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No clinical benefits using a new design of pins for external fixation: a randomized study in 50 patients operated on by the hemicallotasis technique

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Abstract
Background Pin-site infection and pin loosening are complications that can cause discomfort to the patients. The purpose of present study was to evaluate pin-site infection, pain, and the use of medications using the XCaliber pin (Orthofix®) with optimized thread and tip design, and the commonly used standard pin (Orthofix®) during the procedure of hemicallotasis osteotomy (HCO).
Material and methods Fifty patients of mean age 51 (35–66) years treated with HCO were randomized to standard pins (Orthofix®) or XCaliber pins (Orthofix®). Hydroxyapatite-coated pins were used in the metaphyseal bone and non-coated pins in the diaphyseal bone in both groups. Pin sites, pain, and the use of medications were evaluated weekly during the HCO.
Results At week 7 the patients in the XCaliber group had more pain at rest [19 (22) vs. 5 (5) mm, $P = 0.01$] and during activity [32 (32) vs. 12 (13) mm, $P = 0.02$] and used more paracetamol (2,100 vs. 925 mg, $P = 0.04$) than those in the standard group, with similar differences, until the extraction of the pins. There was no difference in the use of antibiotics [10.5 (14.5) days (XCaliber) vs. 7 (7.5) days (standard) ($P = 0.16$)].
Conclusion The commonly used standard pin has important clinical- and patient-related benefits.

Keywords Pin fixation · External fixation · Pin-site infection · Pain · Antibiotics

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Introduction

The pin–bone interface is vital for the stability in external fixation. The insertion torque has been shown to be important for the pin fixation [1, 2]. The surgical technique, including the insertion technique, the pin type (design, coating) as well as its location, forces due to correction, weight bearing and the range of joint movement are other factors that influence the pin fixation during the treatment in external fixation. Pin-site infection and pin loosening are postoperative complications associated with external fixation. A loose pin can cause an infection as well as an infection can cause a loose pin. Complications cause discomforts to the patients, such as pain, delayed mobilization, increased use of medication and the risk of severe complications.

In an attempt to improve pin fixation, the XCaliber pin (Orthofix®) was developed. The key features of the XCaliber pin are a single thread design for all types of bone, increased stiffness, a lesser degree of taper and self-drilling, factors which affect the bone–pin interface and its stability. The biomechanical analysis of Orthofix® standard external fixation pins compared with XCaliber external fixation pins (Orthofix®) has shown inferior biomechanical results for the XCaliber pins when compared with standard pins. The commonly used standard pin showed important benefits of a strong fixation during the treatment of hemicallotasis osteotomy (HCO). The insertion torque was significantly higher for both the proximal and the distal standard pins 2.1 Nm (SD 0.9) and 7.0 Nm (SD 1.3), respectively, than that for the XCaliber pins 1.3 Nm (SD 0.8) and 3.6 Nm (SD 1.4). The extraction torque for the proximal standard pins was 4.3 Nm (SD 3.1) and for the proximal X-Caliber pins 1.5 Nm (SD 1.7). The extraction torque for the distal standard pins was 1.9 Nm (SD 2.0) and for the distal X-Caliber pins 1.4 Nm (SD 1.1) [3].

Clinical outcomes such as pin-site infection and pain are reported, in various ways, in clinical studies concerning biomechanical issues such as coating and insertion techniques [4–8]. Considering the patients' comfort, pin-site infection and pain during the treatment in external fixation are of interest. Magyar et al. [4] found no differences in pain levels, pin-site infection and use of analgesics and antibiotics when comparing uncoated and hydroxyapatite (HA) coated external fixation pins during the treatment of HCO.

