Assessing the Impact of Patient-Specific Instrumentation and Fixation on Accuracy and Radiation Exposure in a Cadaveric Model of Medial Opening-Wedge High Tibial Osteotomy

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Background: Traditional freehand techniques in high tibial osteotomy (HTO) have been shown to lack precision and accuracy. Patient-specific instrumentation (PSI) and fixation created from cross-sectional imaging have recently been introduced to address this problem.

Purpose/Hypothesis: The purpose of the study was to compare traditional freehand techniques versus PSI in a human cadaveric model of HTO. It was hypothesized that the osteotomies performed using PSI would require less radiation exposure for operating room staff and would reduce deviation from the planned correction in the coronal, sagittal, and axial planes.

Study Design: Controlled laboratory study.

Methods: Sixteen matched cadaveric knees underwent medial opening-wedge HTO via the freehand method (n = 8) or PSI technique (n = 8) with a predetermined planned opening-wedge size. Computed tomography was used to measure the achieved wedge size as well as alignment parameters in the coronal, sagittal, and axial planes. Radiation dose, number of fluoroscopic images taken, and total operative time were recorded.

Results: The mean deviation from the planned wedge size was smaller in the PSI group compared with the freehand group (0.505 vs 3.016 mm, respectively; $P < .01$). Total radiation dose to medical staff (0.85 vs 2.04 mGy; $P < .01$) and number of fluoroscopic images (15.5 vs 41; $P < .01$) were also smaller in the PSI versus the freehand group, respectively. No difference was seen in total operative time between the 2 groups ($P = .62$).

Conclusion: In cadaveric specimens, the PSI technique demonstrated superior accuracy and decreased radiation exposure for medical staff compared with the traditional freehand technique without compromising operative efficiency.

Clinical Relevance: The use of PSI when HTO is performed can lead to more accurate operations and potentially improve outcomes.

Keywords: knee; osteotomy; anatomy; biomechanics; articular cartilage; patient-specific instrumentation; cadaver; opening-wedge

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High tibial osteotomy (HTO) is a powerful corrective tool to address limb malalignment that arises from the proximal tibia. HTO has been shown to be an effective joint-preserving technique for early medial compartment osteoarthritis with varus malalignment.[7] Furthermore, HTO has been used to augment cartilage restoration procedures,[12] ligamentous reconstructions,[5] and meniscal transplant.[9]

The goal of the correction via medial opening-wedge HTO (MOW-HTO) is to shift the weightbearing axis away from the affected compartment. To achieve this goal, the surgeon must conduct the osteotomy precisely and accurately and must consider the complex multiplanar anatomic characteristics of the knee in the coronal, sagittal, and axial planes. However, the accuracy and precision

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of traditional freehand methods for MOW-HTO have been called into question.[19] Multiple studies have demonstrated a substantial gap between the goal correction and the achieved correction in the coronal plane.[19] Furthermore, unintentional sagittal plane alterations have been shown to occur in cadaveric and in vivo studies of MOW-HTO using traditional freehand methods.[17] This inaccuracy is likely significant, given the abundance of data that demonstrate the importance of achieving an acceptable mechanical femorotibial alignment after MOW-HTO.[4]

Traditional freehand methods have made use of robust preoperative planning and intraoperative fluoroscopy in an attempt to achieve reproducibility within MOW-HTO. However, fluoroscopy presents its own drawbacks, including dependence on radiology technicians and the risk of significant intraoperative radiation exposure to the surgeon and operating room staff.[2,13] Additionally, freehand methods rely on a high level of technical precision by the surgeon regarding sawing or drilling without the use of guides, as minor technical errors can significantly affect the outcome of the osteotomy.

Three-dimensional (3D)–printed, patient-specific instrumentation (PSI) is a promising technology that has several advantages over traditional freehand methods. PSI is based on cross-sectional imaging, and preoperative plans generated from modern PSI systems allow the surgeon to consider the 3D anatomic features of the patient and perform the osteotomy around a patient-specific, customizable hinge axis. Patient-specific plates could act as an additional point of control over tibial slope beyond wedge size. Furthermore, PSI reduces the reliance on intraoperative fluoroscopy, and custom-printed drill/saw guides have the potential to improve the precision of the osteotomy and subsequent fixation. As such, PSI has the potential to improve the accuracy, safety, and efficiency of surgery.

