee. The micromotion device was set to allow controlled axial implant movement of 0.5 mm with each gait cycle. We mounted cylindrical polymethylmethacrylate (PMMA) implants (diameter, 6 mm; length, 10 mm) onto the device and subjected them to gait-induced micromotion for 8 weeks in the presence of polyethylene (PE) particles (0.5–50 μm ; 0.5×10^8 particles; 85% less than 12 μm) to mimic a loose, cemented implant [3]. This created a cavity with the characteristics of a clinically loose implant as described previously.

We used 20 HA-coated porous titanium (Ti-6Al-4V) implants, manufactured by Biomet Inc (Warsaw, IN), for the revisions. The porous-coated implants were cylindrical with a 10 mm height and 6 mm diameter. The titanium coating was plasma-sprayed, providing a mean pore diameter of 480 μm and a mean porosity of 44% as specified by the manufacturer. We then gave the implants an additional 50- μm thick HA coating with the plasma-sprayed technique.

At the first (primary) surgery (Fig. 1), the micromotion device with an unstable PMMA implant and articulating

Fig. 1 A schematic of the surgical protocol is shown (HA = hydroxyapatite).

PE plug was implanted into the medial condyle of each knee. All surgeries (primary and revision procedures) were performed by the same surgeon (JB). We placed a 2.1-mm guide wire perpendicular to the weightbearing articulating surface in the central portion of the medial condyle. A 30-mm deep cavity (7.5-mm diameter in the superficial 20 mm; 6-mm diameter in the deep 10 mm) was created using a cannulated step drill. The most superficial 3 mm was tapped for placement of a subcortical centralizing ring. The micromotion anchor device was mounted in the cavity and a cylindrical (diameter, 6 mm; length, 10 mm) PMMA implant was screwed onto its motioning piston. The internal spring of the micromotion device pushes the implant back out after it is pushed inward during weightbearing. We filled the 0.75-mm gap surrounding the implant with the PE particles administered in 0.3 mL hyaluronic acid. A PE plug was screwed onto the distal

portion of the threaded piston superficial to the PMMA implant and manually adjusted to a minimal protrusion into the joint space to cause full 0.5-mm axial implant displacement during loading. The joint capsule, muscle fascia, and subcutaneous tissue were closed with resorbable sutures followed by skin closure with staples. We repeated the procedure for the contralateral knee.

We performed the second (revision) surgery (Fig. 2) 8 weeks after the primary surgery under identical conditions and using the same approach. At this second operation, the PMMA implants and primary centralizing rings were removed. The fibrous membrane was removed with a curette. On the cracked side, a cannulated cylindrical tool (the crack tool; Fig. 2) with 12 evenly spaced 1.2-mm axially oriented blades (outer diameter 8.4 cm) was introduced over the anchor piston and advanced by hammer blows, cracking the neocortex on the edge of the cavity with minimal tissue loss. On the reamed side, we reamed the cavity with an 8.2-mm cannulated reamer by which the neocortex was removed. On both sides, a new thread for the revision centralizing ring was tapped and the cavity irrigated with saline. A cylindrical (diameter, 6 mm; length, 10 mm) HA-coated revision implant (Biomet Inc) was screwed onto the piston and stabilized preventing further micromotion. A revision polyethylene plug

(0.25 mm shorter than the primary polyethylene plug) was screwed onto the distal portion of the threaded piston superficial to the HA-coated implant and manually adjusted to a minimal protrusion into the joint space to secure loading during gait. The joint capsule, muscle fascia, and subcutaneous tissue were closed with resorbable sutures followed by skin closure with staples.

The dogs were given 1 g ceftriaxone administered immediately before each surgery and 3 days postoperatively. Buprenorphine hydrochloride at a dosage of 0.3 mg/mL 0.0075 mg/kg per day intramuscularly was given as postoperative analgesia. The dogs were allowed unrestricted weightbearing immediately after both surgeries. All 10 dogs were fully weightbearing within 3 days after surgery and completed the 8 weeks after primary surgery and 4-week observation period after revision surgery without signs of infection or other complications.

