Minimally invasive technique with intramedullary nail for treatment of severe hallux valgus: clinical results and surgical technique

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Abstract

Objective: The purpose of the study was to evaluate early clinical and radiological results with a novel minimally invasive surgery (MIS) technique for Lapidus arthrodesis using intramedullary nail.

Methods: Retrospective review of patients with hallux valgus surgery during an 18-month period. Patients with a procedure other than MIS Lapidus nail fixation were excluded. We describe surgical technique with a percutaneous joint preparation and fixation with an intramedullary nail through a MIS approach. Demographic variables, early complications and radiographic parameters were measured.

Results: Ten feet in 8 patients with severe HV underwent a Lapidus procedure performed with a minimal invasive technique using intramedullary nail for fixation. No soft tissue complications and 1 patient required screw removal after bone healing. Mean HVA decreased from 31,4 degrees (range 17 to 47) SD (±9,3) to 10,3 degrees (range, -8,8 to 31,5) SD (±8,4), mean IMA decreased from 17,91 degrees (range, -17 to 20) SD (±0,9) to 5,46 degrees (range, –7,3 to 15,3) SD (±2,9) and mean DMAA decreased from 20,36 (range, 10-40) SD (±8,4) to 7,67 (range, -5 to 30) SD (±8,0).

Conclusion: Intramedullary nail for Lapidus arthrodesis with minimally invasive technique showed satisfactory radiographic correction and minimal complications, but further follow up is needed to analyze clinical-radiographic results.

Level of Evidence IV; Therapeutic Study; Case Series.

Keywords: Hallux valgus/surgery; Osteotomy/methods; Minimally invasive surgical procedures; Fracture fixation, intramedullary; Treatment outcome.

Introduction

Hallux valgus deformity is a triplanar deformity of the first ray which involves varying degrees of varus of the first metatarsal, valgus of the hallux, and pronation of the first ray. The Lapidus procedure was introduced in 1934 to correct hallux valgus in relation to hypermobility of the first ray(5). The original technique consisted of an arthrodesis of the first cuneiform-metatarsal joint and the first intermetatarsal joint. The fixation was achieved by sewing the joint capsules with catgut. Later on, fixation was achieved by crossed screws performed by Hansen and colleagues(2) and led to a modified technique without intermetatarsal fusion. The Lapidus procedures has a strong ability to correct the pronated first metatarsal and reduce the subluxated sesamoids, due to most of the rotation, occurs at the tarsometatarsal Joint (TMT joint)(3). It has a higher corrective power compared to other procedures for correction of hallux valgus deformity, therefore diminishing the rate of recurrence. Accepted indications for this procedure include: severe hallux valgus deformity being IMA >15, arthritis of the tarsometatarsal joint, metatarsus primus varus and hypermobility of the tarsometatarsal joint among others(1). There are two main concerns regarding Lapidus procedure. The first is nonunion risk, with literature indicating a rate of approximately 2% to 10%(4-6). The second concern is malunion, most commonly shortening and dorsiflexion of the first ray, leading to transfer metatarsalgia(6,7).
During the last few years, research and interest in hallux valgus surgery has grown, resulting in better outcomes and reduced complications. Fixation of Lapidus fusion has evolved in both its approach and method of fixation, looking for avoid soft tissue injury and better biomechanical resistance. It is recently that intramedullary nail has been introduced as a new method of first tarsometatarsal arthrodesis. 

The intramedullary nail can resist superior forces across the fusion site and limits migration during healing to facilitate earlier weight-bearing. Being intramedullary, the nail is capable of accepting greater forces across the fusion site and limits migration during healing while providing even compression across the first TMT joint.

Minimally invasive surgery (MIS) for hallux valgus correction remains controversial. Literature regarding this topic is continuously growing, but at this time, there is scarce literature showing whether MIS for hallux valgus correction is effective compared to traditional approach or if correction remains stable over time. The most common complications following MIS were described by Oliva et al., which are deformity recurrence, incorrect procedure selection or operative technique, and underestimation of osteotomy healing time. In contrast, the biggest advantage of MIS for hallux valgus is that correction can be done with a very small incision, limiting wound problems, maintaining local environment and a less visible scar.

