Harvest of Distal Tibial and Calcaneal Autologous Bone Graft Utilizing Non-Powered Minimally Invasive Bone Harvester in Foot and Ankle Surgical Procedures: A Single Surgeon, Single Center, Retrospective Review

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INTRODUCTION

It has been speculated that over 1 million bone graft procedures take place each year in the United States.[1] Specifically, autogenous bone graft utilization in foot and ankle surgery has become common practice.[2-8] Although the tissue technology for allograft products has improved over time, autogenous bone graft remains the gold standard and retains superior healing capacity when compared to allografts.[9-15] This superiority can be mainly attributed to autograft's histocompatibility and biologic features that it affords, including osteoconductive, osteoinductive and osteogenic properties.[16] Furthermore, significant cost can be associated with synthetic graft options.[17]

PURPOSE

Myriad of acceptable techniques and devices have been described to obtain autologous bone graft from lower extremity harvest sites such as the tibia and calcaneus. Techniques include percutaneous and open approaches, powered and non-powered instrumentation, as well as single use versus re-processed devices.[7, 16-28] There are trends with medical device consumers to utilize sterile, single use, cost conscious devices that require minimal stocking space and maximize efficiency and safety of autogenous bone graft harvest. An example of one such device is the Corex™ (Trinity Orthopedics LLC, San Diego, CA) minimally invasive bone harvester, which is a sterile packaged single-use non-powered metallic trephine with 7 mm and 9 mm diameter options.

The purpose of this study was to analyze the safety and efficacy of the Corex™ device in foot and ankle procedures that involved concomitant harvest of autologous bone graft procured from the calcaneus and distal tibial metaphysis (or both). It is the author's hypothesis that this device presents a safe and efficient option for harvest of autogenous bone graft to supplement foot and ankle surgical procedures.

METHODOLOGY & PROCEDURES

A systematic review of electronic health records was performed on patients that were identified to have had autogenous bone graft harvested from their calcaneus or tibia to augment a primary foot and/or ankle surgery from July 1st, 2018 through July 31st, 2019. Institutional Review Board approval was obtained. Patients were identified for the retrospective review by the primary author (BPA) searching surgical logs, review of records using surgical procedure codes (CPT) 20900, 20902, and 28322 (Current Procedural Terminology, American Medical Association, Chicago, IL), and by cross referencing the search with hospital billing records that would have billed for use of the Corex™ device at the time of surgery. Inclusion criteria included any patient that underwent autogenous bone graft harvest from the distal tibia, calcaneus, or both sites utilizing the Corex™ minimally invasive bone harvesting device. Patients were excluded if there was less than three months of postoperative follow-up, they were skeletally immature (as determined by open epiphyses on preoperative radiographs), had bone graft harvested by a different medical device or technique, or if the author was not the primary surgeon during the procedure. The principle procedure in each case included a variety of different foot and ankle surgical procedures, but each patient underwent some type of pedal joint arthrodesis. In various cases, adjunct procedures were performed in the same operative setting to the primary arthrodesis and bone graft procedure. Patients were followed postoperatively until clinical and radiographic healing parameters were met, when feasible, which included the use of serial postoperative radiographs involving the bone graft donor and recipient sites. The surgical technique pertaining to the minimally invasive bone harvesting device is similar regardless of the anatomical location. Figures 1 and 2 demonstrate clinical and radiographic examples of this technique with the minimally invasive bone harvesting device. In a subset of patients in which data was available, intraoperative variables including operative time for bone graft harvest, estimated blood loss, documented use of any bone allograft product to back-fill the harvest site or supplement the autograft, autogenous bone graft harvest volume, and complications were noted. Figures 3,4, and 5 demonstrate examples of patients involved in the study. Figure 6 demonstrates an example of the estimation of bone graft harvest volume.

FIGURES

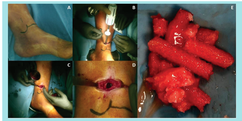

Figure 1 Legend: Intraoperative photograph (A) of a left foot and ankle with bony landmarks outlined, including the medial malleolus, anterior tibiotalar joint, and minimal incision overlying bone graft harvest site within the distal tibial metaphysis. Intraoperative photograph demonstrating the Corex™ minimally invasive bone harvester (B) being used in same patient. Intraoperative photograph (C) demonstrating a cortical window that is created along the distal media tibial metaphysis harvest site and collection of autogenous graft in a sterile cup (C). Close-up intraoperative photograph (D) of cortical window in the same patient. Multiple cores of autogenous cancellous bone graft (E) following successful harvest from the same patient.

