Technical Note

Three-Dimensional Patient Specific Instrumentation and Cutting Guide for Medial Closing Wedge High Tibial Osteotomy to Correct Valgus Malalignment

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Abstract: Achievement of appropriate mechanical knee alignment is crucial to ensure optimal clinical outcomes following osteotomy procedures about the knee. The use of patient-specific instrumentation (PSI) to assist in preoperative planning and intraoperative realignment has gained increasing popularity. The purpose of this article is to describe a surgical technique involving a medial closing wedge high tibial osteotomy performed using three-dimensional (3D) PSI and cutting guide to revise residual valgus deformity following failed distal femoral osteotomy. The correction angle, 3D position of the hinge and wedge, as well as final plate and screw position are planned preoperatively using virtual software and computed tomography imaging to allow precise surgical execution.

Introduction

Osteotomies about the proximal tibia and distal femur are used for the treatment of symptomatic coronal plane malalignment of the knee.[1] Advancements in orthobiologics and cartilage restoration techniques have increased the popularity of knee preservation procedures to prevent early-onset osteoarthritis (OA), while preserving the native knee, especially in younger patients.[2] Regardless of technique, the achievement of proper mechanical alignment is essential to ensure maximal clinical outcomes.[3-5]

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Valgus malalignment of the knee has been shown to cause pain and discomfort, while increasing the risk of lateral meniscal and chondral injury, resulting in early-onset and progressive OA.[6,7] Mechanical realignment has been shown to reduce pain and increase function, while delaying the need for arthroplasty, especially in young and active patients.[8–10] Valgus malalignment of the knee is generally corrected using a medial closing wedge or lateral opening wedge distal femoral osteotomy (DFO).[11] A biomechanical study by Wylie et al. reported that the decrease in lateral compartment pressures following DFO occurred primarily in full extension, with no effect at 90° of flexion and beyond.[12] Meanwhile, performance of a high tibial osteotomy (HTO) to the proximal tibia, has been shown to decrease joint contact pressures during both knee flexion and extension in patients with valgus malalignment.[13] However, HTO is generally reserved for mild corrections measuring less than 12° in the coronal plane,[14–16] leading to gradual lateral tibial subluxation when used for larger corrections.[14,16,17]

The introduction of computer-assisted navigation (CAN) to assist in preoperative planning and intraoperative realignment has gained popularity.[18] CAN offers the advantage of enhanced accuracy and precision of correction angles in real-time when compared to conventional techniques.[18] Furthermore, multiple studies have reported improvement in postoperative alignment using CAN in patients undergoing osteotomies about the knee.[19–22] Although effective in measuring the global alignment of the limb, CAN has not been shown to be effective in controlling tibial alignment or posterior tibial slope.[23] As a result, prior studies have cited the need for patient-specific instrumentation (PSI) to aid surgeons in managing multiplanar deformities.[23–25]

The purpose of this Technical Note is to describe a step-by-step surgical technique of a medial closing wedge high tibial osteotomy (MCW-HTO) performed using three-dimensional (3D) PSI and cutting guide to correct residual valgus deformity in a patient following failed prior DFO.

Preoperative Evaluation and Planning

Standard full-length anteroposterior (AP) radiograph views of the lower extremities are obtained to visualize the hip, knee, and ankle to allow for coronal plane analysis, which is determined by the distance of the lower limb mechanical axis from the center of the knee joint. A detailed coronal plane deformity analysis is then performed, according to malorientation test principles described by Paley et al.[26] (Fig 1) The native mechanical axis is located 8 ± 7 mm medially from the center of the knee joint. Varus deformity is present when the mechanical axis lies medial to the normal range, while a valgus deformity is present in the setting of lateral displacement.

To determine whether the deformity originates from the tibia or femur, the angle between the tibial and femoral mechanical axis and knee joint line is calculated (Fig 1). The normal limit of this angle is 87.5 ± 2°. As such, a lateral distal femoral angle (LDFA) greater than 90° indicates a varus deformity, while an angle less than 85° indicates a valgus deformity (Fig 1B). Similarly, a medial proximal tibial angle (MPTA) less than 85° represents a varus deformity, while an angle greater than 90° indicates a valgus deformity (Fig 1C). Intraarticular alignment can be assessed using the joint-line convergence angle (JLCA), defined as the angle created from a tangential line between the femoral