Forefoot MIS is continuously growing based on third generation techniques, with promising results in terms of deformity correction, wound healing and patient satisfaction. Recently, 2 systematic reviews concluded that MIS is safe and reliable for hallux valgus surgery. Theoretically, it would be of great interest to take advantage of benefits described for MIS surgery and nail fixation, but to our knowledge, there is no available literature regarding clinical results of MIS Lapidus procedure with this technique. Our objective is to describe Lapidus fusion consecutive case series, evaluating clinical and radiological results and description of MIS technique for the first tarsometatarsal arthrodesis using an intramedullary nail.

Operative technique

After obtaining IRB approval, a consecutive case series study was conducted. We retrospectively reviewed data from patients who underwent Lapidus MIS procedure for hallux valgus deformity correction with a Phantom® intramedullary nail (Paragon28, Colorado USA) from April 2018 to October 2019 in a single center with a minimum of 6 months follow-up. The indication for surgery was failure of conservative treatment including shoe modification and pads. Inclusion criteria were patients with severe hallux valgus deformity (defined as a deformity with IMA > 15) and hypermobility or arthritic changes at first TMT joint. Patients were excluded from our study if they had had previous first ray surgery, hallux valgus with indication for other technique, neuroarthropathic disease, incomplete imaging study or if they refused to participate. A patient chart and x-ray review were conducted to collect basic demographic data and deformity measurements: hallux valgus angle (HVA), intermetatarsal angle (IMA) and distal metatarsal articular angle (DMMA) pre and post-operatively.

Clinical assessment

Patient demographic data which include aged, sex, body mass index (BMI) smoking status and relevant comorbidities (diabetes, hypothyroidism). Any complications of wound healing, infection, hardware removal, revision procedure of the first ray, or other complications requiring operative intervention were also recorded.

Radiological assessment

A single orthopedic surgeon reviewed all images. Weight-bearing x-rays of the operative foot were obtained at 2 weeks and 12 weeks, postoperatively for analyzing the radiographic parameters mentioned. Imaging included AP and lateral views. The HVA was defined as the angle between the longitudinal axis of the first metatarsal and proximal phalanx. IMA was defined as the angle between the longitudinal axis of the first and second metatarsals. The DMMA was defined as the angle between the distal first metatarsal articular surface and the longitudinal axis of the first metatarsal.

Results

Retrospectively 111 patients (185 feet) with hallux valgus deformity were analyzed during the study period in which 8 patients (10 feet) met the inclusion criteria, with a mean age of 59 years, all female. Median follow-up was 16 months (9-23) (Table 1). Radiographic measurements demonstrated significant improvements in IMA, HVA, and DMMA that were maintained at 2 weeks and 12 weeks postoperatively. At the final minimum follow-up of 6 months, significant improvements in IMA, HVA and DMMA were noted compared with preoperatively. The mean HVA decreased from 31,4 degrees (range 17 to 47) SD (±9,3) preoperatively to 10,3 degrees (range, -8,8 to 31,5) SD (±8,4). The mean IMA decreased from 17,91 degrees (range, -17 to 20) SD (±10,9) preoperatively to 5,46 degrees (range, -7,3 to 15,3) SD (±2,9) postoperatively and the mean DMMA decreased from 20,36 degrees (range, 10-40) SD (±8,4) preoperatively to 7,67 (range, -5 to 30) SD (±8,0) postoperatively (Table 2). In regard to additional procedures performed in conjunction with the first TMT arthrodesis, all required lateral release, 6 feet required an Akin osteotomy and distal metatarsal osteotomy in 2 feet. At final follow-up there was no recurrence of hallux valgus defined as an HVA greater than 15 degrees or IMA >10. There were no wound complications. One patient needed an additional surgery due to symptomatic hardware in one foot. No cases of overcorrection were noticed.

