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Factors Affecting the Union of Opening Wedge High Tibial Osteotomy Using a Titanium Wedge Plate

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Background: Factors that can affect the success rate of high tibial osteotomy (HTO) include patient selection, surgical technique, type of fixation hardware, supplemental fixation, choice of bone graft, and rehabilitation protocol. The purpose of this study was to define the role of cortical hinge fractures in the risk of nonunion and collapse of opening wedge high tibial osteotomy.

Methods: A total of 60 patients (mean age, 40 years) who underwent 64 primary HTO procedures were identified from our operational database and observed at a mean follow-up of 2 years. Surgical correction was followed by immediate range of motion and a progressive weight-bearing protocol. Clinical and radiographic data were reviewed for patient demographics, bony union, cortical hinge fractures, loss of correction, and other complications.

Results: The average time to radiographic union was 14.8 weeks (range, 8-24). Loss of correction and/or collapse occurred in 6 cases (9.4%). Nine unrecognized cortical hinge fractures were retrospectively identified, of which 4 resulted in nonunion and collapse. We found a significantly higher incidence of unrecognized cortical hinge fractures in cases that collapsed (4/6, 66.7%) compared to cases that healed uneventfully (5/58, 8.6%) ($P=0.003$).

Conclusion: A high index of suspicion must be maintained intraoperatively and postoperatively to identify and treat unstable constructs that increase the risk of nonunion and collapse after opening wedge HTO. This study's patient series explores the relationship between cortical hinge fracture and patient outcomes in the clinical setting by demonstrating a significantly higher rate of collapse and nonunion with unstable constructs.

Keywords: *Bone transplantation, orthopedic fixation devices, osteotomy, tibia*

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INTRODUCTION

High tibial osteotomy (HTO) is an effective procedure for treating a variety of knee conditions, including degenerative arthrosis, idiopathic osteonecrosis, congenital and acquired deformities, ligament deficiencies, osteochondritis dissecans, and chondral lesions. The fundamental goals of the procedure are to unload diseased articular surfaces and to correct angular deformity at the knee.[1,2]

HTO was originally described as a laterally based closing wedge osteotomy of the proximal tibia (LCWHTO) and is used to treat symptomatic medial compartment arthritis of the knee associated with varus deformity in patients <60 years of age.[3] The LCWHTO technique provides a stable construct for weight-bearing and bony union but is associated with several problems including patella infera, lack of precision, proximal fibular osteotomy, disruption of the proximal tibiofibular joint, detachment of the extensor muscles, peroneal nerve injuries, and limb shortening.[2-6]

The medial opening wedge high tibial osteotomy (MOWHTO) was developed to avoid some of these complications and to allow the surgeon to adjust the coronal and sagittal alignment intraoperatively. However, known disadvantages of MOWHTO are the creation of a lateral cortical hinge fracture, hardware failure, iatrogenic fractures, delayed union, and nonunion.[3,6] Patient selection, surgical technique, type of fixation hardware, supplemental fixation, choice of bone graft, and rehabilitation protocol are factors that can affect the success rate of MOWHTO.[1,6]

The clinical success of total knee arthroplasty has resulted in fewer HTOs being performed,[7] yet the procedure remains useful and effective in the appropriate patient.[2] In the past decade, we have seen a resurgence in the use of MOWHTO as a treatment option for several reasons: the prevalence of physiologically young active patients presenting with medial compartment osteoarthritis, improved instrumentation and fixation techniques, and the need for an unloading procedure when performing cartilage restoration.[1,2]

The purposes of this study were to report the results of our series with opening wedge HTO and compare them to the literature and to define the role of cortical hinge fractures. We hypothesized that the risk of nonunion and collapse is directly related to fracture of the cortical hinge during surgery and the resulting unstable construct.

METHODS

After obtaining institutional review board approval, we queried our existing operational database for all cases of HTO performed at the participating institutions by the senior author (D.G.J.). The indications for this procedure were knee malalignment, instability, degenerative arthrosis, and chondral lesions in patients who failed conservative treatment and wished to maintain or regain an active lifestyle. Symptomatic patients wishing to lead a more sedentary lifestyle were instead considered for unicompartmental arthroplasty.

