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Clinical Outcomes and Surgical Satisfaction Following a Lateral Transfibular Total Ankle Arthroplasty: Early Follow-up Results from A Canadian Cohort

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Abstract

Background: The lateral transfibular total ankle arthroplasty (TAA) is a novel surgical technique used for treatment of end-stage osteoarthritis. The purpose of this study was to evaluate perioperative clinical outcomes, surgical satisfaction and complications undergoing this procedure.

Methods: This is a retrospective cohort study of 25 patients undergoing a TAA via the lateral transfibular approach. Clinical data collection was performed preoperatively and postoperatively at 3 and 12 months using the AOFAS, the SF-36 and the VAS for pain. Surgical satisfaction was evaluated using a modified version of the 8-item Surgical Satisfaction Questionnaire (SSQ-8).

Results: Overall AOFAS scores increased from 30.32 preoperatively to 85.32 (p<.001) at 3 months and 87.64 (p<.001) at 12 months. Patient SF-36 scores showed statistically significant increases across all domains (pain, physical, emotional, social) preoperatively to 3 and 12 months postoperatively. Additionally, VAS scores increased from 8.0 preoperatively to 1.7 (p<.001) at 3 months and 1.5 (p<.001) at 12 months postoperatively. Twenty-three patients (92.0%) reported that they were “very satisfied” or “satisfied” with the outcome of their procedure, that they would “do it all over again”, and that they would recommend it to other patients with a similar condition.

Conclusion: Early results show that the lateral transfibular approach to TAA has good clinical outcomes at 3-month and 12-month follow up, with the greatest improvement measured in the first 3 months. Additionally, the surgery was associated with good patient satisfaction.

Keywords: Ankle osteoarthritis; Total ankle arthroplasty; Total ankle replacement; Transfibular

Level of Evidence

Therapeutic, Level III.

Introduction

Total Ankle Arthroplasties (TAAs) have become a standard of treatment for the management of end-stage ankle osteoarthritis as an alternative to arthrodesis once conservative management has failed [1]. One of the major disadvantages to an arthrodesis is loss of range of motion, which has implications for patient quality of life and function. With the evolving technology of third generation prosthetic designs for TAAs, there are multiple studies which have shown superior clinical results [1-6]. The lateral transfibular approach to TAAs is a novel technique which offers early clinical advantages [1-3,5]. Its main indications include primary osteoarthritis (OA), rheumatoid arthritis (RA) as well as secondary and post traumatic OA. With the anterior approach to TAAs still being the most commonly used approach [1,3], the emergence of the lateral approach has gained a competitive interest amongst the orthopedic operative community in that it allows the surgeon to have access to the center of rotation of the talus allowing better visualization of the sagittal plane [5]. With this in mind, it has proposed to be advantageous in that there are less observed complications of instability, early wear and prosthetic loosening, all of which occur with TAAs [1-3,5].

Although the frequency of infections has not been shown to be significantly different compared to the anterior approach, there is a theoretical reduced risk of wound complications with the lateral approach due to avoiding the anterior vasculature of the ankle [3,7,8]. A recent study by Gagné et al. has however shown a higher wound complication rate with the lateral approach due to increased deep layer tension as a consequence of using a fibular plate [9]. Other disadvantages with the lateral approach include longer operative time and malunion of the fibula. However, thus far, studies have shown promising results [1-3]. With multiple studies reporting high survival rates (93-100%) of the prosthesis [1,3,5], as well as stable radiographic angles [2,5], we anticipate similar outcomes for this study. Clinically, multiple studies have also shown improvement in pain outcomes post-operatively [2,3,5,6], increases in the American Orthopedic Foot and Ankle Society Hindfoot Score (AOFAS) hindfoot score (1,2) as well as improvement in the 36-Item Short Form Health Survey (SF-36) [2].

The objective of this study is threefold: (1) To assess pre-operative and short-term postoperative patient outcomes of pain, function and quality of life, (2) Assess early prosthetic and wound complications, and (3) Assess patient satisfaction with surgery.