Methods

After obtaining IRB approval, a consecutive case series study was conducted. We retrospectively reviewed data from patients who underwent Lapidus MIS procedure for hallux valgus deformity correction with a Phantom® intramedullary nail (Paragon28, Colorado USA) from April 2018 to October 2019 in a single center with a minimum of 6 months follow-up. The indication for surgery was failure of conservative treatment including shoe modification and pads. Inclusion criteria were patients with severe hallux valgus deformity (defined as a deformity with IMA > 15) and hypermobility or arthritic changes at first TMT joint. Patients were excluded from our study if they had had previous first ray surgery, hallux valgus with indication for other technique, neuroarthropathic disease, incomplete imaging study or if they refused to participate. A patient chart and x-ray review were conducted to collect basic demographic data and deformity measurements: hallux valgus angle (HVA), intermetatarsal angle (IMA) and distal metatarsal articular angle (DMMA) pre and post-operatively.
radiolucent operating room table. For anesthesia, a regional extremity nerve block is performed. A tourniquet is applied to the operative limb in the proximal thigh to prevent bleeding and better procedure visualization. The procedure starts with a percutaneous lateral release using a Beaver blade. The medial eminence is resected via minimal invasive incision which is made just distal to the medial eminence. A specific driver system with high torque and low speed is required to be mounted to the 13mm length and 3.1mm conical Shannon burr. This offers a good ratio between cutting the bone and the risk of burning the skin. A speed of less than 10,000rpm is recommended. The 3.1mm wide conical shannon burr is introduced to clean the prepared joint. Bone graft is introduced if needed. In all of our cases, bone graft was not required. Reduction in 3 planes of 1st metatarsal is performed utilizing three 1.6mm kirschner wires. One of the pins will drive across the first to second metatarsal diaphysis while the other 2 will hold reduction across the first TMT in an area where it does not interfere with nail placement. Correction is corroborated radiographically in both planes of the foot. Nail’s entry point of is located 23mm distally to first TMT joint in dorsal aspect of the foot. A 3cm incision is made lateral to the extensor hallucis longus centered on the entry point. Dissection of the soft tissue is done until the dorsal bone surface of the first metatarsal is identified. A target pin to aid the correct placement of the intramedullary nail is placed into the plantar and proximal aspect of the medial cuneiform. This is done under radiographically guidance to ensure the adequate position (Figure 1). Then place the radiolucent guide that will rest in the bottom of the medial side of the targeting pin. The radiolucent guide gives the correct angle of the initial starting pin of the nail. Then drill the guide pin being the starting point lateral to midline of the metatarsal and lateral to the extensor hallucis longus, measure the length and ream over the pin guide. Insert the nail with assembly of the proximal and distal part of the outrigger. Place two 3.5mm interlocking screws through nail’s proximal segment and remove the distal outrigger. Compression of the fusion site is made with the torque driver and then position is maintained with two distal 3.5mm interlocking screws. An additional screw from medial side of the first metatarsal to the lateral cortex of the second metatarsal might be needed if there is intercuneiform instability. The incisions are closed with a 3.0 non absorbable suture and soft dressings are applied (Figure 2). The postoperative protocol consists of compression dressing left in place with a rigid sole postoperative shoe. Weight bearing is allowed with crutches as tolerable. Sutures are removed at 3 weeks. Progression into full weight bearing with the aid of a rehabilitation program for 6 weeks. Patients had follow-up appointments at 2 weeks, 6 weeks, 12 weeks and 6 months postoperatively. In general, patients were allowed to return to normal athletic shoes at 6 weeks postoperatively and return to full activity after fusion was observed. All patients followed the same postoperative protocol.

