Suprapatellar Versus Infrapatellar Tibial Nail Insertion: A Prospective Randomized Control Pilot Study

Daniel S. Chan, MD, Rafael Serrano-Riera, MD, Rebecca Griffing, BSc, Barbara Steverson, RN, MHA, Anthony Infante, DO, David Watson, MD, H. Claude Sagi, MD, and Roy W. Sanders, MD

Purpose: The purpose of this OTA-approved pilot study was to compare the clinical and functional outcomes of the knee joint after infrapatellar (IP) versus suprapatellar (SP) tibial nail insertion.

Design: Prospective, randomized.

Setting: Level I trauma center.

Methods: After institutional review board approval, skeletally mature patients with OTA 42 tibial shaft fractures were randomized into either an IP or SP nail insertion group after informed consent was obtained. The SP also underwent prenail and postnail insertion patella-femoral (PF) joint arthroscopy. Patients underwent follow-up (6 weeks, 3, 6, and 12 months) with standard radiographs, as well as visual analog score and pain diagram documentation. At the 6-month and 12-month visits, knee function questionnaires (Lysholm knee scale and SF-36) were completed. Magnetic resonance imaging/image (MRI) of the affected knee was obtained at 12 months. Ten patients in each group were required for a power analysis for the anticipated larger randomized control trial, but enrollment in each arm was not limited because of known problems with patient follow-up over a 12-month period.

Results: A total of 41 patients/fractures were enrolled in this study. Of those, only 25 patients/fractures (14 IP, 11 SP) fully complied with and completed 12 months of follow-up. Six of 11 SP presented with articular changes (chondromalacia) in the PF joint during the preinsertion arthroscopy. Three patients displayed a change in the articular cartilage based on postnail insertion arthroscopy. At 12 months, all fractures in both groups had proceeded to union. There were no differences between the affected and unaffected knee with respect to range of motion. Functional visual analog score and Lysholm knee scores showed no significant differences between groups ($P > 0.05$). The SF-36v2 comparison also revealed no significant differences in the overall score, all 4 mental components, and 3/4 physical components ($P > 0.05$). The bodily pain component score was superior in the SP group (45 vs. 36, $P = 0.035$). All 11 SP patients obtained MRIs at 1 year. Five of these patients had evidence of chondromalacia on MRI. These findings did not correlate with either the prenail or postnail insertion arthroscopy. Importantly, no patient in the SP group with postnail insertion arthroscopic changes had PF joint pain at 1 year.

Conclusions: Overall, there seemed to be no significant differences in pain, disability, or knee range of motion between these 2 tibial intramedullary nail insertion techniques after 12 months of follow-up. Based on this pilot study data, larger prospective trial with long-term follow-up is warranted.

Key Words: suprapatellar, infrapatellar, tibial, tibial nail insertion

Level of Evidence: Therapeutic Level II. See Instructions for Authors for a complete description of levels of evidence.

(*J Orthop Trauma* 2016;30:130–134)

INTRODUCTION

The insertion of a reamed intramedullary nail (IMN) with interlocking screws is the standard of care for operatively managed tibial shaft fractures.[1] Traditionally, an infrapatellar (IP) approach through or around the patellar tendon, with a flexed or hyperflexed knee, is performed to insert an IMN.[2,3] This insertion site, which requires a flexed knee, becomes more difficult to use correctly in proximal third tibial shaft fractures, because the quadriceps muscle forces the proximal fragment into extension, resulting in a procurvatum deformity postnail insertion.[4,5]

The semiextended approach for tibial IMN insertion, to address this risk of malalignment, was first described by Tornetta et al[6] and later modified to a percutaneous suprapatellar (SP) approach by Cole.[7] Through a 2.5-cm incision proximal to the patella, the quadriceps tendon is split to obtain access to the SP pouch and retro-patellar space. A cannula system then allows for the standard insertion of the tibial nail. The full, or near-full, extension position of the leg not only assists in neutralizing the deforming forces of the quadriceps muscle and maintaining proper alignment of the proximal tibia, but the position also helps align comminuted shaft fractures or highly unstable distal third fractures, where maintaining

