Can a Guided Transverse Osteotomy fixed with an Intramedullary Locking Plate correct all possible deformities of Hallux Valgus without the need for Fusion?

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Abstract

Multiple osteotomies and arthrodesis procedures have been described for the correction of hallux valgus deformities. Despite generally good results, no one approach has distinguished itself as optimal to reproducibly and accurately correct metatarsal multi-planar deformities. Specifically, no one procedure has demonstrated superiority in obtaining first metatarsal head lateral displacement, plantar translation, frontal plane de-rotation, axial compression and normalization of the distal metatarsal articular angle (DMAA). The advent of minimally invasive incision approaches has added additional complexity for the surgeon trying to accomplish multi-planar osseous correction through a limited soft-tissue window. Starting in 2015, the CENTROLOCK, a rigid intramedullary angle-stable locked plate, was designed to employ a precise targeting system to achieve optimal multi-planar deformity correction through a minimal incision approach without the need for fusion. To accomplish this, a guided system was developed that allows for precise performance of a Kramer/Bösch transverse first metatarsal head osteotomy, up to 100% lateral displacement, DMAA correction, sagittal plane translation, frontal plane rotation and axial compression. The rigidity of the CENTROLOCK implant allows full weightbearing immediately post-operative, even when performing bilateral procedures in the same surgical session. Through multi-planar deformity correction of the first metatarsal employing a precise transverse osteotomy and instrumented targeting guide system, the CENTROLOCK achieves hallux valgus correction that previously was only obtainable with a fusion.

Introduction

More than 200 methods have been described for correction of the hallux valgus deformity. The majority of these are a combination of procedures including soft-tissue balancing of the first metatarsalphalangeal joint and osseous manipulation of the first metatarsal, most commonly an osteotomy. Each technique can yield excellent results if the circumstances exactly match the profile of the specific procedure employed; however, no single hallux valgus operation meets all the desired criteria without some disadvantages. The fundamental goals of any corrective osteotomy in combination with a soft tissue release is the reduction of a pathological first intermetatarsal angle, correction of the hallux valgus angle and restoration of the sesamoid apparatus.

However, a number of additional parameters must be taken into account. Based on a long history of failed operations for hallux valgus, the following factors are considered essential for the success of hallux valgus surgery:

- The length of the first metatarsal has to be preserved (or only slightly shortened in cases where hallux limitus is associated with hallux valgus);
- 2. A pathological DMAA must be normalized (<15° valgus);
- **3.** A pathological first metatarsal pronation mal-rotation must be corrected;
- **4.** In case of metatarsus primus elevatus the first metatarsal head should be translated plantarly.

Further, the following additional factors that are beneficial for the patient and accelerate healing should be included:

- Immediate full weightbearing of the operated foot to promote prompt bone healing and to minimize swelling and dysfunction.
- 2. Avoidance of an external Kirschner wire that transfixes the metatarsal-phalangeal joint and protrudes out of the toe for weeks, because they may cause stiffness, infection and produce unnecessary patient discomfort.
- **3.** Early full, active first metatarsal-phalangeal joint range of motion to minimize stiffness.

Kramer's osteotomy was used first by Kramer 1978 and published in 1990 (1). It is an extra-articular vertical transverse osteotomy fixed with an axial Kirschner wire introduced into the soft-tissue of the great toe and, after displacement of the head, into the metatarsal shaft. In 1990 Bösch (2) described a percutaneous modification of Kramer's osteotomy. Regardless of incision approach, the Kramer/ Bösch procedure is able to provide good correction in multiple planes; however, the osteotomy is inherently unstable even with the use of the axial Kirschner wire. Further, since the Kirschner wire extrudes from the toe for 6-weeks it may lead to pin tract infections, as well as, cause discomfort for the patient and stiffness of the first metatarsal-phalangeal joint due to the protracted immobilization. The procedure does not permit the surgeon to precisely or reproducibly move the first metatarsal head exactly to the optimum position. Sagittal plane mal-union is a common complication reported.

Bösch et al. published a pin tract infection occurring in 10% while lannò et al. described complications in 30% of cases.