We hypothesized that the lateral transfibular approach will improve patient outcomes in the first year and this will correspond to positive patient satisfaction with the surgery. Additionally, we do not anticipate significant early prosthetic complications.

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Methods

Study characteristics

This retrospective cohort study was approved by the Research Ethics Board of Health Sciences North (REB HSN). Patients gave informed consent to participate in study. Retrospective clinical and radiographic data was obtained from 26 consecutive patients who underwent a primary TAA using the Zimmer Trabecular Metal Total Ankle Replacement between September 2017 to September 2019. One patient was lost to follow-up and therefore data was incomplete and not reported. All TAA operative procedures were performed by the same orthopedic surgeon (P.A.). The indications for surgery and TAA included primary degenerative OA, RA, and post-traumatic OA.

Exclusion criteria for this study included peripheral neuropathy, recent history of septic arthritis and neuromuscular disorders. Additional exclusion was granted to patients with incomplete charts and those lost to adequate follow-up.

Outcome measures

Clinical evaluation of patients undergoing TAAs was collected via questionnaire preoperatively and postoperatively at 3- and 12-month follow-ups. Specific outcome measures used included the AOFAS, the SF-36 and the VAS. Additionally, patient satisfaction with the surgery was assessed using a modified version of the SSQ-8.

Satisfaction with "return to work" was omitted due to the majority of patients being retired. Range of motion was captured in the sagittal plane during a physical exam using a goniometer. Standard plain radiographs of the ankles were obtained in the AP, lateral and oblique views preoperatively and at 3, 6 and 12 months to assess for prosthetic complications [10].

Operative procedure

The operative procedure for all patients was performed according to the standardized operative technique using the Zimmer manufacturer instructions for the lateral transfibular Trabecular Metal Total Ankle Replacement [11]. Percutaneous tendo-achilles lengthening was performed in 23 patients (92%). One patient also had a surgical correction of medial malleolus pseudoarthrosis. In each patient, bone autograft was used to fibular osteotomy site using tibial reamings. A standard dressing was applied, and a full cast was placed with the ankle in a neutral position before leaving the operating room. Standard follow-ups after surgery were at 2 weeks, 6 weeks, 3 months, 12 months and yearly after that, unless complications arose.

Statistical analysis

Descriptive statistics were reported as absolute values, percentages, means and standard deviations. Outcome measure scores were reported as means with 95% confidence intervals. Two tailed student t-tests were used to assess significant differences between preoperative and postoperative AOFAS scores and SF-36 scores. VAS scores were assessed using the Wilcoxon matched-pairs signed-rank test. The Somers' D measure was used to assess the strength and direction of association between ROM and follow-up time at 3 and 12 months. Additionally, McNemar's test for paired data was used to assess differences in paired ROM data preoperatively to 3 and 12 month follow ups [12]. Statistical significance was defined as the 5% ($p<0.05$) level.

SSQ-8 patient responses were reported using stacked bars. Statistical analyses were conducted using JASP statistical software version .12.2 (JASP, Amsterdam, and The Netherlands) and STATA release 16 (StataCorp. 2019, College Station, TX).

Results

This study assessed 25 patients who underwent a primary TAA using the Zimmer Trabecular Metal Total Ankle Replacement. Of the 25 TAAs performed, there were 11 females (44%) and 14 males (56%) of which there were 11 right ankles (44%) and 14 left ankles (56%). The mean age of the patients was 66.8 years (SD 7.6). The average BMI was 33.4 (SD 6.1). Patient demographic data is outlined in Table 1.