Accepted for publication November 16, 2015.
From the Orthopaedic Trauma Service, Florida Orthopaedic Institute, Tampa, FL.
Supported by a grant from the Orthopaedic Trauma Association.
Presented in part at the Annual Meeting of the OTA, October 2014, Tampa, FL.
D. S. Chan: consultant for Biomet, Synthes, Smith & Nephew. A. Infante: consultant for OmniLife Sciences and Arthrosurface. D. Watson: consultant for Smith & Nephew. H. C. Sagi: consultant for Smith & Nephew, Synthes, and Stryker. R. W. Sanders: Editor-in-Chief *Journal of Orthopaedic Trauma*, Consultant (Smith and Nephew, Zimmer-Biomet), Royalties (Smith and Nephew, Zimmer-Biomet, Linvatec). The remaining authors report no conflict of interest.
This study was approved by the Institutional Review Board at the University of South Florida.
Reprints: Daniel S. Chan, MD, Georgia Orthopaedic Trauma Institute, Medical Center of Central Georgia, 840 Pine St, Suite 500, Macon, GA 31210 (e-mail: chan.daniel@mccg.org).

reduction against gravity in the flexed or hyperflexed position can be extremely challenging. Additionally, the extended position of the lower leg allows for easier fluoroscopic imaging.

Although the semiextended procedure requires a formal parapatellar incision, the SP approach is truly percutaneous. The main concern in its use is the potential for damage to the patellafemoral (PF) articulation. This study was a prospective, randomized clinical trial designed to (1) determine whether the SP approach was equivalent to the IP approach with respect to knee pain, (2) determine whether the SP approach was equivalent to the IP approach with respect to healing, alignment, and knee function, and (3) evaluate the safety of the SP approach.

STUDY SUPPORT

This study was funded as an OTA pilot study and approved by our institutional review board. Preinsertion and postinsertion arthroscopies for the SP patients were not billed because it was considered as part of the procedure. Magnetic resonance imaging/image (MRI) studies were paid for by a grant from the OTA. Furthermore, as a pilot study, formal sample size calculations were not performed, because the information obtained from this investigation would specifically enable a proper power analysis for the future larger prospective study. Although 10 fractures were originally agreed on in each group based on the study budget, 20 patients in each group were planned because of known difficulties with patient follow-up for 12 months.

PATIENTS AND METHODS

Between April 2011 and December 2012, skeletally mature patients with OTA 42 tibial shaft fractures were randomized into the IP or SP nail insertion groups after informed consent was obtained. Sealed envelopes in a random order were sequentially opened after each patient was enrolled. At that preoperative moment, the technique for nail insertion was revealed to both the surgeon and patient. Patients with intraarticular involvement, peri-prosthetic fractures, nonunions, ipsilateral concomitant injuries, previous knee surgery, or a history of gout, rheumatoid, osteoarthritis, spinal injury, incarceration; patients not likely to follow-up in the estimation of surgeon; or pregnant women were excluded.

Patient's age, gender, fracture classification (OTA 42 A, B, C[8]), and Gustilo–Anderson type were recorded. Standard surgical techniques were used (medial parapatellar IP approach; quadriceps tendon split SP approach). All fractures were treated with a statically locked reamed IMN (Trigen Meta Nail; Smith and Nephew, Memphis, TN). SP insertion was performed percutaneously with the use of a commercial available cannula system (Smith and nephew). SP patients also underwent arthroscopy limited to the PF joint, prenail and postnail insertion, to obtain