Study Population

Inclusion criteria for this study were patients who underwent primary MOWHTO or primary lateral opening wedge high tibial osteotomy (LOWHTO) performed with the Arthrex, Inc. second-generation locking titanium tibial osteotomy plate (Figure 1) or with the first-generation Arthrex, Inc. nonlocking titanium tibial osteotomy plate. Exclusion criteria were revision HTO, osteotomies fixed with the nonlocking stainless steel plate or other devices, insufficient radiographic or clinical follow-up, insulin-dependent diabetes mellitus, and use of exogenous steroids. Patients who underwent concomitant or staged procedures such as ligament reconstruction, cartilage restoration, or meniscal allograft transplantation were not excluded from this study.

Figure 1. Second-generation locking titanium tibial osteotomy plate. Reproduced with permission of Arthrex, Inc.

Between November 2004 and April 2009, the senior author performed 85 consecutive MOWHTO and LOWHTO procedures. Twenty-one cases were excluded for meeting the exclusion criteria. The remaining 64 cases were studied to assess the union rate and to identify risk factors for nonunion and/or collapse of the construct. The indications for HTO in this group included chondral lesions, meniscal deficiency, osteoarthritis, instability, osteochondritis dissecans, and posttraumatic deformity (Figure 2). Demographic data were obtained from most patients at the time of initial evaluation, including sex, age, body mass index (BMI), and smoking history. Surgical technique was consistent for all patients, including fluoroscopic guidance, creation of the osteotomy, hardware implantation, and postoperative care and rehabilitation. To minimize any difference in surgical technique, all operations were performed by the same surgeon. No changes were made to the surgical technique or to patient care for the purposes of this study.

Radiographic Evaluation

The senior author performed serial clinical and radiographic evaluations of each patient. Clinical signs used to

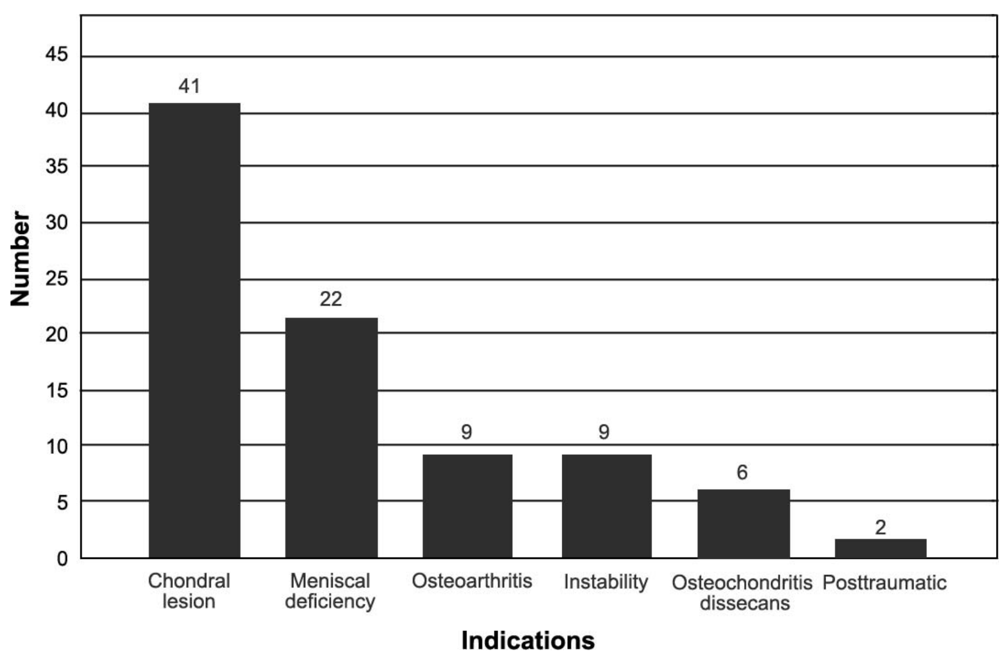

Figure 2. Indications for high tibial osteotomy in our study group. Some patients had more than one indication.

assess healing were pain, warmth, and swelling at the osteotomy site. Radiographic examinations involved anteroposterior (AP) and lateral radiographs of the operative knee at regular intervals. Signs of union at the osteotomy site were increasing density of the graft on serial examination and bone bridging across the wedge opening (Figure 3, right knee). Nonunion for this study was defined as radiographic evidence of lucency or sclerotic margins at the osteotomy site 6 months after surgery, as well as collapse of the construct or hardware failure (Figure 3, left knee).

