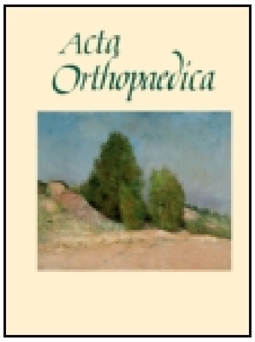

Acta Orthopaedica

ISSN: 1745-3674 (Print) 1745-3682 (Online) Journal homepage: informahealthcare.com/journals/iort20

Inferior fixation with a new pin design for external fixation: A randomized study in 50 patients operated on by the hemicallotasis technique

Sören Toksvig-Larsen & Annette W-Dahl

To cite this article: Sören Toksvig-Larsen & Annette W-Dahl (2008) Inferior fixation with a new pin design for external fixation: A randomized study in 50 patients operated on by the hemicallotasis technique, Acta Orthopaedica, 79:1, 48-52, DOI: 10.1080/17453670710014752

To link to this article: https://doi.org/10.1080/17453670710014752

Published online: 08 Jul 2009.

Inferior fixation with a new pin design for external fixation

A randomized study in 50 patients operated on by the hemicallotasis technique

Sören Toksvig-Larsen and Annette W-Dahl

Department of Orthopedics, Lund University Hospital, Lund, Sweden
Correspondence STL: Soren.Toksvig-Larsen@med.lu.se
Submitted 06-04-02. Accepted 06-07-03

Background and purpose **Tibial osteotomy by the hemicallotasis technique (HCO) requires strong pin fixation. We compared pin fixation in HCO using a new self-drilling XCaliber pin (Orthofix) with optimized thread and tip design, with the commonly used standard pin (Orthofix).**

Patients and methods **50 patients, mean age 51 (35–66) years, to be treated by HCO were randomized to standard pins or XCaliber pins. In the metaphyseal bone, hydroxyapatite-coated (HA-coated) pins were used in both types of pins. In the diaphyseal bone, non-coated pins were used. The torque forces for insertion and extraction (in Nm) were measured.**

Results **The insertion torque was higher for both the proximal and distal standard pins (2.1 Nm (SD 0.9) and 7.0 Nm (1.3), respectively) than for the XCaliber pins (1.3 Nm (0.8) and 3.6 Nm (1.4)). The extraction torque force was higher for the proximal standard pins (4.3 Nm (3.1)) than for the proximal XCaliber pins (1.5 Nm (1.7)) ($p < 0.001$). The extraction torque for the distal standard pins was 1.9 Nm (2.0) and for the distal XCaliber pins it was 1.4 Nm (1.1).**

Interpretation **The commonly used standard pin gives stronger fixation during the treatment of HCO.**

■

Tibial osteotomy by the hemicallotasis technique (HCO) is a procedure with high demands on pin fixation due to early weight bearing, combined with forces for the angular correction. The use of hydroxyapatite-coated pins (OsteoTite Orthofix) in the metaphyseal bone has already been shown to enhance the pin fixation (Magyar et al. 1997, Moroni et al. 1998, 2001).

The XCaliber pin (Orthofix) was developed in an attempt to improve pin fixation. The key features of the XCaliber pin are a single thread design for all types of bone, increased stiffness, a lesser degree of taper, self-drilling, and only 2 lengths of the pin. Factors that affect the bone-pin interface and its stability include the surgical technique, the initial apposition fit (Carlsson et al. 1988), movement at the interface (Aspenberg et al. 1992), the quality and metabolic status of the host bone, and any bioactivity on the implant surface (Merolli et al. 2003). The design of the screw threads affects the fixation. The possibility of thermal injury during drilling and insertion of the screw must also be considered (Wikenheiser et al. 1995). In one biomechanical study, a positive association was found between thread diameter and pin fixation for fine machine screws in cancellous bone (Gausepohl et al. 2001). Pre-drilling should be avoided due to weakening of the pin-bone interface (Gausepohl et al. 2001).

We compared the strength of pin fixation by measuring insertion and extraction torque force, between the self-drilling XCaliber pin (Orthofix) with optimized thread and tip design and the well-known conical standard pin (Orthofix) during HCO.