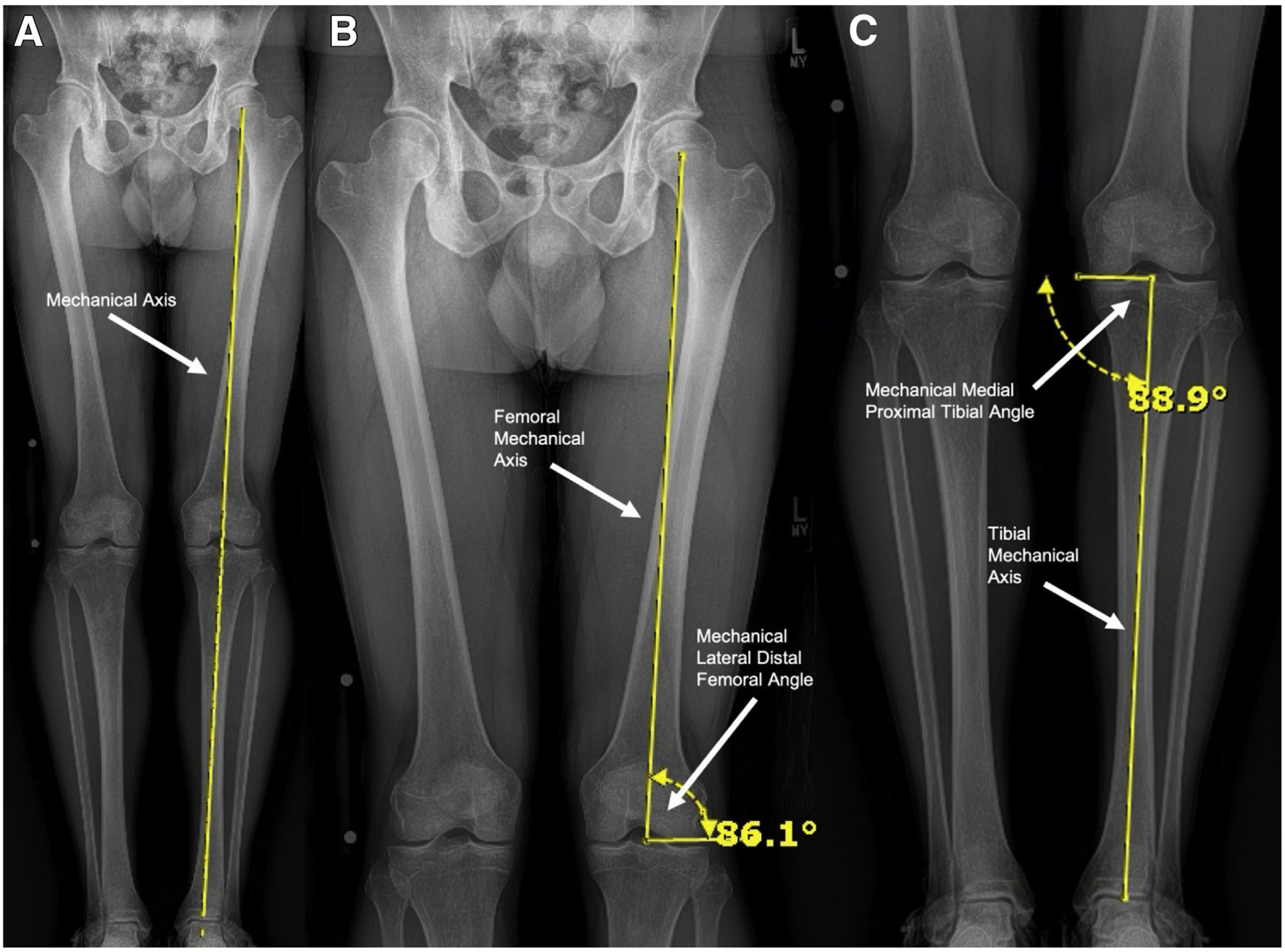

Fig 1. Full-length anteroposterior (AP) radiograph demonstrating neutral mechanical axis of a normal left limb (A), AP radiograph with mechanical axis of a left femur and corresponding mechanical lateral distal femoral angle within normal limits (85° to 90°) (B), AP radiograph with mechanical axis of a left tibia and corresponding mechanical medial proximal tibial angle within normal limits (85° to 90°) (C).