Preoperative full-length standing AP radiographs of both lower extremities were obtained for all patients. The mechanical axis was delineated and used to calculate the amount of correction needed to unload the diseased knee compartment (Figure 4).

Operative Procedure

Regional anesthesia was administered in the preoperative holding area. Preoperative antibiotic prophylaxis was given, and general anesthesia was administered in the operating room. The patient was placed supine on a radiolucent operating table with a roll placed under the hip to obtain a true AP view of the knee joint. Following the standard sterile preparation and draping, arthroscopy was performed to address intraarticular pathology as necessary. The open portion of the procedure was performed with fluoroscopic guidance.

A linear incision was created along the medial aspect of the proximal tibia for MOWHTO. Electrocautery was used to extend directly down to the bone, and subperiosteal dissection was performed of layers 1, 2, and 3, releasing the medial collateral ligament's distal insertion from the tibia. A Hohmann retractor was placed posterior to the tibia to protect vital neurovascular structures. A guide pin was placed through a medial stab incision 1.5 cm distal to the subchondral bone plate and advanced parallel with the joint line to the lateral cortex. The guide system was then applied, and 2 oblique breakaway pins were advanced to the lateral cortex, converging on the initial guide pin. The cutting guide was placed directly over the breakaway pins and secured in place.

Figure 3. Radiograph demonstrates a well-healed osteotomy in the patient's right knee and a collapsed osteotomy in the left knee with failed hardware.

Figure 4. Full-length hip-to-ankle standing anteroposterior radiograph used to assess the mechanical axis of the lower extremities. The black line demonstrates the weight-bearing mechanical axis.

An 18-mm wide large bone oscillating saw was used to create an oblique osteotomy. A flat osteotome was used to advance the osteotomy to a point 10 mm from the lateral cortex. The lateral bony and periosteal hinge was piecrusted with a 3.2-mm drill bit to avoid fracturing the hinge in the following steps. Wedge osteotomes were used to carefully distract the osteotomy while monitoring the knee joint and lateral cortical hinge for fracture propagation. An extramedullary alignment guide was used to assess the

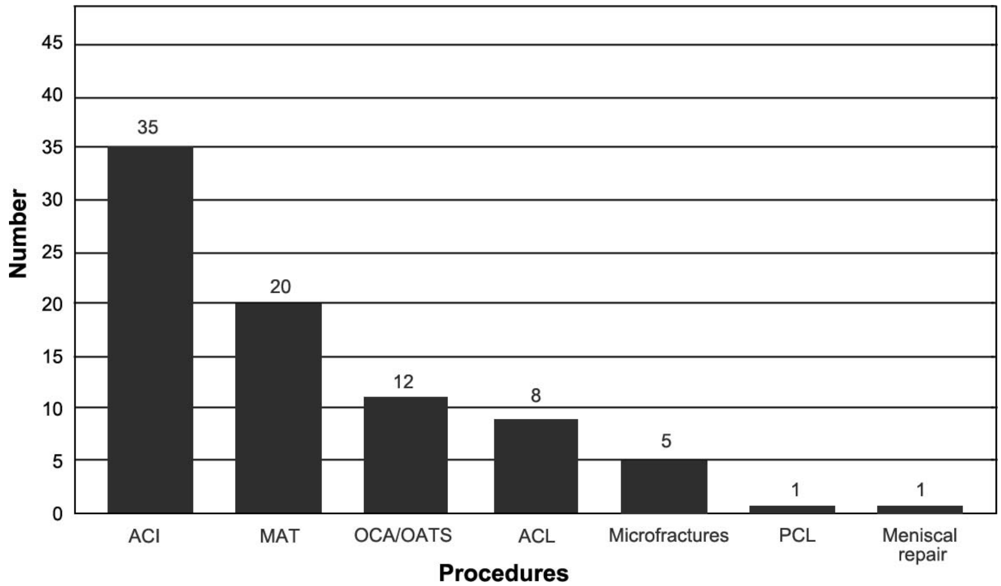

Figure 5. Frequency of concomitant and staged procedures performed in our patients. Some patients had more than one procedure. ACI, autologous chondrocyte implantation; ACL, anterior cruciate ligament reconstruction; MAT, meniscal allograft transplantation; OCA/OATS, osteochondral autograft transplantation/osteochondral allograft transplantation surgery; PCL, posterior cruciate ligament reconstruction.