The animals were euthanized using intravenous sodium pentobarbital (10 mL Beuthanasia-d Special, Schering-Plough, Summit, NJ). The distal femurs were frozen and stored at -20°C immediately after retrieval. The most superficial 0.5 mm of the implant-bone specimen (closest to the joint surface) was cut off and discarded. We divided the rest of the implant with surrounding bone into two transverse sections (perpendicular to the long axis of the implant) with a water-cooled diamond band saw (Exact Apparatebau, Nordenstedt, Germany). Two transverse sections of the implant-bone specimen were used because of the destructive nature of the mechanical test. For consistency, the outermost section closest to the joint was used for mechanical testing and the innermost section for histomorphometric analysis. The outermost implant section was cut to a thickness of 3.5 mm and stored at -20°C until mechanical testing. The innermost implant section was cut through the micromotion anchor screw just below the implant and prepared for histomorphometry. These specimens were dehydrated in graded ethanol (70%–100%) containing basic fuchsin and embedded in methylmethacrylate. Using the vertical sectioning technique [2], we cut each specimen into four 30- μm thick histologic sections parallel to the implant axis with a microtome (KDG-95; MeProTech, Heerhugowaard, Holland) [10]. Finally, these were surface-counterstained with 2% light green (BDH Laboratory Supplies, Poole, UK) for 2 minutes, rinsed, and mounted on glass. This preparation provided red staining of noncalcified tissue and green staining of calcified tissue.

We tested thawed specimens to failure by the axial push-out test on an MTS 858 Mini Bionix test machine (MTS Systems Corporation, Eden Prairie, MN) with a 2.5 KN axial load cell. Testing was performed blinded and in one session. The specimens were placed with the cortical side facing up on a metal support jig with the implant centered over a 7.4-mm opening and under a 5-mm

Fig. 2A–C (A) The cracking tool mounted on a slap hammer arm is shown. (B) The revision cavity is seen after removal of the PMMA implant and fibrous membrane. (C) Axial progression of the cracking tool with light hammer blows is seen.

diameter cylindrical test probe. A preload of 2 N defined the contact position for the start of the test. The implants then were pushed out of the surrounding tissue in the direction of the implant axis at a rate of 5 mm/minute [8]. We continuously recorded load versus implant displacement data. From these data, the mechanical implant fixation parameters as described earlier were calculated: ultimate shear strength, apparent shear stiffness, and total energy absorption [12].

We (JP) performed blinded quantitative histomorphometry using the stereologic software CAST Grid (Olympus Denmark AS, Ballerup, Denmark). With the aid of the software, the region of interest (ROI) was defined as the median surface line (the midline between the innermost pore and the outermost metal) and 0.5 mm into the implant perimeter. Volume fractions of new woven bone, lamellar bone, fibrous tissue, and marrow space were quantified by the point-counting technique [5]. On the implant surface, the area fractions of the same tissues were quantified by the line-interception technique [2]. These techniques provide highly reliable results with negligible bias [1]. Bone was surface-stained green and therefore easy to distinguish from the other tissues. Newly formed bone was woven, appearing less organized with large, round osteocyte lacunae. Lamellar bone was defined by its highly organized lamellas and lamella-oriented long, oval cell lacunae. However, as expected, we observed no lamellar bone in the ROI at this 4-week time postoperatively. We identified

fibrous tissue by the presence of clearly visible fibril fiber complexes and low cell density. The fibrous tissue largely appeared oriented, dense, and well organized, but also as a loosely, not clearly oriented, interconnected fibrous network. Marrow space consisted of fat vacuoles and surrounding blood cells. The histomorphometric intraobserver reproducibility was recorded by recounts of randomly selected specimens (Table 1) [1].

The mechanical data sets followed normal distribution and fulfilled the assumptions for parametric evaluation with paired t-tests. The relative change of volumetric new bone fractions surrounding the implants was represented by normal distribution and evaluated by unpaired t-test. The histologic data sets were evaluated nonparametrically with the Wilcoxon signed rank test, because normal distribution could not be assumed for all parameters, in most cases because of values close to zero. Statistical analysis was performed using Intercooled STATA 9.0 software (Stata-Corp LP, College Station, TX).

Results

The implants revised by cracking had better mechanical fixation than the implants revised by reaming in all three mechanical parameters: ultimate shear strength ($p = 0.006$), apparent shear stiffness ($p = 0.023$), and total energy absorption ($p = 0.026$) (Table 2).

Implant osseointegration was improved with the crack revision technique compared with reaming. Although there was no difference between the groups in the amount of newly formed bone in direct contact with the HA-coated implant surface (Table 3), more bone was formed in the immediate vicinity of the reamed implants (Table 4; Fig. 3). Using the crack revision technique led to a 50%

Table 1. Histomorphometric reproducibility*

Parameter	Woven bone (%)	Fibrous tissue (%)	Marrow space (%)
Ongrowth	6.9	9.0	8.1
Ingrowth	5.0	13.2	3.3

* Variation coefficient (CV %) of double estimates.