**DISCUSSION**

Lapidus fusion for management of hallux valgus deformity is a popular yet challenging procedure. Nonunion is a major concern, having a frequency between 2-10% and rising up to 33% after bilateral procedures and rising up to 33% after bilateral procedures. From this cases, 50% become symptomatic. Typical post-operative protocols include the need for prolonged non weightbearing to help obtaining primary bone healing and prevent secondary elevation of the first ray. Nonetheless recent studies have exposed low nonunion rates for the first TMT fusion, even with the complete debridement of the joint. The lateral margin is the base of the 2nd metatarsal. Once again, the bone paste formed is removed and abundant saline solution irrigation is introduced to clean the prepared joint. Bone graft is introduced if needed. In all of our cases, bone graft was not required. Reduction in 3 planes of 1st metatarsal is performed utilizing three 1.6mm kirschner wires. One of the pins will drive across the first to second metatarsal diaphysis while the other 2 will hold reduction across the first TMT in an area where it does not interfere with nail placement. Correction is corroborated radiographically in both planes of the foot. Nail’s entry point of is located 23mm distally to first TMT joint in dorsal aspect of the foot. A 3cm incision is made lateral to the extensor hallucis longus centered on the entry point. Dissection of the soft tissue is done until the dorsal bone surface of the first metatarsal is identified. A target pin to aid the correct placement of the intramedullary nail is placed into the plantar and proximal aspect of the medial cuneiform. This is done under radiographically guidance to ensure the adequate position (Figure 1). Then place the radiolucent guide that will rest in the bottom of the medial side of the targeting pin. The radiolucent guide gives the correct angle of the initial starting pin of the nail. Then drill the guide pin being the starting point lateral to midline of the metatarsal and lateral to the extensor hallucis longus, measure the length and ream over the pin guide. Insert the nail with assembly of the proximal and distal part of the outrigger. Place two 3.5mm interlocking screws through nail’s proximal segment and remove the distal outrigger. Compression of the fusion site is made with the torque driver and then position is maintained with two distal 3.5mm interlocking screws. An additional screw from medial side of the first metatarsal to the lateral cortex of the second metatarsal might be needed if there is intercuneiform instability. The incisions are closed with a 3.0 non absorbable suture and soft dressings are applied (Figure 2). The postoperative protocol consists of compression dressing left in place with a rigid sole postoperative shoe. Weight bearing is allowed with crutches as tolerable. Sutures are removed at 3 weeks. Progression into full weight bearing with the aid of a rehabilitation program for 6 weeks. Patients had follow-up appointments at 2 weeks, 6 weeks, 12 weeks and 6 months postoperatively. In general, patients were allowed to return to normal athletic shoes at 6 weeks postoperatively and return to full activity after fusion was observed. All patients followed the same postoperative protocol.

**Table 1. Demographic parameters for the minimally invasive Lapidus procedure with intramedullary nail**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Study Group</th>
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<tbody>
<tr>
<td>Age, mean±SD years</td>
<td>59±6.3 years</td>
</tr>
<tr>
<td>Gender</td>
<td>All female</td>
</tr>
<tr>
<td>BMI kg/cm² mean ± SD</td>
<td>23.46±4.9</td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
</tr>
<tr>
<td>Non Smokers</td>
<td>(8/10)</td>
</tr>
<tr>
<td>Current</td>
<td>(2/10)</td>
</tr>
<tr>
<td>Comorbidities, N (%)</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>(1/10)</td>
</tr>
<tr>
<td>Hypothyroidism</td>
<td>(3/10)</td>
</tr>
<tr>
<td>Without</td>
<td>(6/10)</td>
</tr>
<tr>
<td>Additional Procedures</td>
<td></td>
</tr>
<tr>
<td>Akin Osteotomy</td>
<td>(7/10)</td>
</tr>
<tr>
<td>Arthroereisis</td>
<td>(1/10)</td>
</tr>
<tr>
<td>Average follow up (months)</td>
<td>16.4</td>
</tr>
</tbody>
</table>

BMI: body mass index; SD: standard deviation

**Table 2. Radiographical measures preoperatively and after the minimally invasive intramedullary Lapidus procedure**

<table>
<thead>
<tr>
<th></th>
<th>Preoperatively N (degrees)</th>
<th>Postoperatively N (degrees)</th>
<th>Percentage change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HVA mean±SD</td>
<td>31.4 (±9.3)</td>
<td>10.3 (±8.4)</td>
<td>67.1</td>
</tr>
<tr>
<td>IMA mean±SD</td>
<td>17.91 (±0.9)</td>
<td>5.46 (±2.9)</td>
<td>69.5</td>
</tr>
<tr>
<td>DMAA mean±SD</td>
<td>20.36 (±8.4)</td>
<td>7.67 (±8.0)</td>
<td>62.3</td>
</tr>
</tbody>
</table>
Chaparro et al. Minimally invasive technique with intramedullary nail for treatment of severe hallux valgus: clinical results and surgical technique

Figure 1. A. First TMT joint preparation through percutaneous approach with a Shannon burr. B. Clinical appearance during nail insertion. C. Sagittal radiographic appearance after nail insertion and proximal blocking screws.