TABLE 1. Patient Demographics

Pt	Sex	Age (y)	Side	OTA Class	Open Fx/ Grade	Length of F/U (mos)
Suprapatellar						
1	F	51	L	42B1.2	Closed	12
2	M	30	L	42B2.3	Closed	12
3	F	42	L	42C2.2	Closed	12
4	M	48	L	42A3.3	Closed	13
5	M	21	L	42A2.3	Closed	14
6	M	64	L	43A2.3	Closed	32
7	M	23	R	42A3.1	3A	31
8	F	51	R	42A2.2	Closed	19
9	F	55	R	42A3.2	Closed	12
10	F	29	R	42A2.2	Closed	12
11	M	24	R	42B2.1	Closed	15
Infrapatellar						
1	M	20	L	42B2.2	2	12
2	M	23	L	42A2.3	Closed	12
3	F	47	L	42C1.1	Closed	14
4	M	28	L	42A2.2	Closed	14
5	M	45	R	42C2.2	1	13
6	M	62	R	42B2.3	Closed	12
7	F	48	R	42A2.2	Closed	12
8	F	19	R	42B2.3	Closed	13
9	M	69	R	42B2.3	Closed	13
10	M	43	R	42A2.1	Closed	13
11	M	18	R	42A2.3	Closed	19
12	M	59	R	42C3.1	Closed	19
13	F	35	R	42B3.3	Closed	24
14	M	82	L	42A1.2	Closed	12

a visual evaluation of the PF joint. Images were obtained, saved, and reviewed by an independent fellowship-trained sports medicine orthopaedic surgeon to assess the PF joint for any associated injury. The Outerbridge scale was used to describe the condition of the articular cartilage: grade 0, normal cartilage; grade I, cartilage with softening and swelling; grade II, fragmenting or fissuring <1.5 cm diameter; grade III, fragmenting or fissuring >1.5 cm diameter; grade IV, exposed subchondral bone.

Patients underwent routine follow-up (6 weeks, 3, 6, and 12 months) with standard tibia and knee radiographs, as well as a visual analog score (VAS, 0 = excellent, 10 = extreme pain) and pain diagram documentation. At the 6- and 12-month visits, subjective complaints were recorded and a range of motion (ROM) arc was measured. Patient's function was assessed through a completed knee function questionnaire (Lysholm knee scale[9]) and SF-36v2. All clinical examinations for the purposes of this study were performed by research nurses during a separate clinic visit. Additionally, in the SP group, an MRI of the affected knee was obtained at 12 months and independently reviewed by a board-certified, fellowship-trained musculoskeletal radiologist. All radiographs were reviewed by the fellowship-trained orthopaedic trauma attending to assess union and alignment. Successful union criteria were the radiographic presence of callus formation bridging at least 3 cortices on orthogonal views of the fracture.

Descriptive statistics were reported as mean values and SDs for continuous variables and as frequencies and percentages for categorical variables.

RESULTS

A total of 41 patients/fractures were enrolled in this study, 23 SP and 18 IP. All fractures were OTA 42. Twelve SP and 4 IP patients either were lost or refused to come back for the follow-up examinations, leaving 25 patients/fractures available at a minimum of 12 months.

There were 11 SP and 14 IP patients/fractures. The average time from index procedure to final follow-up was 15.55 months (range: 12–32 months) (Table 1). Average age was 42 years (SP = 40, IP = 43), and the predominant sex was male. There were 3 open (SP: 1 3A, IP: 1 type 1, 1 type 2) and 22 closed fractures. All but 1 fracture healed radiographically without deformity. One SP case progressed to a nonunion and required revision IMN insertion, after exchange nailing using the SP portal again. There were no deep infections. Knee ROM was normal and equal to the unaffected contralateral knee in both the SP and IP groups (extension: 0 degree IP, 1 degree SP, $P = 0.5$; flexion 1 degree IP, −3 degree SP, $P = 1.0$) (Table 2).

The VAS pain scores averaged 1.5 for the IP group. 11/14 had a VAS ≤1. One patient who lacked housing and had an alcohol addiction complained of mild pain (VAS = 3), but this was related to the development of recurrent cellulitis in the leg beginning at the 6-month examination. The remaining 2 IP patients complained of knee pain at the incision site as severe (8 and 10). The VAS score in the SP group averaged 0.36, with 9/11 having a VAS of 0, 1 patient having a VAS = 1, and 1 patient complaining of mild pain (VAS = 3) only when bending the knee. There was no significant statistical difference in VAS scores between the IP and SP groups.