In this study, we aimed to compare traditional freehand MOW-HTO methods versus a technique that uses 3D-printed osteotomy guides and plates. We explored differences in operative efficiency, radiation exposure, and accuracy between the 2 methods. We hypothesized that the osteotomies performed using PSI would require less radiation exposure for the medical staff and would decrease deviation from the preoperative plan in the coronal, sagittal, and axial planes. Furthermore, we hypothesized that PSI would not meaningfully affect operative efficiency.

METHODS

Specimens

Sixteen matched lower-limb specimens from the foot to the femoral head were obtained from 8 human specimens originally received from Science Care. Criteria for specimen choice were as follows: (1) entire limb intact (ie, no amputation), (2) no previous orthopaedic surgery about the knee, (3) varus/valgus alignment within 10° of a tibiofemoral angle of 6° of valgus, and (4) skeletally mature at the time of specimen harvest.

Design of PSI

PSI was designed such that a medial wedge size of 10.3 mm would be created after osteotomy and fixation. Software (Bodycad Inc) was used to generate a preoperative plan based on 3D reconstructions generated from computed tomography (CT) scans of the specimens. Anatomic landmarks that were used included the tip of the greater trochanter, the center of the femoral head, the most anterior aspects of the medial and lateral femoral condyles, the most distal points of the medial and lateral femoral condyles, the medial and lateral femoral epicondyles, several points on tibial plateau articular surface, and several points of the tibial plafond. Based on these anatomic landmarks, the "safe zone" for the osteotomy was created such that the hinge axis lay 10 mm from the lateral tibial cortex and 15 mm from the lateral tibial plateau (Figure 1).

The cutting/drilling plane was oriented such that the drill path passed above the tibial tuberosity (Figure 2).

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Ethical approval was not sought for the present study.

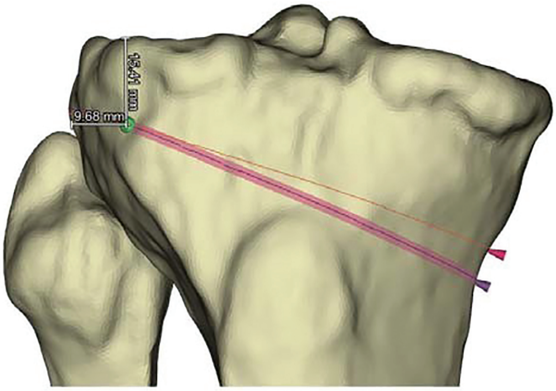

Figure 1. Schematic of the ''safe zone'' of osteotomy (indicated by the 2 red lines), with the hinge axis approximately 10 mm from lateral tibial cortex and at least 15 mm from the lateral tibial plateau articular surface.

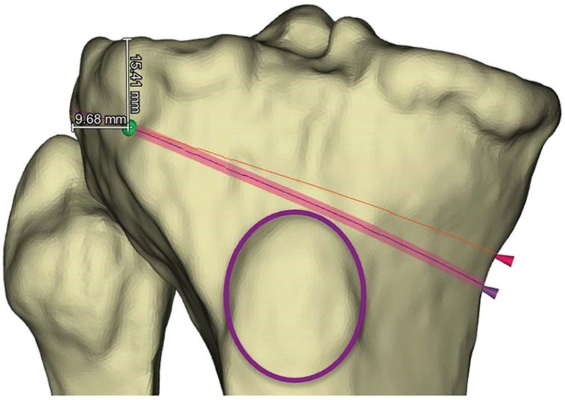

Figure 2. Schematic of the osteotomy plan illustrating the osteotomy path (indicated by the 2 red lines) proximal to tibial tubercle (indicated by the purple circle).