mechanical axis of the lower extremity, and an appropriately sized titanium locking wedge plate was chosen. The plate was secured with locking screws. The first 10 patients received a first-generation Arthrex, Inc. nonlocking titanium tibial osteotomy plate, whereas the remaining patients in the series were stabilized with the second-generation locking titanium implant. The construct was assessed on AP, lateral, and oblique views. Corticocancellous wedge allografts were placed in the defect for $\geq$10-mm corrections. Demineralized bone matrix from the Musculoskeletal Transplant Foundation was applied to the osteotomy site. The incision was closed in layered fashion using VICRYL and MONOCRYL (Ethicon US, LLC) sutures followed by application of a compressive dressing. A hinged knee brace was applied in the operating room.

The LOWHTO was performed in a similar manner as the MOWHTO but produced a medial cortical hinge. An anterolateral incision was made over the proximal tibia, and the fascia over the anterior compartment was incised just lateral to the tibial crest. The musculature was elevated from the anterolateral surface of the tibia, and the procedure was completed as previously described but with the addition of a distal fibular osteotomy.

Postoperative Rehabilitation

A progressive weight-bearing protocol was implemented postoperatively for patients who did not undergo concomitant reconstructive procedures. Full range of motion was allowed immediately without the use of a continuous passive motion device. Patients were instructed to start with toe-touch weight-bearing not to exceed 25% of their body weight for the first 4 postoperative weeks. Partial weight-bearing of 25%-50% was allowed for the next 2 weeks. Weight-bearing as tolerated was allowed starting 6 weeks after surgery. Patients were instructed to wear a hinged knee brace for all upright or ambulatory activities for 4-6 weeks postoperatively. Full weight-bearing was delayed until 10-12 weeks after surgery in patients who underwent concomitant cartilage restoration or meniscal reconstruction. A commercial ultrasound bone stimulator (Exogen, Smith & Nephew) was used with all patients as part of the standard protocol. Patients who used tobacco products preoperatively were counseled and instructed to immediately discontinue the use of these products. Tobacco use was not monitored during the postoperative recovery period. Nonsteroidal antiinflammatory drugs were not allowed during the postoperative healing period.

Concomitant/Staged Procedures

The majority of the patients in our series underwent concomitant and/or staged procedures as part of their surgical treatment (Figure 5). This group included 35 autologous chondrocyte implantations, 20 meniscal allograft transplantations, 12 osteochondral allograft and autograft transplantation surgeries, 8 anterior cruciate ligament reconstructions, 5 microfractures, 1 posterior cruciate ligament reconstruction, and 1 meniscal repair. Concomitant reconstructive procedures required a conservative rehabilitation protocol as previously described. Staged procedures were performed after healing of the osteotomy and included removal of the plate.

Statistical Analysis

Analysis was performed to determine statistically significant differences between the group of osteotomies that united and the group that collapsed. Numerical variables assessed using *t* tests were demographic data such as age, weight, BMI, and the size of the correction. Categorical clinical variables were assessed using Fisher exact test because assumptions of the χ^2 test were not met. *P* values

<0.05 lay within 95% confidence interval and were considered significant.

RESULTS

A total of 39 males and 21 females, ranging in age from 14-57 years (mean age, 40 years) comprised the study population. Fifty-five procedures were MOWHTO, and 9 were LOWHTO. Four patients underwent bilateral procedures, so the total patients and cases were 60 and 64, respectively. Osteotomy size was 5-15 mm (mean, 8.4 mm). Follow-up was 3-56 months with a mean of 2 years. Overall, 58 of the 64 HTOs included in this study united during the follow-up period (90.6%). The average time to radiographic union was 14.8 weeks (range, 8-24 weeks). Loss of correction and/or collapse of the construct occurred in 6 cases (9.4%), of which 3 cases underwent revision osteotomy at a mean of 8 months (range, 6-9 months) after the index procedure. Revision consisted of hardware removal, correction of the deformity to match the alignment obtained immediately following the index procedure, and stabilization with a more robust locking plate.

