Less Invasive TKA

Extramedullary Femoral Reference Without Navigation

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Abstract Femoral intramedullary canal referencing is used by most knee arthroplasty systems. Fat embolism, activation of coagulation, and bleeding may occur from the reamed canal. The purpose of our study was to evaluate a new extramedullary device that relies on templated data. We randomized 100 consecutive patients undergoing primary total knee arthroplasty through a limited parapatellar approach to use of either standard intramedullary femoral instruments (IM group) or a new extramedullary device (EM group). The extramedullary instrument was calibrated using templated data obtained from a preoperative full-limb weightbearing anteroposterior view of the knee. In both groups, an intraoperative double check was performed using an extramedullary rod referring to the anterosuperior iliac spine. Femoral component coronal alignment was within $0^\circ \pm 2^\circ$ of the mechanical axis in 84% of the IM group and 86% of the EM group. Sagittal alignment of the femoral component was $0^\circ \pm 2^\circ$ in 78% of the IM group

and 90% of the EM group. We observed no difference in the average operative time between the two groups. The two groups showed similar postoperative blood loss. Extramedullary reference with careful preoperative templating can be safely used during TKA.

Level of Evidence: Level II, therapeutic study. See the Guidelines for Authors for a complete description of levels of evidence.

Introduction

Recent advances in TKA have focused on the reduction of tissue exposure and damage during the procedure [1, 36, 53]. Particular attention has been paid to avoid or limit the extension of the incision into the quadriceps tendon [45]. Several studies suggest limited incision TKAs have short-term advantages in terms of less postoperative pain and faster recovery compared with TKAs performed through the standard medial parapatellar incision [1, 36, 53]. Research efforts in the field of minimally or less invasive knee arthroplasty are now moving toward reducing trauma to bone and ligaments. We believe one of the most invasive parts of TKA is the violation of the intramedullary femoral canal and the subsequent use of intramedullary (IM) instruments.

Transesophageal echocardiography during the course of conventional IM instrumented total knee procedures has demonstrated showers of fat or intramedullary embolic particles enter the right atrium of the heart in repeated and unpredictable patterns [5, 6, 10, 12, 20, 22, 25, 28, 29, 39, 41, 42, 48–50, 57]. Most often these are clinically unimportant. Fat and bone marrow cell embolization are not eliminated by the technique of femoral canal decompression alone [29, 32, 49]. Many case reports describe fat embolism syndrome

One of the authors (AB) developed and has patented the device investigated in this study. There are no further commercial associations (eg, consultancies, stock ownership, equity interest, etc) that might pose a conflict of interest in connection with the submitted article.

Each author certifies that his or her institution has approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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after TKA, and half of them were fatal [4, 5, 12, 15, 17–19, 22, 29, 32, 34, 37, 41, 44, 48, 54, 55, 57, 58]. A study by Kim reported a rate of clinical signs related to fat embolism in 2% of unilateral TKAs and 4% of bilateral TKAs [29]. Blood loss is one indicator of the invasiveness of TKA. A substantial amount of blood loss seems to be produced by femoral canal reaming (range, 145–396 mL) [9, 13, 26, 27]. Some of this blood loss and the subsequent hematoma can be controlled but not eliminated by plugging the femoral entry hole [27, 31, 33, 46].

Intramedullary instruments are the most widely accepted way to ensure proper component positioning, but the rates of outliers (more than 3° off the neutral mechanical axis), both in the sagittal and coronal planes, reportedly range from 10% to 20% [2, 23, 40, 43, 47]. The orientation of the rod can be nonoptimal depending on the diameter of the femoral canal, the location of the entry point in the coronal plane, and the diameter and length of the rod [38, 43]. A postoperative neutral mechanical axis has been reproduced more consistently using IM instruments with respect to extramedullary ones by several authors [7, 14, 35, 51]. These studies used only the anterosuperior iliac spine (ASIS) as an intraoperative landmark for the extramedullary referencing instruments [8, 14, 35, 51]. However, intraoperative visual assessment of the longitudinal femur axis and the ASIS by extramedullary rods is difficult owing to the large soft tissue cover and tourniquets [24, 35]. Locating the femoral head with intraoperative radiographs could provide more consistency but is time-consuming, expensive, and requires additional radiation exposure for the patient.

Our primary research question was to observe if a new extramedullary instrument combined with preoperative templating of the femur is at least as accurate in reproducing a neutral distal femoral resection on the coronal and sagittal planes during TKA than standard IM instruments. Our secondary hypothesis was the use of extramedullary instruments in TKA would reduce postoperative blood loss compared with instruments that violate the femoral canal.