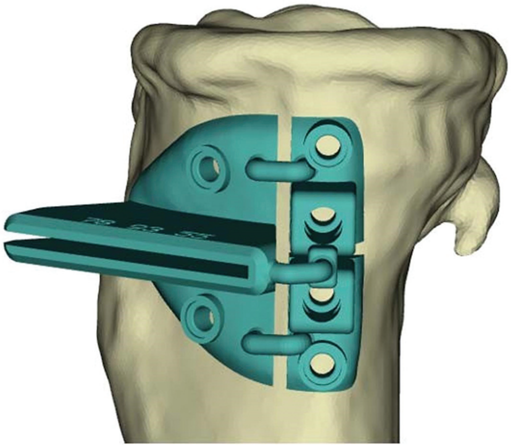

Figure 3. Computer-generated template of the drill guide sitting on the osseous surface of the medial tibial cortex. The holes represent temporary fixation of the drill guide. The horizontal slot is designed to accommodate drill bits and osteotomes.

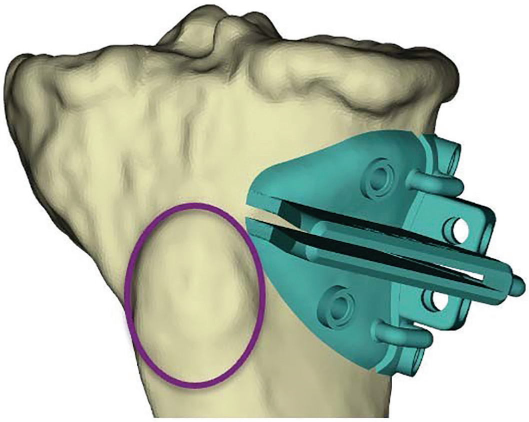

Figure 4. Computer-generated template of the drill guide, demonstrating positioning medial to the tibial tubercle (indicated by the purple circle) and patellar tendon.

Figure 5. Drill guide shown with an additional drill depth limit clipped onto the drill guide. The drill depth limiter has cannulated sleeves through which a length-standardized drill bit is passed. The length of these cannulated sleeves creates a hard stop for the drill, preventing overpenetration with drill bits.

Based on these planning parameters, a 3D computer model of the PSI drill guide was generated. The drill guide was modeled to sit on the medial aspect of the proximal tibia, medial to the patellar tendon (Figures 3 and 4).

Two additional components of the drill guide (drill depth limiters) were created based on the specific tibial morphologic characteristics of the specimen. These 2 additional pieces were designed to clip onto the drill guide pictured in Figures 3 and 4 and create a "hard stop" for a length-standardized drill bit (Figure 5). This design allowed for a predetermined drill bit depth based on the preoperative plan and individual tibial width/depth.

The 3D model of the plate was created using the planning software based on the planned osteotomy size and the specific osseous anatomic feature of the specimen. Each computer numerical control machined plate had 3 holes for shaft screws and 3 holes for proximal screws. Screws, the lengths of which were determined based on tibial width and depth, were also created using the planning software. All cutting guides were 3D-printed for use during the study, with each specimen having a unique drill guide and fixation components.

Design of Traditional Instrumentation

Mockups of traditional freehand fixation were computer numerical control machined for the purposes of this experiment. The mockup hardware was created using commercially available HTO plates as a model. The hardware consisted of an 8-hole titanium plate with 4 shaft holes and 4 proximal tibial holes.

Groups

The 16 specimens were randomized into 2 groups: (1) HTO using PSI (n = 8) and (2) traditional instrumentation (n = 8). Groups were matched based on laterality. Each surgeon was given 2 specimens from each group, such that each surgeon performed 2 HTOs with PSI and 2 HTOs with traditional freehand instrumentation.

Procedure

All procedures were performed by orthopaedic surgeons (A.R., A.F.V., M.A., T.F.) who were fellowship-trained in orthopaedic sports medicine, were experienced in osteotomy surgery, and had >5 years of practice as an attending orthopaedic surgeon. All procedures were performed at the same facility on 2 sequential days.