Statistical analysis was used to compare the group of osteotomies that united with the group that collapsed or had loss of correction (Table). The demographic data were similar between the 2 groups, with no statistically significant differences in the distribution of sex, age, weight, BMI, or history of tobacco use. The average size of the correction was greater in the collapsed group (10.4 mm vs 8.2 mm), but this difference did not reach statistical significance (P=0.09). Tibial osteotomy was performed as an isolated procedure in 83.3% (5/6) of knees in the collapsed group vs 44.8% (26/58) of knees in the united group. Again, this difference did not reach statistical significance (P=0.10). Both MOWHTO 9.1% (5/55) and LOWHTO 11.1% (1/9) had an approximately equal chance of collapse according to our data, and the difference was not significant according to Fisher exact test ($P>0.99$). MOWHTO constituted 86.2% (n=50/58) of the united group and 83.3% (n=5/6) of the collapsed group. Corticocancellous allograft wedges were placed in the osteotomy in 20.7% (n=12/58) of the united group vs 50% (n=3/6) of the collapsed group (P=0.14).

The 2 groups were compared with regard to the incidence of cortical hinge fractures during or after the operation (Figure 6). A total of 11 cases of cortical hinge fractures were identified. Two of the 11 cases were identified intraoperatively and stabilized, resulting in a total of 9 (14.1%) unstable constructs in our series. Loss of the cortical hinge was found in 5/58 (8.6%) of the united group and 4/6 (66.7%) of the collapsed group. Using Fisher exact test, a statistically significant difference was noted between these 2 values (P=0.003). The rate of collapse and construct failure in the unstable group (patients with cortical hinge fractures) was 4/9 (44.4%), approximately 12 times higher

Table. Demographics and Statistical Analysis Data

	Mechanical Complication (collapse / loss of correction)			
Variable	**No**	**Yes**	***P* Value**	**Cases**
Age, years, mean ± SD	39.7 ± 10.9	45.2 ± 5.1	0.23	64
Body mass index, kg/m^2, mean ± SD	27.3 ± 5.2	28.9 ± 3.7	0.47	54
Weight, lb, mean ± SD	183.0 ± 47.4	183.3 ± 18.2	0.97	56
Plate size, mm, mean ± SD	8.2 ± 2.9	10.4 ± 4.0	0.09	64
Sex, n (%)			>0.99	64
Male cases	39 (67.2)	4 (66.7)		
Female cases	19 (32.8)	2 (33.3)		
Allograft, n (%)			0.14	64
No	46 (79.3)	3 (50.0)		
Yes	12 (20.7)	3 (50.0)		
Cortical hinge fracture, n (%)			0.003	64
No	53 (91.4)	2 (33.3)		
Yes	5 (8.6)	4 (66.7)		
Tobacco use, n (%)			0.66	59
No	39 (73.6)	4 (66.7)		
Yes	14 (26.4)	2 (33.3)		
Medial or lateral, n (%)			>0.99	64
Medial	50 (86.2)	5 (83.3)		
Lateral	8 (13.8)	1 (16.7)		
Combined procedure, n (%)			0.10	64
Yes	32 (55.2)	1 (16.7)		
No	26 (44.8)	5 (83.3)		

Numerical variables were assessed using *t* tests. Categorical variables were assessed using Fisher exact test because assumptions of the χ^2 test were not met. Body mass index, weight, and tobacco use data were not available in the medical record for some patients.

Figure 6. Radiograph shows a hinge fracture (completed osteotomy) without evidence of collapse or implant failure. Note the presence of the corticocancellous allograft bone wedge.

than the failure rate observed in the stable group (patients without cortical hinge fractures) of 2/55 (3.6%).

