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Editorial Board Member of *World Journal of Orthopedics*, Antonios Angoules, MD, PhD, Surgeon, Orthopaedic Department, Athens Medical Center, Athens , Greece

AIM AND SCOPE

World Journal of Orthopedics (*World J Orthop*, *WJO*, online ISSN 2218-5836, DOI: 10.5312) is a peer-reviewed open access academic journal that aims to guide clinical practice and improve diagnostic and therapeutic skills of clinicians.

WJO covers topics concerning arthroscopy, evidence-based medicine, epidemiology, nursing, sports medicine, therapy of bone and spinal diseases, bone trauma, osteoarthropathy, bone tumors and osteoporosis, minimally invasive therapy, diagnostic imaging. Priority publication will be given to articles concerning diagnosis and treatment of orthopedic diseases. The following aspects are covered: Clinical diagnosis, laboratory diagnosis, differential diagnosis, imaging tests, pathological diagnosis, molecular biological diagnosis, immunological diagnosis, genetic diagnosis, functional diagnostics, and physical diagnosis; and comprehensive therapy, drug therapy, surgical therapy, interventional treatment, minimally invasive therapy, and robot-assisted therapy.

We encourage authors to submit their manuscripts to *WJO*. We will give priority to manuscripts that are supported by major national and international foundations and those that are of great basic and clinical significance.

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MINIREVIEWS

Intra-operative computed tomography guided navigation for pediatric pelvic instrumentation: A technique guide

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Abstract

Pelvic instrumentation for neuromuscular scoliosis has been part of neuromuscular scoliosis surgery since the era of the Luque Galveston construct. Unit Rod (Medtronic Sofamor-Danek, Nashville, TN) instrumentation brought with it the concept of cantilever correction by placing the implants in the pelvis and then gradually bringing the rod to the spine by sequentially tightening the sublaminar wires, with the goal of creating a level pelvis over a straight spine. More recently surgeons have utilized pedicle screw constructs in which the corrective strategies have varied. Challenges with pelvic fixation using iliac screws linked to the spinal rod have led to the development of the S2-alar-iliac technique (S2AI) in which the spinal rod connects to the pelvic screw. The screw is placed in the S2 ala, crosses the sacro-iliac joint and into the ilium through a large column of supra-acetabular bone. This column is the same area used for anterior inferior iliac spine external fixation frames used in trauma surgery. S2AI screw placement can be technically difficult and can require experienced radiology technologists to provide the appropriate views. Additionally, although the technique was originally described being placed *via* freehand technique with intra-operative flouroscopy, the freehand technique suffers from the anatomic anomalies present in the pelvis in neuromuscular scoliosis. As such, we prefer to place them using intra-operative navigation for all pediatric spinal deformity cases. Below in detail we report our intra-operative technique and an illustrative case example.

Key words: Posterior instrumentation; Pediatric; Spinal deformity; Image guidance; Technique

Core tip: S2-alar-iliac technique (S2AI) screws are used commonly in 2018 in posterior spinal fusion surgery

when a fusion to the pelvis is indicated. The benefits of this instrumentation choice are well known; and now with 3D technology surgeons can safely place S2AI screws reproducibly even in aberrant pediatric anatomy.

Anari JB, Cahill PJ, Flynn JM, Spiegel DA, Baldwin KD. Intra-operative computed tomography guided navigation for pediatric pelvic instrumentation: A technique guide. *World J Orthop* 2018; 9(10): 185-189 Available from: URL: http://www.wjgnet.com/2218-5836/full/v9/i10/185.htm DOI: http://dx.doi.org/10.5312/wjo.v9.i10.185

INTRODUCTION

Neuromuscular scoliosis is a common cause of spinal deformity, and nonambulatory patients commonly have a thoracolumbar or lumbar curve associated with pelvic obliquity (Figure 1). While corrective strategies have varied, the initial approach using the Luque-Galveston technique involved extension of the spinal rod into the posterior ilium/pelvis. The corrective strategy in the unit rod occurred by first placing the pelvic limbs of the fixation in the pelvis, and then gradually bringing the rod to the spine by applying cantilever forces and sequentially tightening sublaminar wires to bring the spine to the rod[1]. Problems include prominence of the implants, loosening of the pelvic limbs within the pelvis ("windshield wipering"), and rod fracture. The unit rod is a pre-contoured rod which was developed to avert the need for intraoperative rod contouring, and the technique for correction was the same. Subsequent variations in lumbo-pelvic fixation have included iliac screws, which are placed into the posterior iliac crest and attached to the spinal rod *via* connectors. Some authors have placed duel screws into the ilium, while others have advocated for screws in both the first sacral vertebra and the ilium. Challenges with this fixation include implant prominence and failure of the implant at the junction between either the screw and the connector or the connector and the rod.

In 2007, Sponseller introduced the S2-alar-iliac technique (S2AI) in which the pelvic screw is placed from the sacrum into the pelvis. The screw head is low profile and connects directly with the spinal rod[2]. While initial reports documented safety and placement in both pediatric and adult spinal deformity patients, much of the recent literature regarding safety of placement using the S2AI technique has been published in adults[3-6]. Shillingford *et al*[3] report a free hand technique without intra-operative imaging that has a cortical breech rate of 7% posteriorly and 1% anteriorly. Anterior perforation into the pelvis or inferior perforation into the sciatic notch can have catastrophic result given the neurovascular and visceral structures found in such locations[3]. There may also be variations in anatomy, for example the relationship between the iliac wings and the pelvis. In the setting of considerable pelvic obliquity, the patient may bear weight on the downside iliac wing, and one may observe asymmetry in the relationship between the iliac wings and the pelvis such as adduction of one iliac wing with abduction of the other.

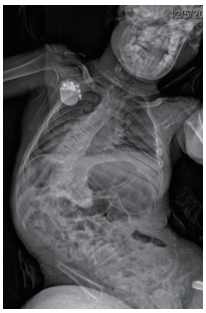

Figure 1 Posteroanterior of a sweeping thoracolumbar curve with pelvic obliquity typical of neuromuscular scoliosis.

Figure 2 Navigation probe.

We have utilized computed tomography (CT) image navigation for placement of pedicle screws at our institution for more than 10 years, and we have extended this practice to the placement of S2AI screws[7]. Here we describe our technique for CT guided pediatric pelvic fixation using the S2AI technique.

TECHNIQUE

The patient is placed in the prone position on an open Jackson table and a subperiosteal exposure from the upper instrumented vertebrae to S2 is performed. Adequate exposure on the sacrum includes visualization of both the S1 and S2 neural foramina. An anchor point is picked proximally in the lumbar or thoracic spine that is sturdy enough to hold a reference array (4 tines at a minimum) and simultaneously remain out of the surgeon's working space while placing instrumentation. Our preferred location is the lower thoracic spine (T11/12) as this is usually far enough away to be out of the working field but not too far from the insertion point to alter the information acquired by the CT scan. Patient lordosis must be taken into account as significant differences in trajectory may lead to interference of the guidance probe with the sensor array.

Once the exposure is complete and the array in a stable location a low dose CT scan (2.25 mSv) is performed from the top of the femoral heads to the lower lumbar spine region (O-Arm Medtronic Sofamor-Danek, Nashville, TN). Following completion of the CT scan the navigation probe (Figure 2) is connected to the

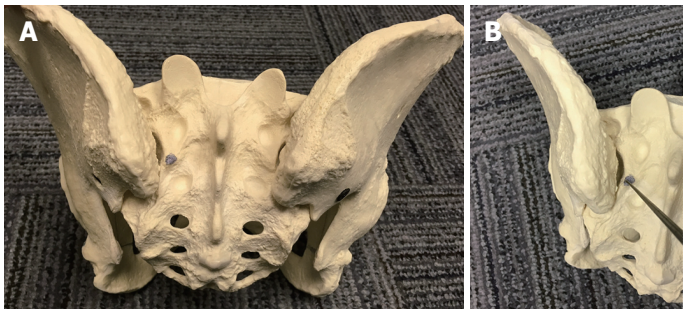

Figure 3 Starting point for the S2-alar-iliac technique screw. A: On pelvis; B: Navigation probe identifying the appropriate location.

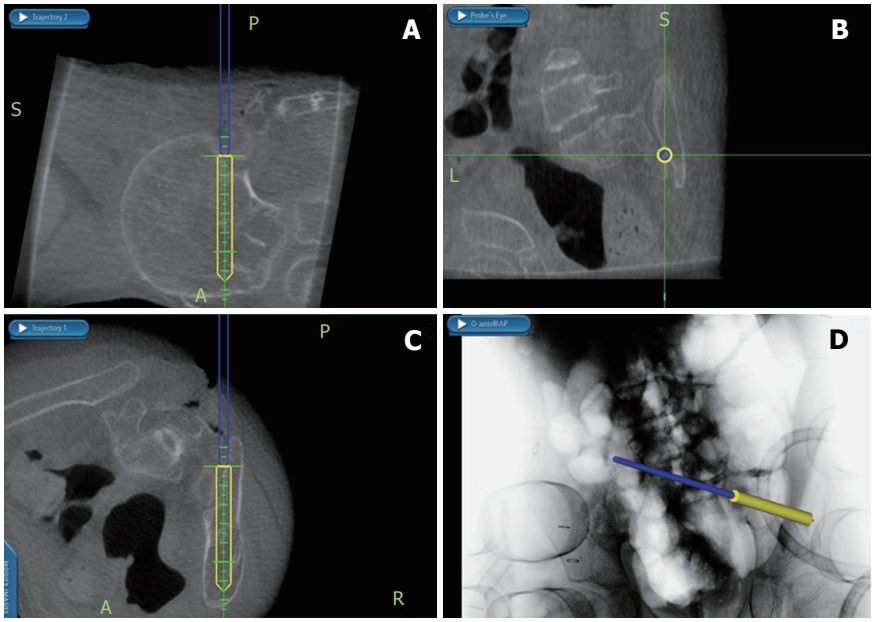

Figure 4 Intra-operative navigation screen depicting safe starting point and projected placement of an S2-alar-iliac technique screw. A: Sagittal; B: Coronal; C: Axial; D: Current position of navigation probe.

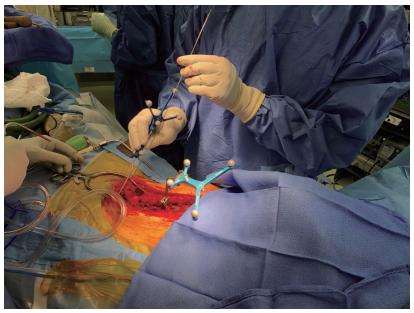

Figure 5 Intraoperative clinical photo depicting the navigation probe placed down the dilated path for the S2-alar-iliac technique screw with a guidewire in place.

array by docking the probe in the array's recess. Once confirmation of coupling occurs 3D anatomy from the CT scan is confirmed by placing the probe over a lumbar spinous process correlating the imaging seen on the screen with the patient. The surgeon, who stands on the patient's left places the right sided S2AI screw and switches sides for the left sided screw. The typical entry point insertion for the S2AI screws are just lateral to the lateral edge of the S1 and S2 foramina midway between the two (Figure 3), although minor variations may be required depending on the local anatomy. Once this point is identified using the probe a 4 mm acorn burr is used to create a pilot hole for the pedicle probe approximately 3 mm in depth. The navigation probe is replaced in the pilot hole to confirm trajectory in both the axial and sagittal planes. Normal anatomy puts the S2AI trajectory at approximately 40° lateral in the axial plane and 20°-40° caudal in the sagittal plane[2,8]. Once surgeon has trajectory memorized the straight gearshift is passed through the sacrum into the sacroiliac joint and into the ilium (Figure 4). In rare cases the proper trajectory may require that the screw be placed directly into the ilium and not through the sacrum.

On the navigation screen depth and trajectory can be checked anytime with gearshift removal and placement of navigation probe. The authors prefer to place gearshift to the desired screw depth, dilate the tract, and then place the navigation probe down the tract to ensure circumferential bone and a floor alongside a guide wire (Figure 5). A ball tip probe then palpates the walls of the tract, and the channel is tapped to a

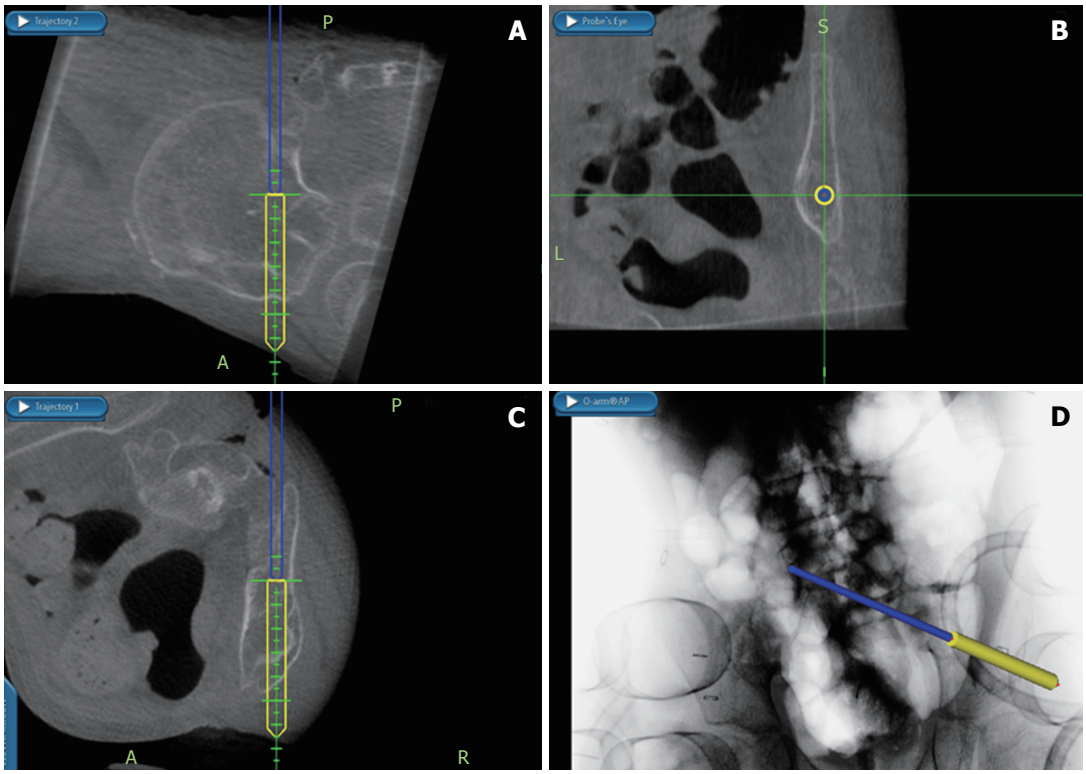

Figure 6 Intra-operative navigation screens depicting a safe trajectory for the S2-alar-iliac technique pelvic screw. A: Sagittal; B: Coronal; C: Axial; D: Anterior-posterior radiograph showing current position of navigation probe.

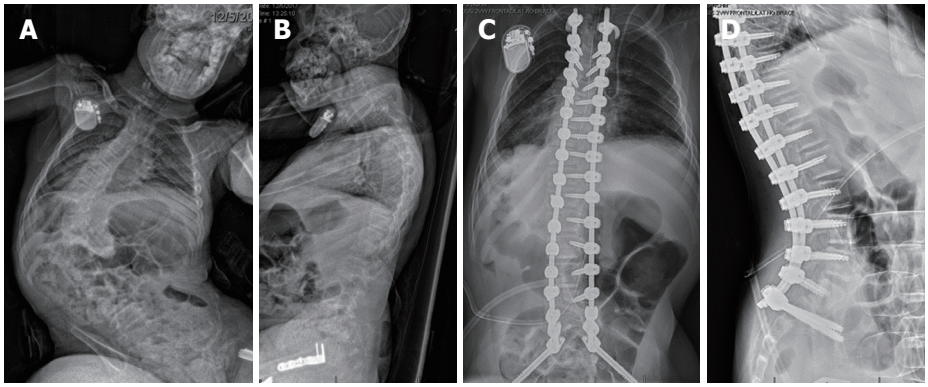

Figure 7 Pre-operative and post-operative radiographs in a patient with neuromuscular scoliosis who underwent T3 to pelvis instrumented posterior spinal fusion using navigation to place pedicle screw and S2-alar-iliac technique instrumentation. A: Posteroanterior; B: Lateral; C: Anteroposterior; D: Lateral.

diameter 0.5 mm less than the desired screw diameter, over the guide wire. The walls of the tract are palpated one last time before the cannulated screw is placed over the guide wire. Lastly the navigation probe is placed down the cannulated screw to palpate a floor as well as ensure the trajectory taken by the screw (Figure 6). Final position of the S2AI screws align with the cephalad instrumentation facilitating rod insertion. Figure 7 depicts a patient with neuromuscular scoliosis and pelvic obliquity who had S2AI instrumentation placed during an instrumented posterior fusion.

DISCUSSION

The extension of spinal instrumentation and fusion across the lumbosacral junction and into the pelvis is required in a number of clinical scenarios in both children and adults. In the pediatric population this is most commonly to address pelvic obliquity in the neuromuscular population, while in adults a common indication is to achieve rigid distal anchors for correcting sagittal imbalance in the setting of osteoporotic bone and to enhance the chances of arthrodesis across the lumbosacral junction[9-12]. Each situation offers varying complexity with regard to the insertion of implants, for example in pediatric patients in which there may be variations in the relationship between the iliac wings and the sacrum. We have also observed that the isthmus may be quite narrow in some pediatric patients, and the navigation allows us to identify this and choose the optimal sized screw, which is important given

the literature suggestion screw diameter < 8 mm are at an increased risk of implant complications[13].

We have utilized a CT guided approach for more than 10 years and have been satisfied with our ability to safely place the implants, and this approach also serves as a valuable training tool for our residents and fellows who are being exposed to the challenge of lumbo-pelvic fixation. Reports concerning both free hand instrumentation and navigation assisted instrumentation are available[14-16]. The discussions include a comparison of cost, radiation safety for patient/surgeon/staff, reliance on technology, and associated risks with the learning curve[17-19]. At our institution the intra-operative CT dose is extremely low and all faculty are prepared to place without image guidance if the technology fails intra-operatively[20].

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ORIGINAL ARTICLE

Basic Study

Dose of alendronate directly increases trabeculae expansivity without altering bone volume in rat femurs

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Author contributions: Weiss SG performed the majority of the experiments and analyzed the data; Kuchar GO, Gerber JT and Tiboni F participated in treatment of animals; Casagrande TC was involved in surgical procedures; Storrer CLM and Giovanini AF contributed to the writing of the paper; Scariot R designed the study, performed some surgical procedures and coordinated the research.

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Abstract

AIM

To evaluate the effects of sodium alendronate on bone repair in fractures created in appendicular bones.

METHODS

Wistar rats (n = 36) were allocated into three distinct groups: group C (control), group B1 (received 1 mg/kg of alendronate), and group B2 (received 3 mg/kg of alendronate). The rats underwent femoral transversal linear fracture surgery using stable internal fixation with a 2.0 mm plate and screw system. Each animal randomly received intraperitoneal applications of sodium alendronate at a dose corresponding to group B1 or B2 three times a week, while the control group received a 0.9% saline solution. Drug administration was performed until euthanasia at 45 d. The femurs were removed and each surgical piece was sent for radiographic, tomographic and microtomographic analysis. Data were submitted to descriptive and inferential statistical analysis (95% confidence interval).

RESULTS
Quantitative evaluations of bone neoformation did not show differences among the groups in the radiographic (P = 0.341), microtomographic (P = 0.581) and tomographic evaluations (P = 0.171). In the qualitative microtomographic analysis, a smaller distance was observed between the internal bone trabeculae in the groups that used alendronate (P = 0.05). On the other hand, group B2 had a higher amount of bone trabeculae per unit length when compared to the other groups (P = 0.04).

CONCLUSION
It is likely that the use of alendronate did not have a direct influence on the amount of bone neoformation, however it did influence the bone quality in a dose-dependent manner, ultimately affecting the distance and quantity of the trabeculae.

Key words: Alendronate; Bone regeneration; Fracture; Femur; Bisphosphonates

Core tip: Several studies have been carried out to determine both the influence of alendronate in bone repair and the appropriate dose of this drug to promote bone regeneration. In this research, 36 Wistar rats were allocated into three distinct groups that received applications of either alendronate at different doses or saline solution three times a week for 45 d. The rats underwent femoral fracture surgery with stable internal fixation. The imaginologic results suggested that the use of alendronate did not have a direct influence on the amount of bone neoformation, however it did influence bone quality in a dose-dependent manner.

Weiss SG, Kuchar GO, Gerber JT, Tiboni F, Storrer CLM, Casagrande TC, Giovanini AF, Scariot R. Dose of alendronate directly increases trabeculae expansivity without altering bone volume in rat femurs. *World J Orthop* 2018; 9(10): 190-197 Available from: URL: http://www.wjgnet.com/2218-5836/full/v9/i10/190.htm DOI: http://dx.doi.org/10.5312/wjo.v9.i10.190

INTRODUCTION

The repair of transversal appendicular bones requires a complex process that involves several biological stages, including cell recruitment, proliferation and differentiation[1]. The literature has described both direct and indirect types of bone repair for these fractures. Direct bone healing is uncommon and is characterized by a healing area that lacks periosteal or endosteal callus formation. This effect occurs when the fracture area is rigidly fixed, causing direct remodeling of the lamellar bone, angiogenesis, and the formation of Haversian channels[2]. Indirect bone repair, the most common form of fracture healing, consists of endochondral and intramembranous bone healing and is characterized by the formation of a bone callus[3].