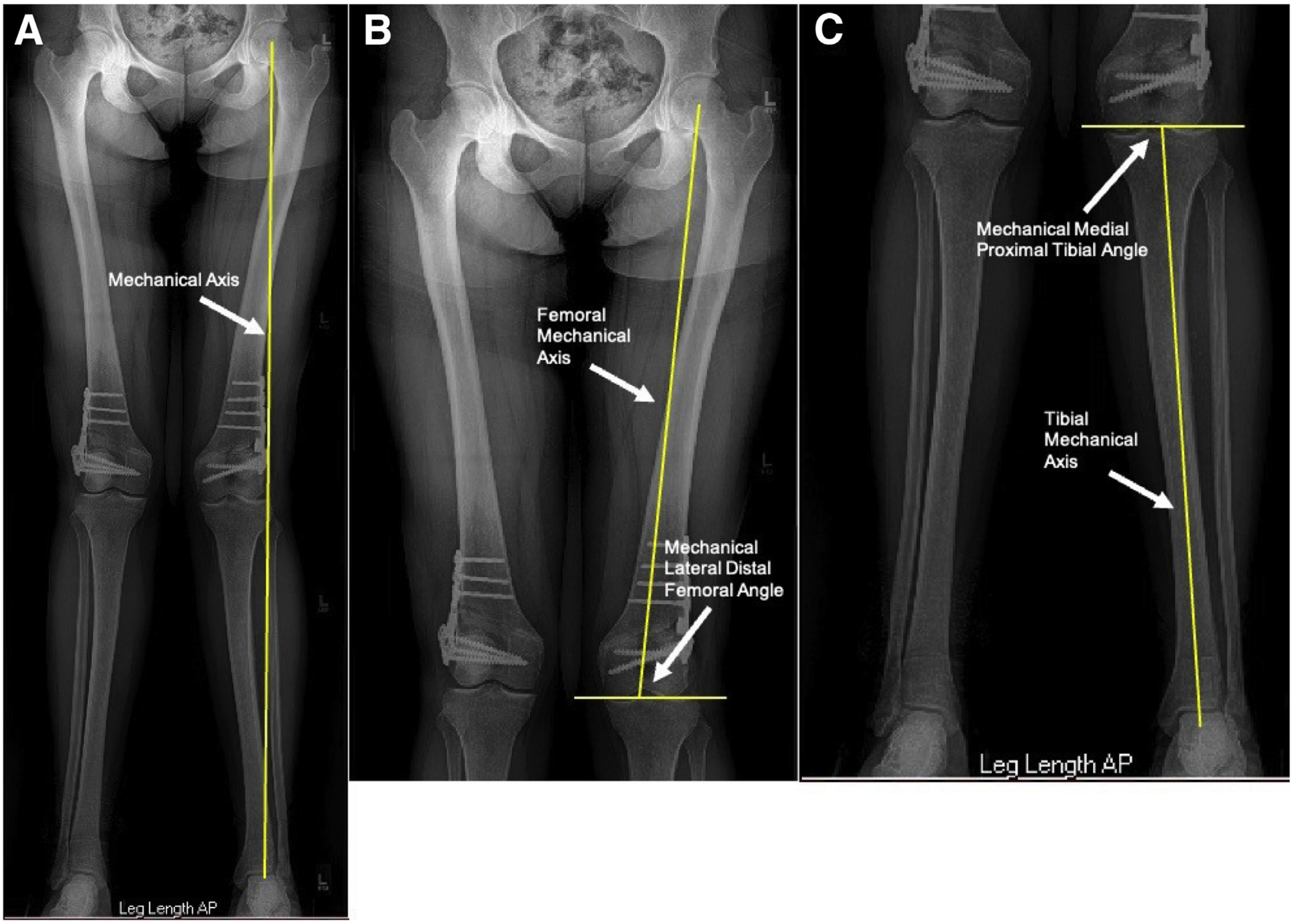

Fig. 2. Full-length anteroposterior (AP) radiograph with mechanical axis of our patient's abnormal left limb demonstrating persistent valgus malalignment with evidence of previous bilateral opening wedge distal femoral osteotomies (A), AP radiograph with mechanical axis of the left femur and corresponding mechanical lateral distal femoral angle (B), AP radiograph with mechanical axis of the left tibia and corresponding mechanical medial proximal tibial angle (C).

condyles and tibial plateau. A JLCA angle measurement greater than 2° is indicative of intraarticular deformity.

Calculating the degree of correction desired begins with identifying a point 62.5% of the width of the tibial plateau.[27] A line is drawn from this point to the center of the femoral head and another to the center of the ankle joint. The angle formed between these two lines determines the correction angle that will restore neutral leg alignment.

Computed tomography (CT) scans of the lower extremity, including the hip, knee, and ankle joints, are obtained preoperatively to help determine deformities outside of the coronal plane. Specifically, CT scan is obtained to verify the tibial slope, correction parameters for desired alignment, final plate position, and 3D position of the hinge and wedge. As 3D planning is essential to create the patient-specific cutting guide (PSCG), these CT scans in addition to weight-bearing, full-length radiographs of the operative lower extremity are then sent to Newclip. The surgeon is also responsible for providing Newclip with the desired osteotomy correction angle. Using NewClip proprietary software (Newclip Technics, Nantes, France), engineers from the company simulate a virtual MCW-HTO to determine the exact planes of the osteotomy cuts, as well as the size of the wedge to achieve the desired correction angle. A virtual Activmotion plate (Newclip Technics, Nantes, France) is then placed over the closed wedge to identify the desired positions of the screw holes on the plate. The software determines the exact length of each guide pin, as well as each screw, with respect to the patient's unique anatomy. Once complete, the surgeon reviews the simulated case for accuracy and approval. Finally, the CT scans are used by Newclip to manufacture the PSCG (Activmotion PSI; Newclip Technics, Nantes, France) to match the patient's unique bony anatomy.

Technique

Patient Positioning and Anesthesia

Following induction of general anesthesia, a thorough physical exam of both knees is performed. With the

Table 1. Pearls and Pitfalls

Pearls	Pitfalls
Radiolucent retractor should be used to ensure that fluoroscopy can identify the correct location of the guide, pins, and depth of saw blade.	There is a risk of neurovascular injury if care is not taken to protect the posterior knee structures.
Marking the saw blade with preplanned depth of cut will minimize risk of disruption to the lateral cortex.	Care must be taken to avoid a lateral hinge fracture; otherwise, instability at the osteotomy site may result in delayed union, nonunion, or loss of correction requiring additional surgeries.
Preoperative deformity analysis is key to correctly identify the osteotomy site (tibia versus femur) and type of osteotomy (closing versus open).	
Preoperative surgical planning is important to achieve the desired degrees of correction.	
Oblique K-wire placement provides protection against damage to the far cortex.	
An osteotome can be used if the osteotomy cut is incomplete or if any residual posterior/anterior cortex remains.	
Use of a long, radiopaque rod can be used to assess the mechanical axis and verify adequate correction.	

patient in a supine position, a padded thigh-high tourniquet is placed onto the operative leg. The patient is positioned on the operative table to allow for unrestricted fluoroscopy to be obtained from hip to ankle without artifact. Appropriate antibiotics are provided prior to surgical incision.

Surgical Technique

The surgical technique is demonstrated in Video 1, and the preoperative full-length radiographs are demonstrated in Fig 2. Surgical pearls and pitfalls of this surgical technique are summarized in Table 1. A vertical 10-cm incision is made over the anteromedial cortex of the tibial surface, starting approximately 1 cm distal to the tibiofemoral joint line. The soft tissue is then dissected down to the hamstring tendons. The sartorial fascia is incised to expose the underlying gracilis and semitendinosus tendons, which are then elevated together as a flap. Dissection is carried down to the anteromedial aspect of the tibia, while avoiding devascularization of the hamstring flap. The distal aspect of the patellar tendon and the superficial medial collateral ligaments (MCL) are identified and protected from disruption using two retractors. Subperiosteal dissection is performed using a Cobb elevator on the anterior aspect of the tibia under the infrapatellar bursa and patellar tendon. It is important to note that osteophytes and/or any bony irregularities should not be removed

