

An Intramedullary Fixation Device for the Modified Lapidus Procedure

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ABSTRACT

INTRODUCTION: First tarsometatarsal joint arthrodesis is commonly performed for hallux valgus and arch collapse as a result of first ray instability. Recent literature has shown a high union rate for the procedure, though the procedure can be technically difficult and hardware prominence can be an issue. The purpose of this study is to review early results of a novel intramedullary tarsometatarsal fusion device used to perform a modified Lapidus procedure.

METHODS: Twenty modified Lapidus procedures were performed with the intramedullary device. All patients were allowed to bear weight on the heel immediately after surgery. Radiographic union rate, correction of hallux valgus deformity, and complication rate were recorded.

RESULTS: At a minimum follow up of 5 months, the overall union rate was 100%. Three of the patients had minor complications, none of which were directly attributed to the implant itself.

DISCUSSION: The results of this early study show a union rate and complication rate for this device which are comparable to those reported in the literature for the modified Lapidus procedure. Based on the patient results outlined in this study, the device allowed for early weight bearing and showed a low implant removal rate. These characteristics make the implant an appealing choice as a fixation device for the modified Lapidus procedure.

INTRODUCTION

First tarsometatarsal joint arthrodesis was originally described in 1934 for treatment of hallux valgus. This procedure was later modified to treat hallux valgus and other conditions as a result of midfoot instability associated with arch collapse. In contrast to using an osteotomy to correct the deformity, the modified Lapidus involves preparing the tarsometatarsal (TMT) joint by removing cartilage, correcting the deformity and fixing it in the appropriate position. This allows for a powerful correction of the deformity. The procedure has been criticized since its introduction, primarily citing high nonunion rates of up to 10-12%.¹⁻⁴ However, recent studies indicate the nonunion rate is much lower than originally thought, citing fusion rates of 94% and above.⁵⁻⁸ These studies also demonstrate high patient satisfaction and low overall complications.^{2,6,8,9}

A number of surgical techniques have been described to perform the fusion. The authors of the current study have extensive experience using an open dorsal approach to prepare the joint and traditional crossing screws across the tarsometatarsal joint to stabilize the fusion.⁶ A number of other approaches and techniques have been described, each with different advantages and disadvantages. A challenge of the modified Lapidus procedure as opposed to a uniplanar or even biplanar osteotomy is controlling the deformity. Once joint preparation is complete, the TMT joint is able to move unrestricted if not controlled by the surgeon.

A novel device was designed to assist the surgeon to stabilize the correction of the metatarsal during reduction, provide compression across the joint, and provide rigid fixation. In addition, the device is internal to the bone, which minimizes the need for hardware removal. Based on the patient results outlined in this study, the design of the device is sufficiently strong enough to allow for early weight bearing (heel weightbearing immediately post-operative as tolerated) in a fixed ankle support boot and then transition to regular footwear.

The purpose of this study is to investigate early outcomes of patients undergoing first TMT fusion using this device. The primary outcome will be first TMT joint union. Secondary outcomes will be radiographic correction of deformity, complications, and recurrent surgery over the first six months after implantation. Our hypothesis is that the fusion rate will be comparable to recent literature.

MATERIALS AND METHODS

A retrospective chart review was conducted over a 2-year period on patients who had undergone tarsometatarsal fusion with an InCore device. The first ten procedures performed by each of the senior surgeons were included. This study was exempt from IRB approval as a retrospective, less-than minimal risk quality improvement study. Patients who underwent TMT fusion with the InCore device and had complete office notes for at least six months postoperatively were included in the study. Exclusion criteria consisted of patients under the age of 16 who were not considered to be skeletally mature, as well as those with a prior history

of trauma or surgery to operative extremity. Six months was chosen as the follow up endpoint to determine fusion rates, resolution of symptoms and correction of deformity. Nonunion was defined by the absence of bone bridging at six months postoperatively on all views, as well as persistence of clinical symptoms. Hallux valgus deformity was defined by the presence of a hallux adductus angle greater than 20 degrees.

Between July 2018 and April 2019, there were 20 patients who met the inclusion criteria and had complete records for review. Records were evaluated for demographic information, complications, and reoperations. Preoperative, immediate postoperative, and three to five-month postoperative radiographs were examined. Intermetatarsal angles (IM) and hallux adductus angles (HAA) were recorded for all patients whose primary indication for surgery was hallux valgus deformity. Days to radiographic union was noted for all patients, regardless of their primary indication for surgery.

Four of the 20 patients were male (25%) and 16 were female (75%). No patient had bilateral procedures. Mean age at surgery was 55.1 years (range, 35 to 63). The average body mass index (BMI) was 28.4 (STDEV 6.04). None of patients were reported to be current tobacco users.

The primary indication for TMT fusion was hallux valgus in 12 of 20 patients (60%). Other indications were related to midfoot instability as a result of arch collapse as previously described.⁵

Surgical techniques

A 6 -7 cm incision was made over the first TMT joint. Subcutaneous dissection was carried down to the extensor hallucis longus tendon sheath, which was opened, and the tendon retracted laterally. The TMT joint capsule is opened and periosteum elevated distally and proximally from the intercuneiform space across the TMT joint to the first and second metatarsal bases. The post drill guide was positioned with the large paddle between the medial cuneiform and the first metatarsal and the smaller paddle in the intercuneiform space. A 2 mm K-wire was then placed through the post drill guide into the medial cuneiform and the drill guide removed. Traditional tarsometatarsal joint preparation was performed. If necessary, the modified McBride procedure is performed at this point. A 5.9 mm post reamer was introduced over the 2 mm K-wire and drilled to the depth of the laser etched line. The drill and K-wire were then removed.