Table 2. Mechanical push-out test*

Groups	Strength (MPa)		Stiffness (MPa/mm)		Energy (kJ/m ²)	
HA ream	3.5	(1.2)	17	(5.2)	0.54	(0.24)
HA crack	4.8	(1.0)	22	(3.3)	0.71	(0.22)
Paired t-test	$p = 0.006$		$p = 0.023$		$p = 0.026$	

* Parameters of biomechanical implant fixation from normalized force-displacement curves (mean [standard deviation]); HA = hydroxyapatite.

Table 3. Histology of implant surface ongrowth*

Groups	Woven bone (%)		Fibrous tissue (%)		Marrow space (%)	
HA ream	49	(43–55)	0.9	(0–15)	44	(35–50)
HA crack	48	(38–50)	2	(0–4)	49	(39–55)
Wilcoxon signed rank test	$p = 0.575$		$p = 0.683$		$p = 0.241$	

* Area fractions of tissues on implant surface in percent (median [interquartile range]); HA = hydroxyapatite.

Table 4. Histology of tissue ingrowth (0–500 μm)*

Groups	Woven bone (%)		Fibrous tissue (%)		Marrow space (%)	
HA ream	19	(17–24)	2.3	(0–7.8)	73	(68–81)
HA crack	28	(22–34)	2.3	(0–5.8)	66	(55–74)
Wilcoxon signed rank test	p = 0.028		p = 0.610		p = 0.114	

* Volume fractions of tissues surrounding implant in percent (median [interquartile range]); HA = hydroxyapatite.

Fig. 3A–B Representative histology from an implant pair in the same dog are shown (**A**) In a reamed implant, bone ongrowth is evident but only a little bone is bridging the gap between the implant and surrounding bone (basic fuchsin and light green; lens magnification $\times 1.25$ (upper image A); $\times 10$ (lower image A)). (**B**) In a cracked implant, a similar amount of bone ongrowth is evident but there is more bone bridging the implant to the surrounding bone (basic fuchsin and light green; lens magnification $\times 1.25$ (upper image B); $\times 10$ (lower image B)).

relative increase ($p = 0.011$) in newly formed bone around the implants compared with reaming.

Fibrous tissue was largely absent and was similar in both groups.

A mean 448 (standard deviation [SD], 49) line intercept counts for tissue area fraction estimation and 496 (SD, 48) point counts for tissue volume fraction estimation were made per implant.

Discussion

The purpose of this study was to compare the crack revision technique with removal of the neocortex by reaming, which is a common way to prepare the revision cavity. We investigated the technique on HA-coated implants. We hypothesized the procedure would improve early mechanical fixation and implant osseointegration.

Although the model is able to replicate some of the features of implant loosening, the data should be

interpreted with the limitations of the experimental model in mind. The bone is canine and not human, and the revision cavity was created over a short period of time and does not reflect the wide variety of revision settings the orthopaedic surgeon encounters. The implants are models and not functional arthroplasties and have a very simplistic cylindrical shape. The cracking tool used for the experimental revisions is designed to produce uniform crack revisions around the individual cavity and between the cavities of different animals. Its design, however, is not suitable for the extreme variability in clinical revisions. All these measures were taken to standardize conditions and increase reproducibility, but it is at the expense of some clinical relevance. The experimental protocol used in this study generates an environment and tissue changes that have the characteristics of aseptic implant loosening [3, 4]. The primary implant is exposed to direct cyclic load and allowed controlled load-induced micromotion. The implant-tissue interface is subject to the oscillating changes in joint fluid pressure and particulate wear debris. The tissue

changes include encapsulation of the implant in dense fibrous tissue, macrophages with intracellular PE, formation of a sclerotic bone rim, increased inflammatory cytokines (interleukin-6 and tumor necrosis factor- α), and a decreased anabolic growth factor (transforming growth factor- β). The stabilized revision implant also is loaded during activity and its interface is exposed to joint fluid. The implant surface is the same plasma-sprayed HA coating on plasma-sprayed titanium alloy as is used on clinical implants and is a well-established implant surface for uncemented revision.