Clinical outcomes

At 3 and 12 months postoperatively, there were statistically significant increases in AOFAS scores from 30.32 preoperatively to 85.32 (95% CI -62.21 to -47.79, $p<0.001$) and 87.64 (95% CI -64.88 to -49.76, $p<0.001$), respectively. There was also a statistically significant increases in the SF-36 preoperatively to 3 months postoperatively

Variable		Estimate	SD/%
Age at surgery (years)		66.8	7.6
BMI (kg/m2)		33.4	6.1
Sex	Men (n)	14	44.0
	Women (n)	11	56.0
Side	Left (n)	14	56.0
	Right (n)	11	44.0
Etiology	Primary OA (n)	11	44.0
	Post traumatic OA (n)	14	56.0
Comorbidities	CAD (n)	3	12.0
	Diabetes (n)	5	25.0
	HTN (n)	15	60.0
	Depression (n)	1	4.0
Smoker	Yes (n)	1	4.0
	No (n)	24	96.0
Body Mass Index (BMI); Coronary Artery Disease; Hypertension (HTN)			

Table 1: Baseline demographics of 25 patients undergoing the lateral transfibular total ankle arthroplasty.

Parameter	Preoperative		Postoperative 3 months		Postoperative 12 months	
	Mean	SD	Mean	SD	Mean	SD
VAS (0-10)	8.04	1.34	1.68**	1.82	1.48**	2.04
AOFAS (%)	30.32	14.55	85.32**	9.94	87.64**	10.06
SF-36 Pain (%)	28.7	15.24	58.90**	25.63	63.60**	25.88
SF-36 Emotion (%)	72.16	19.17	84.16**	12.8	85.44**	11.94
SF-36 Social (%)	62	31.35	76.00*	27.22	91.00**	17.12
SF-36 Physical (%)	34.8	17.58	52.80*	22.78	61.20**	23.06

Visual Analog Scale (VAS); American Orthopedic Foot and Ankle Society (AOFAS) ankle and hindfoot score; 36-item Short Form Health Survey (SF-36). **indicates statistical significance with a p value <0.001, *indicates statistical significance with a p value <0.05.

Table 2: Clinical outcomes of 25 patients with the lateral transfibular total ankle arthroplasty. Values are presented as the mean with standard deviations.

in the pain domain from 28.70 to 58.90 (95% CI -43.43 to -16.97, p<0.001); physical domain from 34.80 to 52.80 (95% CI -28.15 to -7.85, p<0.05); emotional domain from 72.16 to 84.16 (95% CI -17.97 to -6.03, p<0.001); social domain from 62.00 to 76.00 (95% CI -27.10 to -.90, p<0.05). SF-36 scores preoperatively to 12 months postoperatively also showed statistical significance in the pain domain from 28.70 to 63.60 (95% CI -47.66 to -22.14, p<0.001); physical domain from 34.80 to 61.20 (95% CI -35.45 to -17.35, p<0.001); emotional domain from 72.16 to 85.44 (95% CI -19.91 to -6.65, p<0.001); social domain from 62.00 to 91.00 (95% CI -41.88 to -16.13, p<0.001) (Figure 1). Additionally, there was a significant decrease in VAS scores from 8.0 preoperatively to 1.7 (z=4.39, p<0.001) 3 months postoperatively, and 1.5 (z=4.37, p<0.001) 12 months postoperatively. To assess ROM, the Somers' D was used to provide a measure of ordinal association between time point and ROM (D can range from -1 to +1, with 0 indicating no association). Based on our cohort, D=0.40 (95% CI, 0.22 to 0.58, p <0.001), which indicates that ROM ratings increased preoperatively to 12 months postoperatively. Furthermore, McNemar's Test revealed a statistical increase in ROM preoperatively to 3 and 12 months postoperatively (χ^2=15, p<0.001). No significant differences were observed in ROM from 3 to 12 months postoperatively (χ^2=1, p=0.3173). The average operative time was 111 minutes (SD 13.8).

Surgical satisfaction

Twenty-four patients (96.0%) were "very satisfied" or "satisfied" regarding their inpatient pain management. One of the patients (4.0%) was "unsatisfied" with inpatient pain management, however was "satisfied" with post-discharge analgesia. One of the patients (4.0%) reported as being "unsatisfied" with their post-discharge analgesia due to neuropathic pain. Twenty-one patients (84.0%) were "very satisfied" or "satisfied" with the time taken to return to their daily and social activities. Return to work was not reported due the majority of the patients being retired. Twenty-three patients (92.0%) were "very satisfied" or "satisfied" with the time taken to return to their normal exercise routine. Twenty-three patients (92.0%) reported that they were "very satisfied" or "satisfied" with the outcome of their procedure, that they would "do it all over again", and that they would recommend it to other patients with a similar condition. One patient (4.0%) would not repeat the surgery (Figure 2).