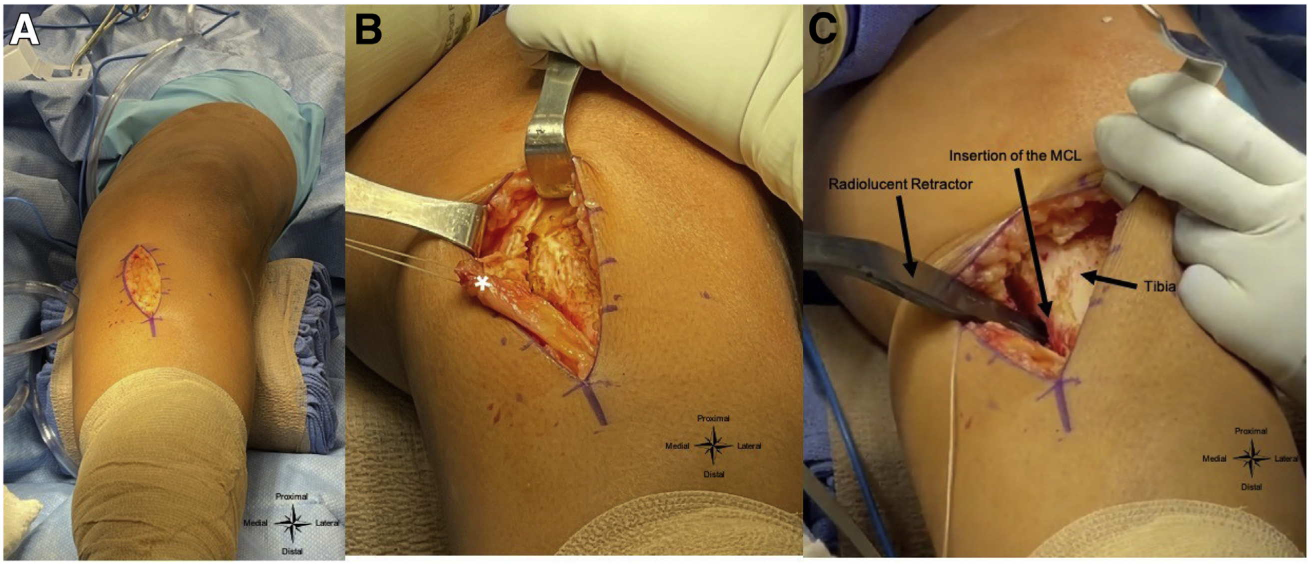

Fig 3. Incision over the anteromedial tibial surface of the left leg, starting approximately 1 cm distal to the tibiofemoral joint line (A). After the hamstring tendon is elevated off the left tibia, 2-0 Ethibond sutures are placed through the tendon complex to allow for retraction (B). A radiolucent Hohmann retractor is placed posterior to the medial collateral ligament (MCL) to expose the anteromedial aspect of the left tibia for placement of the patient-specific cutting guide (C).

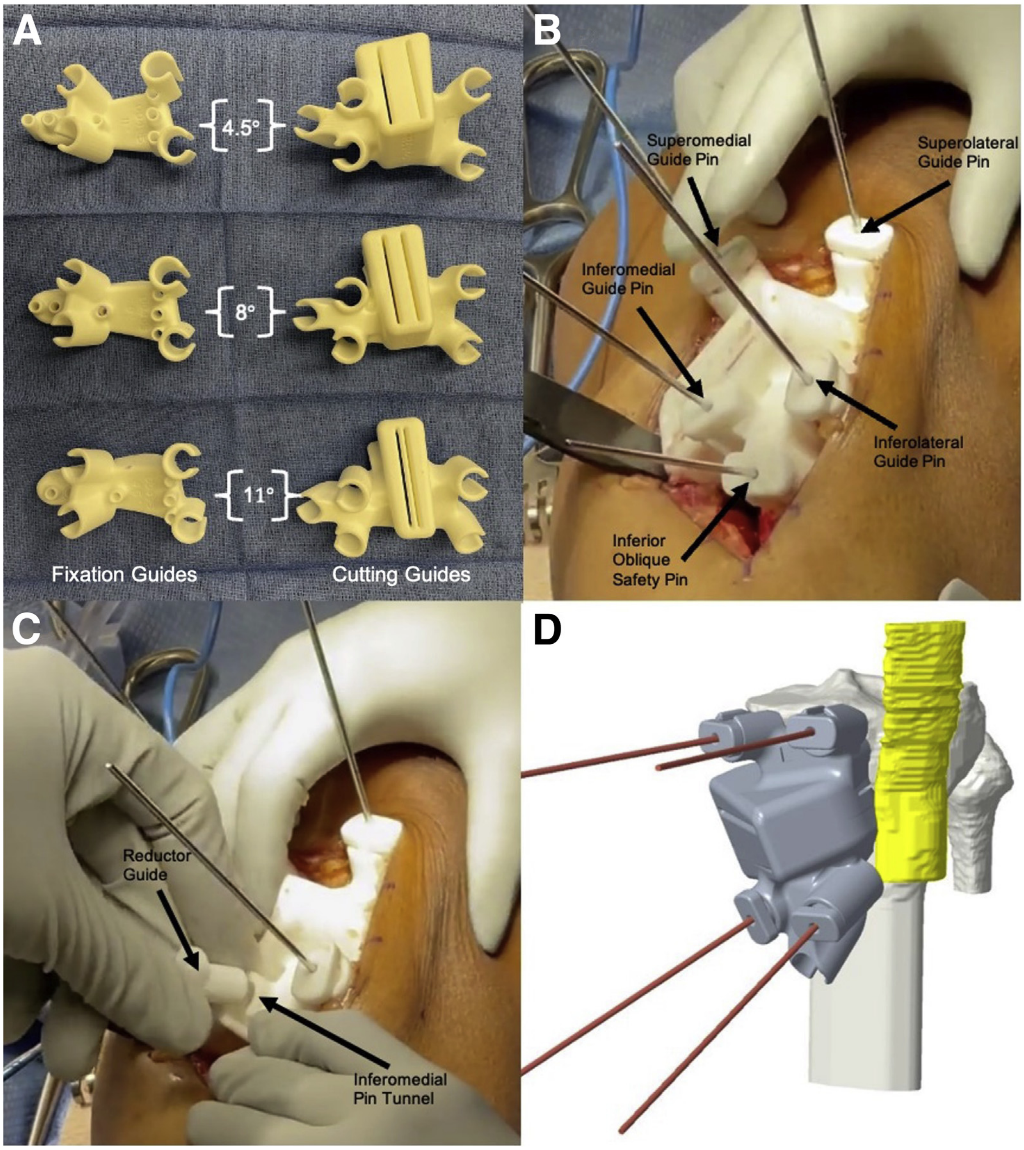

Fig 4. Fixation guides with corresponding cutting guides for three different options (4.5°, 8°, and 11°) of correction (A). Cutting guide placement with five guide pins used to secure the guide to the anteromedial aspect of the left tibia (B). Insertion of the reductor guide into the inferomedial pin tunnel (C). Three-dimensional (3D) virtual planning model used to verify correct placement of the guide onto the anteromedial aspect of the left tibia (D).