The post reamer, connected to the targeting assembly, was then inserted to lie just below the surface of the dorsal cortex. The metatarsal was then rotated to correct the triplanar deformity. Once the metatarsal in its desired location, two 2 mm K-wires were placed through the compression-distraction fixture. Compression is applied across the joint using the compression-distraction fixture. Drill bushings were inserted into the targeting guide and holes drilled for the interlocking 3.5 mm screws. The screws were then advanced until the appropriate torque is reached. The K-wires and the targeting guide were removed and the post plug screw inserted. As indicated, other procedures were then performed.

Postoperatively, patients were placed into a CAM walking boot and allowed to bear weight immediately. They presented to the clinic for follow up at 2 weeks, 8 weeks, 4 months, and then at 3-month intervals as indicated by their surgeon. Radiographs were taken at each postoperative visit. At the 8-week visit, patients were allowed to wean out of their walking boot into regular footwear.

Descriptive statistics were performed using Microsoft Excel (Version 16.32). Paired student t-tests were used to compare pre- and postoperative angular measurements. P-value was set at $p < 0.05$.

RESULTS

Of the 20 patients assessed, all had complete chart data for review. The average number of days to final follow up was 210 days (STDEV 87.6). There was a 100% union rate at the TMT joint at the time of final follow up. The average number of days to radiographic union was 129 days (STDEV 36.6). In the hallux valgus group, the preoperative IMA was 14.99 (STDEV 3.69), the 2-week postoperative IMA was 4.25 (STDEV 2.03), and the 3 to 5-month postoperative IMA was 5.82 (STDEV 2.64). The difference between preoperative and postoperative IMA was 9.17 ($p=8.7 \times 10^{-7}$). In the same group, the preoperative HAA was 30.43 (STDEV 9.92), the 2-week postoperative HAA was 11.70 (STDEV 6.18), and the 3 to 5-month postoperative HAA was 10.77 (STDEV 6.62). The difference between preoperative and 3 to 5-month postoperative HAA was 19.66 ($p=1.6 \times 10^{-5}$).

Additional procedures were performed in all patients. The most common concomitant procedures performed were gastrocnemius lengthening (13/20 or 65%) and modified McBride procedure 12/20 or 60%). Other procedures performed included: hammertoe correction (8/20), metatarsal shortening osteotomy (4/20), medial displacement calcaneal osteotomy (2/20), and modified Brostrom procedure (2/20). Concomitant procedures performed in only one patient were: mass excision, peroneus brevis and superior peroneal retinacular repair, subtalar arthrodesis, ankle arthrotomy, and flexor digitorum longus transfer.

A total of three complications occurred (15%). There was one instance of delayed wound healing, one superficial wound infection, and one stiff hallux metatarsophalangeal joint which was attributed to an extensor hallucis longus (EHL) contracture. The superficial wound infection was treated with local wound care and local antibiotics. The other two cases resulted in subsequent surgery. The case of delayed wound healing was treated with wound debridement, application of Silvadene, and dressing changes. The stiff toe was treated with EHL tenolysis and manipulation under anesthesia. Recurrence of hallux valgus did not occur in any patient for which hallux valgus was the primary indication for surgery.

All patients followed the immobilization and weight bearing protocols as prescribed except for the patients who experienced superficial infection and delayed wound healing.

DISCUSSION

Tarsometatarsal joint fusion is a commonly performed operation for treatment of a number of pathological conditions. Various methods of performing this fusion operation have been described with varying rates of fusion. In this early outcomes and rates of fusion-focused study, we have found a 100% rate of fusion using the InCore device. This high rate of union was achieved despite the patients being allowed to heel weight bear immediately after surgery. The senior surgeons have previously published a metatarsocuneiform fusion rate of 96% for correction of hypermobile first ray resulting in arch collapse or hallux valgus.^{5,6} Similar to the current study, there were a high number of associated procedures and a similar number of complications. In these two studies, however, patients were placed in a splint after surgery and strict non-weight bearing was advocated for the first two weeks, followed by cast application and heel weight bearing. Patients undergoing fusion with the InCore device were allowed to heel bear weight directly after surgery in a boot and avoid use of a splint and cast altogether. Sangeorzan and Hansen reported on using the modified Lapidus for correction of first ray hypermobility. Their original report had a nonunion of 10%, though it should be noted that of the 40 feet operated, 7 of those were revision surgeries.¹ Revision surgery, along with tobacco use, has been shown to increase the nonunion rate for tarsometatarsal joint fusion in other studies.

In this review, there were three complications in twenty patients, two of which returned to the operating room. None of the patients returned for implant removal. This rate of complications is consistent with recent reported rates of complications in studies looking at first tarsometatarsal joint fusion and lower than historical rates.^{5,6}

There are limitations to this study. The sample size of the patient population is small and the follow up short. This short follow up would not affect union rate as all patients had complete fusion at the time of final follow up; however, complications and recurrence of deformity could change with a longer follow up period. Furthermore, there was no direct comparison group. Though historical control group can show contrast, rigorous statistical investigation can't be performed.

CONCLUSION

The modified Lapidus procedure for first metatarsocuneiform instability has been shown to have a high fusion rate, high patient satisfaction rate, and low complication rate.^{5,6,8,9} Use of the InCore device in this study showed a 0% non-union rate with immediate weightbearing in a CAM walking boot. Furthermore, the lack of cases requiring implant removal may be an indication that its intramedullary position did not cause irritation. Further studies with a control group and longer follow up should be performed to provide more statistical significance and determine clinical meaningfulness.

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