PSI. MOW-HTO was performed on each specimen as follows: a 10-cm incision was made on the anteromedial aspect of the proximal tibia. Skin and subcutaneous tissue were sharply divided to the level of the superficial medial collateral ligament. Subperiosteal dissection was carried down to the level of the anteromedial tibial cortex. The positioning device/drill guide of the PSI was then placed on the anteromedial cortex and pinned in place (Figure 6). Positioning was checked by means of fluoroscopy and cross-reference of the preoperative plan, which was made available to the surgeon throughout the case. The PSI drill guide and instrumentation-specific drill bits were used to sequentially drill the proximal tibia (Figure 7). The surgeon then used instrumentation-specific osteotomes sequentially to complete the osteotomy, taking care to preserve the hinge (Figure 8). The drill guides were then removed, and case-specific spacers were used to check the anterior, middle, and posterior-most gaps created from the osteotomy. The 3D-printed patient-specific plate was then placed and secured to the anteromedial tibia (Figure 9). Final postoperative fluoroscopic images were obtained. The wound was then closed in standard layered fashion.

Figure 6. Drill guide sitting atop the medial tibial cortex and secured with 30-mm pins.

Figure 7. Drill guide on the medial tibial cortex, with an additional depth limiter clipped onto the drill guide. Length of the drill sleeves was determined with a preoperative plan and was specific to each specimen.

Freehand. Dissection was performed in an identical fashion to the methods described above. Kirschner wires (K-wires) were placed in line with the approximate saw trajectory and desired osteotomy correction. This placement was then checked with fluoroscopy. If satisfied with K-wire placement, the surgeon began the osteotomy with a standard oscillating saw (Stryker Corporation), taking

Figure 8. Osteotome placed through slot of drill guide and malleted to complete the osteotomy.

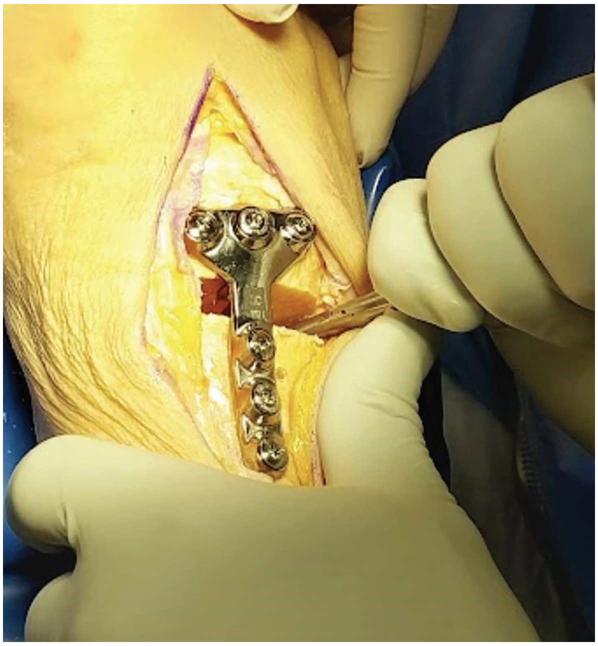

Figure 9. Patient-specific instrumentation plate secured on the medial tibia. Three screws were placed distal to the osteotomy, and 3 screws were placed proximally.

care not to penetrate the far cortex. The osteotomy was then completed with stacked osteotomes with the aid of laminar spreaders. The osteotomy height and width were checked with presized spacers and fluoroscopy. The mock-up anteromedial tibial plate was then secured to the anteromedial tibial cortex. Final postoperative fluoroscopic images were obtained. The wound was then closed in standard layered fashion.

Data Collection

Surgical time was measured for each MOW-HTO procedure as follows:

Start of procedure: The beginning of the case was defined as the time at which the surgeon began the incision.

Start of osteotomy: Defined in the PSI group as the point at which the positioning device/drill guide was placed on the anteromedial tibia. The beginning of the osteotomy for the freehand MOW-HTO group was defined as the point at which the referencing K-wire was inserted into the anteromedial tibial cortex.