Complications

Of the 25 patients, there was one case of a fibular delayed union (4.0%). There were no periprosthetic fractures, dislocations or subluxations reported. No bony necrosis appreciated radiographically. One of the patients (4.0%) requires a secondary operative procedure due to a loose syndesmotic screw..

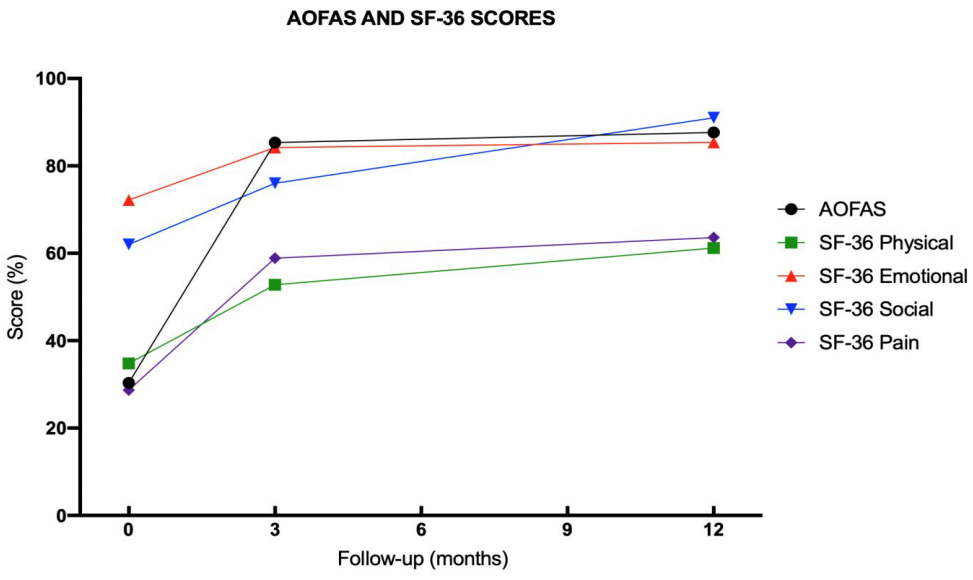

Figure 1: Mean AOFAS and SF-36 percentage scores for the 25 patients who underwent total ankle arthroplasties at 0 months (preoperatively), 3 months and 12 months.

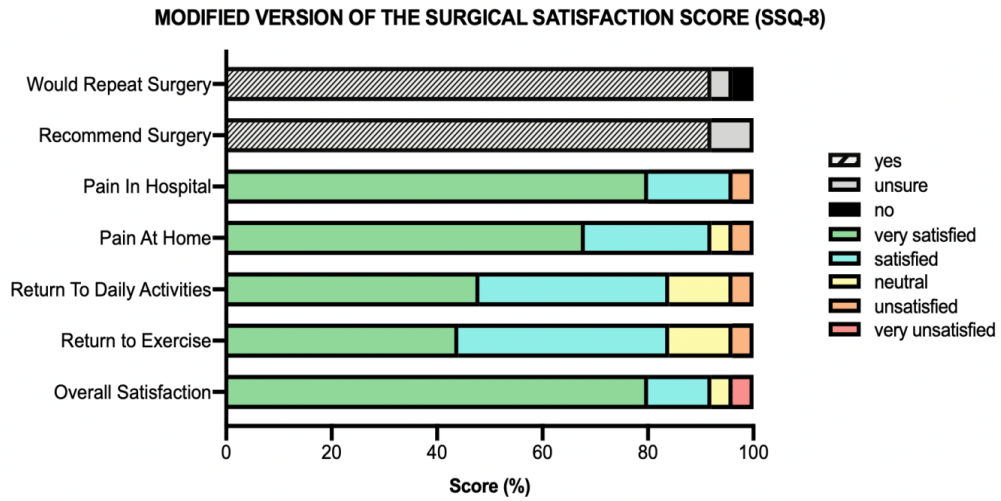

Figure 2: Results from the modified 8-Item Surgical Satisfaction Questionnaire (SSQ-8) at 12 month postoperatively for the 25 patients who underwent a lateral transfibular total ankle arthroplasty.