During several years we have documented pin-site infection and changed the pin-site care step by step. We use infection prophylaxis in an attempt to decrease the number of infections as well as pain to minimize antibiotic and analgesic consumption [9–11]. We found no statistical significant difference in daily pin-site care compared with pin-site care once a week using sodium chloride as cleansing agent, removal of scabs, protecting the pin sites by a dry dressing and prophylactic antibiotics for 14 days [10]. However, the use of antibiotics was high, 47 days/patient during the time in external fixation. We compared sodium chloride and chlorhexidine solution (2 mg/ml) as cleansing agent and used respective solution to moister the compresses and used them as dressing in the attempt to make use of the qualities of chlorhexidine, pin-site care once a week, no removal of scabs and 3 days of prophylactic antibiotics. This resulted in less clinical pin-site infections, statistical significant differences in positive bacterial cultures and the presence of *Staphylococcus aureus* as well as use of antibiotics (22 ± 4 days/patient in the sodium chloride group compared with 9 ± 2 days/patient in the chlorhexidine group $P = 0.002$). The pain and use of analgesics was less in the chlorhexidine group, properly due to less pin-site infections [9]. We found no statistical significant differences in use of antibiotics and complications when comparing 3 days of prophylactic antibiotics to one single dose. By using the same concept as in the aforementioned study apart from that we used chlorhexidine (5 mg/ml) in alcohol (ethanol 70%) instead of chlorhexidine solution (2 mg/ml), we showed further decrease of positive bacterial cultures in both lengths of prophylactic antibiotics [11].

The aim of the present study was to evaluate pin-site infection, pain, and the use of antibiotics and analgesics, using Orthofix® standard external fixation pins when compared with XCaliber external fixation pins (Orthofix®) during the treatment in patients operated on by the HCO.

Method

Patients

Fifty patients (37 men) of mean age 51 (35–66) years treated with tibial osteotomy by the hemicallotasis technique (HCO) for knee osteoarthritis (Table 1) were randomized to standard pins (cortical type, conical shaped, Orthofix® 6/5 mm) or XCaliber pins (Orthofix®), self-drilling, a lesser degree of taper, and less conical (6/5.6 mm) using sealed numbered envelopes.

Pins

In the proximal metaphyseal bone, plasma-sprayed HA coating was applied to the pins, both to the standard (Osteo-Tite, Orthofix®) and to the XCaliber pins. In the diaphyseal bone non-coated pins were used. In the metaphysis, the drill holes were undersized by drilling 3.2 mm Ø when using conical-shaped (6/5 mm) pins. The XCaliber pins were self-drilling and no drilling was done when inserting these pins in the metaphyseal bone. Both for the standard and for the XCaliber pins inserted at the diaphyseal bone, a Ø 4.8 mm drill was used. The HA coating was applied 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 µm.

Three pins were excluded, all XCaliber. Two of these (proximal pins, one patient) were excluded due to the replacement of the pins during the correction, and one distal pin was excluded due to technical error during surgery.

Table 1 Patients' characteristics of the study group

	All $N = 50$	Xcaliber, $n = 25$	Standard, $n = 25$
Sex (*n*)			
Men	37 (74)	19 (76)	18 (72)
Women	13 (26)	6 (24)	7 (28)
Age (year)			
Mean	51.3	51.9	50.6
SD	7.4	7.2	7.7
BMI (kg/m^2)			
Mean	28.9	29.3	28.5
SD	3.3	3.2	3.5
Medial arthrosis (*n*)	42 (84)	20 (80)	22 (88)
Lateral arthrosis (*n*)	8 (16)	5 (20)	3 (12)
HKA-angle			
Medial arthrosis (degree)		170.9 (5.9)	170 (3.9)
Lateral arthrosis (degree)		186.6 (5.9)	186.3 (7.1)

Data presented as number (%) or mean (SD)

BMI body mass index, *HKA-angle* Hip–knee–ankle angle, <180° = varus

Hemicallotasis osteotomy

The hemicallotasis osteotomies were performed using the Orthofix® T-garche as external fixator. Four pins, two HA-coated in the metaphyseal bone and two non-coated in the diaphyseal bone, were inserted extra-articularly. A 5 cm longitudinal skin incision was done ventrally to the tibial tuberosity. The osteotomy was done at the distal level of the tuberosity, and was then tested with regards to the extension of the osteotomy which 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 [12]. The patients were allowed free mobilisation and full weight bearing after the operation. Most patients were discharged after the surgery on the same day.

The distraction starts 7–10 days postoperatively. Eight weeks postoperatively the fixation was dynamized to stimulate the bone healing. At 12 weeks postoperatively a bone healing control was done by radiographic- and ultra sound investigation. If the osteotomy healing was satisfying, the patient did a weight-bearing test. If the patient developed symptoms, the fixator was applied for an additional 2–4 weeks.