as the PSCG is customized to the patient's unique bony anatomy. Subperiosteal dissection is then performed on the posteromedial aspect of the tibia, deep to the superficial MCL. Next, a radiolucent Hohmann retractor (Innomed, Savannah, GA) is placed posterior to the MCL and anterior to the popliteus muscle to protect the neurovascular bundle while exposing the anteromedial surface of the tibia (Fig 3).

The PSCG is then positioned onto the anteromedial tibia, ensuring no soft tissue interposition between the guide and the bone. The superior margin of the guide is positioned directly distal to the joint line. Fluoroscopy is recommended to confirm correct positioning of the PSCG by matching the intraoperative position with the preoperative computer-generated planning. Once proper cutting guide placement in the coronal and sagittal plane is confirmed, the reductor guides are inserted into each pin tunnel to ensure accurate trajectory of the pins. The reductor guides are small cylindrical devices that fit into each tunnel of the cutting guide and center the pin to avoid an eccentric trajectory. After insertion of these devices, four guide pins are inserted to secure the cutting guide to the tibia (Fig 4). A customized indicator is present on each pin that is measured preoperatively to ensure that the length of each pin does not exceed the distance to the lateral cortex, minimizing the risk of cortical violation and injury to the posterolateral structures of the knee. The fifth and final pin is inserted in the inferior-most tunnel and follows an oblique trajectory proximally toward the posterolateral corner of the tibia, resting 10-11 mm from the lateral cortex and serving as a safeguard against the saw blade disrupting the cortex. This minimizes the risk of creating too deep a cut, increasing the

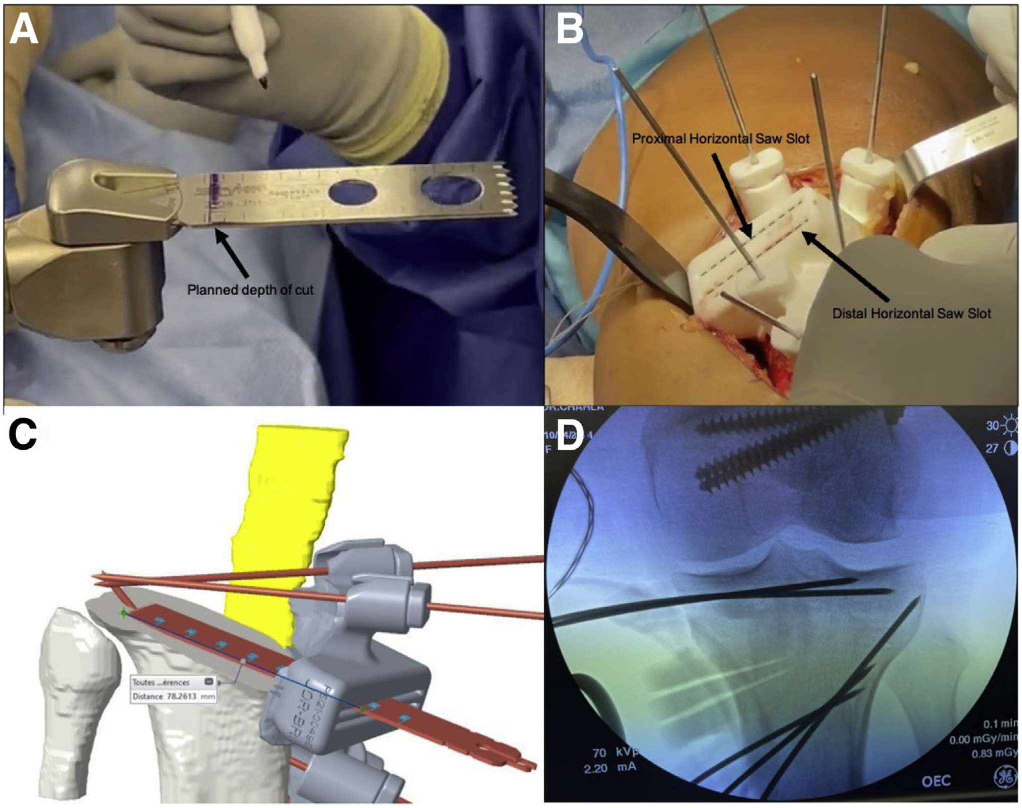

Fig 5. Example of marking the saw blade with preplanned depth of osteotomy cut to minimize risk of disrupting the far tibial cortex (A). Cutting guide showing the proximal and distal horizonal saw slots secured to the anteromedial aspect of the left tibia (B). Three-dimensional virtual planning model demonstrating desired length of the proximal saw blade osteotomy cut (C). Anteroposterior fluoroscopy of the proximal left tibia showing distal and proximal osteotomy cuts prior to wedge removal (D).

potential for a lateral hinge fracture. Proper pin placement is confirmed with fluoroscopy.