DOI 10.1080/17453670710014752

Table 1. Patient characteristics of the study group

	All n = 50	Xcaliber n = 25	Standard n = 25
Sex (n): men	37	19	18
women	13	6	7
Age, mean (SD)	51 (7.4)	52 (7.2)	51 (7.7)
BMI, mean (SD)	29 (3.3)	29 (3.2)	29 (3.5)
Medial arthrosis (n)	42	20	22
Lateral arthrosis (n)	8	5	3
HKA angle			
Medial arthrosis (SD)		171 (5.9)	170 (3.9)
Lateral arthrosis (SD)		187 (5.9)	186 (7.1)

BMI: body mass index;
HKA angle: hip-knee-ankle angle, <180 degrees = varus.

Patients and methods

Patients

50 patients (37 men) with a mean age of 51 (35–66) years, treated by tibial osteotomy by the hemicallotasis technique for knee osteoarthritis (Table 1), were randomized to standard pins (cortical type, conical shape, Orthofix 6/5 mm) or XCaliber pins (Orthofix 6/5.6 mm). Sealed numbered envelopes were used for the randomization process.

Pins and insertion

The XCaliber pin is self-drilling and is less conical than the standard pin. In the proximal metaphyseal bone, plasma-sprayed hydroxyapatite (HA) coating (Orthofix) was for both types of pins. The HA coating was applied by the manufacturer using a plasma-spray technique. The Ca/P ratio was 1.658–1.700, porosity less than 8% and the bounding strength > 30 Mpa. The coating, tested for heavy metals, was below the limits set by the AST F1185 standard test (As < 3 ppm, Cd < 5 ppm, Hg < 5 ppm and Pb < 30 ppm). The thickness was 45–70 mm.

In the diaphyseal bone, non-coated pins were used. In the metaphysis, the drill holes (3.2 mm diameter) were undersized when using conical 6/5 mm screws. The XCaliber pins were self-drilling and no drilling was done when inserting these pins in the metaphyseal bone. A 4.8-mm drill was used for both standard pins and XCaliber pins inserted in the diaphyseal bone.

3 pins were excluded from analysis, all XCaliber. 2 of these (proximal pins in the same patient) were excluded due to replacement of the pins during the correction, and 1 distal pin was excluded because of technical error during surgery.

Hemicallotasis osteotomy

The hemicallotasis osteotomies were performed using the Orthofix T-garche as external fixator. All operations were performed by one surgeon (STL). 4 pins, 2 HA-coated in the metaphyseal bone and 2 uncoated in the diaphyseal bone, were inserted extraarticularly. A 5-cm longitudinal skin incision was done ventral to the tibial tuberosity. Osteotomy was done at the distal level of the tuberosity; the osteotomy was tested and was judged to be sufficient if the gap could easily be opened 4–5 mm. For valgus deformity, the surgical procedure was the same except that a fibulotomy was performed 10–15 cm below the head of the fibula (Magyar 1999).

The patients were allowed free mobilization and full weight bearing immediately after the operation. Most patients were discharged the day at surgery.

The distraction started 7–10 days postoperatively. 8 weeks postoperatively, the fixation was dynamized to stimulate bone healing. At 12 weeks postoperatively, a bone healing control was done by radiographic and ultrasound investigations in all patients. If the osteotomy healing was considered satisfactory, based on both examinations, the patient did a weight-bearing test. If the patient experienced pain during the test, the fixator was used for a further 2–4 weeks.

Pin site care

Pin site care was performed once a week in the orthopedic outpatient clinic. Clean technique (sterile material and clean gloves) was used. Each pin site was cleaned with chlorhexidine (5 mg/mL in 70% ethanol). No crusts were removed unless there were signs of infection. A sterile compress, moistened with chlorhexidine, was placed at each pin site and was fixed by a soft dressing around each pair of pins. When showering, the patient protected the pin sites using a plastic bag. The patients had easy access to the outpatient clinic if they had questions or if any problems arose. In the case of pin site infection or drainage, extra visits were made if needed.

Antibiotics

For prophylaxis, a single intravenous dose of Cloxacillin (2 g) was administered 30 min before surgery. Flucloxacillin (1 g × 3) or an appropriate antibiotic according to the results of culture were used for 7 days in case of infection.

Outcome

The insertion and extraction torque forces (Nm) were measured with a torque force screwdriver (range 0–800 Ncm; Orthofix SRL, Italy). The ratio of extraction to insertion torque was expressed as percentage and defined as the pin performance index (PPI). An equal insertion torque and extraction torque would result in a PPI of 100%. All screws were analyzed radiographically for radiolucent zones around the screws; a wide zone was defined as ≥ 1 mm.