End of osteotomy/beginning of fixation: Defined in both groups as the time at which the plate was placed on the anteromedial tibial cortex.

End of case: Defined in both groups as the time at which final fluoroscopic images were obtained and approved by the operating surgeon.

Fluoroscopy Use

For each MOW-HTO procedure, the total radiation dose for the medical staff (mGy), number of images obtained, and total time of fluoroscopy were recorded.

Measurement of Accuracy and Alignment Parameters

The final fluoroscopic images were used to obtain a radiograph-based medial proximal tibial angle (MPTA), which was compared with the preoperative images and plan. After closure of the specimens, each specimen was carefully preserved and transported to an imaging facility to obtain postoperative CT scans (Siemens). CT scans from hip to ankle were obtained of each specimen. DICOM (medical imaging extension) files from the CT scan were then sent to the researchers for processing. 3D reconstructions were created from the raw DICOM files. The following measurements were obtained from the postprocedure CT scans: (1) mechanical MPTA (mMPTA), (2) anatomic medial tibial slope angle (aMTSA), and (3) opening-wedge size. Two components were used to generate tibial slope measurements. The first was the tibial plateau disk; this disk was generated through an "automatic best-fit process" of the tibial plateau surface of the 3D models generated by the image segmentation process. It was possible for the software user to then manipulate the flexion-extension, coronal tilt, and height of the automatically defined disk. The second component was the tibial anatomic axis. Both the axis and the disk were projected onto the sagittal plane. The overlay process between the 3D models and full-length standing radiograph can change the tibial position and rotation relative to this sagittal plane. These elements reflect the standard lateral radiographic method for tibial slope measurement. Additionally, the opening-wedge size was measured at the maximum opening. These measurements were confirmed by a blinded independent analyst with 3 years of experience. These postoperative values were then compared with the planned values from the preoperative plan.

Statistical Analysis

Data analysis was performed using SPSS 23.0 software (IBM Corp). Comparisons were done on the means using *t* tests assuming unequal variances. Statistical significance was defined as $P < .05$.

RESULTS

Demographic Characteristics

Five male specimens and 3 female specimens were used for this study, with a mean age of 84 ± 10 years and a mean body mass index of 21.5 ± 6.2 kg/m^2. Seven of the specimens were White, and 1 specimen was American Indian/Alaska Native.

Accuracy and Alignment Parameters

The mean deviation from the planned wedge size was 0.505 mm in the PSI group compared with 3.016 mm in the freehand group ($P < .001$) (Table 1). The change in aMTSA in the PSI group was 0.34°, whereas the change in aMTSA in the freehand group was 0.60° ($P < .05$). The mMPTA was not different between the PSI and freehand groups (93.32° vs 93.83°, respectively; $P = .77$).

Radiation Safety and Fluoroscopy Use

The number of fluoroscopic images taken (15.5 vs 40.5 images; $P < .01$) (Table 2), total radiation dose (0.85 vs 2.04 mGy; $P < .01$), and length of exposure for the medical staff (18.75 vs 31.75 seconds; $P < .01$) were all significantly smaller in the PSI group compared with the freehand group, respectively.

Operative Time

The time required to perform the osteotomy was greater in the PSI group compared with the freehand group (15 minutes and 22 seconds vs 10 minutes and 33 seconds, respectively; $P = .01$) (Table 3). No significant differences were seen between the PSI group and freehand group in operative time (27 minutes and 51 seconds vs 26 minutes and 22 seconds; $P = .62$) or duration of fixation (9 minutes and 30 seconds vs 11 minutes and 0 seconds; $P = .38$).

Complications

One type 3 hinge fracture occurred in the PSI group, which propagated vertically into the weightbearing surface of the lateral tibial plateau. The osteotomy was in the appropriate position relative to the preoperative plan. This hinge axis for this specimen was in the appropriate position from the tibial plateau. No hinge fractures were noted in the freehand group.