The establishment of a fracture pattern in an animal model requires both surgical and technical abilities, as well as accurate positioning and adequate bone fixation. The majority of these studies on rats are conducted with intramedullary pins, external fixators, pin-clips, *etc*[4]. The use of plates and screws for stable fixation in animal models is known to both favor and accelerate the repair process when compared to dispositive techniques that lack stable methods[5]. This is even the case when the bone repair is not considered direct. In this pilot study, we determined that the 2.0 system containing 4 hole plates presents better results for the bone repair of femur fractures when compared to other fixation systems.

Pharmacological agents that may modulate bone formation and bone remodeling are widely used and developed for the treatment of osteoporosis and other disorders involving bone fragility[6]. Bisphosphonates are a class of drugs that may act on bone remodeling by reducing bone resorption in a dose-dependent manner, mainly by inhibiting recruitment and promoting apoptosis of osteoclasts, while also stimulating osteoblastic activity. Bisphosphonates are available both orally (alendronate, ibandronate and risedronate) and intravenously (ibandronate and zoledronate). Among these, sodium alendronate (part of the second generation Bisphosphonate class) causes fewer side effects than the first generation class and is the most widely used antiresorptive drug[7].

There are some studies that have investigated the positive effects of sodium alendronate in bone repair[8-10]. Based on the mechanism of action of this drug, it is hypothesized that alendronate, when applied at the appropriate dose following fracture fixation, accelerates the bone repair process and thus makes prognoses more favorable.

MATERIALS AND METHODS

The animal protocol was designed to minimize pain and discomfort to the animals. The experiments were carried out in the Vivarium, in the Imaging Laboratory at Positivo University, and in the Laboratory of Analysis of Minerals and Rocks at Federal University Paraná following approval by the Ethics Committee on the Use of Animals (ECUA 320). This study followed the guidelines of ARRIVE (Animal Research: Reporting *in Vivo* Experiment). Throughout the experiment, the ambient light, temperature and humidity of each room were controlled by a digital panel in order to maintain a photoperiod of 12 h, a temperature range of 18 ℃ - 22 ℃, and 65% humidity. The animals were euthanized on the 45th day.

Experimental design

Thirty-six 4 - 5 mo old Wistar rats weighing approximately 500 g were randomly divided equally into three groups: Group C (control), group B1 (received 1 mg/kg of alendronate) and group B2 (received 3 mg/

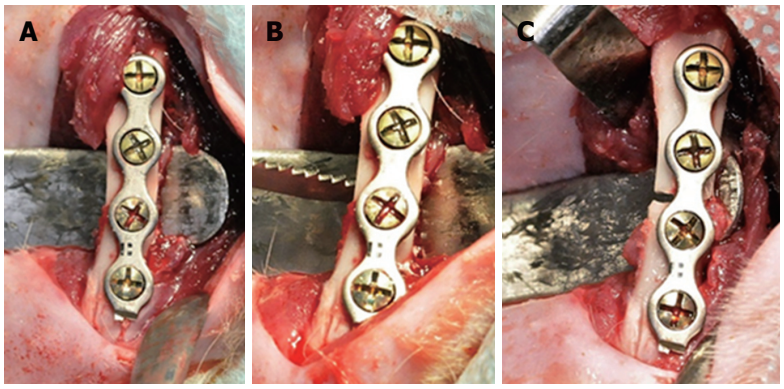

Figure 1 Fracture made with a reciprocating saw. A: First, the bone is fixated with a plate and screws; B: Second, a fracture is induced with a reciprocating saw; C: Finally, the fractured femur is fixed.

kg). Following fracture, the intraperitoneal application of sodium alendronate was administered three times per week, and the control group concomitantly received applications of 0.9% saline solution until the time of euthanasia. Intraperitoneal applications were performed on the opposite side of the fracture.

Fracture preparation and stabilization

During all surgical procedures, aseptic criteria were maintained. The rats were sedated for one minute *via* inhalation with isoflurane (Cristália, Itapira, SP, Brazil) and anesthetized with 10% ketamine hydrochloride (Vetbrands, Paulínia, SP, Brazil) and 2% xylasin hydrochloride (Vetbrands, Paulínia, SP, Brazil) by intraperitoneal injection. After anesthesia, the rats were placed in the left lateral decubitus position, and a right femur trichotomy was then performed with vigorous antisepsis using iodopovidone. A straight incision was made approximately 5 cm along the long axis of the femur with blade number 15C, with the aid of blunt scissors, and the tissue was divulsed into muscular planes. After incision and detachment of the periosteum with a scalpel, the surface of the femur could be accessed.

Before proceeding with the osteotomy, it was necessary to complete the positioning, drilling and adaptation of the 2.0 mm 4 hole titanium plate system with 4 mm-long screws (Orthoface, Curitiba-PR, Brazil) in order to avoid poor positioning of the bone segments. The fracture was then made using a reciprocating saw (Figure 1). Abundant lavage of the wound was done using saline solution. The suture was performed in planes with isolated stitches, using Vicryl-0® thread (Ethicon, Johnson and Johnson, São José dos Campos, SP, Brazil) for the muscular plane, and nylon 4-0 (Ethicon, Johnson and Johnson , São José dos Campos, SP, Brazil) for the skin. Analgesia, inflammation and infection were controlled throughout the postoperative period.

Applications

Immediately following the surgeries, intraperitoneal applications were initiated, which lasted until euthanasia. Three weekly applications were carried out. The control group (C) received 0.9% physiological saline solutions, while the animals in groups B1 and B2 received a 1 mg/kg and 3 mg/kg dose of alendronate, respectively.

Euthanasia

At 45 d, the animals were euthanized, and then the right femurs, plates and screws were removed. The specimens were stored separately in pots containing 10% formaldehyde. For euthanasia, the rats were exposed to overdoses of isoflurane for about 10 min. The specimens were then sent for analysis. The statistical methods used in this study were reviewed by Rafaela Scariot, Professor of Biostatistics in the Masters Program in Dentistry at Positivo University.

Radiographic analysis

In order to evaluate the postoperative recovery as well as the positioning of the bone segments, the animals were submitted to digital radiography at days 7 and 45. The time-point of 7 d served only as a radiographic follow-up to observe the control and evaluate the plaque adaptation, while the time-point of 45 d was used to evaluate bone repair. The animals were sedated within 7 d and their femurs were positioned on a digital sensor (Kodak RVG 5100, Carestream Dental, Rochester, NY, United States) for radiographic imaging with an exposure time of 1.0 sec. The images were then processed and evaluated using Dental Imaging software (version 6.12.17.0 - A, Carestream Dental, Rochester, NY, United States). By the time that radiographic evaluation was taken at day 45, the animals had already been euthanized.

For evaluation of bone neoformation using the Image J program (version 1.49t National Institute of Health-NIH Bethesda, MD, United States), the examiner had previously been trained. The fracture's region of interest was then established. To define the region of interest, a 10 mm line was drawn, 5 mms before the fracture line and 5 mms posterior to it. From this line, a rectangle was then created using the Selection Brush tool to delineate the edges surrounding the bone callus and therein obtain the total area value. Outside of the fracture region, a rectangle was also constructed to obtain the total bone area so that bone formation could later be compared with individual femur thickness. The area value in the

fracture region was subtracted from the total bone area without the fracture. From this value, the excess bone value was calculated.

Tomographic analysis

The 36 specimens were sent to a dental tomography center, which used the same tomography device calibrated at 120 kVp and 36.12 mAs (i-CAT® CONE BEAM 3-D, Kavo Kerr, Joinville-SC, Brazil), to construct images using an exposure time of 40 s with 0.25 Voxel. From this scan, 216 tomographic sections with a 250 μm pixel size were obtained for each set of five samples. In order to decrease the number of intakes, the femurs to be evaluated by tomography were grouped into an acrylic base that accommodated up to five femurs. These were placed vertically and, with the help of utility wax, attached to the base. After acquisition of the tomographic sections, the images were analyzed using I-CAT Vision software.

The longitudinal distance of the defect, in which the amount of bone was generated laterally in the sample, was evaluated. The distance between the contact points of the femurs and the femoral diameter were also measured without considering the effects of formation and the formed bone callus. The I-CAT Vision software helped facilitate the analysis of distances by allowing the examiner to view samples in two distinct ways: through the Implant Screen, which provides an analysis of multiple tomographic sections within a selected region of interest, or the MPR Screen, which displays three views of the obtained femurs. In the MPR Screen, it was possible to analyze distances by using the axial, coronal and sagittal views of the samples, and also by using regions of interest that delineated the femurs individually. This screen was therefore used for analysis. In addition to the advantage of easily performing distance analysis, the brightness and contrast scales could also be altered so that only the femur, which is more radiopaque, is detected. This makes it possible to identify the diameter of the femur. Despite using the diameter for analysis, the femur is not exactly cylindrical, so the distance acquired corresponds to the greater distance of the femur and the longitudinal dimension of the defect. This sample movement was possible with the "Explore" function in the software. Once the region of interest, which corresponded to a single femur, was selected by using the rulers shown on the sides of each image of the figure, the "Explore" function of the software was performed. In the coronal image, the formation of a circle indicating the presence of a diameter was observed. Using the cursor, we could rotate the inscribed sample in any direction within the plane. The distance measurements were done by selecting the "Distance" software tool and dragging the cursor.

Micro-CT analysis

The computerized microtomography analysis was performed using a Skyscan computed micro-CT model 1172 (Bruker Skyscan, Luxembourg, Belgium), with power and current adjusted to 90 kV and 112 μA, respectively. The pixel size was 12.8 μm, and a multichannel acquisition camera with a resolution of 2000 x 1336 pixels was used to detect signal. No filters were used to correct the energy of the X-ray beam. The portion was rotated 180° with a rotation step of 0.4°. A projection image of the part was obtained for each rotation step. The exposure time of the sample within the X-ray beam was 1.1 s per rotation step, and the total acquisition time of the projection images was 30 min. After acquisition, projection images were processed using NRecon software (Bruker, Luxembourg, Belgium). The software reconstructed the projection images into tomographic sections using the Feldkamp algorithm. After obtaining the tomographic sections, the measurements of the three-dimensional space, trabecular formation and bone volume were evaluated by the software, which included the CT Analyzer (v.1.16.1.0 +; Bruker Skyscan, Kontich, Belgium) and the Dataviewer (v.1.5.2.4; Bruker Skyscan, Kontich, Belgium). In the CT Analyser software, it is possible to separate different mineral densities from the contrast difference shown in the tomographic section slices. The contrast in the tomographic section image comes from the different radiopacities of the materials in the sample, according to the interaction of these phases with the X-ray beam. This makes it possible to separate the neoformed bone from both the autogenous bone and cartilaginous material, each of which have different radiopacities.

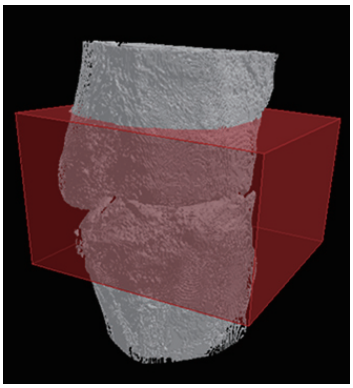

Figure 2 Delimitation of the defect for analysis.

Quantitative analysis

Quantitative analysis begins with the binarization process of the sample's different phases. This binarization process corresponds to a range of gray tones to which each radiopaque material fits. The range of gray tones used to determine neoformed bone volume corresponds to 50 - 105 on a total dimensionless scale from 0 - 255. The determination of this volume occurs through the delimitation of a region of interest into a prismatic format (12 mm x 11 mm x 6.3 mm). This involves the whole region of the defect and bone callus, which is in the center of the defect (Figure 2). Thus, bone formation was investigated both in the defect region and in the volume of bone callus formed. This created region was used for

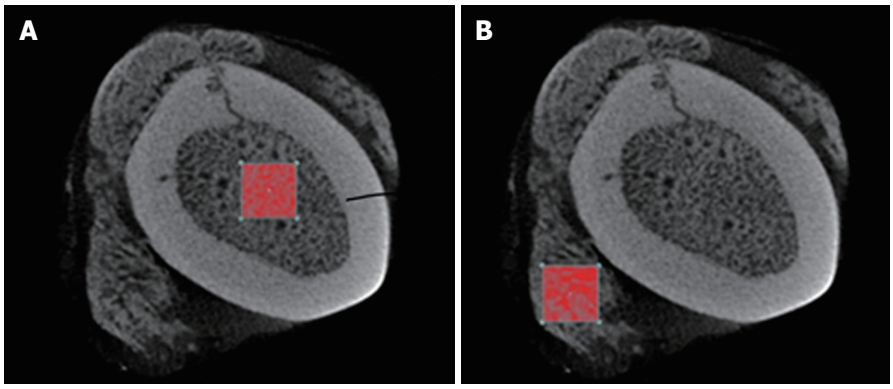

Figure 3 Regions of interest. A: Region of internal interest; B: Followed by region of external interest.

all pieces. From this procedure, the analysis of initial bone, neoformed bone and total surface area of bone formation, including the bone callus (lateral available area of the femoral bone), were obtained. The measurements of the relationship between the new bone formation and the femoral surface area were obtained by determining the difference in thickness between samples.

Qualitative analysis

To analyze the trabeculae that was internally generated in both the bone and external region, a region of interest was made both inside and outside of the femur bone (Figure 3) by selection an area that had the maximum density of trabecular bone within the bone callus. Calculations using CTAn software were made of the following: the mean trabecular thickness (Tb.Th) of the internal and external regions, the trabecular linear density (Tb. N), which measures the average number of trabeculae per unit length, and the average distance between the internal and external trabeculae (Tb.Sp)[11,12].

Statistical analysis

The results were subjected to descriptive and statistical analysis. Statistical evaluation was performed using a frequency data specific test called the Statistical Package for Social Science program (SPSS, version 24.0; SPSS Inc., Chicago, IL – United States) using a 95% confidence interval. The values obtained were subjected to a normality test (Shapiro-Wilk), and parametric variables were described using mean and standard deviation. Nonparametric variables were described as minimum, median and maximum. For comparison between groups, the ANOVA and Kruskal-Wallis tests were used, according to the normality of the variable. When there was a statistical difference detected between the groups, a Tukey test was performed for parametric samples. For nonparametric samples, comparisons were performed in two groups using the Mann-Whitney test.

RESULTS

Radiographic analysis

Bone formation, which was evaluated by radiographic analysis, was higher in group B2 (91.683 ± 35.657 mm²), followed by the control group (65.57 ± 32.642 mm²) and group B1 (62.670 ± 45.578 mm²). The measurements obtained (bone surplus) showed no difference between the groups (P = 0.341).

Tomographic analysis

Tomographic evaluation of the samples did not show quantitative differences in bone neoformation among the groups (One-way ANOVA test; P = 0.171). In Group C, the measurement between the defect and femur ratio (mm³/mm²) was 1.76 ± 0.56. The measurements in group B1 and B2 were 1.59± 0.31 and 1.44 ± 0.21, respectively.

Micro-CT analysis

Considering the relationship between the new bone formation and the femur surface area, the B2 group [5.87 (2.10 – 14.60) mm³/mm²] presented greater bone formation when compared with the B1 group [4.88 (2.30–16.02) mm³/mm²] and C group [5.65 (3.64 – 12.40) mm³/mm²]; however, there was no difference among the groups (Kruskall-wallis test/P = 0.581).

Qualitative analysis

In qualitative microtomographic analysis, it was possible to observe that there was a difference in the number of trabeculae per unit length (Tb.N) between groups (P = 0.05). Group B2, when compared with both groups, had higher linear density.

There was also a significant difference between groups in the spacing of the internal bone trabeculae, showing that the Tb.Sp is lower in the control group *vs.* the B2 group (P = 0.04, Figures 4 and 5). The data for Tb.N, Tb.Th and Tb.Sp can be found in Table 1.

DISCUSSION

The aim of this study was to use image analysis to evaluate the evolution of appendicular femur repair when fixed with plates and treated with varying alendronate concentrations. It is known that during the early stages of bone healing, a less rigid mechanical environment

Table 1 Results of qualitative analysis by micro-computed tomography [median (min-max)]

	Group C	Group B1	Group B2	*P*
Tb.Th	0.11 (0.09-0.14)	0.09 (0.07-0.16)	0.14 (0.09-0.16)	0.07
Tb.N	5.26 (3.39-6.24)[1]	5.45 (1.42-5.87)[2]	5.94 (2.49-6.40)[1,2]	0.05
Tb.Sp	0.10 (0.06-0.16)	0.09 (0.05-0.35)	0.06 (0.05-0.21)	0.07
Tb.Th	0.09 (0.07-0.13)	0.10 (0.06-0.23)	0.12 (0.06-0.15)	0.06
Tb.N	4.60 (0.13-6.15)	4.78 (0.15-6.90)	6.15 (0.22-7.22)	0.13
Tb.Sp	0.20 (0.08-0.50)[3,4]	0.09 (0.05-0.44)[3]	0.07 (0.05-0.42)[4]	0.04

[1]$P = 0.049$; [2]$P = 0.028$; [3]$P = 0.032$; [4]$P = 0.03$. Kruskal-Wallis/Mann-Whitney. Data from external and internal areas, respectively.

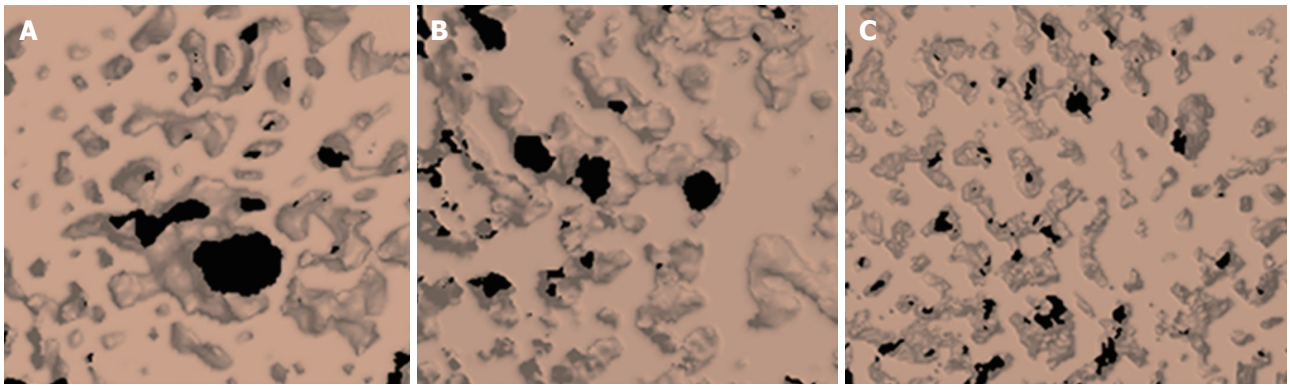

Figure 4 Region of internal interest of the femur, showing different patterns of trabeculae among groups. A; Group C: Control; B: Group B1: Bisphosphonate 1 mg/kg; C: Group B2: Bisphosphonate 3 mg/kg.

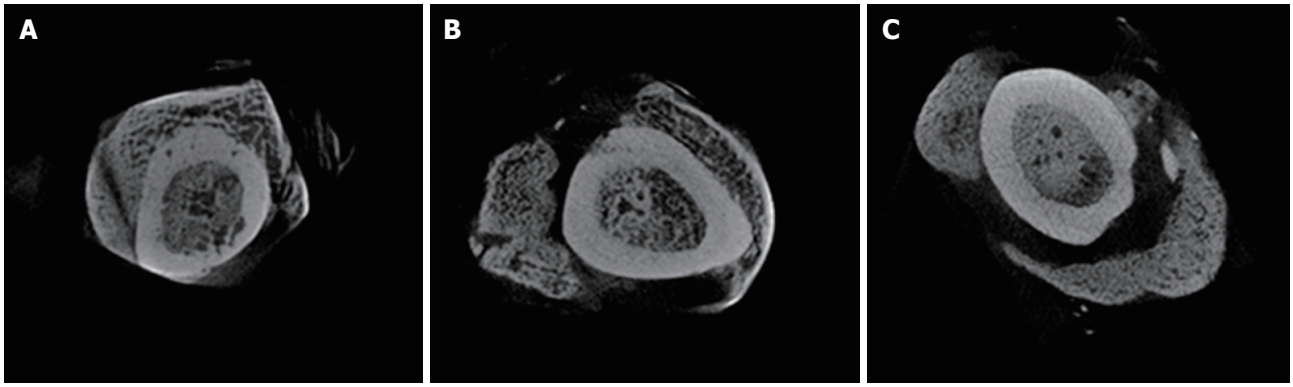

Figure 5 Region of internal interest of the femur, showing different patterns of trabeculae among groups. A: Group C: Control; B: Group B1: Bisphosphonate 1 mg/kg; C: Group B2: Bisphosphonate 3 mg/kg.

results in a prolonged phase of chondral bone regeneration, whereas the intramembranous ossification process appears to be independent of mechanical stability[13]. In direct osseous repair, there is no formation of a bone callus. Therefore, it is possible to predict that when using fixation with plates and screws, direct healing occurs since there is no movement of the bone preserves. However, in animal models, this is not true; indirect healing occurs instead because the animal is not immobilized and the plates are not designed for animals, thus generating micromovement in the region. During early fracture healing, mechanical stimulation appears to enhance callus formation, however the extent of callus formation does not correspond to rigidity[14].

Sodium alendronate is a drug that prevents bone resorption and may induce osteogenesis by inhibiting osteoclast activity. As a result, it is able to both maintain and promote callus formation in bone repair of fractures, as well as increase bone mineral density in the fracture region[15]. In the present study, we demonstrated that alendronate at concentrations of 1 mg/kg and 3 mg/kg did not alter the amount of bone neoformation according to imaging analysis. Remarkably, bone neoformation was equal among all treatment groups.

Under qualitative microtomographic analysis, we observed that bone repair was more effective in the groups that received sodium alendronate applications, especially in the group with the highest dosage. This was visualized through the greater number of trabeculae and smaller spacing between the trabeculae in the 3

mg/kg group. Since alendronate promotes osteoblasts and mesenchymal cell osteoblastogenesis, while also inhibiting osteoclastic activity[6,16], this may suggest that the amount and arrangement of bone trabeculae is directly linked to the dosage and administration of alendronate. This study suggests that the higher the dose, the larger the expansion of mineral-like matrices, while spacing among these areas (chondroid or osteoid matrix) remains lower.

