MINIMALLY INVASIVE HALLUX VALGUS CORRECTION USING RELJA MIS CHEVRON BUNION SYSTEM

A Review of Outcomes and Learning Curve

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RELjA INNOVATIONS

ABSTRACT:

Hallux valgus correction with an open chevron osteotomy has been a mainstay since the 1970s, as it is a stable osteotomy with predicable results. Minimally invasive bunion surgery (MIS) offers the advantage of obtaining equivalent deformity correction through smaller incisions compared to open techniques. Recent MIS bunion literature reports a steep learning curve for the third-generation percutaneous chevron and akin osteotomy, with proficiency reached at 38 cases. The purpose of this study is to evaluate the learning curve and safety profile using the MIS Precision Chevron Bunion System™ (RELJA INNOVATIONS, Brookfield, WI) in patients with mild to moderate hallux valgus. The RELJA MIS Chevron utilizes a precision osteotomy guide to perform a joint sparing chevron osteotomy and fixate with a cannulated screw through a 1cm incision. The results of our cohort retrospectively reviewed 19 RELJA MIS Chevron surgeries performed by 5 different surgeons. Surgical time for each case decreased with all but one of the 5 surgeons during the first 4 cases. All 5 surgeons felt the learning curve was on average 4.7 cases. The only complication was a hardware removal on one patient. The average time to radiographic union was 6.3 weeks. We conclude the RELJA MIS Chevron bunion system is reproducible and is a superior minimally invasive joint sparing option that has been shown to have a lower learning curve compared to other MIS techniques, while still providing the benefits of an MIS approach.

INTRODUCTION

Hallux valgus is a complex deformity that is typically treated with an open osteotomy. The open chevron osteotomy has been a mainstay in hallux valgus correction for many years with good results. However, common complaints with the open osteotomy can include joint stiffness, scar tissue formation, and post operative pain. While surgeons can often address these problems, the post-op recovery process can be difficult for patients. Minimally invasive surgery (MIS) offers the advantage of obtaining equivalent deformity correction but through smaller incisions compared to open techniques. It also allows for a faster recovery, produces less scar tissue, spares the joint, and has less stiffness post-surgery. Finally, the small incision size is both preferred by the patient and poses less risk of skin complications.

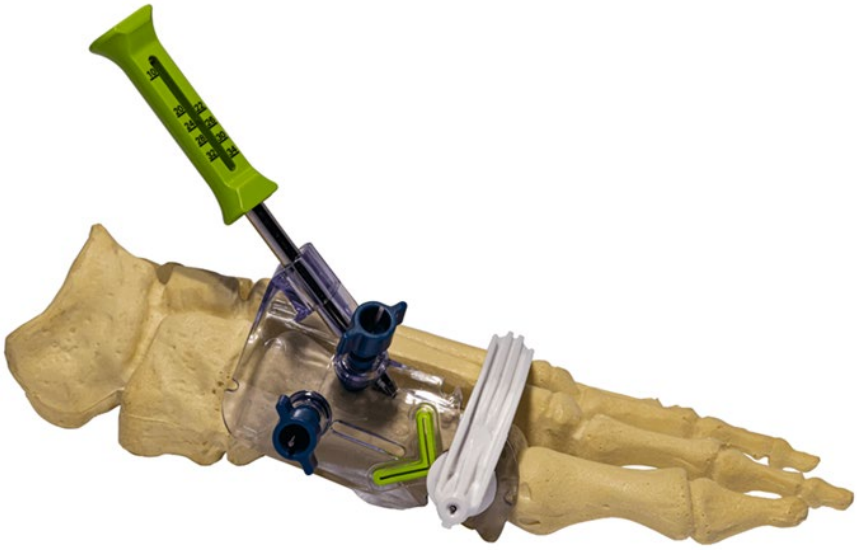
In 2005, Magnan and coworkers looked at 118 consecutive percutaneous distal osteotomies for mild to moderate hallux valgus. (2) Ninety-one percent of patients were satisfied and there was significant improvement in radiographic measures. Sixty-one percent of the patients had dorsal or plantar displacement of the capital fragment.

Complications included hallux valgus recurrence in three patients, first metatarsophalangeal (MTP) joint stiffness in eight patients and one deep infection. (2) Gianni and colleagues popularized the minimally invasive SERI (simple, effective, rapid, inexpensive) technique with their prospective study of 1,000 feet with hallux valgus in 2013. (4) They demonstrated a statistically significant average increase in American Orthopaedic Foot and Ankle Society (AOFAS) score from 47 preoperatively to 89 postoperatively. In this large series of patients, there were no non-unions and all patients had complete healing of the osteotomy. Hallux varus did not occur, and no deep wound infection occurred despite the presence of a 2 mm percutaneous K-wire, which surgeons removed at 30 days.