The mean Lysholm knee scores were 86 and 98 for the IP and SP groups, respectively, they were not statistically different; as was the case for the Lysholm pain component scores (20 IP vs. 24 SP). Additionally, the SF-36v2 scores were 38/47 for the IP group compared with 46/47 for the SP group. This comparison revealed no significant differences in the overall score, as well as all 4 mental components and 3 of the 4 physical components ($P > 0.05$). The bodily pain component score was superior in the SP group (46 vs. 36, $P = 0.035$) suggesting less pain and disability.

All 11 SP patients had prenailing and postnailing PF joint arthroscopy performed. Six patients exhibited prenail insertion PF joint chondromalacia patella (Table 3). Three patients had a change in the degree or location of chondromalacia after the nail was inserted. While one of these had preexisting disease, 2 did not. One SP patient seemed to have sustained an iatrogenic scratching of a small portion of the trochlea notch (normal PF examination, grade 0, pre-IMN; grade 2 trochlea chondral damage post-IMN), whereas 1 patient sustained damage to the undersurface of the patella with changes visible on the MRI (normal PF examination, grade 0, pre-IMN, grade 4 chondromalacia patella post-IMN). All SP patients were clinically symptom-free with full return to normal activities at 1 year after index procedure.

DISCUSSION

There is little information regarding the clinical outcomes in IMN insertion using the SP portal.[10–12] To our knowledge, this is the first report of a randomized clinical

TABLE 2. Twelve-Month Outcome Data Analysis

	IP	SP
Union	100%	100%
Malalignment	0%	0%
VAS	1.5	0.36
Lysholm-Pain	20	24
Lysholm	86	98
SF36-PCS	38	46
SF36-MCS	47	47
Physical Functioning	37	43
Role-physical	38	45
Bodily Pain	36	46*
General Health	48	51
Vitality	48	47
Social Functioning	40	49
Role-emotional	39	45
Mental Health	47	45
Affected Extension	0.8	−0.4
Unaffected Extension	0.8	0.4
Difference-Extension	0	0.7
Affected Flexion	137	131
Unaffected Flexion	138	129
Difference-Flexion	1	−2.4

*$P = 0.035$ (Mann–Whitney U test).
MCS, mental component summary; PCS, physical component summary.

TABLE 3. Patellofemoral Breakdown

Pt	F/U, mo	Arthroscopy		MRI: Chondromalacia Patellae	1-yr F/U Knee Pain	
		Prenail	Postnail Insertion		PFJ	Other
Suprapatellar						
1	12	2P	2P	Yes	No	No
2	12	2P	2P	No	No	No
3	12	2P	2P	No	No	Screw head
4	13	1P	1P	Yes	No	No
5	14	0	0	No	No	No
6	32	0	**4P**	Yes	No	No
7	31	0	0	Yes	No	Screw head
8	19	4P, 2T	4P, **4T**	No	No	No
9	12	2P	2P	Yes	No	No
10	12	0	0	No	No	No
11	15	0	**2T**	No	No	No
Infrapatellar						
1	12				No	No
2	12				No	Incision
3	14				No	No
4	14				No	No
5	13				No	Nail insertion
6	12				No	No
7	12				No	No
8	13				No	No
9	13				No	No
10	13				No	No
11	19				No	No
12	19				No	Screw head
13	24				No	No
14	12				No	Screw head

PFJ, patellofemoral joint.
Site of chondromalacia—T: trochlea, P: patella.
Bold indicates change postnail.

trial comparing IP and SP tibial IMN approaches. Although this was only a pilot study, our results show that the SP approach is equivalent to the traditional IP technique with regard to union, alignment, knee pain, and functional outcomes. Based on our data including arthroscopic prenailing and postnailing assessments, 1 year postoperative MRI, and functional outcomes, it seems that the SP method, when using insertional cannulas, does not cause injury to the PF joint.