With the PSCG secured onto the tibia, a 1.19-mm thick oscillating saw blade is used to begin the proximal osteotomy through the proximal slotted capture of the PSCG into the medial cortex. The distance from the end of the saw blade to the origin of the PSCG is calculated during preoperative virtual planning to ensure that the desired distance of the cut is achieved without disrupting the integrity of the lateral cortex. (Fig 5, A-C) The second cut is then made through the distal slotted capture of the PSCG, again visualizing the desired preset depth on the saw blade. Fluoroscopy is used following both cuts to verify correct positioning and confirm that a lateral bony hinge of at least 1 cm thick is maintained (Fig 5D). Lateral hinge fractures have been shown to lead to instability at the osteotomy site, resulting in delayed union, nonunion, or loss of correction requiring revision surgery.[28]

Once both cuts are made and verified via fluoroscopy (Fig. 6*A*), the reductors and cutting guide are removed, as well as the inferior-most pin. A small osteotome is used to disengage the wedge from the lateral edge and to complete the osteotomy if any incomplete or any residual posterior/anterior cortex is present. A clamp can be used to remove the wedge and any remnant bone. The wedge is then closed by gently moving the distal tibia medially, while firmly holding the distal femur. After closing the medial wedge, leg alignment is confirmed intraoperatively by assessing the mechanical axis deviation using fluoroscopy. Because of the limited fluoroscopy view, a long radiopaque metallic rod can be placed over the operative leg (Fig 6B), with one end over the center of the femoral head (Fig 6C) and the other over the center of the ankle (Fig 6D) to allow for assessment of the mechanical axis across the knee. Desired correction is verified when the radiopaque rod passes through the center of the knee joint or slightly medially. Once confirmed, the fixating guide is then placed over the remaining four pins, followed by four reductors inserted into the two distal and two proximal pin tunnels. A 4.0-mm drill is used to create seven drill holes through the corresponding tunnels on the fixating guide (Fig 7). The appropriate length of each screw, calculated preoperatively using the CT scan and virtual software, is verified using the drill. The guide is then removed and the plate (Newclip Technics, Nantes, France) is placed along the medial cortex to fit the contour of the tibia. The plate is then secured distally with two 4.5-mm cortical screws, two 4.5-mm locking

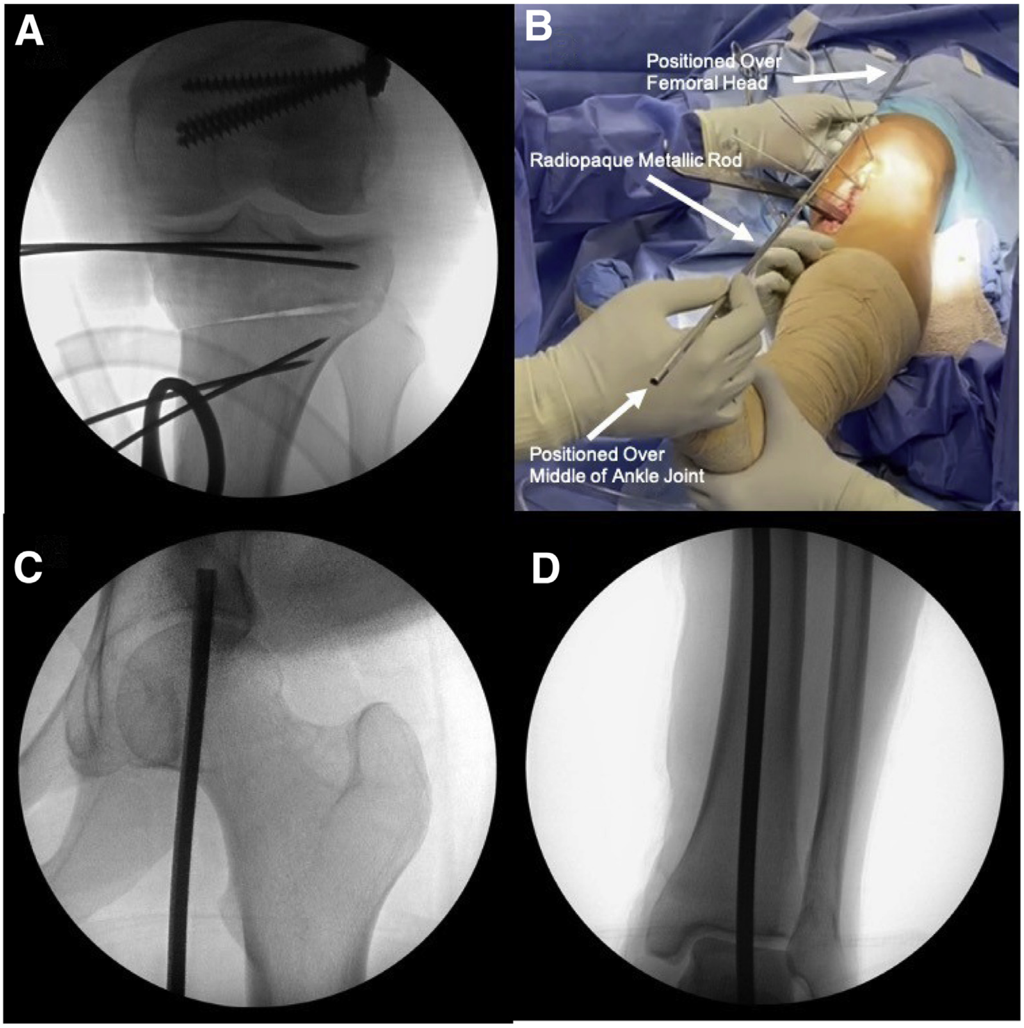

Fig 6. Anteroposterior (AP) fluoroscopy of the left knee following reduction of medial closing wedge high tibial osteotomy (A). Photo demonstrating the use of a long radiopaque metallic rod intraoperatively to assess mechanical axis of the left lower limb while in a supine position following osteotomy correction. The proximal tip of the rod is centered over the center of the left femoral head (C), while the distal end is centered over the middle of the left ankle plafond (D).

screws, and proximally with three 4.5-mm locking screws (Fig 8, A and B). Screw position and length are then confirmed fluoroscopically (Fig 8, C and D).