Pin-site care

A nurse performed the pin-site care once a week in the orthopedic outpatient clinic.

The clean technique (sterile material and clean gloves) was used. All bandages were removed. Each pin site was cleaned with chlorhexidine (5 mg/ml) in alcohol (ethanol 70%). No crusts were removed unless signs of infection perceived. A sterile compress, moistened with chlorhexidine (5 mg/ml) in alcohol (ethanol 70%), 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 full access to the outpatient clinic if they had questions or any problems occurred. In the case of pin-site infection or drainage, extra visits were made if needed.

Antibiotics

As prophylactic antibiotics a single intravenous dose (Cloxacillin 2 g) was administred 20–30 min before surgery. Flucloxacillin 1 g × 3, or the antimicrobial drug susceptible for the positive culture, was used for 7 days as antibiotic treatment during the treatment period in the case of infection.

Pain and analgesics

The patients were asked to estimate how much pain they experienced on (a sheet of paper with) two separate 10 cm lines with no marks. On one line, they were asked to estimate their pain at rest in the operated knee with a mark. On the second line, they were asked to estimate how much pain they experienced in the operated knee at weight-bearing. The pain assessments were obtained once a week. The data were analyzed with a 100-point scale corresponding to the 10 cm line.

The patients were prescribed paracetamol and tramadol hydrochloride as analgesics. They were told to use the analgesics when necessary and not to exceed the daily maximum dose (4,000 mg of paracetamol and 400 mg of tramadol). During the correction phase, the patients were advised to use analgesics regularly starting 30 min before the first correction and continue with an interval of 6 h.

Outcome

Antibiotic use due to pin-site infection was used as a primary outcome of pin-site infection. The use of antibiotics was obtained weekly. As secondary outcomes of pin-site infection, the Checketts–Otterburns classification [13] was used and evaluated weekly. The Checketts–Otterburns classification is a six-graded classification, where grades 1–3 stand for minor infection and grades 4–6 major infection. Grade 1 was more an irritation rather than an infection. Bacterial culturing taken from each pin site at the first, sixth and tenth week, and taken from the tip of the pins at removal, was also used as a secondary outcome. Pain at rest and during weight bearing was evaluated by using a visual analogue scale (VAS) and obtained weekly. The use of analgesics was obtained at every weekly visit. Complications included delayed healing (>112 days in external fixation), pseudoarthrosis, septic arthritis, deep venous thrombosis, nerve damage and interrupted treatment.

Statistical analysis

ANOVA, Fischer's exact test and Chi-squared test were used for statistical analysis. The statistics software Stat View for Windows version 5.0 (SAS Institute, Cary, NC, USA) was used. To detect a difference in the use of antibiotics for 7 days (SD 7) between two groups with a power of 85%, 19 patients were needed in each group with α of 0.05.

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

Results

The time in external fixation was 102 days (SD 17.7) in the XCaliber group and 95 days (SD 18.5) in the standard group ($P = 0.2$).

Pin-site infection

The mean antibiotic treatment was 10.5 (SD 14.5) days in the XCaliber group and 7 (SD 7.7) days in the standard pin group ($P = 0.16$). The mean antibiotic treatment per treated patient was 17.5 (SD 15.1) and 12.7 (SD 5.7) days, respectively ($P = 0.18$). There were no differences in the number of patients treated with antibiotics, 15 patients in the XCaliber group and 14 patients in the standard group, during the treatment in external fixation.

There were no differences in clinically evaluated pin-site infections between the two pin types according to the Checketts–Otterburns classification. Most of the clinical infections occurred in the proximal pins (Table 2).

There was neither any difference in the number of total positive bacteria cultures: 27/260 positive cultures in the XCaliber group and 24/285 in the standard pin group (RR 1.2, 95% CI 0.7–2.1, $P = 0.4$). The majority of the positive cultures were *S. aureus*. However, there was a difference in positive cultures of the distal pins between the two groups: 8/126 (XCaliber) and 1/141 (standard) (RR 8.9, 95% CI 1.5–55, $P = 0.03$).