One hypothesis that should be considered and may explain the results found here is the likely action of TGFβ1, which was previously shown to increase upon alendronate administration[17]. It is noteworthy that this cytokine is an important growth factor that may contribute to mineral expansion. In the endosteum area, bone matrix deposition is common and independent of the chondroid area. Thus, alendronate could be responsible for the increase of this cytokine that may, in turn, increase BMP2 expression. This was observed in a recent study where specimens receiving alendronate showed a significant increase of this protein, which improved bone deposition in rabbit calvarias[18].

On the other hand, the same situation may be extrapolated for the periosteal area. Regarding this peculiar topography, chondrocyte expansion may be an effect that is strictly associated with functional endogenous TGFβ signaling. In addition to this effect, TGFβ1 also induces the differentiation of hypertrophic cartilage, which is required for calcium deposition and ossification in this topography. To reach this conclusion, the authors of this study induced the inhibition of specific TGFβ receptors. They therein verified that TGFβ suppression culminated in the inhibition of cartilaginous growth and chondroid differentiation, while also inhibiting both the medullary area and hematopoiesis[19].

Thus, all these hypotheses are possible explanations of our results. We observed an important growth in minerals through accurate imaging analysis, independent of whether the matrix was chondroid or osteoid.

Sodium alendronate at concentrations of 1 mg/kg and 3 mg/kg, when assessed by imaging tests, did not alter the amount of bone neoformation.

Sodium alendronate interferes with the quality of bone neoformation in the context of the quantity and disposition of bone trabeculae. The higher the dose of alendronate, the greater the number of trabeculae and the smaller the spaces among them.

ARTICLE HIGHLIGHTS

Research background

Bisphosphonates are potent inhibitors of bone resorption. Sodium alendronate is the most used drug of this class, and may act on bone remodeling by reducing bone resorption in a dose-dependent manner. Its mechanism of action works primarily by both inhibiting the recruitment and promoting the apoptosis of osteoclasts, while simultaneously stimulating osteoblastic activity.

Research motivation

Despite what is currently know about alendronate-induced bone repair alterations, the literature has not yet fully elucidated the appropriate dose required to achieve better bone regeneration, nor the effects of this drug when using fixation methods.

Research objectives

To evaluate the dose-dependent effects of sodium alendronate on bone repair in treated femur fractures by using stable internal fixation and imaging tests (radiography, tomography and microtomography).

Research methods

Wistar rats were separated into three distinct groups that received applications of either saline solution (control) or different doses of alendronate. The rats then underwent femoral transversal linear fracture surgery using stable internal fixation. Drug administration lasted 45 d. The femurs were sent for radiographic, tomographic and microtomographic analysis in order to evaluate bone quantity and quality.

Research results

Results did not reveal differences in bone quantity by radiographic, tomographic and microtomography analysis. However, when analyzing bone quality, it was evident that alendronate affected the distance and quantity of trabeculae in a dose-dependent manner, thus promoting better bone regeneration.

Research conclusions

Our research results reveal that sodium alendronate, at concentrations of 1 - 3 mg/kg when assessed by imaging tests, does not alter the amount of bone neoformation. Nevertheless, it does interfere with the quality of bone neoformation when considering the quantity and disposition of bone trabeculae. The higher the dose of alendronate, the greater the number of trabeculae and the smaller the spaces among them.

Research perspectives

More research using this method of fixation and sodium alendronate are required and may relate, for example, to the mechanical force of the specimens. It is also important to compare the effects of alendronate with different markers. We suggest that follow-up studies use a dose of 1 mg/kg alendronate, since we have demonstrated here that it successfully promotes bone regeneration.

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ORIGINAL ARTICLE

Retrospective Study

Reducing costly falls after total knee arthroplasty

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Abstract

AIM

To investigate whether adductor canal nerve block (ACB) reduces patient falls when compared to femoral nerve block (FNB) after total knee arthroplasty (TKA).

METHODS

We conducted an institutional review of all-cause falls after TKA from January 2013 to August 2016 using a quality improvement database. Our inclusion criteria were patients with diagnosis of primary knee osteoarthritis who underwent primary unilateral TKA with either a FNB or an ACB and sustained a fall during their hospitalization. We excluded patients who had revision TKA and extensor mechanism reconstruction. We also excluded patients with a history of post-traumatic arthritis, prior history of lower extremity fracture, history of neurological disease, or cerebrovascular disease.

RESULTS

A total of 834 patients had TKA with femoral nerve block and knee immobilizer (FNB + KI). Of those patients, 11 (1.3%) experienced a fall during their hospital stay. In contrast, 791 patients had TKA with ACB. Of those patients, only one (0.13%) patient fall was recorded within this group. We used the Fisher's exact test to compare the differences between the two groups. The difference between the two groups achieves statistical significance (P = 0.006). We also found that 11 out of the 12 patients that fell had a right TKA procedure while one patient had a left TKA procedure. Nine out of twelve patients that fell were female, while only three patients were male.

CONCLUSION

Given the reduction in the number of falls with ACB, it

is recommended that ACB be considered the preferred analgesia for patients undergoing a TKA procedure.

Key words: Reducing falls; Adductor canal nerve block; Total knee arthroplasty; Femoral nerve block; Costly falls

Core tip: When compared to femoral nerve block, adductor canal nerve block (ACB) contributed to fewer patient falls after total knee arthroplasty (TKA) at our institution from a rate of 1.3% to 0.13%. We also discovered a significant increase in fall rate after right TKA as compared to a left TKA. We recommend ACB as the preferred regional analgesia for the TKA procedure.

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INTRODUCTION

Total knee arthroplasty (TKA) is one of the most replicable and effective orthopedic procedures available. It is used to treat end-stage knee osteoarthritis, post-traumatic arthritis and rheumatoid arthritis of the knee. TKA is an elective procedure performed to relieve pain and restore function to an arthritic knee. The goal of a knee replacement procedure is to relieve pain, improve quality of life, and maintain or improve knee function[1]. It is approximated that 700000 total knee replacement procedures are performed annually in the United States, and it is projected to increase to 3.48 million procedures per year by 2030[2]. With the increasing demand for TKA, recent TKA reimbursement changes and limited hospital beds, most hospitals are transitioning to outpatient TKA procedures. Major limitations to outpatient TKA include management of comorbidities, post-operative fall prevention and postoperative pain control[3].

Inadequate pain control postoperatively can limit rehabilitation and slow down recovery[4]. Femoral nerve block (FNB) used to be the preferred regional analgesic modality for TKA due to adequate pain control and ease of application. It is administered around the femoral nerve at the level of the inguinal crease. At this level, the femoral nerve contains both motor and sensory distribution. Therefore, one of the complications of FNB is motor blockade, which is due to the anesthesia infiltrating the femoral motor nerve. This causes quadriceps weakness, which could lead to instability in the affected extremity, subsequently increasing the risk of falls. Several studies have shown that quadriceps weakness slows the rehabilitation process and limits ambulatory distance post-operatively[5]. To reduce post-operative falls at our institution, we started placing patients' operative extremity in DeRoyal 24-in knee immobilizers (KI) to help improve knee stability. Previously, we performed a retrospective study comparing the fall rate between TKA patients who used KI post-operatively and patients that did not use KI. The study showed that the use of KI reduces the number of patient falls from 3.7% to 1.6%[4]. A fall rate of 1.6% was considered unacceptable given the high cost and morbidity associated with patient falls. During the study and after polling the floor staff, we discovered that the majority of patients were noncompliant with the use of the KI and a couple of patients fell while wearing the KI. Given the unsatisfactory compliance with the use of the KI and relatively high fall rate, the adult reconstruction team discontinued the use of KI and started considering better alternatives to help reduce fall rate. One of the alternatives proposed was switching the regional anesthesia from FNB to adductor canal block (ACB).

There have been multiple recent studies indicating that ACB, a relatively new sensory block technique that predominantly blocks sensory nerves by anesthetizing only the saphenous nerve in the adductor canal, might be a safer option when compared to FNB, as it preserves quadriceps function while still effectively alleviating post-operative pain[5,6]. Most studies, including a randomized control trial and a meta-analysis, have shown that patients who receive ACB have faster pain relief, greater quadriceps strength, earlier ambulation, greater average distance of ambulation during physical therapy, faster timed up and go test, and decreased hospital length of stay[5]. There have been several studies comparing the fall rate between the two regional block techniques (FNB *vs* ACB), and all findings thus far have been equivocal[7]. A great deal of knee replacement centers has adopted ACB as the analgesia of choice, even though the data comparing fall rates between the two nerve blocks are inconclusive. Our institution transitioned to using ACB as the preferred anesthesia over FNB for TKA in 2015 to reduce patient falls, however the effects of this change in practice has yet to be evaluated. Therefore, the purpose of this study was to perform an institutional review comparing the fall rate between ACB and FNB + KI after TKA to evaluate its effectiveness at our institution and compare our own fall rates to those reported in the literature.

MATERIALS AND METHODS

We identified patients that fell during their hospitalization period after TKA using our institutional quality improvement reporting database, Be-Safe. The Be-Safe database is used by the floor staff at our Hospital to report in-house unexpected patient outcomes, including falls. All data obtained from the Be-Safe database is used for quality improvement and is exempt from Institutional Review Board approval. The fall data from January 2013 to September 2016 was evaluated. The data included documentation of the date of the fall, procedure performed, the patient's medical record number and a

Table 1 The annual number of reported falls after total knee arthroplasty

Year	Total number of TKA	No. of falls
2013	402	9
2014	432	2
2015	434	0
2016	357	1

TKA: Total knee arthroplasty.

Table 2 The total number of reported falls for each regional nerve block

Nerve block	No. of TKAs per block	No. of reported falls per block	*P*-value
ACB	791	1	0.006
FNB + KI	834	11	

TKA: Total knee arthroplasty; ACB: Adductor canal nerve block; FNB: Femoral nerve block; KI: Knee immobilizer.

brief description of the circumstances surrounding the incident. We then accessed the electronic medical records for each patient to confirm the procedure that was performed on the patient, the type of regional anesthesia received prior to the fall and the patient's past medical history. We also reviewed operative notes, fall event notes, injuries sustained secondary to the fall, treatments received and any deviation from a normal post-operative course as a result of the fall, including requirement for additional imaging studies. Inclusion criteria included patients with the diagnosis of primary knee osteoarthritis who underwent primary unilateral TKA with either a FNB or ACB regional block and sustained a fall during their hospitalization. Exclusion criteria were patients with history of post-traumatic arthritis, prior history of lower extremity fracture, history of neurological disease, cerebrovascular disease, psychiatric diagnosis, non-ambulatory patients, and patients with a history of chronic opioid use. We also excluded patients who had revision TKA, unicondylar knee replacements, history of total hip arthroplasty and extensor mechanism reconstruction.

We reviewed anesthesia records on all the patients who fell to confirm the type of regional anesthesia they received. The standard protocol for FNB done for all the TKA patients at our institution consisted of a single shot of 20 mL of 0.5% Ropivacaine injection around the femoral nerve under ultrasound guidance with a continuous infusion of 0.2% Ropivacaine at a rate of 6 mL/h through a femoral catheter that was removed on post-operative day two. The protocol for the ACB consisted of a single shot of 30 mL of 0.5% Ropivacaine under ultrasound guidance around the saphenous nerve in the adductor canal. For both types of regional blocks, a resident performed or assisted with the procedure while a supervising attending was always present.

Statistical analysis

A statistical review of the study was performed by a biomedical statistician. We used the Fisher's exact test to evaluate differences between the two groups. A *P*-value < 0.05 was considered statistically significant.

RESULTS

Seven patients were excluded from the study. One patient was excluded from the ACB fall group due to prior history of falls and history of a neurological disease. Five patients were excluded from the FNB group because they had revision TKA. One patient was excluded from the FNB fall group because the patient had an extensor mechanism reconstruction procedure along with a revision TKA. There was a total of 834 patients that had TKA with FNB + KI between January 2013 and December 2014 (Table 1). Of those patients, 11 (1.3%) experienced a fall during their hospital stay (Table 2). One patient had an ankle fracture necessitating operative fixation. One patient sustained facial laceration, which required sutures. Three patients' injuries necessitated X-rays of their extremity after the fall, but no fractures were identified. Within the FNB group, four patients fell on post-operative day one and seven patients fell on post-operative day two. The age range of the patients that fell after FNB was between 49-92 years old with an average age of 65.5. Eight of the eleven patients in this group were females. The average body mass index (BMI) of the patients that fell after FNB was 33.3. In contrast, of the total 791 patients that had TKA with ACB between January 2015 and August of 2016, only one patient (0.13%) fall was recorded (Table 1). The patient who fell after ACB was a 59-year-old female with a BMI of 41.77, who fell on post-operative day two. The difference between the two groups reached statistical significance ($P < 0.006$) (Table 2). It was noted that out of the total twelve patients that fell, 11 (92%) had right TKA compared to one patient fall after a left TKA. Also, nine out of twelve patients that fell were female, while only three patients where male. These last two findings warrant further investigation.

DISCUSSION

Most large joint replacement institutions have switched to ACB as the preferred regional anesthesia for TKA. The reasoning in most cases revolves around reducing the fall rate after TKA. There is a considerable amount of literature to support the use of ACB over FNB due to faster pain relief, greater quadriceps strength, earlier ambulation, greater average distance of ambulation during physical therapy, faster timed up and go test, and decreased hospital stay[5]. However, there is no evidence to support reduction in fall rate when ACB is compared with FNB to date[7]. Our study showed a reduction in fall rate after institution-wide transition to ACB as the preferred analgesic method over FNB. Caution must be taken when interpreting and applying our study because this study is a retrospective, non-matched design without control groups for possible confounding variables or

differing patient group risk factors. Underreporting by staff members is an inherent limitation to using a quality assurance report like the one used in this present study. We also had a very low number of falls.

While gathering data for this study, we reviewed fall data exclusively from the dedicated orthopedic surgery post-operative acute inpatient ward. In very rare circumstances, patients were transferred to other floors if the orthopedic ward was at capacity or if the patient's co-morbidities or intra-operative complications required admission to the intensive care unit or the intermediate care unit. It is possible that some of the TKA patients fell while on other floors.

A major confounding variable is the general institutional emphasis on reducing all cause falls during the same time period. Over the past five years, there has been a hospital wide initiative to reduce the number of falls at our institution. Our institution has invested in fall prevention awareness programs, which included frequent education of floor staff, replacing old hospital beds with new beds equipped with bed alarms and motion sensors that detect patients' movement out of bed and automatically notify floor staff. All patients with increased fall risk are now identified early in the pre-admission phase based on several factors including age, past medical history and medications being taken. These patients are provided bright yellow wristbands, yellow gowns, yellow slip resistant socks and are monitored more frequently. All patients having an arthroplasty procedure are now required to attend an arthroplasty course in which they are well educated on fall prevention. We believe that the new fall prevention initiative could possibly have contributed to the reduction in fall rate, but the effect of ACB is likely additive. Our analysis would be strengthened with more fall patients, which will allow us to have more data points to analyze and perform a multivariate analysis for potentially confounding variables (spinal *vs* general anesthesia, use of PCA *vs* oral analgesics, BMI and age).

An interesting result we found during this study was increased fall rate after right TKA compared with left TKA. A literature search showed no prior studies comparing the fall rate between right TKA *vs* left TKA. The increase in fall rate could be due to several factors, including extremity dominance, higher rate of right TKA procedures than left TKA at our institution, or it could be a stochastic anomaly. Nevertheless, the association of laterality with fall risk merits further investigation given our findings.

In conclusion, the present study found a significant relationship between ACB and fall reduction as compared with FNB + KI. This study is limited by the small numbers of falls and confounding variables that were not controlled for.

ARTICLE HIGHLIGHTS

Research background

There have been multiple recent studies indicating that adductor canal block (ACB) might be a safer option for patients undergoing total knee arthroplasty (TKA) procedure when compared to femoral nerve block (FNB) because of its potential ability to reduce patient falls, as it preserves quadriceps function while still effectively alleviating postoperative pain. Most studies, including a randomized control trial and a couple meta-analysis studies, have shown that patients who ACB have faster pain relief, greater quadriceps strength, and decreased hospital length of stay. There have been several studies comparing the fall rate between the two regional block techniques (FNB *vs* ACB), and all findings thus far have been equivocal. A lot of institutions have switched to ACB as their preferred regional analgesia simply based on preservation of quadriceps strength and early mobilization. Our institution made the switch to ACB as the primary regional analgesia after the occurrence of several patient falls following a TKA procedure using FNB. This study is significant and was done to evaluate the effectiveness of ACB at preventing falls at our institution and compare our fall rates to those reported in the literature.

Research motivation

The motivation behind this research is to evaluate and compare the fall rate after TKA procedure between ACB and FNB at our institution. This research is significant because it allows us to evaluate how effective ACB is at reducing patient falls after TKA when compared to FNB. Results from this study can be applied at various institutions to help decrease patient falls. Results from this study could also be a source of data points for future meta-analysis.

Research objectives

The main objective of this study was to evaluate and compare the fall rate after TKA procedure between ACB and FNB at our institution. Our results indicated that there was significant reduction in patient falls after TKA procedure after switching to ACB. This is important because our institution will continue to use ACB as the preferred regional analgesia for TKA procedure.

Research methods

In this study, we analyzed the fall data at our institution using our institutional quality improvement reporting database, Be-Safe from January 2013 to September 2016. We then accessed the electronic medical records for each patient that fell to confirm the procedure that was performed on the patient, the type of regional anesthesia received prior to the fall and the patient's past medical history. We only included patients with the diagnosis of primary knee osteoarthritis who underwent primary unilateral TKA with either a FNB or ACB regional block and sustained a fall during their hospitalization. We excluded patients who had revision TKA, unicondylar knee replacements, history of total hip arthroplasty and extensor mechanism reconstruction. We then compared the fall rates in patients after receiving ACB *vs* FNB after a TKA procedure. We used the Fisher's exact test to compare differences between the two groups, and there was a statistical significant difference between the groups ($P < 0.006$).

Research results

A total of 11 (1.3%) experienced a fall during their hospital stay after receiving FNB for a TKA procedure while one patient (0.13%) fell after receiving ACB for a TKA procedure. Results from this study indicated a significant drop in the fall rate at our institution after switching from FNB to the ACB. Our data indicate that patient and staff education on fall prevention and the use of ACB for patients undergoing TKA is effective at reducing falls.

Research conclusions

New findings in this study highlighted that there was an increased rate of patient falls after right TKA compared to left TKA. We also found that more female patients fell after TKA compared to male patients. We propose a new theory that due to extremity dominance, patients are more likely to fall after having a TKA procedure on their dominant lower extremity due to instability and weakness in their dominant/lead extremity. For unknown reasons, we also think that female patients are more likely to fall after TKA procedure when compared to male patients. We summarize that switching to ACB helped contribute to reducing the fall rate after TKA at our institution. We believe that the reduction in the fall rate is related to the preservation of the quadriceps strength with ACB as demonstrated by multiple prior studies[5]. We hypothesize that a systematic review or a case control study will help confirm our theory that female patients and patients that have TKA on their dominant extremity are more likely to fall

when compared to male patients and patients that have TKA on their non-dominant extremity. There were no new methods proposed by this study. Our hypothesis that ACB reduces patient falls was confirmed in this study. Based on this study, our institution will continue to use ACB as the regional anesthesia for a TKA procedure. We will also continue to educate and take special precautions with patients that are high fall risk.

Research perspectives

This study helped highlight the importance of developing and maintaining patient safety initiatives in healthcare. It also helped in displaying the importance of patient and staff education and awareness to difficult safety issues in the hospital. The direction of future research will be to do a meta-analysis or retrospective study to further investigate if there is truly an increased risk in patient falls in females and after TKA on the dominant extremity. The best method for future research will be to perform a prospective study looking at the degree of quadriceps weakness, ambulatory distance, earlier or late ambulation, distance of ambulation during physical therapy, timed up and going test, and hospital length of stay post-operatively in male *vs* female patients and in dominant *vs* non-dominant extremity.

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ORIGINAL ARTICLE

Retrospective Study

Screw placement is everything: Risk factors for loss of reduction with volar locking distal radius plates

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Author contributions: Drobetz H, Black A, Davies J, and Heal C developed the study protocol; Drobetz H, Black A, Davies J initiated the study, and performed literature research and proofreading for scientific content; Drobetz H and Black A participated in patient recruitment and follow-up, data collection, and writing of the manuscript; Heal C performed statistical analysis and interpretation, write up of data, preparation of ethics submission, and provided overall oversight of conduct of study; Buttner P performed statistical analysis of raw data, and revised the manuscript for statistical content.

Institutional review board statement: This study was reviewed and approved by the Human Research Ethics Committee of Queensland Health, Australia.

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Abstract

AIM

To determine factors correlated with postoperative radial shortening in patients with distal radius fractures treated with volar locking distal radius plates.

METHODS

A total of 250 patients with a distal radius fracture sta-

bilised with volar locking plates between January 2010 and December 2014 were included in a multicentre retrospective cohort study. We measured the distance of the distal locking screws to the joint line immediately postoperatively and then measured radial shortening after six to eight weeks using the change in ulnar variance.

RESULTS
Multivariate linear regression analysis showed that there was a significant linear association between the distance of the screws from the joint line and radial shortening. No other patient, injury, or treatment-related characteristic significantly influenced radial shortening in multivariate analysis.

CONCLUSION
Distal locking screws should be placed as close as possible to the subchondral joint line to prevent postoperative loss of reduction.