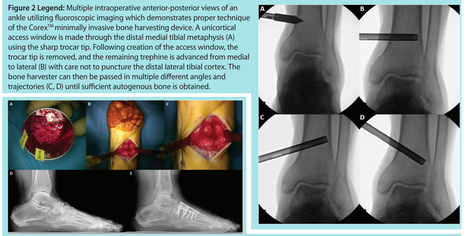

Figure 2 Legend: Multiple intraoperative anterior-posterior views of an ankle utilizing fluoroscopic imaging which demonstrates proper technique of the Corex™ minimally invasive bone harvesting device. A unicortical access window is made through the distal medial tibial metaphysis (A) using the sharp trocar tip. Following creation of the access window, the trocar tip is removed, and the remaining trephine is advanced from medial to lateral (B) with care not to puncture the distal lateral tibial cortex. The bone harvester can then be passed in multiple different angles and trajectories (C, D) until sufficient autogenous bone is obtained.

Figure 3 Legend: Intraoperative photograph of autogenous cancellous bone graft in a sterile cup (A) harvested from the distal tibia and calcaneus in a 59 year old female with end-stage degenerative joint disease of the tarsometatarsal joints and navicular cuneiform joints. Intraoperative photographs of the same patient's right foot with autogenous bone graft employed in the extended midfoot arthrodesis site (B), and a close-up image (C) prior to placement of internal fixation. Preoperative weightbearing lateral foot radiograph (D) in the same patient demonstrating advanced degenerative changes to the navicular cuneiform and tarsometatarsal joints. Postoperative weightbearing lateral view (E) demonstrating well-healed midfoot arthrodesis and harvest sites within the calcaneus and distal tibia without complication.

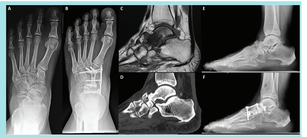

Figure 4 Legend: Preoperative left foot weightbearing AP (A) and lateral (E) radiographs in a 55 year old female with non union fracture of navicular and degenerative changes of the talonavicular and navicular cuneiform joint levels. Preoperative left foot magnetic resonance sagittal plane T1 imaging (C) in same patient demonstrating avascular changes to distal talus and navicular fracture with findings consistent with Mueller-Weiss syndrome. Preoperative left foot computed tomography sagittal plane image (D) confirming non-union of navicular fracture and degenerative changes. This patient underwent extended medial column arthrodesis with autogenous bone graft augmentation that was harvested using the Corex™ minimally invasive bone harvester. One year postoperative weightbearing left foot AP (B) and lateral (F) radiographs in same patient demonstrating successful well-healed arthrodesis of the talonavicular and navicular cuneiform joint levels and harvest sites from the distal tibia and calcaneus without complication.

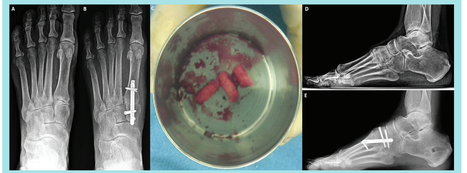

Figure 5 Legend: Preoperative weightbearing left foot AP (A) and lateral (D) radiographs of a 56 year old female with history of post-traumatic degenerative joint disease of the first tarsometatarsal joint and metatarsus primus elevatus deformity noted on lateral radiograph. Patient underwent re-positional arthrodesis of the first tarsometatarsal joint augmented with cores of autogenous bone graft (C) procured from the ipsilateral calcaneus utilizing the Corex™ minimally invasive bone graft harvester. Postoperative weightbearing left foot AP (B) and lateral (E) radiographs in the same patient demonstrating well-healed arthrodesis site, calcaneal bone graft harvest site, and anatomic restoration of the first ray without complication.

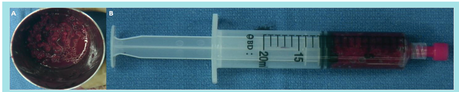

Figure 6 Legend: Intraoperative photograph of autogenous bone graft collected within a sterile cup (A) after being harvested from the distal medial tibial metaphysis. The same autogenous bone graft after being transferred to a sterile syringe to be quantified (10 cc) and sealed to prevent contamination until its future use in the surgical procedure.

RESULTS

A total of 24 surgical cases that used the Corex™ device on 23 separate consecutive patients (one patient had left and right lower extremities operated on in separate surgical settings) for a total of 26 harvest sites were identified during the study timeframe. Six patients were excluded from the retrospective review. One patient was excluded because the main author was an assistant surgeon and not the primary surgeon in the case, and 5 more patients were excluded because their follow-up timeframes failed to meet a minimum of 3 months. This left an inclusion of 18 patients over 18 consecutive surgeries for a total of 20 harvest sites. There were 11 (55%) harvests from the distal tibia and 9 (45%) from the calcaneus. Ten (55.6%) right lower extremities and 8 (44.4%) left lower extremities were involved, with 11 (61.1%) female versus 7 (38.9%) male. All patients (100%) were white or Caucasian with a mean age of 51.7 (range 17 – 78) years, and an average body mass index (BMI) of 33.4 (range 21.5 – 46). They were followed over a mean of 26.9 (range 12-51) weeks. The reason for autogenous bone graft harvest in every patient (100%) was for an arthrodesis as the primary procedure, with 5 (27.8%) involving a forefoot arthrodesis, 6 (33.3%) midfoot, and 7 (38.9%) hindfoot. There were no (0%) delayed unions, mal-unions, or non-unions noted in this patient cohort. None of the patients had to return for any type of additional surgery (0%), including for either hardware removal or infection.