The wound is then irrigated, and the hamstring tendons are reattached using 2-0 Ethibond sutures, followed by deep-tissue closure in a layered fashion. The skin is closed in a standard fashion using absorbable suture. A sterile dressing is applied over the incision.

Postoperative Protocol

The patient is made non-weight bearing in a hinged knee brace locked in full extension until the first-operative visit 2 weeks following surgery. At 2 weeks, patients begin range of motion exercises to 90° of flexion, remaining non-weight bearing with crutches until 6 weeks postoperatively. At 3 to 4 weeks post-operatively, patients are expected to achieve knee flexion to at least 135°. After week 6, formal physical therapy is initiated, focusing on strengthening, including leg lifts and the stationary bike with limited resistance, with patients gradually progressing to squat exercises. Patients may begin high-impact activities such as jogging by 12 months.

Discussion

Proper restoration of the mechanical axis of the lower limb is crucial to improve and optimize clinical outcomes in patients with lower extremity malalignment.[29] Undercorrection errors are likely to cause persistent pain and may require additional surgeries, while overcorrection may lead to functional limitations.[23,30] Furthermore, studies have shown that even minor mechanical malalignment result in significant changes in load distribution through the knee joint, often resulting in early degenerative changes and dysfunction.[31,32] Hsu et al. reported in their biomechanical study that the medial compartment of the knee experiences 75% of body weight in 1o of varus malalignment as compared to 63% in neutral alignment.[31,33] As such, errors in cut angle increase the risk of eccentric loading, leading to hardware failure,

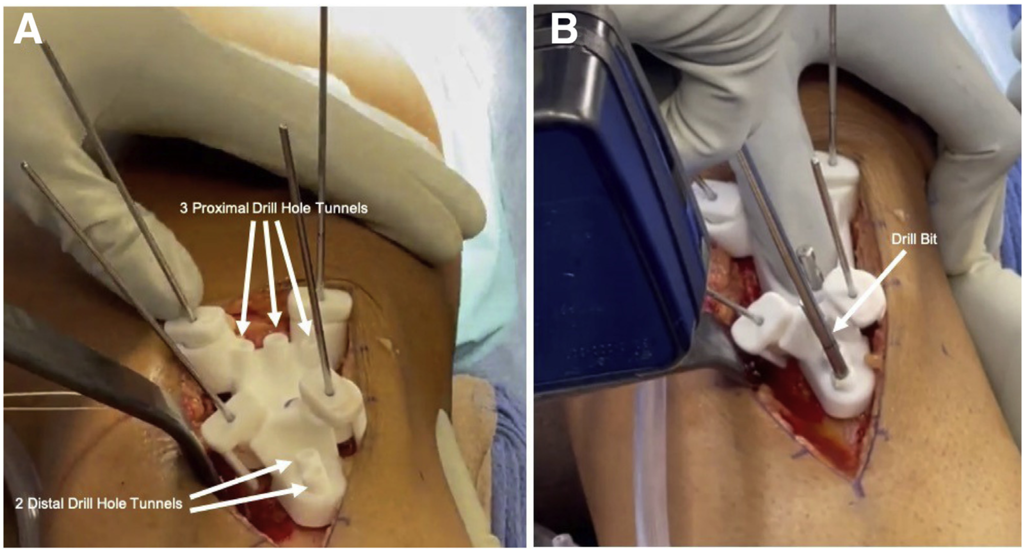

Fig 7. Photograph demonstrating the fixating guide secured in place over the anteromedial proximal left tibia with guide pins prior to drilling (A). 4-0 mm drill creating hole into the proximal left tibia through the distal drill hole tunnel of the fixating guide (B).

delayed union, or nonunion, as well as further degenerative changes.[34]

Traditionally, preoperative planning for osteotomies about the knee are performed using two-dimensional (2D) plain radiographs, restricting surgeons from appreciating the 3D anatomy of the knee.[24] Kawakami et al. identified errors using 2D methods for surgical planning of knee osteotomies by reporting the marked effect limb rotation has on the femorotibial angle and hip-knee-ankle angle. The authors concluded 3D surgical planning methods to be preferable, as they decrease the influence of limb rotation on lower limb alignment calculations.[35] Additionally, Victor et al. reported that traditional intraoperative instruments, such as rulers, calipers, and protractors, to be rudimentary and inaccurate, especially in cases of multiplanar or rotational deformities.[24]

Van den Bempt et al. performed a systematic review analyzing the accuracy of limb alignment correction using traditional methods versus CAN.[36] A total of 23 studies ($n = 966$ patients) were included, consisting of 552 ($n = 14$ studies) patients undergoing HTOs using traditional techniques versus 414 ($n = 9$ studies) patients undergoing HTOs using CAN. The authors considered a technique successful if at least 75% of the study population fell within the accepted range of accuracy (RA). It was reported that only 43% ($n = 6/14$; $n = 280$ patients) of patient groups treated with conventional techniques were successful. Meanwhile, 78% ($n = 7/9$) of patients undergoing osteotomies using CAN were reported as successful. Of the 306 ($n = 8$ studies), patients that underwent a conventional technique with reported incidence of under- or overcorrection, more patients were more likely to be undercorrected ($n = 56$ patients) than overcorrected ($n = 26$ patients). The authors concluded that CAN is a promising technique that may improve the accuracy of HTO correction, as compared to conventional methods.[36]

Clinical studies reporting on the accuracy of osteotomy corrections using PSCGs have reported superior outcomes when compared to conventional methods.[21,22,37] Munier et al. evaluated cut accuracy using PSCGs by analyzing postoperative 3D CT scans in 20 patients undergoing medial opening-wedge HTO. The authors reported that less than a 2° difference was observed in 19 of 20 patients when comparing planned versus achieved correction.[25] A similar study by Victor et al. enrolled 14 subjects who underwent osteotomies about the proximal tibia or distal femur with PSCGs created from preoperative CT scans. The accuracy of correction was evaluated using radiographs and, when necessary, CT scans at 3 weeks, 6 weeks, and 3 months following surgery. The authors reported 0° (range, $-1°$ to 1°) of difference in the coronal plane and 0.3° (from $-0.9°$ to 3°) in the sagittal plane.[24]

Use of PSCGs is not without limitation. Surgeons must be aware that the removal of osteophytes and other bony irregularities during dissection and exposure may lead to guide malpositioning, as the PSCG is modeled on the patient's unique bony anatomy at the time of imaging. As such, a relatively larger incision may be necessary to apply the PSCG correctly. A comprehensive list of advantages and disadvantages are detailed in Table 2.