Key words: Loss of reduction; Volar locking distal radius plate; Distal radius fracture; Screw placement; Cohort study

Core tip: The aim of this study was to determine risk factors for postoperative radial shortening in patients with distal radius fractures treated with volar locking distal radius plates. Retrospective analysis of 250 X-rays and clinical data determined immediate postoperative distance of the distal locking screws from the joint line and degree of radial shortening 6-8 wk postoperatively. Radial shortening was significantly and linearly correlated with increased distance of locking screws from the joint line. No other factor analysed in the study was significant. We recommend subchondral placement of distal locking screws in order to maintain reduction postoperatively.

Drobetz H, Black A, Davies J, Buttner P, Heal C. Screw placement is everything: Risk factors for loss of reduction with volar locking distal radius plates. *World J Orthop* 2018; 9(10): 203-209 Available from: URL: http://www.wjgnet.com/2218-5836/full/v9/i10/203.htm DOI: http://dx.doi.org/10.5312/wjo.v9.i10.203

INTRODUCTION

Distal radius fractures are the most common type of fracture of the human skeleton[1-3]. The treatment of distal radius fractures has undergone a paradigm shift in the last fifteen years, and fixation with volar locking distal radius plates (VLDRP) has become the operative standard[1,4-6], despite lack of clear evidence of benefit over any other treatment modality[7-10]. VLDRP dohave a distinct advantage over any other treatment method as they allow immediate postoperative mobilisation[11], provided optimal placement of the plate/screw construct is achievedintraoperatively. Biomechanical studies[12-15] and clinical observations[16-20] indicate the best placement of the distal locking screws is as close as possible to the subchondral area of the joint to prevent loss of postoperative reduction. The aim of our study was to evaluate the relationship between distal screw placement and postoperative radial shortening in a large consecutive cohort of dorsally displaced distal radius fractures plated with VLDRP. Our hypothesis was that loss of reduction after plating is related to the distance the distal locking screws are placed from the subchondral joint line.

MATERIALS AND METHODS

Study design

We performed a longitudinal multicentre retrospective cohort study including patients who underwent VLDRP fixation of a dorsally displaced distal radius fracture. X-rays and charts of patients undergoing surgery at two Australian regional hospitals between January 2010 and December 2014 were assessed (Ethics approval HREC/15/QTHS/10).

Participants

Consecutive patients with dorsally displaced distal radius fractures managed with VLDRP were included. Ten patients had bilateral wrists fractures - one wrist was randomly chosen for inclusion for each. Patients with Kirschner wires in addition to VLDRP were excluded. Patients without documented follow-up were excluded.

Data collection

Data were collected from pre-, intra- and post-operative standard anterior-posterior and lateral X-rays. Images were measured using digital radiology software (AGFA^{R} HealthCare Impax 6, Belgium). Fracture classification, angle and distance measurements were assessed by the second author. The first author validated all measurements. If there was more than ten percent difference between measurements, a board-certified radiologist repeated the measurement.

We recorded anterior-posterior radial inclination (degrees), ulnar variance (radial length; millimetre) and lateral volar tilt (degrees). The distance of distal locking screws from the deepest point of the subchondral joint line was measured on intra-operative lateral tilted images. The subchondral line was defined as the dense area, which denotes the articular surface. The optimal most distal screw placement was defined as the area just proximal to the subchondral line without breaching it. Radial shortening as a parameter of reduction loss was determined as the change in ulnar variance between six and eight weeks post-operatively (Figure 1). Pre-operative images were used for AO fracture classification[21]. Patient age, gender, mechanism of injury (high or low energy), likelihood of osteoporosis and

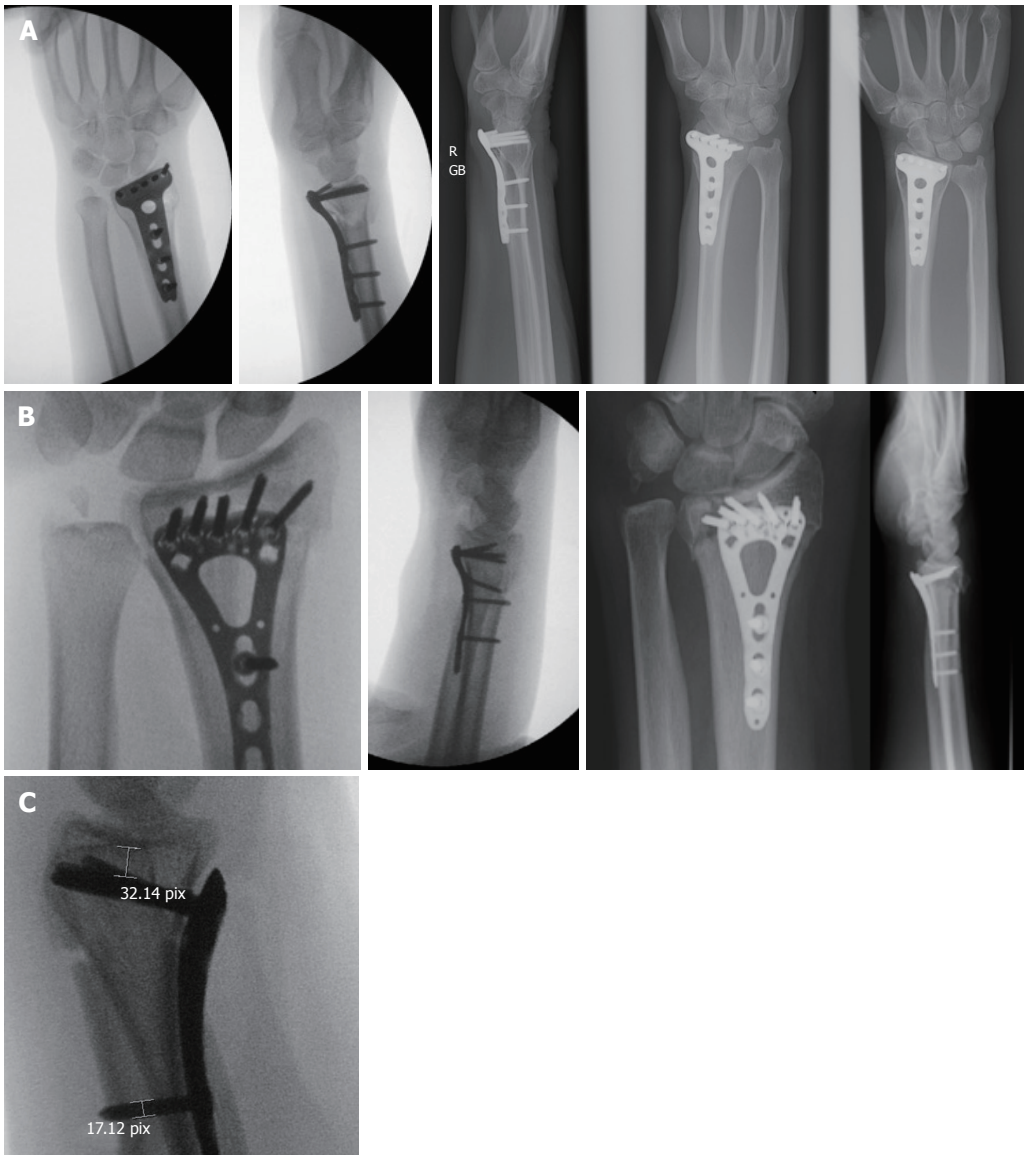

Figure 1 Examples of distal screw placement. A: Intraoperative image shows that screws are placed immediate to the subchondral joint line. Postoperative image does not show any loss of reduction; B: Placing the screws at a distance from the subchondral joint line causes postoperative loss of radial length; C: Intraoperative measurement. As the diameter of the screws was known, the distance of the screws was able to be calculated.

comorbidities [American Society of Anaesthesiologists (ASA)] classification[22] and postoperative immobilisation were sourced from patient charts.

Statistical methods

A pilot study including 31 cases was used to calculate the sample size, as variability was unknown. Accounting for eight potential independent characteristics, the R^2 was 0.28 and Cohen's f^2 effect size was 0.39, indicating that 50 fractures would be required to have power in excess of 80% and a level of significance of 0.05.

Bivariate statistical comparisons used unpaired *t*-tests, one-way Analysis of Variance, Pearson's correlation coefficient and Spearman rank correlation coefficient (r) to identify factors influencing postoperative radial shortening. Factors included in the analysis were age, sex, mechanism of injury, affected wrist (left or right), AO classification, time between injury and surgery, VLDRP characteristics including number of distal screw rows, total number of distal screws, distance of the distal locking screws from the subchondral joint line, and whether the wrist was immobilised postoperatively.

Multiple linear regression analysis identified independent factors associated with postoperative radial shortening. A Kolmogorov-Smirnov test verified that the outcome measure was normally distributed (P = 0.240). After identifying independent significant factors, the remaining variables were investigated for potential confounding effects. Statistical analysis was conducted using Stata release 12 (StataCorp LP, Texas, United States) and SPSS for Windows, Version 22 (SPSS Inc., Chicago, IL, United States). Statistical analysis was performed by one of the authors, PB, a biostatistician (www.tropicalhealthsolutions.com/petrabuttner).

Table 1 Description of characteristics of 250[1] patients with 250 dorsally displaced distal radius fractures managed with volar locking distal radius plates documented between 2010 and 2014 at two regional hospitals in north Queensland, Australia

Characteristic	Descriptive statistics
Patient	
Mean age (SD)[2]; range (yr)	49.1 (16.7); range 16 to 88
Female	63.2% (*n* = 158)
Comorbidities (ASA classification)[4] (*n* = 67)	
ASA 1	34.3% (*n* = 23)
ASA 2	59.7% (*n* = 40)
ASA 3	6.0% (*n* = 4)
With Osteoporosis[5] (*n* = 164)	51.2% (*n* = 84)
Injury	
High energy mechanism (*n* = 160)	46.9% (*n* = 75)
Right wrist fractured (*n* = 248)	42.3% (*n* = 105)
AO fracture classification[6]	
A2	14.8% (*n* = 37)
A3	14.8% (*n* = 37)
B1	2.8% (*n* = 7)
B2	4.0% (*n* = 10)
C1	12% (*n* = 30)
C2	34.4% (*n* = 86)
C3	17.2% (*n* = 43)
Median number of days from injury to surgery (IQR)[3]; range (*n* = 164)	6 (1, 16); range 0 to 71
Treatment	
With 1 distal screw row	25.6% (*n* = 64)
Median number of distal screws (IQR); range	4 (4, 5); range 3 to 8
Median number of distal screws in first row (IQR); range	4 (4, 4.25); range 2 to 5
Median number of distal screws in second row (IQR); range	2 (1, 3); range 1 to 4
With 4 or less distal screws in most distal row	75.2% (*n* = 188)
Median distance from joint line (IQR); range (mm)	3.1 (2.1, 4.1) range 0 to 11
Postoperative immobilisation[7] (*n* = 224)	87.9% (*n* = 197)
Outcome measure	
Mean radial shortening (SD); range (mm)	1.9 (1.3); range 0 to 5.6

[1]*n* = 250 unless otherwise stated; [2]SD = standard deviation; [3]IQR = interquartile range; [4]ASA classification; [5]osteoporosis was classified as "yes" when chart information was available and in females > 60 years of age with low energy trauma; [6]AO fracture classification. B3 fractures were excluded from the analysis as they are volar shear fractures and follow different biomechanical principles; [7]postoperative immobilisation was either by cast (*n* = 128) or by thermoplastic splint (*n* = 77). Duration of immobilisation varied between two and four weeks. ASA: American Society of Anaesthesiologists.

RESULTS

For detailed results, see Table 1. A total of 250 patients were included from Hospital 1 (*n* = 141; 56.4%) and Hospital 2 (*n* = 109; 43.6%). In all, 186 plates (74.4%) had two distal screw rows. Plates used were Medartis® Aptus TriMed® volar fixed angle plates or Synthes® VA. Sixty-four plates (25.6%) had one distal screw row (Synthes® volar locking buttress plate 2.4 mm). There was disagreement regarding two fractures. The board-certified radiologist agreed with the first author's measurements.

Factors influencing postoperative loss of radial length

Bivariate analysis showed that the mean postoperative loss of radial length was higher for AO type A and C fractures (mean: 2.0, SD: 1.3) and less for AO type B fractures (mean: 1.2, SD: 0.8) (P = 0.033). There was a weak negative correlation between number of distal screws in the most distal screw row and radial shortening (r = -0.13; P = 0.042). There was a strong positive correlation between the distance of the distal locking screws from the subchondral joint line and postoperative loss of radial length (r = 0.61; P < 0.001). None of the other factors (see Table 1 for complete list of factors investigated) was statistically significantly related to radial shortening.

Multiple linear regression analysis showed that the distance of distal locking screws from the subchondral joint line was the only independent factor statistically significantly associated with radial shortening (coefficient 0.379, 95%CI: 0.304-0.454; P < 0.001). No confounding variables were identified. The linear regression line was estimated as radial shortening = 0.7 mm + 0.4 × the distance from joint line (mm) (P < 0.001) (Figure 2). Volar tilt and the change of radial inclination did not change in the postoperative period and were not analysed.

DISCUSSION

The results of our study show that placement of distal locking screws is the only independent factor significantly associated with postoperative loss of radial length. Postoperative shortening is proportional to the distance of the distal locking screws from the subchondral joint line. The soft metaphyseal bone of the distal radius fragment cannot support the distal locking screws. The distal fragment will settle and "sink through" until the screws are in the hard subchondral area just proximal of the joint. Placing the distal screws as close as possible to the joint line prevents loss of postoperative displacement, independent of age, gender, osteoporosis and immobilisation.

Our study expands on a previous biomechanical study and clinical observations[13,16,18-20,23]. Drobetz *et al*[13] found a statistically significant linear association between loss of radial length and distance of the distal locking screws from the subchondral joint line. They also noted that the distal fragment "sank straight" without loss of volar tilt and radial inclination, an observation which was confirmed in our study population. The current study translates these findings into a clinical setting. The clinical relevance of our results is that "distance from the joint line" is a modifiable risk factor. Postoperative loss of reduction therefore seems to be mainly surgeon-dependent.

Our findings also indicate that loss of reduction is independent of the number of distal screws, provided there are at least four distal screws with a minimum diameter of 2.3 mm each (the type of plates we assessed).

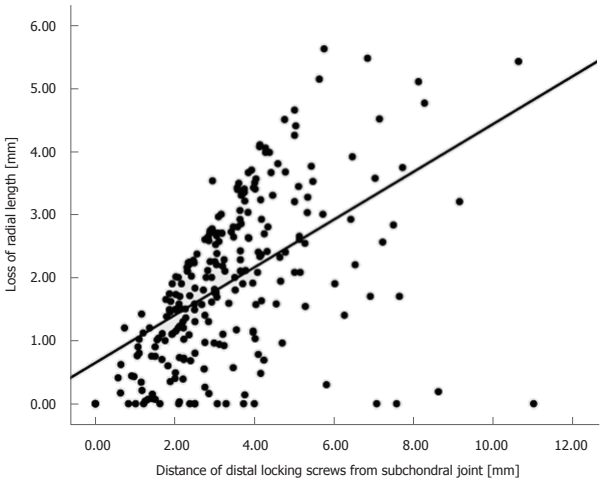

Figure 2 Correlation of loss of radial length (mm) and distance of distal locking screws from the subchondral joint line (mm) of 250 patients with dorsally displaced distal radius fractures managed with volar locking distal radius plates. The linear regression line was: radial shortening = 0.7 mm + 0.38 × distance from joint line (mm) ($P < 0.001$).

A second distal screw row does not have any positive influence on postoperative radial shortening. This is in accordance with biomechanical studies[12,14,24-26].

The clinical and biomechanical advantage of a second distal screw row eludes the authors. According to operation manuals of various implant companies, two screw rows either provide a "three-dimensional scaffold for optimal subchondral support" or "intra- operative solutions for different fracture requirements", "intra-operative fine contouring of the radial and intermediate columns", "optional three point support for more stability" or "creation of a scaffold to allow two plane fixation of distal metaphyseal fragments". Katsunori[27] and Kawasaki[28] have reported on a double tiered subchondral support (DSS) procedure in which the screws of the second distal screw row are placed long, so that their tips support the dorsal part of the distal radius. Their findings showed less loss of radial length and volar tilt when using the DSS construct compared to placing screws only in the distal row. Other studies[29-31], found that a screw length of 75% of the sagittal distal radius diameter is sufficient to withstand postoperative displacement loads, which somewhat contradicts Katsunori's and Kawasaki's findings.

Our findings further demonstrated that immediate postoperative mobilisation did not lead to increased loss of radial length and consequently that postoperative immobilisation did not prevent loss of radial length when the distal screws were placed into the soft metaphyseal bone. Only 12.4% of fractures underwent early mobilisation, the remainder being immobilised by splint or a cast (Table 1). We speculate that this is an ingrained surgeon practice rather than behaviour based on evidence.

Previous studies have identified osteoporosis as a risk factor for radial shortening after plating with VLDRP[32], and it has been postulated that this is due to poor bone quality. This finding was not supported in our study. Age could be considered to be a surrogate marker for osteoporosis, but this was also not shown to be associated with radial shortening. Our findings highlight that volar locking plates are suitable and effective in this subset of patients. However, it was difficult to diagnose osteoporosis, as chart information was limited and it was not feasible to retrospectively perform bone mineral density measurements on all patients. This is a weakness of our study. Osteoporosis was classified as "yes" when chart information was available and in females > 60 years of age with low energy trauma[5].

There were other limitations in our study. We did not evaluate clinical outcomes in our patient population, but this was not within the scope of our study. However, a recent prospective cohort study[3] showed that radial shortening of more than 2 mm was associated with worse patient-reported outcome scores. These findings indirectly indicate the possible clinical relevance of our paper. There are also several other studies which show that "function follows form", *i.e.,* that good clinical outcomes are associated with healing in near anatomical position[33-35].

The study strengths are adequate sample size and the large number of variables analysed. In addition to measurements performed by two authors independently, the same X-ray departments, machines and viewing program counteracted possible bias. In summary, the distance of the distal screws in relation of the subchondral joint line is the only independent variable associated with postoperative loss of reduction. The loss of reduction is independent of age, gender, osteoporosis, ASA status, fracture severity, immobilisation, number of distal screws and the presence or absence of a second distal screw row. Surgeons using VLDRPs for fixation of distal radius fractures should attempt to place the distal screws as close as possible to the subchondral joint line.

ARTICLE HIGHLIGHTS

Research background

Treatment of distal radius fractures with volar locking distal radius plates (VLDRP) has become the most popular treatment method in the last ten years. Biomechanical and clinical studies indicate that distal screw placement as close as possible to the articular surface is crucial to prevent loss of postoperative reduction. To our knowledge, no study has been undertaken that proves or disproves this observation.

Research motivation

Our hypothesis was that postoperative loss of reduction will occur when the distal VLDRP screws are placed more proximal, in the distal radius fragment metaphysis, rather than in the subchondral hard area close to the articular surface. We also hypothesized that the loss of postoperative reduction is directly related to the distance of the distal screws from the articular surface. We undertook a retrospective study analyzing pre- and postoperative X-rays of 250 consecutive distal radius fractures treated with VLDRP.

Research objectives

Objectives of the study were to determine factors correlated with postoperative radial shortening in patients with distal radius fractures treated with VLDRPs.

Research methods

This is a longitudinal multicentre retrospective cohort study including patients who underwent VLDRP fixation of a dorsally displaced distal radius fracture in

which 250 wrist fractures were included. Collected parameters were fracture classification, radial length, radial inclination, volar inclination of the joint surface, patient age, gender, mechanism of injury, likelihood of osteoporosis, comorbidities and postoperative immobilisation. The distance of the distal locking screws to the articular surface was measured on intraoperative lateral tilted X-rays. Radial shortening as a parameter of loss of reduction was measured on X-rays obtained at a minimum of six weeks postoperatively. Bivariate statistical comparisons were used to identify factors influencing postoperative radial shortening. Multiple linear regression analysis then identified independent factors associated with postoperative radial shortening.

Research results

Multiple linear regression analysis showed that the distance of the distal locking screws from the articular surface was the only independent factor associated with radial shortening. The relationship between shortening and distance of the distal screws to the articular surface was linear and statistically highly significant.

Research conclusions

Our study showed that in order to prevent postoperative loss of reduction in fractures plated with VLDRP, it is crucial that the distal screws are placed as close as possible to the articular surface. The study further indicated that loss of postoperative reduction is not associated with any other parameters measured - age, gender, osteoporosis, ASA status, fracture severity, immobilisation, number of distal screws and the presence or absence of a second distal screw row.

Research perspectives

A major advantage of treating distal radius fractures with VLDRP is that patients can be treated without postoperative immobilisation. VLDRP are in fact the only treatment modality that allows for immediate postoperative use of the wrist. Based on the findings of our study and provided that the distal screws are placed as close as possible to the articular surface, immediate postoperative mobilization should be possible without loss of reduction. Future studies should attempt to verify our findings in a clinical setting.

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ORIGINAL ARTICLE

Observational Study

Long-term results of an anatomically implanted hip arthroplasty with a short stem prosthesis (MiniHip™)

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Abstract

AIM

To evaluate the clinical and radiological outcome nine

and ten years after short-stemmed, bone preserving and anatomical hip arthroplasty with the MiniHip™ system.

METHODS

In a prospective study, 186 patients underwent hip arthroplasty with a partial neck preserving short stem (MiniHip™, Corin). Elderly patients were not excluded from this study, thus the mean age at the time of surgery was 59.3 years (range 32 to 82 years). Surgery and the follow-up assessments were performed at two Centers. Up until now, the mean follow-up was 112.5 ± 8.2 mo. The Oxford Hip Score (OHS) and the Hip Dysfunction Osteoarthritis and Outcome Score (HOOS) was assessed pre- and each year after surgery. The clinical follow-up was accompanied by standardized a.p. and axial radiological examinations. Periprosthetic lucencies, hypertrophies within the Gruen zones one to fourteen were assessed. A subsidence of the stem was investigated according to Morray and heterotopic ossifications were assessed according to Brooker.