In 2013, Vernois and Redfern radiographically analyzed 100 feet with hallux valgus after a minimally invasive chevron and Akin osteotomy and demonstrated a mean correction of 9 degrees. (3) The mean preoperative intermetatarsal angle was 14.5 degrees and 7.3 degrees postoperatively. (3) In a systematic review of percutaneous osteotomies involving 18 studies and a total of 1,594 feet with hallux valgus, Bia and colleagues identified the following complication rates: infection (1.6 percent, K-wire cases only), recurrence (1.8 percent), nonunion (0.4 percent, K-wire cases only), complex regional pain syndrome (0.9 percent, K-wire and unfixated cases), transfer metatarsalgia (1.2 percent, mostly unfixated cases), osteonecrosis (0.1 percent, K-wire cases only) and joint stiffness (1.9 percent, K-wire and unfixated cases). (5)

These previous reports have studied the early iterations of minimally invasive hallux valgus surgery. However, recent advances in technology have allowed improvements in fixation and surgical technique. A recent study comparing minimally invasive surgery versus open osteotomies showed good to excellent clinical and radiologic outcomes at final follow-up in both groups. (6) However, the minimally invasive surgery group has significantly less pain in the first 6 weeks following surgery. (6) Current MIS techniques involve the use of screw fixation and appears to offer fewer complications compared to percutaneous K-wire techniques.

RELJA MIS CHEVRON BUNION SYSTEM



The Relja Innovations MIS Precision Chevon Bunion System™ is a new MIS bunion system allowing surgeons to perform a traditional chevron osteotomy through a 1cm incision. The technique utilizes a precision cut guide to allow a reproducible Chevron-type osteotomy. This allows the osteotomy to become inherently stable and is internally fixated with a 3.5mm cannulated screw. These features work cooperatively through a 1cm incision to minimize soft tissue damage. Recent studies have shown that the learning curve of MIS bunion surgeries can be steep. (7) Reported wound problems from burning of the skin with the burr has been reported in up to 13% by various experts. (8) Other complications of MIS bunion surgery such as shortening of the first metatarsal and elevated risk of first metatarsophalangeal joint non-congruency have also been associated with its steep learning curve. (9) A steep learning curved was reported for the third-generation percutaneous chevron and akin osteotomy at 38 cases. (13)

The purpose of this study is to evaluate the learning curve and safety profile using the Relja MIS Precision Chevon Bunion System™ in patients with mild to moderate hallux valgus. We hypothesize that the learning curve of the Relja Precision MIS Chevron Bunion System will have a lower learning curve and complication rate compared to previously reported MIS bunion techniques.

SURGICAL TECHNIQUE

Indications for the Relja MIS Precision Chevon Bunion System™ include patients with symptomatic mild to moderate hallux valgus deformities that have failed conservative treatment and have been determined to be satisfactory surgical candidates. Contraindications include infection or open wounds, skeletal immaturity, hypermobility of the first ray, insufficient bone quality or quantity, material sensitivity, physiologically inadequate patient.

At the surgeon's discretion, a lateral release is first performed which requires a small incision over the lateral aspect of the first MTP joint. Dissection is carried to the level of the conjoined adductor tendon. A #15 blade is used to release this tendon and the lateral 1st mpj joint capsule to allow correction of the hallux. Next, landmarks are marked on the operative foot using 25-gauge needles to mark the midline of the first metatarsal shaft. The 25-gauge needles are used to locate the midpoint of the dorsal and plantar aspect of the first metatarsal at the neck and again at the mid-diaphysis. These 2 points are then connected in a straight line to find the anatomic axis of the first metatarsal.

A small mark is placed on the skin on the dorsal aspect of the fourth MTP joint. Align osteotomy guide on medial aspect of foot with the targeting guide in place and aimed at the 4th MTP. Align the central slot and horizontal notches on the osteotomy guide with the midline of the first metatarsal. Utilizing live fluoroscopy
place the osteotomy guide in the correct position, midline in the neck of the 1st metatarsal (Image below). Insert the first K-wire through the targeting guide and osteotomy guide and into the bone, aiming toward 4th MTP joint. Next, remove the white targeting guide and utilize fluoroscopy to perform a standard lateral x-ray while holding the osteotomy guide in alignment with the marked lines. The lateral x ray should be positioned to shoot directly down the first K-wire (this should have the appearance of a BB). Confirm the osteotomy slot on the osteotomy guide (which is radiopaque) is midline of the first metatarsal and properly positioned in the neck of the first metatarsal. If needed, the osteotomy guide can be finely adjusted without reinserting the K-wire by sliding the osteotomy guide off the K-wire and reinserting the guide using one of the 4 surrounding adjustment holes. Confirm position as previously done on fluoroscopy.