TABLE 1
Postoperative Alignment Parameters[a]

Alignment Parameter	PSI	Freehand	*P*
Deviation from planned wedge size, mm	0.505 ± 0.68	3.02 ± 1.45	<.001[b]
Change in aMTSA, deg	0.34 ± 0.2	0.60 ± 0.25	.019[b]
mMPTA, deg	93.32 ± 3.04	93.83 ± 3.83	.77

[a] Values are expressed as mean ± SD. Wedge size is expressed as the absolute value of the deviation of the postoperative measured wedge size from the preoperative planned wedge size. The aMTSA is expressed as a deviation of the postoperative measured aMTSA from the preoperative measured aMTSA. The mMPTA is expressed as the postoperative measured mMPTA. aMTSA, anatomic medial tibial slope angle; mMPTA, mechanical medial proximal tibial angle; PSI, patient-specific instrumentation.

[b] Statistically significant, defined as $P < .05$.

TABLE 2
Procedural Radiation Use[a]

Radiation	PSI	Freehand	*P*
Shots, n	15.5 ± 11.25	40.5 ± 14.93	<.01[b]
Dose, mGy	0.85 ± 0.63	2.04 ± 0.95	<.01[b]
Length of exposure for medical staff, s	18.75 ± 13.19	31.75 ± 13.64	<.01[b]

[a] Values are expressed as mean ± SD. Shots represent the number of fluoroscopic images taken during the procedure. PSI, patient-specific instrumentation.

[b] Statistically significant, defined as $P < .0$.

TABLE 3
Efficacy Parameters[a]

Parameter	PSI	Freehand	*P*
Operative time	27:51 ± 5:58	26:22 ± 5:33	.62
Osteotomy duration	15:22 ± 4:00	10:33 ± 3:28	.01[b]
Fixation duration	9:30 ± 3:27	11:00 ± 3:12	38

[a] Values are expressed in minutes:seconds as mean ± SD. Operative time is the time from incision to attainment of final fluoroscopic images. Osteotomy duration is the time from placement of drill guide or insertion of guidewire to the time at which the plate was initially positioned on the tibia. Fixation duration is the time from placement of plate positioning to the attainment of final fluoroscopic images. PSI, patient-specific instrumentation.

[b] Statistically significant, defined as $P < .05$.

DISCUSSION

MOW-HTO is an important joint-preserving technique for knee pathology associated with varus alignment of the lower extremity at the knee. By altering the weightbearing axis of the lower extremity and preferentially directing joint forces through the lateral compartment, HTO can dramatically decrease contact pressures in the medial compartment. As such, considerable interest has been directed toward patients who have MOW-HTO with lower extremity malalignment and medial compartment disease, who are too young or are otherwise poor candidates for an arthroplasty procedure.

The success of MOW-HTO is critically dependent on an accurate correction of the weightbearing axis. Undercorrection of the mechanical axis results in continued medial compartment pathology.[18] Overcorrection into excess valgus can also have untoward effects on the health of the knee, specifically lateral compartment overload, anterior cruciate ligament degeneration, and worsened knee kinematics.[6,14,16] Multiple studies have demonstrated that traditional freehand methods have considerable shortcomings with regard to accuracy and precision. In a systematic review of 15 studies, Van den Bempt et al[19] demonstrated that coronal plane correction did not fall within the "acceptable" range of accuracy in 42% of cases with use of conventional freehand osteotomy methods.

In addition to showing poor accuracy and reproducibility of mechanical axis correction in the coronal plane, multiple studies have demonstrated that MOW-HTO via freehand methods often results in an increase in posterior tibial slope.[1,15,20] An increase in posterior tibial slope has been shown to increase forces across the native anterior cruciate ligament, with the potential for attenuation or injury.[3,5] Between inconsistencies in the coronal plane and unintended consequences in the sagittal plane, the need for improved methods for MOW-HTO is clear.