RESULTS

The OHS and HOOS improved from 18 ± 3.3 to 46 ± 2.0 and from 30 ± 8.3 to 95 ± 4.6 points, $P < 0.001$ respectively. There were no differences regarding age, etiology, friction pairings, *etc*., ($P > 0.05$). Two stems were revised due to a symptomatic subsidence four and twelve months postoperatively. Thus, the survivorship for aseptic loosening at nine to ten years was 98.66%. Including one stem revision due to a symptomatic exostosis, bursitis and thigh pain as well as one revision because of a septic stem loosening, the overall survival for the stem with revision for any reason was 97.32%. Besides one asymptomatic patient, radiological signs of a proximal stress-shielding, such as bone resorptions within the proximal Gruen zones, were not noticed. Findings suggesting a distal loading, *e.g.*, bony hypertrophies or bone appositions of more than 2 mm, were also not detected.

CONCLUSION

Regarding these first long-term results on the MiniHip™, the implant performed exceedingly well with a high rate of survivorship for aseptic loosening. Our radiological results within the Gruen zones support the design rationale of the Minihip to provide a reliable metaphyseal anchoring with the expected proximal, more physiological load transfer. This might minimize or exclude a stress shielding which might be associated with thigh pain, proximal bone loss and an increased risk of aseptic loosening. The MiniHip™ is a reliable partial-neck retaining prosthesis with good a clinical long-term outcome in younger as well as elderly patients.

Key words: Primary hip arthroplasty; Long-term results; Short stem endoprothesis; Prospective follow-up study; Stress-shielding

Core tip: An innovative aspect of the MiniHip™ short stem prosthesis is that the design provides the possibility to restore the joint geometry by using an individual femoral neck cut. In general, there is an increasing demand for long-term results of newer arthroplasty systems. In contrast to other studies on short stems for hip replacement, this study was explicitly not only conducted in young and active patients. Therefore, this clinical and radiological long-term follow-up study is of particular interest. This study revealed an excellent and lasting clinical outcome, a reliable metaphyseal anchoring with a physiological proximal load transfer and an excellent long-term stem survivorship which is at least comparable to standard prostheses and other short stem concepts.

von Engelhardt LV, Breil-Wirth A, Kothny C, Seeger JB, Grasselli C, Jerosch J. Long-term results of an anatomically implanted hip arthroplasty with a short stem prosthesis (MiniHip™). *World J Orthop* 2018; 9(10): 210-219 Available from: URL: http://www.wjgnet.com/2218-5836/full/v9/i10/210.htm DOI: http://dx.doi.org/10.5312/wjo.v9.i10.210

INTRODUCTION

Short-stemmed cementless hip arthroplasty prostheses have been designed to preserve bone stock, facilitate an eventual revision surgery and achieve a more physiological loading to the proximal part of the femur[1-4]. In comparison to conventional cementless stems, short stems are therefore described to reduce the stress shielding around the stem, which might be associated with thigh pain, bone loss and an increased risk of aseptic loosening[5-8].

In different conventional stems as well as short stems, digital planning analysis studies and clinical studies on the radiological outcome frequently demonstrate an inadequate reconstruction of the individual femoral offset[9,10]. Such changes in hip geometry often lead to a reduced soft tissue tension as well as a decreased muscular preload. This might be accompanied by an insufficiency of the gluteus muscle group and/or a relevant hip instability[11,12]. However, the widely used standardized femoral neck cut of most prosthesis stems leads to a "bottom up strategy" where the restoration of the joint geometry can only be guaranteed by selecting different modular conus components for a modular tapered stem or different designs of a monoblock prosthesis. The MiniHip™ short stem (Corin Group PLC, Cirencester, United Kingdom) is different. Based on a large series of preoperative CT data collected in hip arthroplasty patients, it is designed to allow the use of individual resection levels for the femoral neck[13]. According to this concept, the MiniHip™ implant is a partial neck retaining prosthesis. This leads to a "top down concept" which provides a completely different possibility to restore the individ-

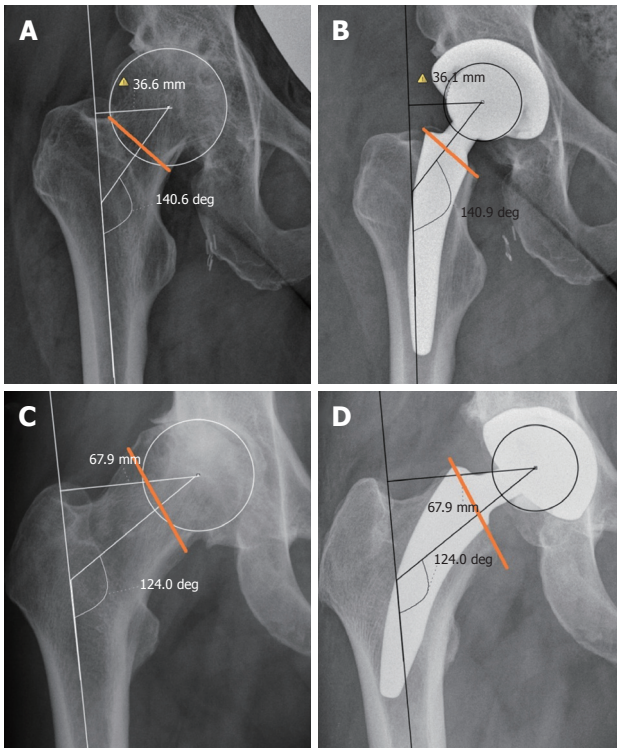


Figure 1 "Top down concept" of the MiniHip™ to restore the individual joint geometry. The individual femoral neck cut and physiological orientation of the partially retained femoral neck allows the reconstruction of the individual joint geometry. A: Valgus hip deformity; B: A deeper femoral neck cut leads a reduction of the femoral offset with an accurate reconstruction of the joint geometry; C: Varus hip; D: A low femoral neck provides a reconstruction of the geometry with an increased femoral offset with an appropriate successfully reconstructed joint geometry.

ual joint geometry. Thus, the physiological orientation of the partially retained femoral neck allows a much easier and reliable reconstruction of the individual anteversion, offset and CCD angle (Figure 1)[13-15]. Using 3-dimensional CT scans in cadaver hips, Mihalko *et al*[16] investigated the value of different femoral neck resection levels for the implantation of a short stem prothesis without modular components. They showed that all geometrical parameters, including the femoral neck anteversion, the CCD angle and the center of the femoral head, were reconstructed within a mean error of 2° and/or 1 mm[16]. Moreover, Windhagen *et al*[17] have shown that a short stem partial neck-retaining implant provides a more balanced hip in terms of the surrounding soft tissue structures, whereas a straight stem alters the head position and induces much more non-physiological strains.

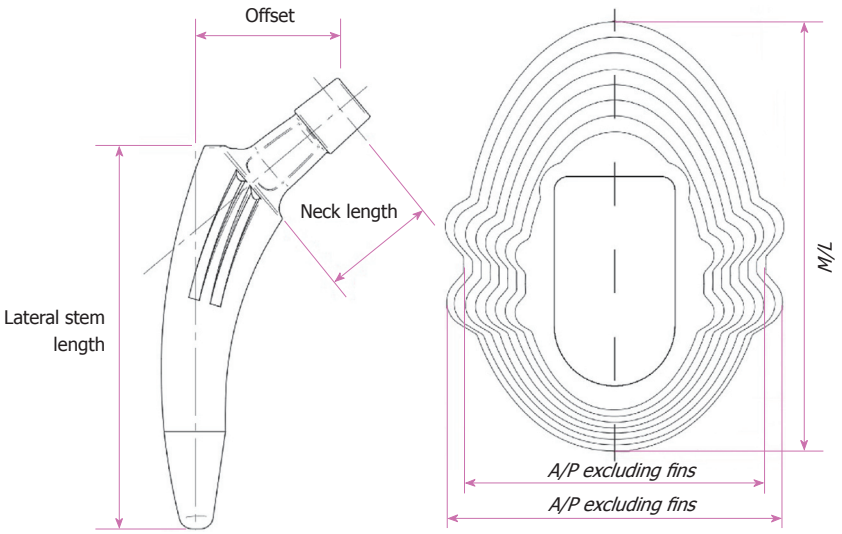
Clinical follow-up studies of the MiniHip™ showed a good short-term clinical outcome[18-20] as well as good densitometric results with a comparatively lower proximal bone density reduction[1,21]. To our knowledge, this is the longest study on this well-established femoral neck retaining metadiaphyseal prosthesis. In contrast to other studies on short stems for hip replacement, this prospective study was explicitly not only conducted in young and active patients. The purpose of the current study was to assess the clinical and radiological long-term outcome of the MiniHip™ in a relatively diverse population with a wide range of patient age.

MATERIALS AND METHODS

This prospective follow-up examination has been approved by the Ethical Committee of the Medical Association of North Rhine (Ärztekammer Nordrhein) in Düsseldorf, Germany under the No. 2011379. All patients gave their written informed consent before enrollment in the study. A total of 186 consecutive hip joint arthroplasties (right/left = 97/89) in 186 patients (m/f = 94/92) were included for the follow-up assessment. Fourteen patients received a bilateral hip arthroplasty with the MiniHip™ as a two-staged procedure. Patients' mean age at the time of surgery was 59.3 years (range 32 to 82 years). Indications for surgery included advanced osteoarthritis arthritis recalcitrant to conservative treatments. All surgeries were carried out between 2008 and 2010 at the Department of Orthopedics, Trauma Surgery and Sports Medicine of the Johanna-Etienne Hospital Neuss (*n* = 108) and at the Munich Ortho Center (*n* = 78) in Germany.

During the subsequent follow-up, 37 patients were excluded from this study. Reasons were an osteosynthesis on the same leg in one patient, one aseptic loosening of the stem on the other side (no MiniHip™), a severe, immobilizing spinal canal stenosis in one case, two severe other diseases, nine patients wanted to quit the study, one patient died and 22 were lost for unknown reasons.

Pre-operative planning of the prosthesis components was performed in all cases on scaled anteroposterior digital radiographs using the MediCAD® software. In all patients, the meta-diaphyseal anchoring short-stem system MiniHip™ (Corin Group PLC, Cirencester, United Kingdom) was implanted. The MiniHip™ was introduced by Jerosch[13] in 2008. The stem is designed to fit and fill the retained part of the femoral neck. After the femoral neck cut and the opening of the metadiaphyseal cavity, the implant side is prepared by using impactors with an increasing size. This compression of the metadiaphyseal spongious bone might improve the filling of the metaphysis. Moreover, the MiniHip™ stem is designed to provide an extended contact area with a wide load transfer at the femoral calcar region. The MiniHip™ stem is available in nine sizes, each providing a centrum collum diaphyseal angle of 130° (Figure 2). The material of the stem is an alpha-beta titanium alloy (Ti-6Al-4V) and it is coated by a layer of hydroxyapatite applied over a layer of pure titanium (Bi-coat™). The elevated roughness might contribute to the primary stability of the prosthesis, whereas the additional hydroxyapatite coating may serve as an osseoconductor between bone and prosthesis and therefore enhance the secondary



size	stem length	offset	neck length	A/P diameter excluding fins	A/P diameter including fins	M/L diameter
1	79.5	32.2	25.0	13.6	15.0	22.0
2	84.2	33.3	26.0	15.2	16.7	23.9
3	89.0	34.5	27.0	16.7	18.4	25.8
4	93.8	35.6	28.0	18.3	20.2	27.6
5	98.5	36.8	29.0	19.8	21.8	29.5
6	103.3	37.9	30.0	21.4	23.6	31.4
7	108.0	39.1	31.0	22.9	25.2	33.3
8	112.8	40.2	32.0	24.5	27.0	35.1
9	117.5	41.4	33.0	26.0	28.6	37.0

Figure 2 Dimensions (mm) of the different sizes of the MiniHip™ stem.

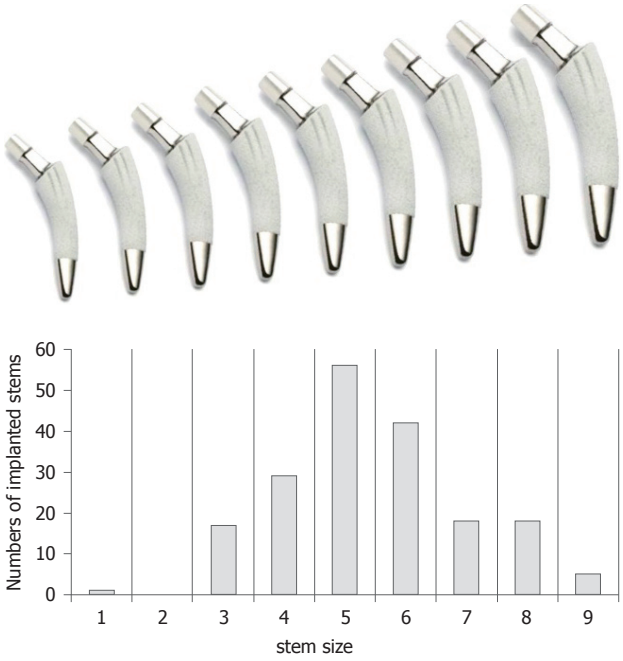


Figure 3 Frequencies of the implanted stem sizes used in this study. The distribution of sizes used in this study is similar to a Gauss curve. The increasing dimensions of the conus according to the nine different sizes of the implant are depicted. The distal bullet tip of the prosthesis is polished. This design might prevent a fixation in this area and therefore reduce the risk of thigh pain.

stem stability. The stem is intended to be used with 12/14 taper heads of different lengths. The distal tip of the prosthesis is polished and is designed to prevent a fixation in this area. This feature is expected to reduce the risk of anterior thigh pain (Figure 3). The frequencies of implanted stem sizes used in this study are depicted in Figure 3. At the Johanna-Etienne Hospital Neuss, surgery was performed in the supine position using the antero-lateral minimal invasive (ALMI) for supine position described by Jerosch[22]. This approach protects the abductor muscles to facilitate the post-operative rehabilitation. The exposure of the femur and the acetabulum as well as the positioning of the patient allows an excellent orientation which is mandatory for an optimal positioning of the prosthesis components. At the Munich Ortho Center, two approaches were used. In 60 patients, a standard direct anterior approach through the intermuscular plane was performed. Similarly to the ALMI approach, this approach has been described to preserve the hip abductor muscles[23,24]. In 18 patients, a lateral, transgluteal approach with a splitting of the gluteus medius muscle was used[25]. During the implantation of the MiniHip™, the stem follows the curvature of the medial calcar. Therefore, an individual femoral neck can be used to restore the joint geometry[15]. The height of the femoral neck cut is planned on the preoperative X-ray. In a valgus hip,

a deep resection leads to an increased CCD angle and a smaller offset, whereas a high cut near to the head neck junction is used to reconstruct the low CCD angle of a varus hip (Figure 1). Intraoperatively, the landmark for the femoral cut is the piriformis fossa, which is easy to visualize when a minimally invasive approach is used. The cut is made parallel to the head neck junction and at 90° to the femoral neck. Then, the implant side is prepared by using different impactors of increasing size. The postoperative and rehabilitative treatment was started in all patients on the first postoperative day. Patients started weight-bearing as tolerated with two crutches for six weeks. If there were no contra-indications, Ibuprofen was recommended for ten days as prophylaxis for heterotopic ossifications.

The follow-up examinations were performed preoperatively and annually by two independent examiners. The preoperative and follow-up clinical evaluations included the Oxford Hip Score (OHS)[26], and the Hip Dysfunction Osteoarthritis and Outcome Score (HOOS)[27]. Both the HOOS and the OHS are validated and reliable scores used to assess the functional and symptomatic results after total hip arthroplasty[26,27]. First descriptive statistics were used to compare our data to the literature. To assess predictors such as sex, age, friction pairings, *etc*. which might influence the outcome scoring, we used a linear mixed model analysis.

The X-ray assessments were performed preoperatively, postoperatively immediately after the initial mobilization and at the follow-up appointments. Standardized standing antero-posterior (AP) and lateral radiographs of the proximal femur were taken. To assess the bone remodeling around the prosthesis, radiographs were inspected within the Gruen zones for the presence of radiolucencies, bony hypertrophies or atrophies, reactive lines and pedestal formation according to the criteria by Engh *et al*[28]. A change of the stem position was investigated according to Morray by using the osteotomy as a bony reference[29]. A subsidence of the stem as a detectable pathology was documented for a position change of at least 2 mm. Ossifications were analyzed according to the Brooker classification[30]. All complications related to the prosthesis such as a septic or aseptic loosening, infection, subsidence, dislocation and all operative revision were documented.

Data analyses were reviewed and supported by a biomedical statistician. Analyses were performed with Excel Statistics software (Microsoft, Redmond, WA, United States) and SPSS Statistics software 22.0 (SPSS Inc., Chicago, IL, United States).

RESULTS

Functional outcome

One year after surgery, both, the HOOS and OHS improved significantly from a mean of 30 ± 8.3 to 91 ± 6.7 and from 18 ± 3.3 to 44 ± 5.8 points, $P < 0.001$, respectively. After this initial improvement after one year, the scorings at the follow-up investigations two to ten years after the implantation stayed on the same level or showed only slight increases, which were not significant, $P > 0.05$ respectively (Figure 4). A further linear mixed model analysis revealed that there were no significant differences regarding sex, age, component sizes, etiology and friction pairings ($P > 0.05$).

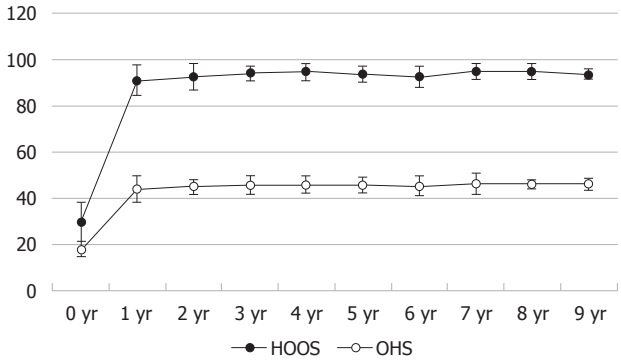


Figure 4 Outcome at the Hip Dysfunction Osteoarthritis and Outcome Score and Oxford Hip Score scoring over ten years. After the initial improvement after one year, the subsequent scorings at our follow-up investigations two to ten years after the implantation showed only slight increases, which were not significant, $P > 0.05$ respectively. HOOS: Hip Dysfunction Osteoarthritis and Outcome Score; OHS: Oxford Hip Score.

Revisions and complications

The primary outcome measure was the stem revision for loosening as the failure endpoint of the stem. In our series, we noticed two cases with an aseptic stem loosening four and twelve months after surgery with a symptomatic subsidence of 12 and 15 mm (Figure 5). In these patients, a one-stage revision to a conventional stem was conducted. Thus, the survivorship for aseptic loosening at nine to ten years is 98.66% (147 of 149). Another patient had a symptomatic exostosis with a chronical bursitis and thigh pain. Besides the removal of the exostosis a revision of the stem was performed. One patient suffered a septic stem loosening with the detection of proprioni bacteria 20 mo postoperatively. Therefore, the overall survival for the stem with revision for any reason was 97.32% (145 of 149). Another important outcome measure was the number of cup revisions for any reason as the failure endpoint for the cup. In our series, we had one patient with an aseptic cup loosening four months postoperative. Another patient had a symptomatic iliopsoas impingement at the anterior border of the cup which showed an early loosening three weeks postoperatively. These early revisions lead to an overall survival for the cup with revision for any reason of 98.66% (147 of 149). Other major complications, such as dislocations, periprosthetic fractures, a deep venous thrombosis and nerve injuries were not observed during the immediate postoperative inpatient care and the subsequent follow-

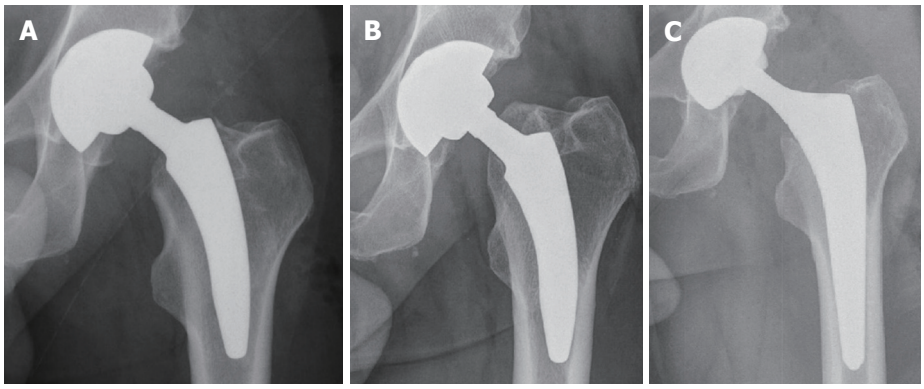


Figure 5 Exemplary X-ray of one of the two cases with a symptomatic subsidence. A: Postoperative X-ray; B: Subsidence of 15 mm twelve months after surgery; C: X-ray of the one-stage revision to a conventional stem.

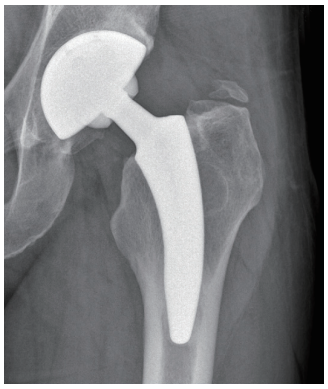


Figure 6 Exemplary X-ray of one of the nine cases with a heterotopic ossifications grade Ⅰ according to Brooker.