Materials and Methods

Between September 2006 and April 2007, we prospectively enrolled 100 patients undergoing unilateral primary TKA for varus osteoarthritis in a randomized, blinded (patient and evaluator) study. A power analysis with 95% confidence interval was performed and suggested 100 patients were needed to show a difference of 2° in achievement of a sagittal and coronal femoral alignment of 0° ± 2° from the mechanical axis with a value (1 – β) of 0.8. We excluded patients with valgus deformities, extraarticular deformities of the involved limb, previous distal femoral osteotomy,

Table 1. Demographic and intraoperative patient data

Parameters	IM group (n = 50)	EM group (n = 50)
Age (years)*	71 (58–84)	70 (59–80)
Female/male ratio	2:1	1.7:1
Body mass index*	28.6 (27–33)	28.9 (27–34)
Varus deformity (degrees)*	8 (4–25)	6 (3–22)
Tourniquet time (minutes)*	52 (35–65)	55 (45–70)
Postoperative blood loss (mL)*	820 (400–1250)	740 (350–1200)

* Values are average (range); IM = intramedullary femoral instruments; EM = new extramedullary device.

ipsilateral THA, or inadequate preoperative full-limb radiographs. Major demographic variables such as age, gender, body mass index, and preoperative degree of varus deformity were similar in the two groups (Table 1). The study was approved by the authors' Institutional Review Boards, and informed consent for participation in the study and to take part in the randomization process for surgery was obtained. Patients were randomized into two groups using computer-generated numbers and a closed-envelope design. At the time of postoperative radiograph analysis, patients and the authors were not informed of the patients' group assignments.

All patients had unilateral TKA performed by one of the authors using the NexGen® Legacy Posterior Stabilized Flex fixed-bearing prosthesis (Zimmer, Warsaw, IN). All procedures were performed through a medial parapatellar approach without everting the patella. Fifty patients had the distal femoral resection using an IM instrument (IM group), whereas the other group of 50 patients had this resection performed with a new extramedullary instrument with a variable valgus angle based on preoperative template data (EM group).

The IM technique was performed through an entry hole in the distal femur created by a sword drill 1 cm superior and medial to the posterior cruciate femoral insertion. After aspirating fluid from the medullary canal with suction, a distal femoral cutting jig connected to an IM rod and a platform preassembled at 6° of valgus was inserted. Final position of the cutting slot aimed to 0° of flexion and 6° of valgus. At the end of the procedure, before cementing the femoral component, a bone plug was always used to fill the IM canal entry hole.

The EM set of instruments was developed through a reverse prototyping process by one of the authors (AB) and a manufacturing company (Italorthopaedics, Milan, Italy). A metal prototype was customized based on a rough design project, tested on cadaveric knee specimens, and reshaped. When the final shape of the metal parts was defined, they were measured, designed with three-dimensional resolution, plastic rapid prototypes were created, and retested on

cadaveric specimens. Final parts were then created. This set of EM instruments includes several parts (Fig. 1). An L-shaped sliding tool (5 cm long) over the anterior cortex controls the flexion-extension parameter of the resection and is intended to allow a cut flush with the anterior cortex at 0° of angulation with the distal aspect of the femoral

Fig. 1 Extramedullary instrument set. Two paddles sizes are available, large and small, to fit all types of knees. The distance between the two paddles and the cutting slot can be preset for different resection options, which are the same as the standard intramedullary guide. The “0” level means 9-mm bone removal from the most prominent condyle. Options “−2 mm” and “+3 mm” are available.

Fig. 2A–C (A) L-shaped sliding tool inserted under the suprapatellar soft tissues through a small window of the synovial membrane. The position is on the medial flat aspect of the anterior cortex. (B) Two headless pins are inserted through holes of the first block connected to the L-shaped tool. They will be perpendicular to the anterior cortex of the distal third of the femoral diaphysis. (C) A second block is inserted on the headless pins. This block has a dovetail-shaped rail that engages the main body of the cutting instrument. The instrument has two paddles regulated at different levels based on the preoperative radiographic calculations.