Image showing proper setup of foot and fluoroscopy position. This allows easy positioning of the osteotomy guide on the foot utilizing live fluoroscopy images.

Next, the osteotomy guide is rotated 90 degrees dorsally and a 1 cm incision is marked along the skin marking line and soft tissue dissection performed at the osteotomy site. Place the retractors in the incision. The longer retractor is placed dorsally to protect the Extensor Hallucis Longus (EHL). Confirm K-wire is midline on the 1st metatarsal by visualizing or feeling the dorsal and plantar cortex with a freer elevator. The guide is then rotated plantarly and realign with marks on skin. Insert K-wire into the second hole (proximal medial) and the third hole (dorsal), while confirming the distal osteotomy guide is resting on the skin of the medial eminence. Insert the screw guide into the osteotomy guide slot until the serrated tips reach the skin. Make a small incision and dissect down to bone. Place the screw guide down to the bone. Then insert the guide wire through the screw guide and into dorsal central area of the 1st metatarsal until it is in correct alignment with the first metatarsal head; stop just short of 1st MTP joint. Aim slightly lateral to central in the 1st metatarsal head. Confirm correct position of the guidewire on AP, and standard lateral (shooting directly down K-wire #1). Measure the screw length with the screw guide against the bone. If the measurement is 32 mm or greater, the dark blue 27 mm cannulated screw will be used. If the measurement is less than 32 mm, the green 24 mm cannulated screw will be used. Drill and countersink and leave the drill bit in place in the bone. (disconnect from the quick connect on the drill).