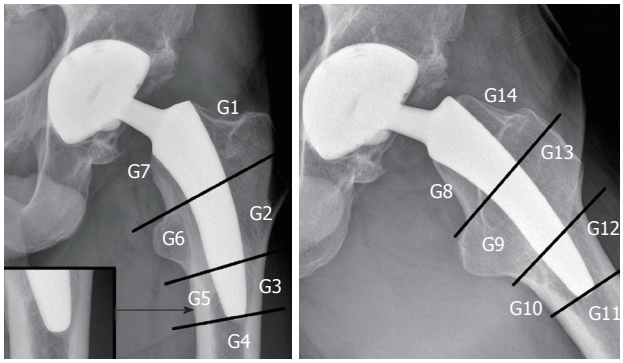


Figure 7 Periprosthetic bone resorptions or bony hypertrophies were assessed within the Gruen zones 1-14. A small ostolysis of less than 2 mm outlined by a discrete sclerotic margin was detected in a large number of patients around the tip of the stem. Being detected exclusively around the polished tip of the stem, it might be indicative for a fibrous ingrowth at the bullet polished tip of the stem. Further radiological and/or clinical signs of a loosening were not noticed in these cases.

up investigations.

Radiological results

A subsidence was investigated according to Morray[29]. Besides the patients with a symptomatic subsidence mentioned above, we documented one asymptomatic sintering of the stem at the one-year control. The subsidence measured 6 mm and remained unchanged during our subsequent follow-up investigations.

Heterotopic ossifications were assessed according to Brooker *et al*[30]. Radiologically, we saw nine cases of heterotopic ossifications, three with a Brooker grade Ⅱ and six cases with a grade Ⅰ finding (Figure 6).

In a further inverstigation, periprosthetic bone resorptions or bony hypertrophies within the Gruen zones were assessed (Figure 7). One patient showed a bony atrophy with an ostolysis of more than 2 mm in Gruen zones 1, 2, 8 and 14 (Table 1). Further patients with extended bony resoprtions of more than 2 mm were not detected. A small ostolysis of less than 2 mm outlined by a discrete sclerotic margin was detected in a large number of patients around the tip of the stem. This finding was only noticed in the distal Gruen zones 3, 4, 5, 10, 11, 12 (Table 1). Because this finding was exclusively noticed around the polished tip of the stem, it might be indicative for a fibrous ingrowth at the polished tip of the stem. Further radiological and/or clinical signs of a loosening were not noticed in these cases (Figure 7). Bony hypertrophies of less than 2 mm were detected in three cases in Gruen zone 3 und in one case in Gruen zone 5 (Table 1). Further cortical hypertrophies, neocortex formations or a spot welding with new bone formations between the endostal surface and the stem were not noticed in our series.

DISCUSSION

The bi-coating and an optimized initial press fit within an extended contact area at the proximal femur is expected to provide a solid primary and secondary fixation of the MiniHip™[13-15,18,31]. This might provide a good long-term survival. Searching for data on the survival in short stems, short- and mid-term but only a few long-term results are published[18,32-35]. In a review article by van Oldenrijk *et al*[35], the majority of the studies had a follow-up of less than 5 years. Out of 49 studies on 19 short stems, midterm result were only reported for the Mayo (Zimmer Inc., Warsaw,

Table 1 Periprosthetic bone density changes within the Gruen zones (G1-14) detected in standardized a.p. and axial X-rays

a.p.	Axial
G1: 1 × bony atrophy > 2 mm	G8: 1 × bony atrophy > 2 mm
G2: 1 × bony atrophy > 2 mm	G9: No abnormality
G3: 3 × bony hypertrophy < 2 mm 16 × RL[1]	G10: 36 × RL[1]
G4: 47 × RL	G11: 21 × RL[1]
G5: 1 × bony hypertrophy < 2 mm 54 × RL[1]	G12: 31 × RL[1]
G6: No abnormality	G13: No abnormality
G7: No abnormality	G14: 1 × bony atrophy > 2 mm

[1]Small radiolucency < 2 mm with discrete sclerotic margin.

United States), Metha (B.Braun Aesculap, Tuttlingen, Germany) and CFP stem (Collum Femoris Preserving, Waldemar Link GmbH, Hamburg, Germany). In contrast to this relatively poor data pool, an increasingly large number of different short stem designs are currently available. Thus, we have to notice a strong need for follow-up studies. For the Minihip™ stem, an overall survival of 98.16%, 97.26% and 99.3% was reported after 60, 18 and 37 mo, respectively[18-20]. These short- and mid-term results are encouraging. The present study is the first one in the Minihip™ after a follow-up of nine to ten years. Two of 186 stems subsided within the first year and required revision (Figure 5). Both patients reported a severe thigh pain. A third case of a subsidence of 6 mm at the first-year follow up was asymptomatic. During the following radiological controls, the stem remained stable without any further subsidence and/or loosening. Further cases with a subsidence of more than 2 mm were not noticed. Thus, the rate of aseptic stem loosening as an important outcome measure showed an overall survivorship of 98.66%. This rate is similar to a recent seven year follow-up study in the monoblock design of the Metha stem, where the revision rate was 1%. Zero point five percent were revised for aseptic loosening and 0.4% because of a femoral fracture during the postoperative follow-up. It is important to mention that the revision rate for the modular design of this stem was 9.4% for the titanium and 4.6% for the cobalt chrome neck[34]. Thus, the adapter fractures of the modular Metha stem lead to much higher stem revision rates, whereas the revision rates for the monoblock were similar compared to conventional stems. This supports our preference for a short monoblock prosthesis which we combine with our "top down" concept for an exact joint geometry reconstruction[13]. In the present study, one late infection and one exostosis with thigh pain lead to two further stem revisions. Therefore, the overall survivorship, including all revisions for any reasons was 97.32%. Regarding these long-term results, the implant performed exceedingly well. This is in accordance with the clinical outcome showing a lasting improvement at the OHS and HOOS scorings (Figure 4). Corresponding to these clinical data, the assessment of bone resorptions within the Gruen zones demonstrate good long-term results. Nonetheless, regarding the distal Gruen zones (Table 1) the large number of small (< 2 mm) radiolucencies outlined by a discrete sclerotic margin has to be mentioned (Figure 7). These findings were always noticed around the polished bullet tip of the stem and are indicative for a fibrous interface membrane without any bony ingrowth. This special radiological finding has frequently been documented in uncemented polished taper designs and never been described to be indicative for a loosening or as any other detrimental condition[36,37]. On the contrary, this finding has to be recognized differently. According to the design rationale of the Minihip™, the polished bullet tip is expected to minimize endosteal abutment. This way, pressure peaks and/or a bony ingrowth at the tip of the stem are expected to be avoided. Moreover, this might decrease the stiffness of the implant and prevent the occurrence of thigh pain at the tip of the stem[38]. Another aspect is the more proximal and therefore more physiological load transfer to the metaphysis of the femur. This proximal load transfer, which is an important goal of the design of the Minihip™, should not be affected by the tip of the prosthesis. Therefore, the absence of a bony ingrowth around the polished bullet tip is a desirable finding for the Minihip™ stem. Our investigations on bone density changes within the proximal Gruen zones (Table 1) might support our thesis that this principle of a proximal load might actually work. Besides one single patient, where we documented an asymptomatic bone atrophy of more than 2 mm in Gruen zones 1, 2, 8 and 14, further resorptions were not detected within these proximal areas. In regard to these findings, a distal load transfer leading to a stress shielding and bone resorptions within the proximal zones appears quite unlikely. Moreover, bony hypertrophies within the distal Gruen zones, which might be indicative for an unphysiological distal load transfer, were only detected in one patient. For the CLS Spotorno stem (Zimmer, US), in contrast, bony hypertrophies and/or appositions within the distal zones with or without a bone loss within the proximal areas have been described after a 2-4 years in 53% of the cases[39]. For the Hipstar (Stryker, Duisburg, Germany) and the Zweymueller stem (SL-Plus®-Plus Orthopedics AG, Rotkreuz, Switzerland) similar findings were detected already after one year in 60% and 87% of the cases[40]. These findings are indicative for an unphysiological distal load with correspondingly high rates of a proximal stress-shielding. As a logical consequence, the authors discussed, if a progression of these proximal bone resorptions may influence the clinical results and the survival of the implant[40]. Our radiological long-term results showing a more physiological proximal load transfer and a reduced stress-

shielding, have been confirmed by several densitometric studies comparing the bone remodeling between different short and conventional straight stems[41,42]. For the Minihip™ but also for other stems, an initial bone resorption in all periprosthetic zones is a typical finding immediately after the implantation[1,21]. However, in studies on the Minihip™, the initial bone resorption within the first months had a much lesser extend compared to different conventional stems[13,41-43]. More important is that a relatively strong subsequent bone remodelling within the proximal Gruen zones was documented during the following years. Thus, compared to conventional straight stems, a much lower proximal bone density loss was noticed[1,21]. Because of this process of bone formation, which continued till the second year, the bone-friendly design of the Minihip™ as a representative of a partially neck-sustaining stem has been discussed[21]. Similar results were demonstrated on other partially neck-retaining prostheses, demonstrating a significant bone remodeling leading to a markedly lower bone density reduction in the proximal Gruen zones[44,45]. Taken together, all these radiographic and osteodensitometric data support the thesis of a more physiological proximal load. Regarding these convincing data, it is not surprising that a lower frequency of thigh pain was reported in short stems compared to straight, conventional stem types[46].

Short stems have become increasingly utilized in younger patients[38]. This may reflect the surgeon's desire to conserve bone stock in these patients. Because of the lack of long-term studies, this may also reflect some concerns regarding the achievement of a lasting stable fixation in elderly patients. In regard to studies reporting an increased intraoperative fracture risk with advanced age[47], worries about such complications might further influence the indication of a short stem in elderly patients. Therefore, the wide range of patients' ages between 32 and 82 years is an interesting feature of this study. The analysis of the outome scorings revealed no significant differences regarding the patients' age. Intraoperative fractures were not noticed and a loosening of the stem with a subsidence was a rare and early occurring complication in two patients of a mean age. Thus, in comparison to conventional stems as a current benchmark level[48], the Minihip™ short stem might also be a reliable alternative in elderly patients.

In conclusion, this long-term study revealed an excellent and long-lasting clinical outcome, low complication rates, a reliable metaphyseal anchoring with a more physiological proximal load transfer and an excellent long-term stem survivorship. Therefore, the MiniHip™ might be a convincing concept for a partial-neck retaining prosthesis in a wide range of patients.

ARTICLE HIGHLIGHTS

Research background

In contrast to a poor scientific data pool, an increasingly large number of different short stem designs are currently available. Thus, we have to notice a strong need for follow-up studies especially on long-term results of these stems. Regarding the Minihip™ stem, previous short-term results are encouraging, whereas long-term studies are lacking. Thus, the present study is the first one after a follow-up period of nine to ten years. In contrast to studies on short-stemmed hip replacements, which are mainly conducted in relatively young and active patients, this study included a wide range of patients including elderly persons.

Research motivation

The MiniHip™ monoblock stem is designed to fit and fill the retained part of the femoral neck and the metaphysis. Using an individual femoral neck cut, the implant is normally used as a partial neck retaining prosthesis. This leads to a "top down concept" which provides a completely different possibility to restore the joint geometry. Using this concept, the physiological orientation of the partially retained femoral neck allows an easy and reliable reconstruction of the individual anteversion, CCD angle and offset. Moreover, this might lead to a more physiological loading of the proximal femur. The key question is, if these design features are useful to reduce the stress shielding around the stem with its' complications such as thigh pain, bone loss and aseptic loosening. Thus, this concept might possibly solve or reduce some typical problems of conventional hip arthroplasty. Our optimistic expectation is that this might also secure a good long-term outcome of such prostheses.

Research objectives

The design of the MiniHip™ prosthesis seems to provide some reasonable advantages. The main objective was to assess the long-term clinical and radiological outcome and the complication rates of this prosthesis in a relatively diverse study cohort with a wide range of patients' age. This might support the understanding in recent developments of partial-neck retaining, short-stemmed hip prostheses, which provide a metaphyseal anchoring as well as a more physiological proximal load transfer to the femur.

Research methods

This study on the MiniHip™ is the first one after such a long mean follow-up period of nine to ten years. 186 patients, with a comparatively wide age range between 32 and 82 years, were included. Hip arthroplasty with the MiniHip™ prosthesis was performed at two Centers. The clinical follow-up, which included the Oxford Hip Score (OHS) and the Hip Dysfunction Osteoarthritis and Outcome Score (HOOS), was accompanied by standardized p.a. and axial radiological examinations. The radiological evaluation included the assessment of periprosthetic lucencies, hypertrophies within the Gruen zones, the assessment of a possible stem subsidence and the detection of heterotopic ossifications.

Research results

The OHS and HOOS score improved significantly from 18 to 46 and from 30 to 95 points. Stem related complications included two cases with a symptomatic subsidence after four and twelve months. The survivorship for aseptic loosening remained unchanged after the subsequent follow-up of nine to ten years. Thus, the final survivorship was 98.66%. Including one stem revision due to a symptomatic exostosis, bursitis and thigh pain as well as one revision because of a septic stem loosening, the overall survival for the stem with revision for any reason was 97.32%. Besides one asymptomatic patient, signs of a proximal stress shielding, such as corresponding bone resorptions within the proximal Gruen zones, were not noticed. Bony hypertrophies and/or bone appositions which might be indicative for a distal loading, were also not noticed.

Research conclusions

This study is the first one on the MiniHip™ prosthesis evaluating the long-term outcome in patients with a wide range of ages. This study revealed a convincing and lasting clinical outcome. The radiological findings suggest a physiological proximal load transfer with a reliable metaphyseal anchoring and an excellent long-term stem survivorship, which is at least comparable to standard prostheses and other short stem concepts. The MiniHip™ is designed to fit and fill the retained part of the femoral neck. During surgery, the implant side is prepared and compressed by using impactors with an increasing size. Moreover, the MiniHip™ stem is designed to provide an extended contact

area and an optimized filling with a wide load transfer at the femoral calcar region. This new concept is expected to provide a solid fixation. Moreover, a porous coating of a hip stem leads to an elevated roughness and an additional hydroxyapatite coating may serve as an osteoconductor between bone and prosthesis. All these features of this partial neck-retaining prosthesis might enhance the primary as well as secondary stem stability, provide an optimized proximal loading and finally provide a good long-term survival of this prosthesis. We hope that this concept might solve or reduce some typical problems of conventional hip arthroplasty stems. Short-stemmed, partial neck retaining hip arthroplasty seems to realize a more physiological proximal load transfer with a reliable metaphyseal anchoring and an excellent long-term stem survivorship. Partial neck retaining hip arthroplasty using the MiniHip™ stem might be a convincing concept for a wide range of patients. The study presented here was a necessary step in exploring this prosthesis, which seems to provide reasonable advantages. Short-stemmed, partial neck retaining hip arthroplasty by using an individual femoral neck cut provides a physiological proximal load transfer and an excellent long-term stem survivorship, which is at least comparable to other prosthesis concepts. This might be a contributory factor to the convincing and lasting clinical outcome demonstrated in this study. This study includes a population with a wide range of ages. The follow-up comprises a long-term period of nine to ten years. The radiological assessment included typical changes of the periprosthetic bone within the Gruen zones as well as the detection of a possible stem subsidence. In contrast to other studies on short stems for hip replacement, this study was explicitly not only conducted in young and active patients. Therefore, this clinical and radiological long-term follow-up study might be of particular interest and might provide a better understanding of such partial neck retaining prostheses. This long-term study on theMiniHip™ revealed an overall survivorship for an aseptic stem loosening of 98.66%. The promising clinical and radiological outcome was proved to be lasting in a wide range of patients. The radiological findings within the Gruen zones suggest a more physiological proximal load transfer and a reliable proximal metaphyseal anchoring. This might explain the excellent long-term stem survivorship of the MiniHip™ prosthesis. In our future clinical practice, we will follow this concept of a proximal, metaphyseal anchored partial-neck retaining prosthesis. Especially the concept of the MiniHip™, which allows an individual femoral neck cut and which recommends a compression of the implant side by using different impactors, might provide some reasonable advantages to achieve such reliable and long-lasting results. Moreover, this concept might be interesting in a wide range of patients including those with an advanced age.

Research perspectives

In consideration of conventional stems as a current benchmark for survival rates and for typical complications occurring intraoperatively, but also in the long-term follow-up, a proximal-metaphyseal anchored partial-neck retaining prosthesis might be a reliable alternative in younger as well as elderly patients. Further clinical outcome studies in larger study populations might be useful to find out limitations regarding the indication for this short-stemmed, partial neck retaining hip prosthesis. Perhaps the indication for such short-stemmed prostheses will be reconsidered in the future. Regarding our initial long-term results, signs for an upcoming implant failure based on a material failure or a mechanical mismatch of implant and bone structure are not imminent. Ongoing assessments with longer follow-up periods will evaluate the durability of these first nine to ten year results. Follow-up studies with larger cohorts and longer follow-up periods will be a useful method for the future research.

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ORIGINAL ARTICLE

Observational Study

Does ethnicity and education influence preoperative disability and expectations in patients undergoing total knee arthroplasty?

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Abstract

AIM

To investigate whether minority ethnicity and the duration of education influence preoperative disability and expectations in patients undergoing total knee arthroplasty.

METHODS

We prospectively included 829 patients undergoing primary unilateral total knee arthroplasty (TKA) from April 2013 to December 2014 at a single centre. Patients filled in pre-operative questionnaires with information regarding place of birth, duration of education, expectations for outcome of surgery and baseline characteristics. Patients were stratified based on ethnicity. Majority ethnicity was defined as born in

the study country and minority ethnicity was defined as born in any other country. Similarly, patients were stratified based on duration of education in groups defined as < 9 years, 9-12 years and > 12 years, respectively.

RESULTS

We found that 92.2% of patients were of majority ethnicity. We found that 24.5%, 44.8% and 30.8% of patients had an education of < 9 years, 9-12 years and > 12 years, respectively. The mean preoperative (pre-OP) oxford knee score (OKS) in the total population was 23.6. Patients of minority ethnicity had lower mean pre-OP OKS (18.6 *vs* 23.9, $P < 0.001$), higher pain levels (VAS 73.0 *vs* 58.7, $P < 0.001$), expected higher levels of post-OP pain (VAS 14.1 *vs* 6.1, $P = 0.02$) and of overall symptoms (VAS 16.6 *vs* 6.4, $P = 0.006$). Patients with > 12 years education had lower mean pre-OP OKS (21.5 *vs* 23.8 and 24.6, $P < 0.001$) and higher pre-OP VAS pain (65.4 *vs* 59.2 and 56.4, $P < 0.001$) compared to groups with shorter education. One year post-operative (post-OP) patients of minority ethnicity had lower mean OKS, higher pain and lower QoL. One year post-OP patients with > 12 years education reported higher pain compared to patients with shorter educations. However, the response-rate was low (44.6%), and therefore post-OP results were not considered to be significant.

CONCLUSION

Minority ethnicity and the duration of education influence preoperative disability and expectation in patients undergoing TKA. This should be taken into account when patients are advised pre-operatively.

Key words: Socioeconomic factors; Ethnicity; Education; Expectations to surgery; Preoperative disability; Total knee arthroplasty

Core tip: We investigated whether minority ethnicity and duration of education influence preoperative disability and expectations in patients undergoing total knee arthroplasty. We prospectively included 829 patients scheduled to undergo primary total knee arthroplasty in a single centre. We found that patients of minority ethnicity suffer from more severe preoperative symptoms and expect a poorer post-operative outcome compared to patients of majority ethnicity. We also found that patients with > 12 years education have more severe preoperative symptoms compared to patients with shorter educations. This information can assist surgeons in appropriate treatment plans and preoperative consultation for all patients.

Kudibal MT, Kallemose T, Troelsen A, Husted H, Gromov K. Does ethnicity and education influence preoperative disability and expectations in patients undergoing total knee arthroplasty? *World J Orthop* 2018; 9(10): 220-228 Available from: URL: http://www.wjgnet.com/2218-5836/full/v9/i10/220.htm DOI: http://dx.doi.org/10.5312/wjo.v9.i10.220

INTRODUCTION

Thousands of patients undergo total knee arthroplasty (TKA) every year worldwide. In recent years, pre-operative (pre-OP) planning and patient information has been streamlined by using the fast-track concept[1]. This operation has excellent results in terms of survival, with a reported ten-year prosthetic survival of close to 95% (National Hospital Discharge Survey 2010); however, patient satisfaction remains a challenge, with up to 20% of patients being dissatisfied with their one-year post-operative (post-OP) outcomes[2,3].

Outcome is known to be influenced by patient-related factors that include age, pre-OP symptoms[4-6], comorbidities and mental health status, such as depression and anxiety[7]. Previous studies have shown that patient satisfaction can be influenced by both surgery-related factors, such as implant alignment[8-10], implant brand and hospital type[8], as well as patient-related factors including age, pre-OP symptoms and expectations[2]. Other less well-defined factors have also been shown to influence outcome following TKA and THA, such as socioeconomic factors[11,12] and duration of education[13]. Understanding the way that ethnicity and the duration of education influence both pre-OP symptoms and post-OP outcome in TKA patients will assist healthcare providers in determining specific areas of possible improvement and adjusting treatment options appropriately. Furthermore, it will assist in more accurate comparisons of study populations in future research.

The purpose of the study was to investigate whether minority ethnicity and duration of education influence pre-OP disability and expectations in patients undergoing TKA.