Pain and analgesics

The patients in the XCaliber group had significantly more pain (VAS) both at rest and at activity from week 7 [rest; 19 (22) mm vs. 5 (5) mm, $P = 0.01$ and activity; 32 (32) mm vs. 12 (13) mm, $P = 0.02$] until extraction of the fixation and pins (rest; 13 (20) mm vs. 3 (3) mm and activity 21 (26) mm vs. 5 (4) mm, $P = 0.005$) than patients in the standard pin group (Fig. 1). During the same period of the treatment (week 7 to extraction of the fixation and pins) the use of analgesics was higher in the XCaliber pin group. The use of paracetamol was significantly higher in the XCaliber pin group at week 7 (2,100 mg vs. 925 mg, $P = 0.04$) and at week 9 (1,670 mg vs. 500 mg, $P = 0.02$). There was no significant difference in the use of tramadol between the groups (Fig. 2). Patients with loose pins (11 patients) reported more pain (VAS) at the time of extraction of the pins than those who had well-fixed pins 28.6 mm (SD 27.7) compared with 9.9 mm (SD 17.3), $P = 0.016$.

Table 2 Pin-site infection according to the Checketts–Otterburns classification during the treatment by HCO

	Standard pins, $n = 100$	XCaliber pins, $n = 97$	RR (95% CI)	P value
Grade I				
Pins (distal)	18 (1)	19 (3)	1.1 (0.6–1.9)	0.9
Patients (n)	12/25	11/25		
Grade II				
Pins (distal)	9 (2)	11 (3)	1.2 (0.6–2.9)	0.8
Patients (n)	5/25	7/25		

Data presented as number of pins and patients

RR relative risk, *95% CI* 95% confidence interval

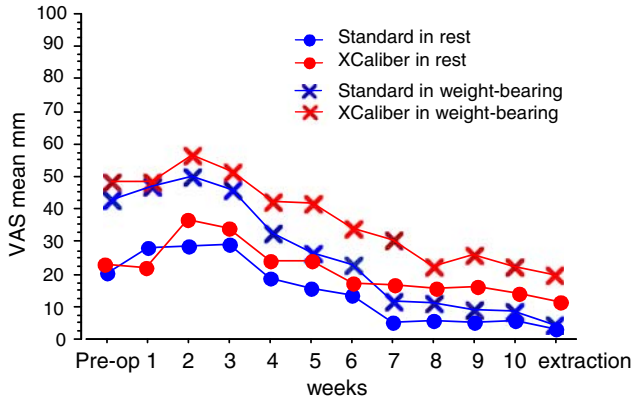

Fig. 1 Pain in rest and weight bearing during the treatment in external fixation

After exclusion of the patients with loose pins in both groups, the pain (VAS) at rest was estimated to 11.2 mm (SD 19.1) in the XCaliber group and 3.2 mm (SD 2.6) in the standard group, $P = 0.06$, and to 15.1 mm (SD 23.8) and 5.7 mm (SD 7.2), respectively, in activity, $P = 0.09$.

The subjective impression was that patients treated with the XCaliber pins had more pain during extraction of the pins (removal), especially the distal pins.

Complications

There were 9/97 XCaliber pins loose at extraction compared with 2/100 standard pins (RR 4.6 95% CI 1.2–18.9 $P = 0.03$). All loose pins were proximal. In the standard pin group, four patients had delayed healing and one of these patients lost the achieved correction partly. In the XCaliber pin group, eight patients had complications. Reposition of the proximal pins was necessary in one patient to achieve correction; this patient developed septic arthritis after 11 weeks and healed after additional surgery. In one patient the treatment was interrupted due to loose proximal pins at week 14, and an orthosis was used instead. One patient lost the correction and five patients had delayed healing. There were twice as many complications in the XCaliber group; however, the difference was not statistically significant (RR 2.0, 95% CI 0.7–5.8, $P = 0.2$)

Discussion

This study showed clinical- and patient-related benefits using the standard pin, compared with the XCaliber pin in