Three patients (12.0%) experienced a superficial infection. Each patient was subsequently treated with 6 weeks of intravenous antibiotics and fully recovered. Two patients (8.0%) experienced postoperative nerve damage with 1 patient experiencing full recovery.

Discussion and Conclusion

There are few options when it comes to managing end-stage OA of the ankle, once conservative measures have failed. Aside from arthrodeses, there are two main approaches to TAAs including anterior and lateral approaches, the latter being the approach of interest for this study. To our knowledge many groups have assessed clinical outcomes of the lateral transfibular TAA using combinations of the AOFAS, SF-36, VAS and ROM [1-3,5,8,13-17]. In terms of exclusive Canadian cohorts, Gagné et al. [9] investigated the difference in reoperation rate after lateral and anterior approach ankle arthroplasty. However, outcomes of interest were not assessed.

Additionally, few studies have looked at measures of surgical satisfaction; we addressed this through the use of the SSQ-8 adapted from validated gynecological, urological and otolaryngology studies [18,19]. This study found a significant improvement in short-term clinical outcomes in 25 consecutive patients undergoing a TAAs using the lateral transfibular approach.

A number of factors affect wound healing. Patient factors include prior open operative procedures at the same site, immunosuppression, poor nutrition, diabetes, obesity (BMI >30), smoking and chronic kidney disease [20]. Operative factors affecting wound healing include location of the incision, soft tissue and tourniquet time [20]. In our study, 3 patients (12.0%) developed a superficial infection. Two of these patients were diabetic and had a BMI >30, which inherently put them at risk. This rate is slightly higher than reported infection rates in previous studies. According to a study by Usuelli et al. [21], 3 of the 66 patients (4.5%) developed a postoperative infection. Similarly, Barg et al. [3] had 3.6% of their patients develop superficial infections. In a more recent study by Tiusanen et al. [15] they deduced a higher rate of wound infection when a plate was used to fix the fibular osteotomy vs. a 2-3 screw fixation (14% *vs.* 5.6%). This rate is consistent with our patients having had lateral plates to fix their fibular osteotomy.

Although the lateral approach has been criticized for a proposed longer operative time, the average surgery time for our study was 111 minutes (SD=13.8), which is under the average surgery time of 115 minutes reported by Usuelli et al. [8] for the anterior approach. Studies by Usuelli et al. [8] and DeVries et al. [22] revealed average surgery times of 165 minutes and 176 minutes, respectively. This is clinically relevant as longer operative time has been implicated as a factor influencing periprosthetic infections in patients undergoing ankle joint replacements [23,24].

Another complication unique to the lateral approach is the risk of a delayed union or non-union, which can lead to instability of the prosthesis, improper alignment and/or implant failure [5]. One of 25 patients (4.0%) experienced an asymptomatic delayed union of their fibula. This is lower than numbers obtained from Bianchi et al. (2019) which had a 6.7% fibular non-union rate and lower than Devries et al. [22], with a delayed/non-union rate of 18.8%. There is a risk of delayed or non-union with any fracture, and with the fibula, this risk may be increased due to less soft tissue coverage, and therefore blood supply. Although the patient in our study remains asymptomatic, appropriate follow up is indicated to monitor precipitation of destabilization of the ankle mortise in valgus and further operative repair.