Decreased ROM postoperatively is an undesirable outcome of IMN of the tibia and well documented in the literature.[13] Lefaivre et al[14] reported on long-term follow-up after standard (IP) tibial IMN insertion and found equivalent knee ROM to the unaffected contralateral knee. Our study reproduced these findings in both IP and SP patients alike.

Anterior knee pain is frequently associated with IMN insertion of tibia fractures. Its incidence has been reported to be as high as 56%.[15,16] The cause is still unclear. Toivanen found that 69% of patients treated with an IMN using the IP approach continued to have pain even after implant removal.[17] In our small series, 2 IP insertion patients complained of anterior knee symptoms (one incisional, one tibial IMN insertion site). In the SP group, none of the patients complained of anterior knee pain. This was also the finding in a recent report evaluating anterior knee pain in SP IMN insertion patients.[18] The absence of an incision or dissection around the IP area with complete avoidance of the IP branches of the saphenous nerve may be the reason for this finding. In any event, the fact that no SP patient had anterior knee pain was encouraging.

Nork et al[19] evaluated patients well-being using the SF-36 after tibial IMN using an IP approach, with a minimum follow-up of 1 year, and noted that physical function, role-physical, and bodily pain were significantly worse than standard normative data. Our SF-36 data indicated that all components but one were equivalent between the 2 groups: bodily pain was worse in the IP group when compared with the SP cohort at 1 year postoperatively. We surmise that again this may be related to anterior knee pain in IP insertion patients.

The Lysholm knee scores provide a validated and quantified comparison of patient activities of daily living. Song et al[20] reported a significant correlation between Lysholm scores and anterior knee pain in patients who underwent tibial IM nailing. In our study, the SP score of 98 is considered an "excellent" outcome, compared with the IP

group score of 86 which is considered "good". Similarly, pain measured through the Lysholm pain component showed that the SP group reported less pain while walking compared with their IP counterparts. Although there were no significant differences between groups, both groups did report low incidences of knee pain. Interpreting all of the outcome results, we found overall consistency. The Lysholm knee scores are a functional assessment and are not limited to pain, much like the role-physical subscale of the SF-36; therefore, the equivalence of both scores between SP and IP was expected. The VAS score is more specific to pain and was not statistically significantly different; however, the SP patients did trend to having less pain. The SF-36 bodily pain score also showed that the IP group had worse pain; questionnaire differences likely led to statistical significance. Finally, although MRIs were used to assist in the evaluation of any cartilage changes at the 1-year mark, they did not seem to offer any significant benefit due to lack of sensitivity and/or specificity.

There were a few limitations in this study. It was not a blinded study. If the nail insertion technique was blinded to the patient with an additional incision, an added level of objectivity would have been an enhancement, but this was not contemplated for obvious reasons. There did not seem to be any characteristics or anticipated outcomes about those lost to follow-up that would have affected the observed results. The main limitation of this study was that it was a pilot study designed to develop a larger cohort to evaluate. Based on these data, we plan a larger, multicenter randomized control trial, in the hopes of determining both the efficacy of this technique and whether this approach can minimize anterior knee pain.

CONCLUSIONS

Based on the data of this OTA-approved pilot study, we conclude that the SP approach is equivalent to the IP approach with respect to tibial fracture healing and alignment, knee pain, functional disability, or knee ROM. We were unable to find any PF joint damage clinically and were able to show that anterior knee pain was less prevalent in the SP than the IP approach. A larger prospective trial with long-term follow-up is needed to improve statistical power and establish if any late sequelae exist, when the procedure is properly performed.