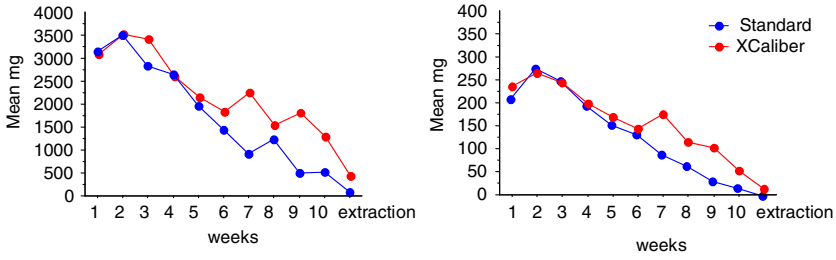

Fig. 2 **a** Paracetamol consumption during the treatment in external fixation. **b** Tramadol consumption during the treatment in external fixation

terms of pain and use of analgesics during the treatment by HCO. The results of difference in pain both at rest and activity, and the use of analgesics, could be explained by inferior biomechanical results for the XCaliber pins compared with standard pins important benefits of a strong fixation during the treatment of HCO and more loose pins in the XCaliber group. The size of differences in pain, measured by VAS, could be considered as clinically significant. The subjective impression that XCaliber pins caused more pain when extracted could be related to the smaller pitch, and less conical design. A smaller pitch involves more threads and with less conical design each thread is painful when the pin is removed through the bone and soft tissues. This problem could be solved by anesthesia and removal of the pins in the theater. However, it becomes a more cumbersome procedure for both the patient and the health care than extraction of pins in an outpatient clinic.

There were no differences in pin-site infection between the two groups considering the use of antibiotics during the treatment. The wider spread (SD) in the XCaliber group could indicate that some patients in this group needed longer or several cures of antibiotics during the treatment due to repeated pin-site infections.

Choosing the use of antibiotics as a primary outcome of pin-site infection is based on the fact that the use of antibiotics reflects the problem of pin-site infection under the condition that complications are taken into consideration.

A classification such as Checketts–Otterburns in treatments corresponding to the characteristics of the affected pin site has disadvantages in clinical studies and is a limitation when evaluating the pin sites. Pin sites regularly become painful and tender before any other symptoms of infection [14, 15]. This is an indication to start antibiotic treatment; experience shows that this sign can develop into a grade 2 infection in very short time and cause unnecessary pain to the patient. Other biomechanical studies using Checketts–Otterburns classification, as Piza et al. [8] and Magyar et al. [4], found no difference in pin-site infection between HA-coated and uncoated pins. However, Moroni et al. [5, 16] found a difference in pin-site infection in favour of HA-coated pins.

The most common outcome is clinical evaluated pin-site infection. The evaluation of clinical pin-site infection as a primary outcome is subjective. There are several different clinical definitions and classifications of a pin-site infection described in the literature; however none of them are valid [14, 17, 18]. And if the infections also are going to be graded, the evaluation becomes even more subjective. We have also experienced that clinical evaluations of pin sites are an insensitive outcome. Comparing two protocols using the same cleansing agent, but different lengths of prophylactic antibiotics and difference in the concept of removal of scabs, there was considerable statistical significant differences ($P < 0.0001$) in positive bacterial cultures, the presence of *S. aureus* and use of antibiotics but no differences in clinical-evaluated pin-site infections [9, 10]. The use of antibiotics may be a proper outcome of a pin-site care. A low consumption of antibiotics during the treatment in external fixation indicates a low incidence of pin-site infection. However, it provides that we concern about complications. But each outcome, clinical evaluations of pin sites, positive bacterial cultures, presence of *S. aureus*, complication, pain and use of antibiotics and analgesics contributes to make a conclusion of how a specific factor of the pin-site care or biomechanical characteristic affects the incidence of infections.

The presence of pin-site infection in studies concerning the effect of changes on biomechanical characteristics and pin-site care protocols are varying, dependent on the definition and the way to report pin-site infections. Pin-site infections are very rare (0.9% of the pins) if it is defined as De Bastiani et al. [19], a pin-track infection as drainage or inflammation persisting despite antibiotic therapy, followed by pin loosening and very common (71% of the patients) if defined as Sims and Saleh [20] a classification according to a six-graded scale related to responding treatment of pin-site infection. Other limitation of the possibility of evaluating the effect of, especially, different pin-site care protocols are the case mix of patients included in the studies, fractures of different locations, open and closed fractures as well as different reconstructions, different numbers of pins and/or wires and treatment time and thereby different risks of pin-site infections. There are some randomized studies published during the past few years; however, these studies have a weak power depending on small sample size and/or several pin-site protocols compared simultaneously [21–23].