Our study corroborates the findings of cadaveric and clinical studies, demonstrating considerable variability in radiographic outcomes after MOW-HTO with traditional freehand methods. Additionally, our study suggests that the use of PSI can improve reproducibility and accuracy in the coronal plane. Furthermore, our study indicates that PSI results in a less dramatic, unintended alteration of sagittal plane alignment. Our data are consistent with a recent study by Miao et al,[11] who showed that PSI can accurately achieve a preoperative planned mMPTA, posterior slope angle, and opening-wedge size. Our data also corroborate the findings of Mao et al,[10] who performed a prospective comparative study in patients who underwent MOW-HTO by means of PSI or conventional freehand techniques. Mao et al found that mMPTA deviated less from the planned postoperative mMPTA in patients who underwent MOW-HTO with PSI. Their study is of value, because they were able to demonstrate superior Lysholm and International Knee Documentation Committee scores at 3 months, which suggests that the improved accuracy of PSI likely has a meaningful clinical impact as well.

With regard to posterior tibial slope, our data suggest that PSI may help prevent the unintended change of posterior slope when an MOW-HTO is performed for an isolated coronal plane correction. With non-PSI plates, the slope could be changed and the standard proximal tibial locking plate has no way of ensuring appropriate relative position of the tibia proximal and distal to the osteotomy site. However, if the slope were changed when the osteotomy was started, the PSI plate would not fit properly and should indicate the unintended change. This is of particular importance in the context of an abundance of data demonstrating the importance of posterior tibial slope to knee stability and anterior cruciate ligament injuries. Our findings are consistent with those of Liu et al,[8] who showed that the magnitude of unintended posterior tibial slope change was significantly lower in PSI compared with freehand techniques. The introduction of secondary iatrogenic pathology is clearly an undesirable outcome, and PSI offers a potential way reduce this. Clinical outcomes research with long-term follow-up would be needed to ascertain whether these differences in accuracy would have a substantial clinical impact.

Our study showed that fluoroscopic use is considerably less when PSI is used. The potential benefits of fluoroscopy include less radiation exposure to the surgical and anesthesia teams and less reliance on radiographic technicians. These findings are again consistent with those of Mao et al,[10] who showed that radiation duration and dose exposure were significantly lower when PSI was used compared with freehand methods. Given that several studies have demonstrated increases of illnesses such as cataracts and malignancies as a result of cumulative radiation exposure in surgical staff,[1012] these findings are an important consideration for surgeons who perform a high volume of MOW-HTOs.

Limitations

Our study had several limitations. Although we were able to effectively measure several alignment parameters, other variables that require weightbearing for accurate measurement (ie, hip-knee-axis, mechanical axis deviation) could not be ascertained in our cadaveric model. An effective, validated method for simulation of weightbearing for the measurement of these variables in cadaveric models is of particular interest and will be an area of future study. Further, our study lacked power to detect uncommon but important differences in complications, such as hinge fracture. There was indeed a hinge fracture in the PSI group; however, the effect of randomness is amplified in small sample sizes and the fracture could have happened in either system due to random chance. Iatrogenic fractures are rare but known complications of HTO, and our sample sizes were too small to infer a legitimate difference in fracture risk between the 2 systems. There also was not a clear difference in the hinge point's proximity to the articular surface that could explain this hinge fracture. Furthermore, having only 1 blinded observer for the measurements limited the generalizability of our data. This will be an important goal for future studies on this topic; however, power will likely consistently be a limitation, perhaps requiring multicenter or retrospective studies or meta-analyses to appropriately detect any differences in rare complications between PSI and freehand methods. Additionally, PSI itself has the limitation of costing 2 to 3 times as much as freehand instrumentation. However, PSI comes with the additional advantage of allowing staff to preplan reconstruction cases and multilevel correction without changing the cost. Last, the lack of ability to effectively blind the surgeons, given the different appearance and technique between freehand and PSI systems, introduced a possible source of bias. Clinical studies with larger sample sizes and long-term follow-up are necessary to compare clinical benefits in the face of these limitations.

CONCLUSION

PSI offered more accurate and more precise methods to perform MOW-HTO compared with traditional freehand methods, while reducing radiation exposure for medical staff and without sacrificing operative efficiency.

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