REFERENCES

1. Bone LB, Johnson KD. Treatment of tibial fractures by reaming and intramedullary nailing. *J Bone Joint Surg Am.* 1986;68:877–887.
2. Weller S, Kuner E, Schweikert CH. Medullary nailing according to Swiss study group principles. *Clin Orthop Relat Res.* 1979;138:45–55.
3. Lottes JO. Medullary nailing of the tibia with the triflanged nail. *Clin Orthop.* 1974;105:253–266.
4. Freedman EL, Johnson EE. Radiographic analysis of tibial fracture malalignment following intramedullary nailing. *Clin Orthop Relat Res.* 1995;315:25–33.
5. Josten C, Marquass B, Schwarz C, et al. Intramedullary nailing of proximal tibial fractures. Complications and risk factors. *Unfallchirurg*. 2010; 113:21–28.
6. Tornetta P III, Riina J, Geller J, et al. Intraarticular anatomic risks of tibial nailing. *J Orthop Trauma.* 1999;13:247–251.
7. Cole JD. Distal tibia fracture: opinion: intramedullary nailing. *J Orthop Trauma*. 2006;20:73–74.
8. Marsh JL, Slongo TF, Agel J, et al. Fracture and dislocation classification compendium—2007: Orthopaedic Trauma Association classification, database and outcomes committee. *J Orthop Trauma.* 2007;21: S1–S133.
9. Collins NJ, Misra D, Felson DT, et al. Measures of knee function: international knee documentation committee (IKDC) subjective knee evaluation form, knee injury and osteoarthritis outcome score (KOOS), knee injury and osteoarthritis outcome score physical function short form (KOOS-PS), knee outcome survey activities of daily living scale (KOS-ADL), Lysholm knee scoring scale, oxford knee score (OKS), western ontario and mcmaster universities osteoarthritis index (WOMAC), activity rating scale (ARS), and tegner activity score (TAS). *Arthritis Care Res (hoboken).* 2011;63 (suppl 11):S208–S228.
10. Gelbke MK, Coombs D, Powell S, et al. Suprapatellar versus infrapatellar intramedullary nail insertion of the tibia: a cadaveric model for comparison of patellofemoral contact pressures and forces. *J Orthop Trauma.* 2010;24:665–671.
11. Eastman J, Tseng S, Lo E, et al. Retropatellar technique for intramedullary nailing of proximal tibia fractures: a cadaveric assessment. *J Orthop Trauma.* 2010;24:672–676.
12. Eastman JG, Tseng SS, Lee MA, et al. The retropatellar portal as an alternative site for tibial nail insertion: a cadaveric study. *J Orthop Trauma.* 2010;24:659–664.
13. Keating JF, O'Brien PI, Blachut PA, et al. Reamed interlocking IMN of open fractures of the tibia. *Clin Orthop Relat Res.* 1997; 338:182–191.
14. Lefaivre KA, Guy P, Chan H, Blachut PA. Long-term follow-up of tibial shaft fractures treated with IMN. *J Orthop Trauma.* 2008;22:525–529.
15. Keating JF, Orfaly R, O'Brien PJ. Knee pain after tibial nailing. *J Orthop Trauma.* 1997;11:10–13.
16. Court-Brown CM, Gustilo T, Shaw AD. Knee pain after intramedullary tibial nailing: its incidence, etiology, and outcome. *J Orthop Trauma.* 1997;11:103–105.
17. Toivanen JA, Vaisto O, Kannus P, et al. Anterior knee pain after intramedullary nailing of fractures of the tibial shaft. A prospective, randomized study comparing two different nail-insertion techniques. *J Bone Joint Surg Am.* 2002;84-A:580–585.
18. Sanders RW, DiPasquale TG, Jordan CJ, et al. Semiextended IMN of the tibia using suprapatellar approach: radiographic results and clinical outcomes at a minimum or 12 Months Follow-up. *J Orthop Trauma.* 2014; 28:S29–S39.
19. Nork SE, Schwartz AK, Agel J, et al. IMN of distal metaphyseal tibial fractures. *J Bone Joint Surg Am.* 2005;87-A:1213–1221.
20. Song SY, Chang HG, Byun JC, et al. Anterior knee pain after tibial IMN using a medial paratendinous approach. *J Orthop Trauma.* 2012; 26:172–177.