The use of antibiotics for each patient due to pin site infection was recorded, as were complications including delayed healing (>16 weeks in external fixation), pseudoarthrosis, septic arthritis, deep venous thrombosis, nerve damage, and interrupted treatment.

Statistics

Analysis of variance (ANOVA), Fischer's exact test, and Chi-squared test were used for statistical analysis using StatView for Windows version 5.0 (SAS Institute Inc., Cary, NC). 25 samples were needed in each group of pins (proximal medial (PM), proximal lateral (PL), diaphyseal proximal (DP), and diaphyseal distal (DD)) to obtain a power of 85% in the study. The power calculation was based of an estimated mean difference in insertion and extraction torque force of 1.00 Nm between the two pin designs and an α of 0.05.

The study was approved by the Ethics Committee of Lund University, Sweden.

Results

Mechanical results

The time in external fixation was 95 (SD 8.5) days for the standard pin group and 101 (18) days for the XCaliber pin group (p = 0.2). 9/97 XCaliber pins were loose at extraction, as compared to 2/100 standard pins (RR 4.6, 95% CI: 1.2–19) (p = 0.03). All loose pins were proximal. No radiolucent zones surrounding the pins were found in either group.

The insertion torque was statistically significantly higher for both the proximal and distal standard pins than for the XCaliber pins (Table 2). The extraction torque was significantly higher for the proximal HA-coated standard pins than for the HA-coated XCaliber pins. There were no differences between the extraction torques of the two types of uncoated distal pins (Table 3). In both groups, the proximal HA-coated pins improved fixation; however, the increased fixation of the XCaliber pins was marginal (Table 4). The uncoated distal pins lost fixation in both groups. The difference between insertion torque and extraction torque (PPI) for the HA-coated pins in the metaphyseal bone was higher for the standard pins. However, the loss in fixation was less for the XCaliber pins than for the standard pins (Table 4).

Table 2. Mean (SD) insertion torque force (Nm) for both types of pins, for the 4 pin positions

Position	Standard pin n = 25	Xcaliber pin n = 25	P-value
Proximal			
medial	2.21 (0.85)	1.39 (0.82) [a]	0.001
lateral	2.05 (0.97)	1.12 (0.78) [a]	< 0.001
Diaphyseal			
proximal	6.89 (1.40)	3.78 (1.26) [a]	< 0.001
distal	7.14 (1.20)	3.40 (1.60) [a]	< 0.001

[a] one pin excluded.

Table 3. Mean (SD) extraction torque force (Nm) for both types of pins for the 4 pin positions

Position	Standard pin n = 25	Xcaliber pin n = 25	P-value
Proximal			
medial	4.22 (3.47)	1.69 (1.99) [a]	0.003
lateral	4.44 (2.79)	1.27 (1.42) [a]	<0.001
Diaphyseal			
proximal	2.01 (2.05)	1.56 (1.19)	0.4
distal	1.85 (1.9)	1.28 (0.89) [a]	0.2

[a] one pin excluded

Clinical results

There were no differences in pin site infections between the two pin types according to the use of

Table 4. Mean (SD) difference between insertion and extraction torque force (Nm) and mean pin performance index (PPI) for both types of pins, for the 4 pin positions

Position	Standard pin n = 25 Mean diff. (Nm)	Xcaliber pin n = 25 Mean diff. (Nm)	P-value	Standard pin n = 25 PPI (%)	Xcaliber pin n = 25 PPI (%)	95% CI
Proximal						
medial	2.01 (3.32)	0.30 (1.99) [a]	0.04	208	170	-144–68
lateral	2.23 (3.10)	0.21 (1.63)	0.007	285	173	-252–30
Diaphyseal						
proximal	–4.92 (1.75)	–2.22 (1.48) [a]	< 0.001	24	41	4–31
distal	–5.31 (1.72)	–2.10 (1.58) [a]	< 0.001	27	45	1–36

[a] one pin excluded.
95% CI: 95% confidence interval.

antibiotics. The mean antibiotic treatment was 11 (SD 15) days in the XCaliber group and 7 (7.7) days in the standard group (p = 0.2).

In the standard pin group, 4 patients had delayed healing and 1 of these patients partly lost the correction that had been achieved. In the XCaliber pin group, 8 patients had complications. Repositioning of the proximal pins was necessary in 1 patient to achieve correction; this patient developed septic arthritis after 11 weeks, and healed first after additional surgery. In 1 patient, the treatment was interrupted because of loose proximal pins at week 14 and an orthosis was used instead. 1 patient lost correction and 5 patients had delayed healing.