MATERIALS AND METHODS

We conducted a prospective cohort study that included all patients undergoing primary TKA at our institution from April 1st 2013 to December 8th 2014. Exclusion criteria were simultaneous bilateral TKA and missing data on education/country of origin. Prior to surgery, patients were asked to fill in a questionnaire regarding patient demographics, pre-OP symptoms and expectations about surgery outcome. All patients were asked to fill in another questionnaire one year post-OP *via* email or regular mail, and 370 patients completed a one-year follow-up questionnaire (Figure 1). A clinical control was not conducted. Patients filled in the questionnaire independently or with help from

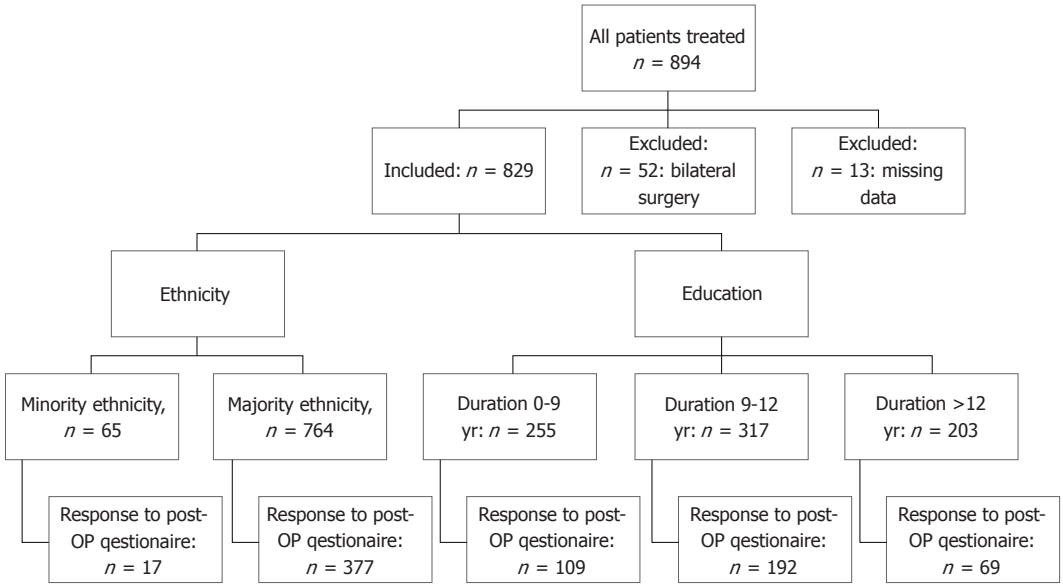

Figure 1 Flowchart of patient distribution.

family members. All surgeries were performed in a standardized fast-track setup[1] by experienced surgeons specializing in arthroplasty surgery, each having performed > 100 primary TKAs annually. The standard surgical protocol for TKA includes spinal analgesia, standardized fluid management, use of preoperative intravenous tranexamic acid, preoperative single-shot high-dose methylprednisolone[14] and absence of drains. All TKAs were performed with a standard medial parapatellar approach without the use of tourniquet, with an application of local infiltration analgesia (LIA)[15] and postoperative compression bandaging[16]. Postoperative opioid-sparing pain treatment consisted of celecoxib 200 mg/12 h and paracetamol 1 g/6 h with rescue analgesics [administered if visual analogue scale (VAS) > 50 mm at rest] consisting of 10 mg oral morphine as needed. Physiotherapy was started on the day of surgery and continued until discharge. Rivaroxaban (Bayer, Denmark) was used as oral thromboprophylaxis starting 6 to 8 h postoperatively and continued daily until discharge[17]. Mechanical thromboprophylaxis and extended oral thromboprophylaxis were not used. Patients were discharged to their own home upon fulfilling functional discharge criteria[18].

Preoperative disability was measured by Oxford knee score (OKS), self-reported quality of life (QoL)[19], knee pain during activity measured on VAS, and overall symptoms and expectations. OKS ranges from 0 to 48, with lower numbers indicating more severe symptomatic disease. All VAS scales in this study range from 0 to 100. For pain and symptoms, higher values represent the worst conditions, while high values on the scale for QoL represent the best conditions. Patients were stratified based on duration of education and place of birth. Ethnicity was divided into two groups, majority and minority ethnicity. Majority ethnicity was defined as patients born in Denmark (the study country), and minority ethnicity was defined as all patients born outside Denmark. As the level of education varies between countries, education was stratified based on duration (< 9 years, 9-12 years and > 12 years of education). Preoperatively, we registered baseline-characteristics including alcohol consumption, smoking, BMI and comorbidity. Comorbidity was registered as heart disease, lung disease, previous stroke, kidney disease, liver disease, diabetes and autoimmune disease. We also registered symptoms (OKS, use of walking aids, walking distance, pain on VAS score during rest and activity) self-reported QoL, and expectations for post-OP symptoms and QoL. Finally, we registered self-reported post-OP symptoms and self-reported QoL using the one-year post-op questionnaire.

As all our results are based on patient reported outcome measures, we take into account the minimal clinically important difference (MCID). For OKS, this is acknowledged to be four-five[20,21]. For VAS scales in knee arthritis patients, MCID has been reported to be around 20 points[22].

Statistical analysis

All data were processed in R 3.2.2. All measurements were reported as mean with standard deviation (SD) for continues variables and number with percent for categorical variables. Tests for association of minority ethnicity with continues interest variables was done by *t*-test or for non-normal distributed variables by Wilcoxon sum rank test. Association with categorical interest variables was done by chi-squared or, in cases with expected values below 5, Fishers exact test. Associations between education duration groups and the interest variables were done for continues variables by uni-

Table 1 Characteristics of the total patient population *n* (%)

	All patients
Baseline characteristics	
BMI (mean ± SD)	29.7 ± 5
Age (mean ± SD)	66.8 ± 10
Gender	
Male	308 (36.6)
Female	534 (63.4)
Smoking	
Non-smoker	492 (58.6)
Former smoker	213 (25.4)
Active smoker	134 (16)
Duration of education	
More than 12 yr	255 (30.8)
9-12 yr	371 (44.8)
0-9 yr	203 (24.5)
Ethnicity	
Born in Denmark	764 (92.2)
Born outside Denmark	65 (7.8)
Preoperative level of function and symptoms	
Walking aid outside the home:	
None	597 (71.2)
One cane	133 (15.9)
Two canes	34 (4.1)
Wheeled walker	69 (8.2)
Do not leave the home	6 (0.7)
Oxford knee score (mean ± SD)	23.6 ± 8
Knee pain during activity[1], median (range)	63 (0:100)
Quality of life[1], median (range)	47 (0:100)
Level of symptoms[1], median (range)	50 (0:100)
Preoperative expectations	
Knee pain 1 yr after surgery[1], median (range)	2 (0:100)
Quality of life 1 yr post-OP[1], median (range)	94 (0:100)
Level of symptoms. 1 yr post-OP[1], median (range)	3 (0:99)

[1]Visual analogue scale 0-100. BMI: Body mass index.

variable linear regression with TYPE Ⅲ test or Kruskal-Wallis sum rank test for non-normal distributed variables, and for categorical variables chi-square and Fishers exact test. Additionally, to adjust for multiple testing, a Bonferroni correction was done for all *P*-values, and the correction scale was given by the number of tests performed within each outcome group. The adjusted *P*-value was calculated by multiplying the original *P*-values by the given scale. $P < 0.05$ was considered significant.

RESULTS

We included 894 consecutive and unselected patients undergoing TKA at our institution. The following were excluded: simultaneous bilateral TKA ($n = 52$) and missing data on education/country of origin ($n = 13$), thus leaving 829 patients for analysis.

For the total population, mean ± SD at time of surgery was 66.8 (10) years, 63.4% were female and 764 (92.2%) of patients were of majority ethnicity. Specifically, 24.5% of patients had an education of < 9 years, 44.8% of 9-12 years and 30.8% > 12 years (Table 1). Mean pre-OP OKS (SD) was 23.6 (8). Patients of minority ethnicity were younger compared to patients of majority ethnicity ($P = 0.045$) and had a shorter education (72.3% had an education of 0-9 years while only 20.4% of patients with majority ethnicity had an education of this length ($P < 0.001$) (Table 2). Patients of minority ethnicity had a lower pre-OP OKS ($P < 0.005$), higher knee pain during activity ($P < 0.001$), and a significantly larger proportion were dependent on a walking aid ($P = 0.026$) (Table 2). Furthermore, this patient group had a significantly lower expectation to their post-OP pain during activity ($P = 0.016$) and overall symptoms ($P = 0.016$). Patients with an education of > 12 years were older at the time of surgery, with a mean age of 67.7 years compared to 64.8 years for patients with an education of 0-9 years ($P < 0.001$). Patients with an education > 12 years reported a lower pre-OP OKS compared to the groups with 9-12 years and < 9 years of education ($P < 0.001$). Concurrent to this, patients with an education > 12 years had a higher pre-OP VAS for knee pain during activity compared to the other groups ($P = 0.002$, expectation measures also differed between the education groups (all $P \leqslant 0.008$)). Women composed a higher proportion of the highly educated group, with 73.4% compared to 57.1% and 63.0% in the middle and low education groups, respectively ($P = 0.003$) (Table 3).

Response-rates to the post-OP questionnaire were 44.6% ($n = 370$). We found a higher response-rate for patients of majority ethnicity (46.2% *vs* 26.2% for minority ethnicity patients). We also found that responders overall had a longer duration of education, the biggest difference seen in education of 0-9 years (29.2% for non-responders *vs* 18.6% for responders, $P < 0.001$). The differences between responders and non-responders for other parameters was not statistically significant.

Patients of minority ethnicity had significantly lower mean OKS one year post-OP compared with patients of majority ethnicity ($P = 0.002$). Patients of minority ethnicity also reported higher pain during activity ($P = 0.001$), a significantly lower QoL ($P = 0.001$) and significantly higher overall symptom score ($P = 0.001$) compared with patients of majority ethnicity. Although patients of minority ethnicity had higher post-OP pain, we also found a larger difference between pre-OP and post-OP pain compared to patients of majority ethnicity ($P = 0.049$) (Table 2). Patients with educations > 12 years had significantly higher knee pain post-OP ($P = 0.006$), however there was also a larger difference between pre-OP and post-OP pain during activity ($P = 0.069$) and QoL ($P = 0.017$) (Table 3).

DISCUSSION

In this prospective study, we found that patients of minority ethnicity report more severe pre-OP symptoms (lower OKS and higher overall pain level) and have lower expectations for post-OP outcome compared to patients of majority ethnicity. Patients of minority

Table 2 Significance of ethnicity *n* (%)

	Majority ethnicity	Minority ethnicity	*P* value (adjusted)
Baseline characteristics			
BMI (mean ± SD)	29.7 ± 5	29.9 ± 4	0.702 (3.508)
Age (mean ± SD)	67.0 ± 10	64.0 ± 9	0.009 (0.045)
Gender			
Male	294 (37.36)	11 (15.22)	< 0.001 (0.004)
Female	470 (62.64)	54 (84.78)	
Smoking			
Non-smoker	430 (56.3)	55 (84.6)	
Former smoker	207 (27.1)	4 (6.5)	< 0.001 (< 0.001)
Active smoker	127 (16.6)	6 (9.2)	
Duration of education			
More than 12 yr	248 (32.5)	7 (10.8)	
9-12 yr	369 (47.1)	11 (16.9)	< 0.001 (< 0.001)
0-9 yr	156 (20.4)	47 (72.3)	
Preoperative level of function and symptoms			
Walking aid outside the home:			
None	556 (72.8)	34 (52.3)	
One cane	111 (14.9)	20 (30.8)	
Two canes	30 (3.9)	3 (4.6)	0.005 (0.026)
Wheeled walker	61 (8)	8 (12.3)	
Do not leave the home	6 (0.8)	0 (0)	
Oxford knee score (mean ± SD)	23.9 ± 7	18.6 ± 8	< 0.001 (< 0.001)
Knee pain during activity[1], median (range)	61.0 (0:100)	76 (13:100)	< 0.001 (< 0.001)
Quality of life before surgery[1], median (range)	47.0 (0:100)	38 (0:100)	0.388 (1.938)
Level of symptoms before surgery[1], median (range)	50.0 (0:100)	61 (0:100)	0.276 (1.380)
Preoperative expectations			
Expectations to knee pain caused by use of hip 1 yr after surgery[1], median (range)	2.0 (0:100)	4 (0:99)	0.005 (0.016)
Expectations to quality of life 1 yr after surgery[1], median (range)	94.0 (0:100)	92 (0:100)	0.296 (0.888)
Expectations to level of symptoms 1 yr after surgery[1], median (range)	3.0 (0:99)	6 (0:99)	0.005 (0.016)
Postoperative level of function and symptoms:			
Oxford knee score, median (range)	39.0 (3.0:48.0)	24.0 (10.0:47.0)	< 0.001 (0.002)
Knee pain during act[1], median (range)	18.0 (0.0:100.0)	62.0 (5.0:90.0)	< 0.001 (< 0.001)
Quality of life[1], median (range)	71.5 (0.0:100.0)	40.0 (0.0:95.0)	< 0.001 (0.001)
Level of symptoms[1], median (range)	21.0 (0.0:100.0)	62.0 (10.0:90.0)	< 0.001 (0.001)
Difference in outcome parameters:			
Difference in Pain[1], median (range)	13.0 (90.0:100.0)	47.0 (37.0:90.0)	0.008 (0.0499)
Difference in Quality of life after surgery[1], median (range)	15.0 (100.0:98.0)	44.0 (99.0:38.0)	0.013 (0.078)
Difference in level of symptoms[1], median (range)	17 (56.0:100.0)	46.0 (36.0:88.0)	0.299 (1.796)

[1]Visual analogue scale 0-100. BMI: Body mass index.

ethnicity also report more severe symptoms post-OP, however our response rate was too low to regard the results as significant. Patients with an education > 12 years report more severe pre-OP symptoms (OKS and overall pain level) compared to patients with both < 9 years and 9-12 years of education. Post-OP, we found that patients with an education > 12 years reported higher overall pain.

It is generally acknowledged that patient's overall health is associated with socioeconomic factors[23]. Recently, Lavernia *et al*[11] showed that expectations and the knowledge of prosthetic surgery in patients with knee and hip arthritis depend on ethnicity. The same observation was made by Krupic *et al*[12], who showed that patients born outside of Sweden had a poorer outcome after total hip replacement than patients born within Sweden. This is concurrent with our results, as we find that patients born outside the country have greater preoperative disability (lower OKS and higher VAS for pain). However, the studies describing the correlations between ethnicity and surgery are few and based on short-term observation.

In general, minority groups in western countries are less likely to undergo knee replacement than their locally-born counterparts[24-26]. Our data show that patients of minority ethnicity have lower expectations for surgery and suffer from more severe symptoms pre-OP than patients of majority ethnicity. The reason for this difference is unknown, but we could speculate that patients of minority ethnicity might seek doctors at a more progressed stage of the disease compared to patients of majority ethnicity due to cultural or language barriers. Shahid *et al*[25] reports that racial disparities in African Americans compared to Caucasian Americans are caused by patient preferences, patients education/knowledge of osteoarthritis (OA) and expectations for post-OP outcome. Minority Americans were found to have lower expectations of the overall effect of OA surgery and higher expectations of post-OP pain[24,27-29]. This supports our findings that patients of minority ethnicity

Table 3 Significance of duration of education *n* (%)

	Education 0-9 yr	Education 9-12 yr	Education > 12 yr	*P* value (adjusted)
Baseline characteristics				
BMI, mean ± SD	28.7± 5	30.0 ± 6	30.5 ± 5	< 0.001 (0.007)
Age, mean ± SD	64.8 ± 10	67.8 ± 10	67.7 ± 11	< 0.001 (0.005)
Gender				
Male	92 (36.1)	159 (42.9)	54 (26.6)	< 0.001 (0.003)
Female	163 (63.9)	212 (57.1)	149 (73.4)	
Ethnicity				
Majority ethnicity	248 (97.3)	360 (97)	156 (76.8)	< 0.001 (< 0.001)
Minority ethnicity	7 (2.7)	11 (3)	47 (23.2)	
Smoking:				
Non-smoker	155 (60.8)	207 (55.8)	123 (60.6)	
Former smoker	74 (29)	100 (27)	37 (18.2)	0.003 (0.017)
Active smoker	26 (10.2)	64 (17.3)	43 (21.2)	
Preoperative level of function and symptoms				
Walking aid outside the home	198 (77.6)	273 (73.6)	119 (58.6)	
None	35 (13.7)	55 (14.8)	41 (20.2)	
One cane	11 (4.3)	12 (3.2)	10 (4.9)	0.005 (0.002)
Two canes	10 (3.9)	27 (7.3)	32 (15.8)	
Wheeled walker housebound	1 (0.4)	4 (1.1)	1 (0.5)	
Oxford knee score, mean ± SD	24.6 ± 8	23.8 ± 7	21.5 ± 8	< 0.001 (< 0.001)
Knee pain during activity[1], median (range)	59 (0:99)	63 (0:100)	67 (6:100)	< 0.001 (0.002)
Quality of life before surgery[1], median (range)	45 (0:100)	47 (0:100)	50 (0:100)	0.634 (3.170)
Level of symptoms before surgery[1], median (range)	51 (0:100)	50 (0:100)	50 (0:100)	0.634 (3.171)
Preoperative expectations				
Expectations to knee pain caused by use of hip 1 yr after surgery[1], median (range)	4 (0:95)	2 (0:96)	2 (0:100)	0.003 (0.008)
Expectations to quality of life 1 yr after surgery[1], median (range)	90 (0:100)	94 (0:100)	96 (0:100)	< 0.001 (0.002)
Expectations to level of symptoms 1 yr after surgery[1], median (range)	4 (0:82)	2 (0:99)	2 (0:99)	< 0.001 (0.001)
Postoperative level of function and symptoms:				
Oxford knee score, median (range)	40 (8.0:47.0)	37 (3.0:48.0)	37.5 (7.0:48.0)	0.240 (0.960)
Knee pain during activity, Post-OP[1], median (range)	12 (0.0:90.0)	20 (0.0:100.0)	26 (0.0:97.0)	0.002 (0.006)
Quality of life after surgery[1], median (range)	77.5 (13.0:98.0)	70 (0.0:100.0)	69 (0.0:100.0)	0.055 (0.219)
Level of symptoms after surgery[1], median (range)	21 (0.0:94.0)	23 (0.0:100.0)	31 (0.0:95.0)	0.182 (0.728)
Difference in outcome parameters:				
Difference in Pain[1], median (range)	8 (-11.0:84.0)	15 (-90.0:100.0)	21 (-48.0:97.0)	0.012 (0.069)
Difference in Quality of life Post-OP[1], median (range)	-7 (-67.0:95.0)	-20 (-100.0:98.0)	-18 (-99.0:98.0)	0.003 (0.017)
Difference in level of symptoms[1], median (range)	15 (-14.0:89.0)	17 (-56.0:100.0)	18 (-41.0:95.0)	0.532 (3.193)

[1]Visual analogue scale 0-100. BMI: Body mass index.

have lower pre-OP expectations. African Americans have been found to be less knowledgeable regarding OA, to have a lesser understanding of the risks and benefits of surgery compared to White Americans[30,31], and to have a lower preference for surgical treatment[25]. This could explain our finding of more severe pre-OP symptoms in patients of minority ethnicity, as patient preference has been associated with referral from GP to orthopaedic evaluation in OA patients[25]. Many American-based studies report that minorities are more likely to undergo surgery at low volume hospitals and that this is a cause for poorer outcome. This does not apply in Denmark, as most patients are treated in the public system and all our data are based on patients treated in one high-volume public institution. Severity of pre-OP symptoms has been shown to influence outcome[4-6]. Although our post-OP response rate was too low to make any conclusions, we did find that the overall outcome for patients born outside the country was poorer compared to patients born in the country, which is concurrent with the reportings of Krupic *et al*[12]. Similar findings have been reported in American patients, where minorities are reported to have a higher post-OP complication rate, mortality and longer hospital stay compared to white Americans[25,26].

The duration of education is key to how individuals seek and handle information[32], and therefore important with regard to how patients cope with medical treatment. We found that patients with > 12 years of education had more severe pre-OP symptoms than those with shorter educations. This result is not concurrent with findings in previous studies, as these have found more severe symptoms in patients with shorter education; an educational level less than high school in the United States has been associated with greater pre-OP pain and lower function in TKA patients by Lopez-Olivo *et al*[33]. Although we found significant *P*-values

for these parameters, the differences of OKS was only three, two and nine on VAS, thus both below MCID and not convincingly clinically-relevant. High education has previously been found to be a predictor for better post-OP outcomes by Greene *et al*[13], while others report no significance[34]. We found that patients with short educations reported a lower post-OP pain severity (MCID below cut-off level), and could find no other significant influence of education on other outcome parameters. Although statistically significant, Greene *et al*[13] also found very small differences that were not clinically relevant. It is thus uncertain whether education can be used as an outcome predictor for TKA patients. Combined with our low response rate, no findings regarding education and post-OP outcome were convincing.

Our study has several limitations, as this is a purely descriptive and hypothesis-generating study. External validation is a major limitation for our study, as both ethnicity and education differ between countries. Education differs greatly across the world; we have, however, tried to accommodate this by dividing patients into three groups based on their number of education years rather than completed degrees. Ethnic minority groups within a country are of course different across the world. In this study, we try to address the issues that arise in healthcare for people born outside their residential country and not the health care behaviour of specific ethnic groups. We believe that our results can contribute to the knowledge base for how to approach racial disparities within a population.

Our results are based on regression analysis, adjusting for patient-related factors such as gender, smoking, alcohol consumption, co-morbidities, symptoms, self-reported QoL and expectations as shown in the Tables. Residual confounders include the missing evaluation of radiologic status/alignment. Surgical factors have been shown to influence patient satisfaction in other studies, and this is unaccounted for in our study; however, all patients were treated by the same high-volume surgeons in a well-defined fast-track setup with standardized treatment for pain, mobilisation and post-OP care, as described in the Methods section[1]. All treatments in Denmark are free of charge, and therefore socioeconomic factors do not affect the choice of implant in our population. Only 44.6% of patients responded to our post-OP questionnaire, and response rate was even lower for patients born outside the country (26.2% *vs* 46.2% for patients born in the country). We therefore make no conclusions regarding significance of either ethnicity or education on post-OP measurements. In this study, we have only evaluated results based on patient-reported outcome measures, and not other outcome measures such as the length of hospital stay, infection rate or other complication rates.