diaphysis on the sagittal plane (Fig. 2). This instrument is easily inserted, with the knee in full extension, through an entering hole in the suprapatellar synovial tissue proximally to the femoral trochlea. Two headless pins are inserted in a modular block perpendicular to the anterior femoral cortex (Fig. 2). A second slotted modular block is inserted on the headless pins. The main body of the instruments is a platform connected to a cutting slot. Attached to this main part are two moving paddles on each side of the platform, which are the reference of the instrument with respect to the distal femoral condyles. The body of the EM cutting jig slides through its dovetail-shaped slot until the two paddles are in contact with the most prominent portion of the distal medial and lateral condyles (Figs. 3, 4). Two sets of paddles are available so they can fit either large or small knees. The paddles can be engaged in two different positions, at 0° or 25° with respect to the main instrument platform, to anatomically follow the obliquity of the lateral and medial distal femoral condyles, respectively. Distal femoral resection was planned according to the template and considering a bone cut perpendicular to the mechanical axis of the femur. Because the cartilage which can be present in the lateral condyle of a varus knee is not visible on radiographs, an additional thickness of 2 mm was taken into account in our measurements (Fig. 3). Data obtained from templating the preoperative long-limb radiograph were reproduced on the two paddles of the distal femoral cutting jig (Fig. 3). The level of resection (standard was considered 9 mm from the most prominent condyle) and varus-valgus orientation of the resection were established by moving the two paddles according to templated data (Fig. 3). An intraoperative check was performed using an EM rod 2.5 fingerbreadths medially to the ASIS in both groups to assess the distal femoral cutting slot was perpendicular to the mechanical axis of the femur (Fig. 4). The intraoperative check with the EM rod resulted in a modification in the original position of the distal cutting slot in six patients in the IM group and three in the EM group. Postoperative blood loss was taken as the sum of recorded loss from drains during the first 24 hours.

We obtained anteroposterior, lateral, and full-limb weightbearing views preoperatively, and at the first followup 6 weeks postoperatively, taking care of neutral limb rotational positioning in all patients enrolled in the study. All radiographs had a magnification marker and were in digital format and 100% magnified. We (AB, PA) assessed all radiographs with regard to implant position according to the Knee Society TKA roentgenographic evaluation form [16]. The authors measured all radiographs twice and interobserver and intraobserver variability was calculated using the Student's *t* test. Intraclass correlation coefficient for intraobserver and interobserver measurements were 0.932 (*K* = 0.83) and 0.885 (*K* = 0.79), respectively.

Fig. 3A–C (A) Preoperative long-limb radiographs are used for templating. Templating is performed on the femur with a T-shaped template that points at the femoral head center with the long arm, whereas the short arm is kept tangent to the most prominent condyle. Distance in millimeters is calculated from the short arm of the T and the nonprominent lateral condyle. In this example, a 4-mm distance offset between the medial and the lateral femoral condyle was

calculated. (B) Two millimeters of cartilage thickness is taken into account in calculating the distance to be reproduced on the extramedullary (EM) instrument lateral paddle (4 mm – 2 mm = 2 mm). (C) In this example, 2-mm offset is reproduced on the EM cutting guide by adding 2-mm distance on the lateral paddle and 0-mm distance on the medial one.

Fig. 4 With the extramedullary instrument in place, a second check is performed with an external rod pointing two fingerbreadths medial to the anterosuperior iliac spine.

According to the Knee Society form, α angle of the femoral component (which represents varus-valgus angulation) was measured in the coronal plane on the full-limb anteroposterior film, and γ angle of the femoral component (which represents flexion-extension angulation) was measured in the sagittal plane on the lateral view. Femoral component alignment of neutral $\pm 2^\circ$ was rated as correct.

Postoperative alignment of 3° or more of varus has been correlated to tibial component loosening and wear in clinical and retrieval studies [3, 11, 56].

Differences in coronal alignment, sagittal alignment, and blood loss between the EM and IM groups were determined by a two-tailed, unpaired t-test. These tests were applied to the interval measures of the study. Each measure approximated a normal distribution (Figs. 8, 9). Differences in “outliers” (coronal and sagittal malalignment greater than 3°) rate between the EM and IM groups were determined by the chi square test. We used Microsoft Excel software (Microsoft Corp, Redmond, WA) for all analyses.

Results

The percentages of patients with postoperative femoral component coronal alignment within $0^\circ \pm 2^\circ$ (α angle) of the mechanical axis was similar ($p = 0.09$) between the two groups (84% of the IM group and 86% of the EM group). Similar ($p = 0.34$) percentages in the two groups also had the femoral component α angle within $0^\circ \pm 3^\circ$ (90% of the patients in the IM group and 94% in the EM group). We observed outliers in valgus malalignment of only 3° to 4° with respect to the mechanical axis in two

Fig. 5 Distribution of data for the femoral α angle (coronal alignment) for the two groups. The percentage of patients with postoperative femoral component coronal alignment within $0^\circ \pm 2^\circ$ was comparable in the two groups. We did not observe major (greater than 5°) femoral component malalignment in either group. IM = intramedullary; EM = extramedullary.

Fig. 6 Distribution of data for the femoral γ angle (sagittal alignment) for the two groups. The extramedullary (EM) group showed higher accuracy in femoral component sagittal position than the intramedullary (IM) group. A neutral $\pm 2^\circ$ γ angle was achieved in a greater percentage ($p = 0.005$) of the EM group than in the IM group (90% versus 78%, respectively).

patients in the IM group and four in the EM group. Outliers in varus malalignment of 3° to 5° occurred in six patients in the IM group and three in the EM group. We observed no malalignment over 5° in either varus or valgus in either group (Fig. 5). Postoperative femoral component sagittal alignment within $0^\circ \pm 2^\circ$ (γ angle) occurred less often ($p = 0.005$) in the IM group than in the EM group (78% versus 90%, respectively). Furthermore, fewer ($p = 0.04$) of the patients in the IM group had the femoral component γ angle within $0^\circ \pm 3^\circ$ (86% versus 96%, respectively).