Egol et al. [21] found no significant differences in clinical pin-site infection when comparing three different protocols in 118 patients treated for unstable distal radial fracture with external fixation. Gant et al. randomized 18 patients (age 23–86 years) in a pilot study and compared two pin-site protocols. The length of time the pins remained in situ until removal was 4–120 days. 15/62 pins showed an incidence of clinical signs of infection using povidone-iodine and 13/44 pins with soft white paraffin ointment showed an incidence of clinical signs of infection [22]. No differences in pin-site infection rate was found in 92 patients, randomized to 7 different pin-site care protocols [23]. Age as well as fixator type and location of the fixator showed relationship to pin-site infections in aforementioned studies [21–23]. Findings that indicate the need of homogeneous study group to have the possibility to measure what is intended to measure; the effect on pin-site infection by different interventions in purpose to minimize the infection problem.

Davies et al. [24] randomized 120 patients to two different protocols including both the operative technique and pin-site care and used the definition of pin-site infection as an episode of pain or inflammation at a pin site, accompanied by a discharge which was either positive on bacterial culture or responded to a course of antibiotics. Each protocol includes six different factors [insertion technique (3 factors), theatre dressing, time to first postoperative pin-site care and pin-site care protocol during the time in external fixation] and only one of the factors (bone swarf removal) is equal between the protocols. Their conclusion that the risk of pin-site infection is lower if attention is paid to avoiding thermal injury and local formation of haematoma during surgery and if after-care includes the use of an alcoholic antiseptic and occlusive pressure dressings is doubtable. Considering that the protocol including these factors resulted in a lower risk of pin-site infection; however, the study does not show that it is a benefit to avoid thermal injury, use described dressing, etc.

As there are no validated clinical classifications of pin-site infection, a more specific and sensitive definition and outcome measure of pin-site infection is needed which makes it possible to evaluate the effect of an intervention. The risk of an infection varies depending on the number of pins/wires, treatment time, frequency of evaluation, etc. This in term affects the possibility of making a "fair" evaluation of the effect of an intervention with different types of treatment (fractures, reconstructions) by external fixation as the risk of complications increases by the time in external fixation. To develop a "pin-site infection index" would be a future challenge that could make it possible to compare different materials and studies.

As one of the benefits using external fixation is an early and active mobilization, pin-site infection and pain are the factors that affect the possibility to an active and early mobilization. Clinical- and patient-related outcomes as pin-site infection, pain and use of analgesics are important and should be considered in clinical studies evaluating design, insertion techniques and other biomechanical issues.

The strength of present study is the uniform study group with a standardized surgical procedure and the frequency and regularity of the follow-up during the treatment.

The limitation of our study may be our choice to use the antibiotic consumption during the time in external fixation as primary outcome. The already existing low use of antibiotics as a result of previous studies on different factors, affecting the incidence of the pin-site care we use, including the power calculation to detect a difference in the use of antibiotics for 7 days (SD 7) between two groups with a power of 85%. It is well known that it needs an especially effective intervention to show a difference in an already, as in this case, low use of antibiotics. We could calculate for a lower difference in use of antibiotics with consequences such as more patients needed to be included and increased costs of the study. But we were more interested in a clinical relevant significant difference than the smallest statistical significant difference. Another alternative was to use another primary outcome. However, as mentioned previously, clinical pin-site infection is a subjective and insensitive outcome and presence of positive bacterial cultures and *S. aureus* do not necessarily mean that there is an infection. Instead, we used them as secondary outcomes and they contributed to make a conclusion of how two different pin designs affected the clinical- and patient-relevant outcomes.

In conclusion, the qualities of the XCaliber pin, as optimized thread and tip design to secure fixation, in this clinical study in patients operated on by the HCO showed no clinical- and patient-related benefits compared with the commonly used standard pin.

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