In conclusion, minority ethnicity and duration of education influence pre-OP disability and expectations in patients undergoing TKA. This should be taken into account when patients are advised pre-operatively.

ARTICLE HIGHLIGHTS

Research background

The background, present status, and significance of the study should be described in detail. It is known that patient-related factors, socioeconomic factors and education influence patient outcomes in general, however this area is difficult to investigate and thus these factors are often confounding in scientific work. These factors are also known to be of significance in patients scheduled to undergo total knee arthroplasty (TKA), and this study provides information regarding the significance of education and ethnicity in these patients.

Research motivation

During recent years, a trend towards optimized care, standardized patient evaluations and fast-track surgery has been influencing orthopaedic surgery. Although beneficial in many ways, this concept may not be appropriate for all patients. Levels of education and ethnicity is known to influence patients, and understanding the significance of these factors in TKA patients will assist healthcare providers in optimizing treatment plans for individual patients.

Research objectives

The objectives of this study were to determine if level of education and ethnicity influence the preoperative status of patients undergoing primary TKA or patient expectations for surgery. The significance of ethnicity and level of education on outcome following TKA is still uncertain and should be an objective for future research.

Research methods

We prospectively included 829 patients undergoing TKA. Patients filled in pre-operative questionnaires with information regarding place of birth, duration of education, expectations for outcome of surgery and baseline characteristics. Statistical analyses were performed to identify the significance of ethnicity and level of education.

Research results

We find that patients undergoing TKA in a country different to where they were born report more severe preoperative symptoms and lower expectations for postoperative outcome. We also found that patients with a longer duration of education report more severe pre-operative symptoms. We found that patients of minority ethnicity and with an education > 12 years had more severe symptoms post-operatively. However, due to a low response rate, we cannot draw generalizable conclusions about these results. The significance of ethnicity and education on post-operative results remain to be sufficiently described.

Research conclusions

Minority ethnicity and duration of education influence preoperative disability and expectations in patients undergoing TKA. Patients undergoing TKA in a country different to where they were born need individualised evaluation to accommodate potential differences from the general patient population. Patients of minority ethnicity report more severe pro-operative symptoms before undergoing TKA and lower expectations for post-operative outcome. Patients with educations longer than 12 years report more severe symptoms before undergoing TKA. Minority ethnicity and duration of education influence preoperative disability and expectations in patients undergoing TKA. Ethnicity and education influence patients' perception of disease. Socioeconomic factors should be considered when evaluating patients.

Research perspectives

Our study provides knowledge regarding the significance of ethnicity and education on preoperative disability and expectations of outcome. This information is key for healthcare professionals when evaluating patients prior

to TKA, as it allows for the identification of individuals who may not be suitable for a standardized information regimen. It is important to investigate the significance of socioeconomic factors on outcome following TKA.

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SYSTEMATIC REVIEW

Total knee arthroplasty in patients with Paget's disease of bone: A systematic review

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Abstract

AIM

To determine the functional outcomes, complications and revision rates following total knee arthroplasty (TKA) in patients with Paget's disease of bone (PDB).

METHODS

A systematic review of the literature was performed. Four studies with a total of 54 TKAs were included for analysis. Functional outcomes, pain scores, complications and revision rates were assessed. The mean age was 72.0 years and the mean follow-up was 7.5 years.

RESULTS

All studies reported significant improvement in knee function and pain scores following TKA. There were 2 cases of aseptic loosening, with one patient requiring revision of the femoral component 10 years after the index procedure. Malalignment, bone loss, soft tissue contractures were the most commonly reported intra-operative challenges. There were five cases (9%) that were complicated by intra-operative patellar tendon avulsion.

CONCLUSION

The findings support the use of TKA in patients with PDB. The post-operative functional outcomes are largely similar to other patients, however there are specific perioperative challenges that have been highlighted, in particular the high risk for patellar tendon avulsion.

Key words: Total knee arthroplasty; Paget's disease of

bone; Revision; Loosening; Paget's disease

Core tip: Patients with Paget's disease of the bone commonly develop significant mal-alignment, structural bone deformities and soft tissue contractures, making total knee arthroplasty (TKA) in this patient group challenging. In addition, exposure of the knee joint can prove particularly difficult, with this review demonstrating a high incidence of patella tendon avulsion. This systematic review has demonstrated that TKA improves pain and functional outcomes in patients with Paget's disease of the bone. The rate of loosening and revision in this patient group appears comparable to other patients undergoing TKA.

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INTRODUCTION

Sir James Paget first described Paget's disease of bone (PDB) as "osteitis deformans" in 1877[1]. PDB is a bone disorder that typically manifests in middle-aged patients and affects approximately 2%-4% of people older than 40 years. It is a chronic affliction of adult bone, which undergoes aggressive osteoclast-mediated bone resorption, followed by abnormal osteoblast-mediated bone repair[2].

Although the exact etiology is still unknown, PDB is thought to result from a viral infection in genetically predisposed individuals[3]. The disease process evolves through three distinct phases. Initially, there is an osteolytic phase with a collection of destructive osteoclasts spreading to encompass the entire bone. This is followed by a mixed osteolytic and osteoblastic phase, and finally by the osteoblastic or sclerotic phase[4]. This process results in bone that is mechanically weaker, larger, less compact, more vascular and more susceptible to fracture than normal adult lamellar bone[3].

PDB is slightly more common in men and more prevalent in Europe, North America and Australasia[5,6]. It can affect any bone but is most commonly found in the pelvis, skull, lumbosacral spine, femur or tibia, and is polyostotic in 75% of cases[7].

PDB is usually asymptomatic and only 5%-10% of patients with the disease experience any symptoms, most commonly poorly localized bone pain. Patients may also present with bone deformity, fracture, skin temperature changes, or neurological complications[8]. Concurrent symptomatic osteoarthritis of the knee affects 10%-12% of individuals with PDB[8]. Differentiating the pain of PDB from osteoarthritis of the knee joint can be challenging as both can give a dull ache that may worsen with weight bearing[2]. An intra-articular injection with local anaesthetic can help solve the diagnostic conundrum, as relief of the symptoms would suggest osteoarthritis as the source of pain. Similarly, pain due to PDB can be improved with medication, such as bisphosphonates and calcitonin, further assisting in clarifying the diagnosis.

The non-operative management of osteoarthritis in patients with PDB involves activity and lifestyle modifications, physical therapy, analgesics, functional bracing and anti-Paget's medication. If these fail to alleviate the pain, surgical intervention in the form of total knee arthroplasty (TKA) is indicated. The disease process characterized by bone expansion, softening, cortical thickening and hypervascularity can lead to sclerotic bone, deformity and soft tissue contractures around the knee joint[9]. Marked bone loss and large bone cysts have also been described. These morphological changes can present specific technical challenges when performing TKA in patients with PDB.

With the number of TKAs performed each year growing rapidly, there is a high likelihood that arthroplasty surgeons will increasingly need to perform TKA in patients with PDB. Understanding the challenges associated with this group of patients is, hence, very important. We have, therefore, performed a systematic review of the literature to determine the functional outcomes, failure rates and complication rates of TKA in patients with PDB of the knee.

MATERIALS AND METHODS

Search strategy

A search of Medline and EMBASE was performed on 01/03/2018. The keywords used for the searches were "total knee arthroplasty" or "total knee replacement" and "Paget's disease". All relevant studies in the English literature describing the results of TKA in patients with PDB, between 1986 and 2017, were identified in accordance with the PRISMA statement. We also identified relevant studies or reviews by assessing the bibliographies of all papers that were included.

Eligibility criteria

All papers that described the results of TKA in patients with PDB published in the English language were included. All the articles adhered to the PICO Criteria for systematic reviews (Population, Intervention, Comparison and Outcomes).

Data extraction

One reviewer (Ravi Popat) scrutinised the articles and collected the data using a standardised data collection form. All information relating to the number of patients, their demographics, follow-up period, complications, revision rates and functional outcomes were entered in a spreadsheet. Another reviewer (KT) checked the accuracy

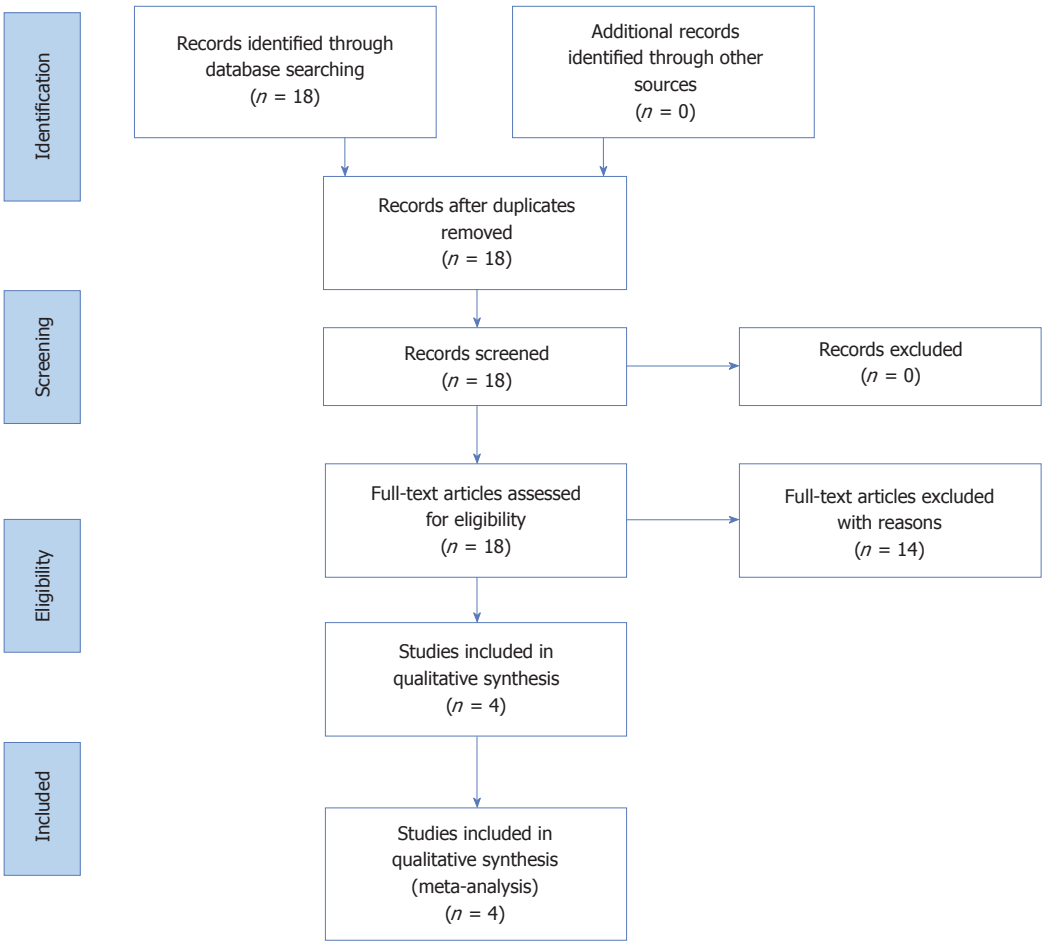

Figure 1 PRISMA flowchart illustrating the search strategy and number of records screened and included.

of the data collection. There were no inconsistent results.

Statistical analysis

The results were summarized using descriptive statistics for continuous variables, and frequencies and percentages for categorical variables. Microsoft Excel, 2016 version (Microsoft Corporation, Redmond, Washington) was used for data analysis.

RESULTS

Search results

The literature search identified 18 articles. The full text of each article was reviewed. A total of 4 studies satisfied the eligibility criteria. Figure 1 outlines the search strategy.

Quality assessment

All studies were small to medium retrospective case series (*n* = 7-21 patients) describing the outcome of TKA in patients with PDB. The range of follow-up in these studies was from 2 to 20 years.

Cohort characteristics

The studies included 54 TKAs performed in patients with PDB. These patients had a mean age of 72 years (range, 57-86 years) with an average follow-up of 7.5 years (range, 2-20 years). Table 1 summarises the patient demographics.

Outcome analysis

Functional outcome: All the studies reported improvement in knee function following TKA. Two studies reported a pre and post-operative comparison of the Knee Society Score (KSS) and demonstrated an average improvement of 42 points post-operatively[8,10]. Schai *et al*[11] provided post-operative functional scores only, with a mean of 62.

Pain outcome: All the studies reported an improvement in pain scores post-operatively. Two studies demonstrated an average improvement of 46 points post-operatively[8,10]. The average pain score for patients in Schai *et al*[11] was 83. Five out of 7 patients in the cohort from Broberg *et al*[12] reported no post-operative pain. The remaining patients reported mild pain.

Aseptic loosening and revision

There were 2 cases of aseptic loosening out of a total of 54 cases. There was one revision of the femoral

Table 1 Demographics of the patients included in the studies and a summary of the results

Ref.	No. of knees	Age (yr)	Follow up (yr)	Complications	Revision rate	Functional outcomes
Lee *et al*[10], 2005, United States	21	71 (57-85)	9 (2-20)	Patellar tendon avulsion (3/21)	1 (4.8%)	Knee Society Pain Score 41 to 87
Gabel *et al*[8], 1991, United States	15	72 (61-85)	7 (2-15)	Aseptic loosening (1/15) Patella tendon avulsion (1/16) Femoral notching (2/21)	0	Knee Society Pain Score 42 to 88 Knee Society Functional Score 33 to 86
Schai *et al*[11], 1999, United States	11	75 (59-86)	5.7 (2-16)	Patellar tendon avulsion (1/11) Necrosis of patella (1/11)	0	Knee Society Pain Score 83 (post-op only) Knee Society Functional Score 62 (post-op only)
Broberg *et al*[12], 1986, United States	7	71 (66-85)	6.6 (3-12)	Partial patellar tendon avulsion (1/7)	0	No pain - 5 Mild Pain - 2 (post-operatively)

component, 10 years after the index procedure.

Patellar tendon avulsion

Difficulties during the surgical approach, soft tissue contractures and thickening of the patellar tendon were described in all studies. A total of 5 out of 54 patients (9.3%) had patellar tendon avulsion intra-operatively.

DISCUSSION

TKA has been shown to be a generally successful procedure in patients with PDB. All the studies that were included in this systematic review reported a post-operative improvement in knee function and pain scores. Furthermore, the overall rate of aseptic loosening was 3.7% in 7.5 years, and the revision rate was 1.85%, with one revision of the femoral component 10 years after the index procedure. This failure rate is comparable to other patients undergoing TKA. According to the most up to date report of the National Joint Registry, a revision rate of 1.85% at 7.5 years is considered reasonable[13].

The overall reported incidence of patellar tendon avulsion was 9.3%. This is an extraordinarily high incidence for this complication and surgeons undertaking TKA in the context of PDB should be aware of interventions that can help prevent it. We are discussing such interventions in a dedicated paragraph later in this review. Conversely, although the incidence of heterotopic bone (HO) formation has been reported to be as high as 46% following total hip arthroplasty for PDB, HO does not appear to be a concern following TKA[14].

The studies included in this review reported on a variety of TKA implants with variable levels of constraint. Some of these implants are also historical. Due to the small number of cases and the wide variation of implant type and constraint, further analysis of potential subgroups, such as cruciate retaining *vs* posterior stabilised, or cemented *vs* uncemented, was not feasible.

The main challenges when performing TKA in the context of PDB are malalignment (more commonly varus), extensive bone loss, soft tissue contractures and thickening of the patellar tendon. With the steadily increasing number of TKAs performed annually, it is reasonable to expect that there will be a proportional increase in the burden of PDB cases. It is, therefore, important to employ a systematic approach in order to ensure optimal outcomes.

Per-operative considerations

Initially, it is very important to isolate articular pain from the deep and aching pain that is associated with the later stages of Paget's disease. The use of intra-articular injections can help to identify and delineate whether the patient's pain is from an intra-articular source, providing greater certainty that an arthroplasty procedure will alleviate the patient's symptoms.

Good quality, full-length radiographs are recommended to establish the type of alignment of the affected limb and to assist in pre-operative planning. Long leg views can also identify potential deformity in the femur, which needs to be considered when using intramedullary cutting guides. The use of CT scans has grown in popularity in the last two decades and can display information related to bony morphology that is not available on plain radiographs.

Pre-operative assessment and optimisation of haemoglobin and cardiac function is recommended. The hypervascularity of pagetoid bone means that these patients are in a high cardiac output state, which can have implications for the anaesthetic intervention. The use of bisphosphonates or calcitonin can reduce the disease activity and theoretically reduce blood loss, however, this has not been established. Pre-operative autologous blood donations may also be considered.

Intra-operative considerations

The morphological changes that occur in bones affected by PDB may require intra-operative adaptations and pre-emptive precautionary measures. PDB around the knee is characterised by enlarged bones and correspondingly larger joint surfaces. A size mismatch between the femoral and tibial components is often encountered, especially in cases where there is isolated involvement of either the tibia or the femur. Additionally, the arthritic changes may be more pronounced, with extensive bone loss, large bone cysts and tight collateral ligaments[8,11].

Exposure of the knee joint can prove particularly challenging because of joint stiffness, particularly in case of thickening of the patellar tendon. Patellar eversion can result in avulsion of the patellar tendon and this

was described as a complication in 5 out of 54 patients. Schai *et al*[11] recommended that the patellar preparation should be performed early during the procedure to allow for improved exposure. Vail and Callaghan[14] also advised for early patellar preparation, but also performed lateral releases to help achieve adequate exposure. Pre-emptive measures to protect the patellar tendon insertion are essential, especially in cases where there is pagetoid involvement of the tibial tuberosity.

Significant varus or valgus malalignment in this patient group presents challenges both due to the respective bone loss and in achieving optimal soft tissue balancing. Extensive medial or lateral releases may be required in order to achieve adequate exposure as well as to help balance the joint, although the latter may not be feasible with low-constraint implants.

Disease-involvement of the femur, especially in the context of increased varus angulation of the distal femur can present a challenge when intra-medullary guides are used to plan the distal femoral cuts[15]. It has been previously reported that intramedullary guidance may lead to mal-positioning of the femoral components. It has been recommended that extra-medullary guides are preferable for the preparation of both the femur and tibia[8].

On the tibial side, there can be significant anterior tibial bowing and the use of an extra-medullar tibial cutting guide may lead to excessive bone loss. In order to preserve tibial bone, Gabel *et al*[8] have recommended utilising a tibial cutting guide with 10 degrees of posterior slope and then using a flat tibial component.

Hard sclerotic bone can often be found in the proximal tibia and the use of a tibial punch during preparation of the bone may lead to fractures. It has been recommended that a high-speed burr should be utilised for the preparation of the proximal tibia, instead of a tibial punch[16]. Additionally, the presence of sclerotic bone and its tendency to bleed, may have a bearing on cement interdigitation.

Due to bone hypervascularity and the high cardiac output state present in many of these patients, the use of tranexamic acid and blood salvage techniques should be considered.

Post-operative considerations

Bisphosphonate therapy should continue if disease activity is high (as measured using ALP levels). The main limitation of this review is that it included largely historical studies. Three of the papers were published in the 20th century and the fourth more than a decade ago. Nevertheless, the overall results were still favourable. With the number of arthroplasty procedures performed each year increasing rapidly, and with PDB being relatively common, we feel that this review is relevant to current and future clinical practice.

The findings of this review support the use of TKA to alleviate the functional limitation and pain due to osteoarthritis in patients with PDB. Post-operative pain relief and functional improvement appear to be significant and comparable to other patients. Surgeons that treat this unique group of patients need to be aware of the particular challenges and interventions that are essential for optimal outcomes.

ARTICLE HIGHLIGHTS

Research background

Paget's disease of bone (PDB) affects approximately 2%-4% of people older than 40 years. With an ageing population and the number of TKAs performed each year growing rapidly, there is a high likelihood that arthroplasty surgeons will need to perform total knee arthroplasty (TKA) in patients with PDB.

Research motivation

Patients with PDB can develop significant mal-alignment, structural bone deformities and soft tissue contractures. Understanding the problems and challenges associated with performing TKA in patient with PDB is key to achieving successful outcomes.

Research objectives

To aid appropriate consenting of patients and to assist surgeons in achieving the best outcomes for their patients, it is important to understand the outcomes that have previously been achieved following TKA in patients with PDB.

Research methods

A systematic review of the literature was performed. A total of 54 TKAs were included for analysis. Functional outcomes, pain scores, complications and revision rates were assessed.

Research results

All studies demonstrated a substantial improvement in function and pain following TKA in patients with PDB. The mean follow-up was 7.5 years. There were two cases of aseptic loosening, with one patient requiring a revision TKA at 10 years. Five cases (9%) of intra-operative patellar tendon avulsion were reported, suggesting that exposure of the knee joint in patient with PDB can be particularly challenging.

Research conclusions

This systematic review supports the use of TKA to improve function and alleviate pain in patients with Paget's disease around their knee joints. The post-operative functional outcomes appear to be similar to those experienced by patients that do not have PDB. At an average of 7.5 years follow-up, implant survival appears comparable with patients that receive TKA for primary OA. Pain scores also improve substantially in this patient group. Morphological changes that occur secondary to PDB, may require intra-operative adaptations and a high rate of patella tendon avulsion (9%) suggests additional care needs to be taken when gaining access to the knee joint, especially in case where there is Pagetoid involvement of the patella/tibial tuberosity.

Research perspectives

Surgeons treating patients with PDB need to be aware of the particular challenges posed by this patient group, with intra-operative adaptations potentially required to avoid complications. Further studies that compare functional, pain and revision outcomes in patient with PDB around the knee, against a matched control group, with the use of modern TKA implants, will provide further information about the results that can be expected in this patient group.

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