Patients rated their preoperative and postoperative overall pain level using a visual analogue scale (0 – 10). The average preoperative overall pain rating was 4.5 (range 0 – 8) and average postoperative overall pain rating at patient's last follow-up appointment was 0.6 (range 0 – 3). All 20 harvest sites (100%) had sterile collagen-based gel foam packed within the bone graft harvest site, but none (0%) required any back-filling with bone allograft products.

Furthermore, there were no intraoperative complications observed (0%). No thromboembolic events (deep venous thrombosis and/or pulmonary embolus) transpired (0%). There were no major postoperative complications (0%). One minor postoperative complication (5.6%) was identified, which included delayed incisional wound healing at the harvest site of the autogenous bone graft along the patient's lateral calcaneus, which was defined as an incision that did not heal primarily prior to the 4 weeks postoperative timeframe.

ANALYSIS & DISCUSSION

The results of this retrospective review demonstrate that the Corex™ minimally invasive bone harvester is a safe and reliable device to utilize for reproducible and successful harvest of autogenous bone graft from the distal tibia or calcaneus. Furthermore, there is low associated risk of intraoperative or postoperative complications. Other studies have concluded similar findings [7, 20, 27, 29, 30,] indicating harvest from the tibia or calcaneus to augment foot and ankle surgical procedures carries less pain and potential morbidity than the iliac crest and still offers the biological healing benefits of autogenous bone graft that is often desired for these procedures to be successful. Moreover, the calcaneus and distal tibial metaphyseal bone offers sufficient bone volume to augment a variety of forefoot, midfoot and rearfoot arthrodesis procedures as demonstrated in this review. The two harvest sites can be safely combined if additional bone volume is required. Results also demonstrated the autogenous bone graft harvest site does not routinely require any bone allograft products to back-fill the harvest site nor to supplement the harvested autogenous bone for the primary procedure, suggesting a potential cost benefit. Operative time to harvest the bone graft was less for the calcaneus, but appears to have a direct relationship with the volume of bone being harvested, which would be expected.

The author recognizes that an inherent weakness of this study is its retrospective nature, as well as relatively small sample size. This could lead to biased or skewed results. No controls for patient demographics or medical co-morbidities were present, nor for confounding variables. Similar to any retrospective chart review, the current study could be subject to biased results inherent in patient medical records due to incomplete or inaccurate information. Although the author felt the cohort was inclusive of all patients that met the inclusion criteria and underwent bone graft harvest using the minimally invasive harvesting device, coding or billing errors could have existed that failed to capture additional patients. It should be noted that a biostatistician reviewed the results and data points of this study as well, but due to the small sample size and low rate of complications no further statistical analysis was felt beneficial to draw any reliable conclusions. Only half of the patients in this review had data that was prospectively recorded intraoperatively and postoperatively to specifically examine variables that could influence the safety and efficacy of these procedures. Further conclusions could be drawn from this type of data (intraoperative time for harvest, volume of bone harvested from each location, estimated blood loss, use of allograft products at donor site or to augment autogenous bone, etc…), which is scarce in the current literature. Patients were only followed until complete clinical and radiographic healing of their primary procedure, and in some cases follow-up was still ongoing for these patients. It's certainly plausible that late complications could be witnessed which would not have been identified in this current study, and when feasible, patients should be followed for at least one year after surgery. To these points, the author does have an ongoing prospective study involving the same bone harvesting device at the same anatomical locations, with the goal of enrolling enough patients with long-term follow-up to draw reliable conclusions on the use of this device to harvest autogenous bone graft from the tibia and/or calcaneus for use in foot and ankle surgery.

In summary, given the results of this review, and despite the aforementioned weaknesses, the author concludes that the Corex™ minimally invasive bone harvester is a safe and efficient device for satisfactory harvest of autogenous bone graft from the calcaneus and distal tibia to augment foot and ankle surgical procedures. Further prospective comparative studies with long-term follow-up controlling for confounding variables as well as patient factors should continue to be performed to establish the overall safety and efficacy of autogenous bone graft harvest from lower extremity sites.

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Disclosure: Author is a consultant for Trinity Orthopedics and is involved in ongoing prospective research pertaining to the Corex device.