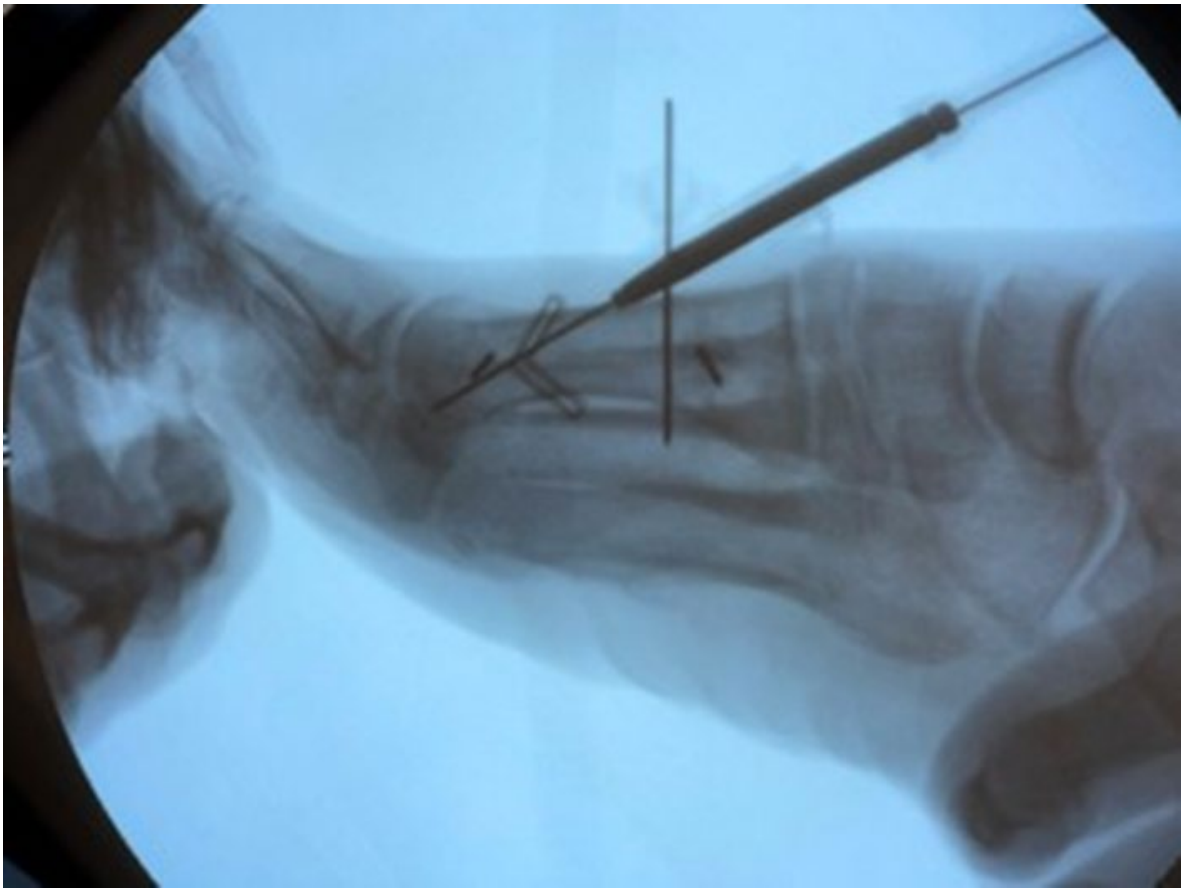


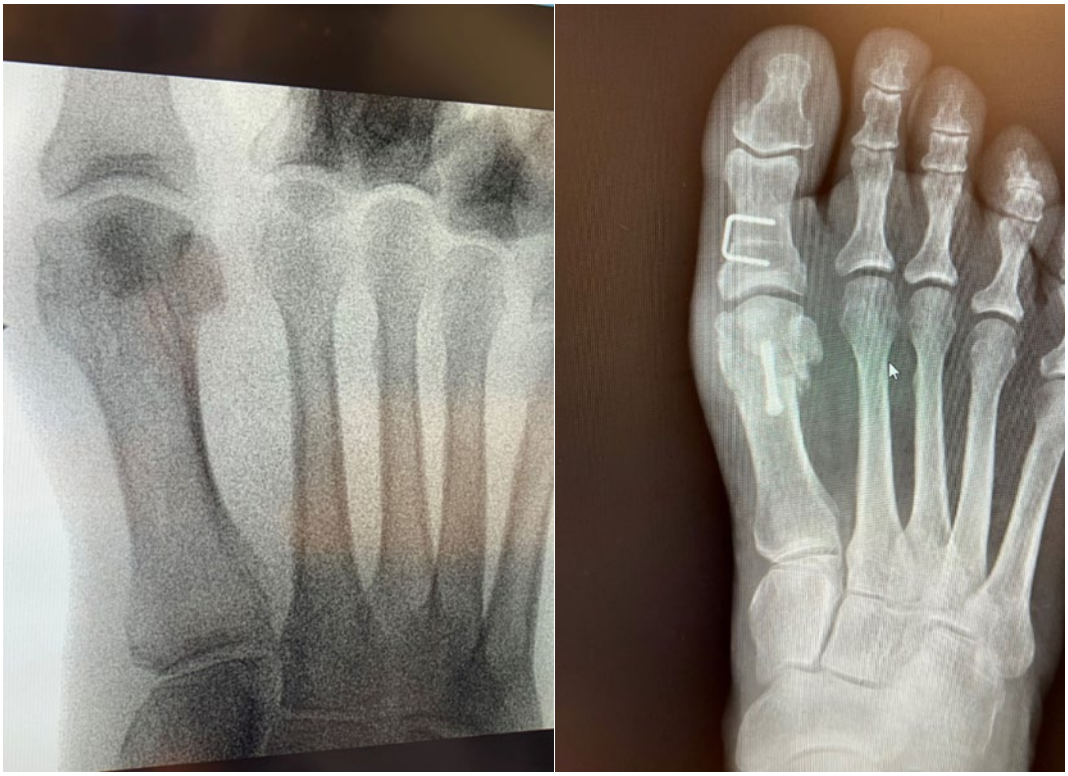
Image shows osteotomy guide in proper position (midline of the 1st metatarsal in the neck) and guide wire in the proper position. Fluoroscopy image obtained shooting directly down K wire #1.

Next, retract the skin and perform the osteotomy. A 9 x 31 x 0.38 mm saw blade is required. Do not start the saw until it is contacting the bone. Ensure the osteotomy is complete by inserting blade as far as possible into the osteotomy guide from dorsal cortex to plantar cortex. Next, remove all three K-wires and remove the osteotomy guide by sliding it over the drill bit. Confirm the osteotomy is complete. Shift metatarsal head by distracting the hallux and moving the head laterally. Confirm adequate correction of the deformity with AP and Lateral fluoroscopy images. Also, visualize there is no gapping of the osteotomy. With drill bit in place, reinsert the guide wire just into the 1st MTP. Create temporary fixation by inserting a K-wire on the medial side of first metatarsal from proximal medial to distal lateral. Confirm proper position of guidewire and temporary fixation with AP and lateral images on fluoroscopy. Remove the drill bit and while protecting the EHL, insert the cannulated screw previously selected over the guide wire. Use the cannulated screwdriver to drive the screw into position. Confirm screw position with AP, lateral and weightbearing lateral images on fluoroscopy. Confirm screw head is seated into the bone properly. At surgeon's discretion, resect and smooth the medial bone shelf with power bone rasp / saw. Remove guide wire and temporary fixation.