The overall reoperation rate for complications directly related to the osteotomy was 7.8% (5/64). Three cases required revision HTO because of nonunion and collapse. One patient was inadvertently overcorrected at the index procedure and required revision to readjust the mechanical axis of the lower extremity. Another case required incision and drainage for a deep infection 2 weeks after the index procedure. Wound cultures demonstrated the growth of *Staphylococcus epidermidis*. Two other cases required incision and drainage for deep infections following staged procedures well after their respective osteotomies united. We found no cases of subtle collapse or subsidence of bone at the osteotomy site and no cases of neurovascular injury, deep venous thrombosis, pulmonary embolism, or compartment syndrome. Hardware removal was performed in all patients who underwent staged reconstructive procedures.

DISCUSSION

The hypothesis for this study was that the risk of nonunion and collapse following opening wedge HTO is directly related to fracture of the cortical hinge during surgery. A complete fracture increases micromotion as well as shear and tensile forces on the construct that in turn decrease the threshold to implant failure. Our data demonstrate an approximately 12-fold increase in the rate of nonunion and collapse in cases without preserved integrity of the cortical hinge. Statistical analysis confirms that the collapsed group had a significantly higher percentage of breached cortical hinge compared to the united group. These findings stress the importance of maintaining the lateral cortex when performing this procedure and the crucial role played by the intact cortical hinge. Completed fractures should receive supplemental fixation.

Miller et al[8] demonstrated the effect of disruption of the lateral cortex in MOWHTO in a controlled laboratory study of 50 replicate tibias. Fracture of the lateral hinge resulted in a 58% reduction in axial stiffness and a 68% reduction in torsional stiffness compared to control specimens ($P<0.05$). Increased micromotion at the osteotomy site was observed. Repair of the lateral cortex with 3 different methods (1 staple, 2 staples, periarticular plate and screws) restored stiffness values to those of the control group. The Miller et al findings provide evidence that stabilizing a disrupted cortical hinge decreased the risk of mechanical complications in patients undergoing this procedure.

Nine of our 64 cases involved performing a LOWHTO for genu valgum associated with lateral compartment pathology. This specific technique is not commonly described in the literature because distal femoral osteotomy is typically performed in this setting. We prefer LOWHTO for correction in patients with valgus deformities because it unloads the lateral compartment in full extension and allows for correction in varying degrees of flexion. A varus-producing osteotomy of the distal femur has the advantage of avoiding joint-line obliquity but is biomechanically efficient only in full extension.[2] Performing a LOWHTO requires a fibular osteotomy to distract the lateral tibial cortex. We prefer to osteotomize the fibula at the junction of the middle and distal one-third, avoiding injury to the ankle syndesmosis. LOWHTO performed equally compared to MOWHTO in regard to mechanical complications in our study.

We used demineralized bone matrix in all osteotomy sites, as it is readily available and possesses both osteoconductive and osteoinductive properties. As previously stated, corticocancellous allograft bone wedges were used in osteotomy sites when the correction was ≥10 mm. Allograft was chosen over autograft in primary cases because of recent evidence of its efficacy in this type of procedure and the decreased donor site morbidity compared to autograft. Yacobucci and Cocking[6] reported a low incidence of nonunion (4%) in a consecutive series of 50 MOWHTO procedures using a corticocancellous proximal tibial wedge allograft in all cases. They instituted a conservative protocol postoperatively with weight-bearing delayed until 8 weeks after surgery in most cases. The delay was attributed to the use of allograft wedges as opposed to autograft. The authors determined that good results can be obtained with the use of an allograft that offers the benefits of less operative time, no donor site morbidity, and avoidance of graft harvest–related complications.

Interestingly, our data showed a higher percentage of isolated tibial osteotomy procedures in the collapsed group vs the united group. This higher percentage may be explained by the more aggressive return to full weight-bearing when weight-bearing was not restricted to protect a meniscal allograft or chondral implant. This difference, however, did not reach statistical significance.

Using data from a single surgeon series with all procedures performed with the same technique and a similar implant was a strength of this study. However, the use of allograft bone wedges was variable. The retrospective design of this study presents inherent limitations. Furthermore, clinical and radiographic assessment of bony union was subjective, as it was performed by a single examiner.

CONCLUSION

A high index of suspicion must be maintained intraoperatively and postoperatively to identify and treat unstable constructs that increase the risk of nonunion and collapse after opening wedge HTO. This study's patient series explores the relationship between cortical hinge fracture and patient outcomes in the clinical setting by demonstrating a significantly higher rate of collapse and nonunion with unstable constructs.

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