The study was prompted by previous findings on non-coated porous titanium revision implants in which cracking gave improved mechanical fixation compared with leaving the neocortical bone shell unprepared [7]. In combination, these studies indicate the beneficial effect comes from the combination of disrupting the neocortex and at the same time minimizing the bone loss at revision. The presumption that the intact neocortex delays, or even blocks, osseointegration of the revision implant seems valid. This study shows it is sufficient to disrupt the integrity of the neocortical bone shell (crack) and that leaving its cracked remains in situ is beneficial for implant fixation. We presume the increased fixation and osseointegration are caused largely by an osteoconductive effect of the cracked bone, serving as a scaffold for new bone ingrowth.

In clinical practice, the principles of this study can be implemented with as simple surgical tools such as a standard curved osteotome to perforate the sclerotic bone rim with light hammer blows. This is now routine in our department. To what extent this technique increases the risk of clinical complications (eg, iatrogenic fractures) compared with reaming is beyond the scope of this experiment. The primary focus of this experimental setup has been implant fixation in metaphyseal bone. Many revisions of the femoral component rely on distal fixation, but even in these cases, it may be beneficial to use bone-sparing procedures in the metaphysis. Whereas the endosteal neocortex may inhibit implant osseointegration, its removal by reaming may cause unnecessary bone loss. It seems the worst revision strategy is to leave the neocortical bone shell intact [7], which we do not recommend. Our data suggest the best implant fixation is achieved by local and systematic cracking of the neocortex, by which its shell-like continuity is disrupted at regular intervals and bone loss minimized.

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References

1. Baas J. Adjuvant therapies of bone graft around non-cemented experimental orthopedic implants: stereological methods and experiments in dogs. *Acta Orthop Suppl.* 2008;79:1–43.
2. Baddeley AJ, Gundersen HJ, Cruz-Orive LM. Estimation of surface area from vertical sections. *J Microsc.* 1986;142:259–276.
3. Bechtold JE, Kubic V, Soballe K. A controlled experimental model of revision implants: Part I. Development. *Acta Orthop Scand.* 2001;72:642–649.
4. Bechtold JE, Mouzin O, Kidder L, Soballe K. A controlled experimental model of revision implants: Part II. Implementation with loaded titanium implants and bone graft. *Acta Orthop Scand.* 2001;72:650–656.
5. Gundersen HJ, Bendtsen TF, Korbo L, Marcussen N, Møller A, Nielsen K, Nyengaard JR, Pakkenberg B, Sørensen FB, Vesterby A, et al. Some new, simple and efficient stereological methods and their use in pathological research and diagnosis. *APMIS.* 1988;96:379–394.
6. Karrholm J, Borssen B, Lowenhielm G, Snorrason F. Does early micromotion of femoral stem prostheses matter? 4–7-year stereoradiographic follow-up of 84 cemented prostheses. *J Bone Joint Surg Br.* 1994;76:912–917.
7. Kold S, Bechtold JE, Mouzin O, Elmengaard B, Chen X, Soballe K. Fixation of revision implants is improved by a surgical technique to crack the sclerotic bone rim. *Clin Orthop Relat Res.* 2005;432:160–166.
8. Linde F, Norgaard P, Hvid I, Odgaard A, Soballe K. Mechanical properties of trabecular bone: dependency on strain rate. *J Biomech.* 1991;24:803–809.
9. Nelissen RG, Bauer TW, Weidenhielm LR, LeGolvan DP, Mikhail WE. Revision hip arthroplasty with the use of cement and impaction grafting: histological analysis of four cases. *J Bone Joint Surg Am.* 1995;77:412–422.
10. Overgaard S, Soballe K, Jørgen H, Gundersen G. Efficiency of systematic sampling in histomorphometric bone research illustrated by hydroxyapatite-coated implants: optimizing the stereological vertical-section design. *J Orthop Res.* 2000;18:313–321.
11. Ryd L, Albrektsson BE, Carlsson L, Dansgård F, Herberts P, Lindstrand A, Regnér L, Toksvig-Larsen S. Roentgen stereophotogrammetric analysis as a predictor of mechanical loosening of knee prostheses. *J Bone Joint Surg Br.* 1995;77:377–383.
12. Soballe K. Hydroxyapatite ceramic coating for bone implant fixation: mechanical and histological studies in dogs. *Acta Orthop Scand Suppl.* 1993;255:1–58.
13. Vestermark MT, Bechtold JE, Swider P, Soballe K. Mechanical interface conditions affect morphology and cellular activity of sclerotic bone rims forming around experimental loaded implants. *J Orthop Res.* 2004;22:647–652.