None of the patients had early periprosthetic arthroplasty failure. Aside from the fibular mal-union, there were no clinical or radiographic signs of instability. One of the patients (4.0%) experienced a loose syndesmotic screw at their 3-month visit with an operative removal scheduled in fall of 2020. Two patients (8.0%) experienced nerve injuries, consistent with the plantar nerves. One of the patients has ongoing paresthesia and decreased plantar flexion active range of motion 1 year postoperatively, suggesting potential tibial nerve involvement. The other patient had no motor deficits but had neuropathic type burning, sharp pain and paraesthesia along the lateral aspect of the foot and heel. The latter patient was treated by their primary health care physician with amitriptyline 10mg once daily and had near complete resolution of symptoms by 6-months postoperatively. As hypothesized by Tiusanen et al. [15], with the lateral approach, there is a theorized risk of plantar nerve injury as a result of multiple mechanisms including the removal of the talus medially using the burr, nerve stretching, or poor placement of talar pin medially.

Overall, significant pain relief was observed, with statistically significance achieved at 3 and 12 months. Whereas some studies evaluating pain post ankle arthroplasty have demonstrated a relapse of pain at 3 months (25), our postoperative education and rehabilitation guidelines of walking and early return to activity may have contributed to early restoration of ROM and a faster decrease in VAS pain scores at 3 months. Usuelli et al. [21] reported similar results with a decrease from 8.9 to 2.2 at 12 months. Bianchi et al. [2] also showed significant decreases in VAS scores from 7.81 preoperatively to 2.29 postoperatively. However, mean follow up time was 29.7 months thus further follow up on our cohort is warranted for comparison.

The most significant improvement in AOFAS occurred preoperatively to 3 months with a greater than threefold increase in mean score. This is consistent with the notion that most recovery in the AOFAS score occurs in the first 3 months [10]. Similar results were obtained from a multicenter cohort with improvements from 39 preoperatively to 68.2 at 6 weeks and 82.6 at 1 year [17]. SF-36 scores revealed similar statistically significant improvements in pain and emotional, physical and social domains at 3 and 12 months postoperatively. This coincides with the improvement in VAS seen in our study at 3 months. According to a study that looked at Canadian normative data for the SF-36 health survey [25,26], the mean score for physical function in ages 65-74 was 75.7 (SD=22.2). Given that our cohort's mean physical function score preoperatively was greater than one standard deviation below the normative data's mean, it is promising that our study did achieve a score of 61.2 at 12 months postoperatively.

Of particular interest to our study was whether patients would repeat the surgery and whether they would recommend the surgery. In the study by Bianchi et al. [2], 91% of patients were "very satisfied" or "satisfied" and would repeat the surgery. With an overall positive response of 92.0%, not only are objective measures of operative outcome promising, but we are re-assured that patients are also satisfied at long term follow-up. Despite this positive response, one patient (4.0%) was "very unsatisfied" with the results of the surgery and would not repeat the surgery. One major limitation with this survey is that given it was retrospectively administered to patients, the follow up time for the questionnaire varied from 1-2 years. A secondary limitation of the SSQ-8 is that although it has been validated in urological and gynecological surgeries, it has not been studied in the context of elective orthopedic arthroplasty surgery. That being said, questionnaire data regarding surgical satisfaction had a moderate correlation with AOFAS. (r=-0.71) Further validation of the questionnaire with orthopedic surgery and potential modification of the questionnaire should be considered for future studies.

Other inherent limitations in this study include our sample size; due to the limited number of lateral TAAs performed at this center on a yearly basis, we have a finite number of patients. Additionally, objective measurement of range of motion was performed using a goniometer as opposed to radiographically. The final limitation is that results from this study are short-term and remain relatively preliminary warranting ongoing collection of clinical outcomes at 2- and 5-year follow-ups.

In conclusion, our study showed that the lateral transfibular approach to TAA using the Zimmer Trabecular Metal Total Ankle Replacement is an effective procedure for end-stage OA. Specifically, it showed to be associated with good clinical outcomes at 3- and 12-month follow up, with the greatest improvement measured in the first 3 months. Additionally, the TAA was associated with good patient satisfaction.

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