Use of 3D PSCGs offers the benefits of virtual planning, allowing the surgeon to better visualize and appreciate the length and directionality of osteotomy cuts and hinge positions, especially in complex deformity cases. Preoperative planning also provides measurements of the length of guide pins, screws, and the

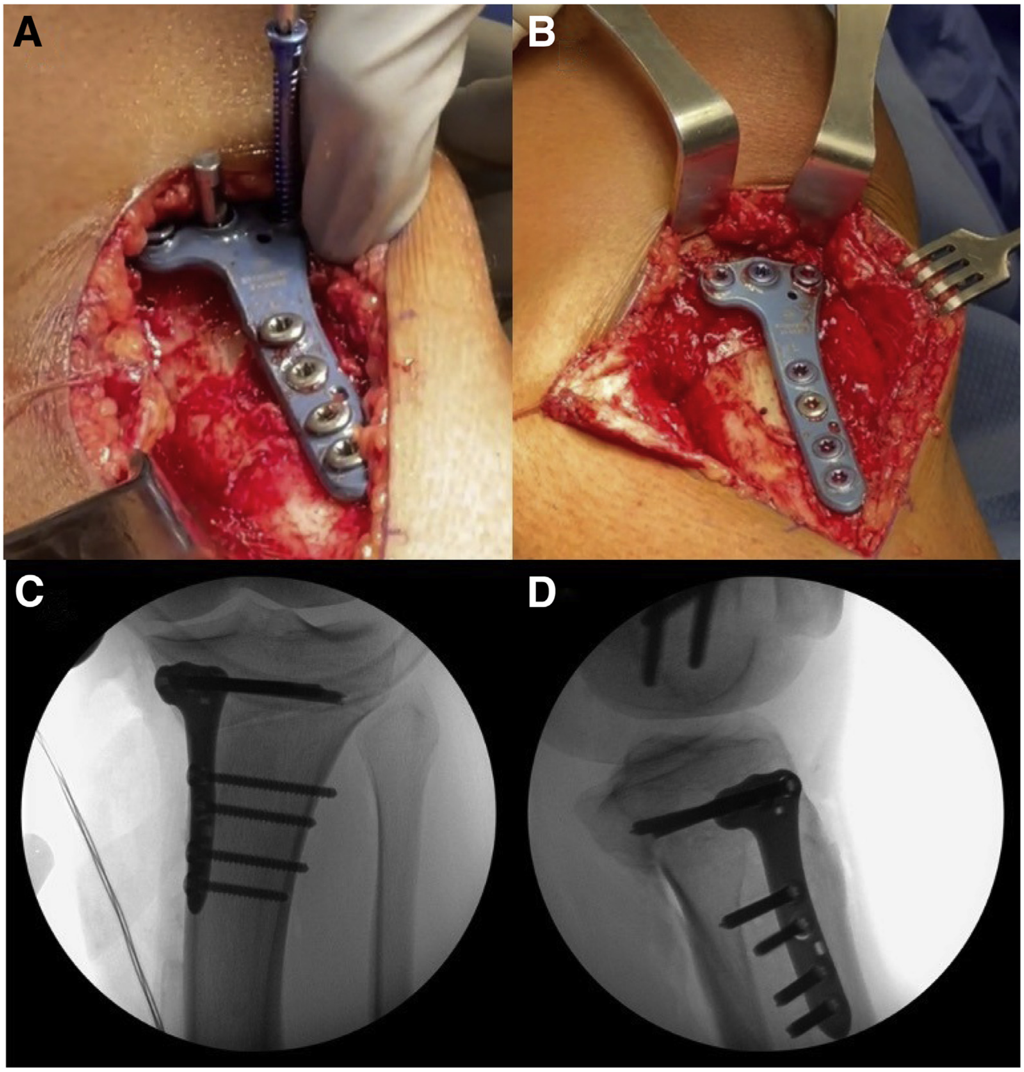

Fig 8. Securing plate to the anteromedial proximal left tibia with screw (A). Final placement of plate and screws on proximal anteromedial tibia prior to closure (B). Final anteroposterior (C) and lateral (D) fluoroscopy views of proximal tibia demonstrating hardware placement.

appropriate saw cut depth to minimize risk of iatrogenic injury to the posterior neurovascular structures, while preserving the integrity of the lateral hinge. While clinical studies are warranted, PSCG may improve precision in reproducing desired correction values, while eliminating variables traditionally associated with complications inherent to osteotomy procedures about the knee.

Table 2. Advantages and Disadvantages

Advantages	Disadvantages
Patient-specific guide is unique to the patient's unique bony anatomy.	Increased time to surgery pending the manufacturing of patient-specific guide
Three-dimensional preoperative planning allows the surgeon to determine accurately the location of saw blade cuts, depth of cuts, size of wedge, and screw sizes prior to surgery.	May require relatively larger incision to fit the patient-specific cutting guide correctly onto tibia
Increased precision of correction	Lack of freedom to remove osteophytes or bony irregularities as the patient-specific guide is created according to preoperative computed-tomography scan
A variety of fixating guide sizes are available intraoperatively based on correction target.	
Decreased operative time	
Decreased fluoroscopy exposure	
Healing generally occurs within 4 weeks postoperatively.	

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