We observed more ($p = 0.03$) outliers in femoral component hyperextension malalignment of less than 3° in the EM than in the IM group (three patients versus none, respectively). However, we observed fewer ($p = 0.006$) outliers in femoral component flexion malalignment of 3° to 6° in the EM than in the IM group (three versus 11, respectively). We found no malalignment over 3° of hyperextension and 6° of flexion in either group (Fig. 6).

There was no difference in average operative time between the two groups (52 and 55 minutes on average for the IM and EM groups, respectively). Postoperative blood loss was similar in the two groups and on average 740 mL in the EM group versus 820 mL in the IM group ($p = 0.07$). Postoperative pain, knee swelling, and functional recovery were also similar in the two groups.

Discussion

Invasion of the femoral IM canal increases the fat emboli rate to the lungs and brain during TKA [6, 25, 29, 30, 41, 42, 49, 50, 57]. In a small percentage of patients, this phenomenon may lead to clinical symptoms such as mental confusion. We developed a set of EM instruments calibrated with preoperative templating, which allow one to perform distal femoral resection without violating the femoral canal. The aim of this study was to compare the accuracy in femoral component positioning, on the coronal and sagittal plane obtained with a new EM instrument, with a standard IM distal femoral cutting jig.

This study has a number of limitations. The series included only varus osteoarthritic knees, and our conclusions may not apply to all types of deformity. All operations were performed by experienced knee arthroplasty surgeons, and the results may differ in another scenario. Because it was an exploratory study, there are no strictly comparable data in the literature. The aim of our study was not focused on evaluating clinical results and patients' postoperative vital parameters and we are unable to speculate on any additional morbidity of EM approaches.

Coronal alignment was similar using the two types of instruments. Our data for the IM technique are consistent with those in the literature demonstrating postoperative femoral coronal alignment of $0^\circ \pm 2^\circ$ on the mechanical axis in 80% to 90% of cases [2, 40, 43, 47, 51]. Historically, EM femoral alignment techniques have had inferior accuracy with approximately 10% more outliers on the coronal plane compared with the IM technique [8, 14, 21, 35, 52]. However, these studies date back to the late 1980s or early 1990s, and all the authors were using the EM instruments referring only to the ASIS intraoperatively. Only the study from Morawa et al. [42], which used a sophisticated intraoperative pneumatic tensioning device in

35 cases, achieved 97% of $0^\circ \pm 2^\circ$ without violating the IM canal. Recently, focus on the EM system has been reconsidered owing to computer navigation. However, navigation technology is not completely ready for routine clinical use because of cost, length of the procedure, and learning curve [4]. In the largest series in the literature comparing computer-assisted versus standard TKA, Jenny et al. [23] reported better radiographic alignment using the computer-assisted EM technique compared with the standard IM femoral technique. Their computer-assisted IM technique resulted in 11% of patients outside of the range of $0^\circ \pm 2^\circ$ in the coronal plane and 20% outside that range in the sagittal plane [23]. By referencing the anterior femoral cortex with a simple instrument, we had 10% outliers in postoperative sagittal alignment of more than 2° . We found the EM technique had better accuracy than the IM technique in the sagittal plane. Using the IM technique, it is difficult to control flexion-extension insertion of the femoral rod, particularly when the canal is large. The possibility of alignment mistakes using an IM rod can range from 5° of varus to 9° of valgus and from 3° of extension to 10° of flexion [38, 43].

Our study did not show a major decrease in blood loss when the femoral canal was not reamed. Blood loss after TKA is multifactorial, and this study was not exactly powered for that purpose. We believe that, to expect a consistent and evident reduction in blood loss by changing only one intraoperative variable, a study with a larger cohort and strict patient selection criteria would be required. Other authors reported a considerable (range, 145–396 mL) reduction of blood loss when the femoral canal was not violated [9, 13, 26, 27].

We confirm our hypothesis that the use of EM instruments, calibrated with preoperative radiograph measurements, to perform the distal femoral bone cut in TKA is reliable and at least as accurate as the standard IM technique. At present, we definitely favor the EM technique for bilateral, simultaneous TKA. Other indications for the use of EM instruments include all major femoral extraarticular deformities, the presence of ipsilateral long-stemmed hip arthroplasty, and the presence of hardware such as distal femoral plates and screws or IM nails.

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