Figure 2. A. Severe hallux valgus deformity with markings in site of TMT joint (black arrow), nail insertion site (white arrow) and MTP joint (star). B. Postop result with correction of hallux deviation.

early weightbearing\textsuperscript{16,17}. A multicenter study of 367 patients compared early weightbearing (<21 days) versus deferred weightbearing (>21 days) after Lapidus procedure and found no differences in union rates\textsuperscript{17}. A more stable fixation would theoretically help reduce the nonunion rate and allow for early postoperative weight-bearing. The intramedullary nail
provides a stable fixation by resisting forces in 3 planes of direction. Comparison of fixation devices for Lapidus were previously studied. A cadaver study by Klos et al.(4) demonstrated that plates fixed in the plantar region are stiffer and have better load to failure than plates placed in the medial dorsal region. Another study compared first TMT fusion fixation in synthetic bones using a dorsal locking plate, a plantar locking plate, and fixation with an intramedullary device. The intramedullary device had the highest initial compression force.(38) The intramedullary nail contains a torque indicating driver which allows the surgeon to apply proper compression between 80-100N. This will allow compression and a stable fixation in the fusion site which could help obtain satisfactory fusion and allow for earlier weight bearing.

MIS surgery for hallux valgus correction is continuously gaining popularity among foot and ankle surgeons, but there is still a lack of good evidence to support it against traditional procedures. There are reports that state MIS for hallux valgus can obtain similar clinical and radiological reports to open procedures.(19,20) However, in order to obtain similar results, surgeons need to have previous MIS training. One of the advantages of minimal invasive surgery is diminishing soft tissue damage and maintaining local inflammatory environment that could promote healing. In our cohort of patients, there were no wound complication and swelling was managed by physiotherapy program contained in the postoperative protocol.

In terms of radiological parameters, our study showed a significant correction of all measured parameters, similar as expected with open fashion. The mean HVA decreased 21,1° (67,1% reduction), IMA 12,45° (69,5% reduction) and DMMA 12,69° (62,3% reduction). The rate of reduction of the HV angle and IMA has been described to 10°-22° and 6°-9°(13,21) after Lapidus procedure, which correlates with magnitude of improvement obtained with this technique (Figure 3). Malalignment typically results in shortening and dorsiflexion of the first metatarsal and may lead to transfer metatarsalgia of the second and/or third rays.(21) It can occur in up to 10% of the cases. None of our patients presented transfer metatarsalgia after 6 months follow up.

There were no major complications. Only one patient needed additional surgery due to symptomatic hardware, specifically a medial interlocking screw irritating the skin. In terms of fusion, at 12 weeks follow up, there was only one patient with no radiological signs of union albeit did not refer symptoms attributable to TMT joint non-union.

*Figure 3. A. Preoperative and B. Postoperative anteroposterior (AP) radiographs demonstrating first tarsometatarsal arthrodesis with intramedullary nail.*
The strengths of this study include reporting a novel technique for Lapidus fusion through MIS with an intramedullary implant that could have biomechanical advantages over traditional used implants (e.g., plates and screws) and is suitable for MIS usage. The main limitations of the study is short follow up of less than a year and small number of cases with no control group to compare clinical and radiological results. Radiographic evaluation in terms of fusion with CT-scan was incomplete so it was not possible to include it as an evaluation parameter. Further studies to investigate long-term outcomes, complications, and recurrence rates of MIS Lapidus procedure with intramedullary nail is needed.

**Conclusion**

The MIS Lapidus procedure with intramedullary nail is a safe and reliable procedure that allows early weight bearing, small incisions in order to minimize wound problems and adequate deformity correction. We believe this technique it’s an attractive alternative in severe hallux valgus deformity management but larger population and long term clinical-radiological follow up studies are needed.

**References**