Multiple final views are obtained using fluoroscopic intensification. These views should confirm appropriate placement of implants, stable osteotomy, satisfactory correction of the previous bunion, and congruency of the first metatarsophalangeal joint. A sterile compression bandage is applied to the operative foot and ankle with the hallux splinted in neutral position. The surgeon should follow their standard chevron post op protocol. Postoperative weightbearing x-rays are obtained at 6 weeks, which is when the patient is allowed to transition into a supportive shoe. Postoperative x-rays are obtained at 9-12 weeks.

Image showing clinical appearance at 6 weeks postoperative follow-up visit.

Post op radiographs at 6 weeks showing good correction of the deformity with a healed osteotomy at 6 weeks post op.



Preoperative and postoperative weightbearing radiographs following MIS surgical correction with the Relja MIS Bunion System.

RESULTS

The average operative time was 44.6 minutes. Of the 5 surgeons, 4 experienced decreasing operating time with each subsequent case. There was an overall complication rate 5.2% (one patient required hardware removal). The average time to radiographic union was 6.3 weeks. In their opinion, these 5 surgeons felt the learning curve was on average less than 5 cases. These findings are summarized in Table 1.

Surgeon	Number of surgeries completed	Surgical Time Per Case (minutes)	Any reported patient complications	Time (weeks) to radiographic union of MIS Chevron Osteotomy	Number of MIS Chevron Cases required to complete the learning curve?
1	4	Case 1: 54 Case 2: 50 Case 3: 48 Case 4: 42	None	Case 1: 6 Case 2: 7 Case 3: 8 Case 4: 4	4
2	3	Case 1: 40 Case 2: 40 Case 3: 40	None	Same compared to open Chevron	5-10
3	4	Case 1: 48 Case 2: 45 Case 3: 40 Case 4: 33	None	Case 1: 7 Case 2: 7 Case 3: 7 Case 4: 7	4
4	4	Case 1: 65 Case 2: 55 Case 3: 40 Case 4: 32	None	Case 1: 6 Case 2: 8 Case 3: 6 Case 4: 4	3
5	4	Case 1: 55 Case 2: 45 Case 3: 42 Case 4: 33	Hardware pain requiring hardware removal	Case 1: 6 Case 2: 6 Case 3: 6 Case 4: 6	5

DISCUSSION

Surgical correction of hallux valgus deformities is a challenging but common endeavor for foot and ankle surgeons. Employing an MIS or percutaneous approach for these forefoot deformities offers patients and surgeons additional benefits over traditional open approaches. These include earlier postoperative weightbearing, less pain, decreased joint stiffness, superior cosmesis with less scarring, and reduced risk of wound healing or other complications. MIS surgery for hallux valgus correction has evolved and now incorporates new techniques and technology. However, learning curve continues to be a concern regarding new techniques. A study that evaluated the minimally invasive SERI technique reported a high number of complications such as dorsal malunion, recurrence, osteonecrosis, and wound complications. (10) Due to these complications, it has been estimated that the learning curve of MIS bunionectomies to be 20 to 50 cases. (11,12) Surgery time is shown to decrease from approximately 2 hours to around 45 minutes after the 21st procedure, and that intraoperative fluoroscopy decreased over the first 27 surgeries. In a study of 58 consecutive PECA cases by a single surgeon, technical proficiency was reached after 38 cases. Operation time and radiation exposure significantly decreased after this transition point. (13) In the current study, the average operative time for the Relja MIS Bunion System was found to be 44.6 minutes. This compares favorably to other surgical techniques. (12) All surgeons in this study felt the learning curve was felt to be 10 or fewer cases with the average less than 5. This is likely due to the reproducibility of the precision osteotomy guide.

The Relja MIS Chevron Bunion System provides a reproducible precision osteotomy guide for the surgeon while providing stable osteotomy fixation. This allows early weightbearing and maximizes the surgical corrective power through a minimally invasive approach. This surgical technique and case series highlight the advantages provided by the Relja MIS Chevron Bunion System. Furthermore, Relja MIS Chevron Bunion System affords the foot and ankle surgeon a reproducible and superior minimally invasive option that has been shown to have a lower learning curve compared to other MIS techniques, while still providing the aforementioned benefits of a MIS approach.

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