Discussion

We found no benefit of using the XCaliber pin with a lesser degree of taper and a lower conical form. Our results confirm earlier studies that HA coating increases the pin-bone interface over time, but this was only true for the standard pin design. We found, surprisingly, that the XCaliber pin, coated with HA, did show increased fixation strength in metaphyseal bone over time—but only marginally. Under ideal interface conditions with a tight interface fit, minimal motion, and no direct loading, HA coating is known to enhance host tissue reaction and early fixation. Ideal interface conditions are not always attainable, but HA coating improves fixation even under suboptimal interface conditions (Soballe 1993, Moroni et al. 2001).

The XCaliber pin lost less of its fixation strength than the conventional conical standard pin. However, they had inferior initial fixation. The insertion torque has been shown to be important for pin fixation. Lawes and Goodship (1997) found a time-related decrease in torque force; there was a positive association between screw stability and the initial insertion torque. A recently published in vivo study found that high insertion torque enhanced the stability 10 weeks postoperatively using commercial tapered external fixation pins in both diaphyseal and metaphyseal bone (Lawes et al. 2004). This indicates that tapered external fixation pins should be inserted with a high torque, to enhance the long-term integrity of the pin-bone interface. The initial fixation strength is highly important. The risk of failure will be less, independently of pin design, with high initial fixation.

We found more loose pins in the XCaliber pin group. It is generally accepted that a loose pin means an increased risk of infection. However, we found no differences in pin site infections (according to the use of antibiotics) between the two pin designs.

In conclusion, we found inferior mechanical results with the XCaliper pins than with the standard pins, which give strong fixation during the treatment of HCO.

Contributions of authors

The authors contributed equally to the study design, data collection, data analysis, and preparation of the manuscript.

No competing interests declared.

Aspenberg P, Goodman S, Toksvig-Larsen S, Ryd L, Albrektsson T. Intermittent micromotion inhibits bone ingrowth. Titanium implants in rabbits. Acta Orthop Scand 1992; 63 (2): 141-5.

Carlson L, Rostlund T, Albrektsson B, Albrektsson T. Implant fixation improved by close fit. Cylindrical implant-bone interface studied in rabbits. Acta Orthop Scand 1988; 59 (3): 272-5.

Gausepohl T, Mohring R, Pennig D, Koebke J. Fine thread versus coarse thread. A comparison of the maximum holding power. Injury (Suppl 4) 2001; 32: SD1-7.

Lawes T J, Goodship A E. Cortical profile external fixation screws maintain torque in the metaphysis. J Bone Joint Surg (Br) (Suppl 3) 1997; 79: 370.

Lawes T J, Scott J C, Goodship A E. Increased insertion torque delays pin-bone interface loosening in external fixation with tapered bone screws. J Orthop Trauma 2004; 18 (9): 617-22.

Magyar G, Toksvig-Larsen S, Moroni A. Hydroxyapatite coating of threaded pins enhances fixation. J Bone Joint Surg (Br) 1997; 79 (3): 487-9.

Magyar G. Osteotomy for gonarthrosis - with special references to the tibial callus distraction technique. Thesis. Department of Orthopedics, University Hospital, Lund, Lund University, 1999.

Merolli A, Moroni A, Faldini C, Tranquilli Leali P, Giannini S. Histomorphological study of bone response to hydroxyapatite coating on stainless steel. J Mater Sci Mater Med 2003; 14 (4): 327-33.

Moroni A, Aspenberg P, Toksvig-Larsen S, Falzarano G, Giannini S. Enhanced fixation with hydroxyapatite coated pins. Clin Orthop 1998; (346): 171-7.

Moroni A, Faldini C, Marchetti S, Manca M, Consoli V, Giannini S. Improvement of the bone-pin interface strength in osteoporotic bone with use of hydroxyapatite-coated tapered external-fixation pins. A prospective, randomized clinical study of wrist fractures. J Bone Joint Surg (Am) 2001; 83 (5): 717-21.

Soballe K. Hydroxyapatite ceramic coating for bone implant fixation. Mechanical and histological studies in dogs Acta Orthop Scand (Suppl 255) 1993: 1-58.

Wikenheiser M A, Markel M D, Lewallen D G, Chao E Y. Thermal response and torque resistance of five cortical half-pins under simulated insertion technique. J Orthop Res 1995; 13 (4): 615-9.