In 2001, following direct observation of the Kramer/Bösch transverse first metatarsal osteotomy performed through a minimally invasive incision, the author conceived an intramedullary plate and locked screw construct intended to rigidly stabilize the first metatarsal head and avoid and the traditional axial Kirschner wire. In the following years, several companies developed intramedullary stemmed implants with the same purpose to varying degrees of success but never achieved widespread use. Review of the literature reveals that, although the implants represented an improvement over no fixation at all or isolated axial Kirschner wire fixation alone, the deformity correction lacked reproducibility and precision and the implants lacked rigidity. In 2015, the author along with engineers from NOVASTEP, sought to develop a system applicable to the Kramer/Bösch transverse first metatarsal osteotomy since this osteotomy allows for up to 100% lateral displacement, DMAA correction, sagittal plane translation, frontal plane rotation and axial compression of the first metatarsal head.

The original concept included performing a free-hand osteotomy followed by placing a hemostat within the intramedullary canal to achieve lateral translation of the metatarsal head. Fixation was achieved through an intramedullary implant designed with a triangular tapered long stem within the first metatarsal and locked with two transverse screws in the metatarsal head along with an optional oblique screw in the distal metatarsal shaft. Early in the design concept it became clear that this approach lacked reproducibility and the implant itself lacked the ability to correct frontal plane as well as achieve compression. Multiple iterations were subsequently developed that culminated after nearly 5-years of continuous evolution to the patented, final FDA 510k cleared CENTROLOCK guided transverse osteotomy system.

CENTROLOCK Guided Transverse Osteotomy System Technique

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A dorsal-medial, longitudinal incision of 1.5 to 2.5cm is made overlying the first metatarsal head. The neuro-vascular bundle is isolated and protected. The first metatarsal-phalangeal joint capsule is incised according to the surgeon's preference to expose the first metatarsal medial eminence. If deemed clinically necessary, the fibular suspensory ligament, lateral capsule, oblique head of the tendon of the adductor hallucis and lateral head of the flexor hallucis brevis can be performed through the space that exists between the inferior articular surface of the first metatarsal head and sesamoids.

Medial eminence resection is an important procedural step since this can alter lateral translation, DMAA correction and frontal plane rotation of the first metatarsal. First, by resecting the smallest amount of bone necessary, the implant will achieve a larger lateral translation of the first metatarsal head thereby reducing the intermetatarsal 1-2 angle.

Second, a wedge shaped medial eminence resection removing less bone proximally and more bone distally will afford first metatarsal head rotation in the transverse plane and achieve a congruous joint thereby correcting the hallux valgus angle.

Third, an oblique resection of the medial eminence allows for frontal plane de-rotation of the first metatarsal head.

Specifically, when viewing the metatarsal head end on, removing more bone dorsally than plantarly will rotate the first metatarsal head internally correcting an everted metatarsal head position. In contrast, removing more bone plantarly than dorsally will rotate the first metatarsal head externally correcting an inverted metatarsal head position.

Next, the osteotomy guide is positioned against the first metatarsal head with the distal flange placed within the first metatarsal-phalangeal joint and then stabilized with 2mm guide-wire. The ideal osteotomy location is at the level of the surgical neck, specifically just proximal to the entrance of the nutrient artery laterally and vascular leash just proximal to the sesamoid articulation. Based upon these vascular entry sites the osteotomy guide was designed with three levels of osteotomy: 18, 20 or 22mm proximal to the first metatarsal head articular cartilage. Under image intensification, the osteotomy position is checked relative to one of the three cutting guide notches using a 0.9mm K-wire or saw blade. Some slight proximal-distal angulation of the saw blade is possible if minor first metatarsal length adjustments are needed. Once the ideal osteotomy level has been verified a transverse osteotomy is performed through the first metatarsal using the cutting guide.

The first metatarsal head is displaced laterally using an elevator developed specifically for this purpose. A lateral first metatarsal head translation of 100% is possible given the extremely rigid fixation achieved with the implant. As a result, only point-to-point contact between the first metatarsal head and residual first metatarsal shaft is necessary. The first metatarsal head is then stabilized temporarily with an axial with a 2mm guide-wire inserted parallel to the residual first metatarsal axis. The intramedullary portion of the guide-wire should be placed directly adjacent to the lateral cortical wall and advanced into the first metatarsal base subchondral bone (or advanced across the first metatarsal-cuneiform joint for additional stability in osteopenic bone).

Following guide wire placement its position should be confirmed with image intensification. The hand reamer is then inserted over the 2mm guide-wire and gently twisted to ream a channel for the intramedullary stem of the implant until the black laser marking is at the level of the first metatarsal osteotomy. Trial implants (right or left) can be connected to the impactor to choose the 2, 4 or 6mm offset implant needed. The selected implant is attached to the impactor, inserted through the implant cannula over the 2mm guide-wire and impacted until the laser marking on the implant is flush with the first metatarsal osteotomy. During insertion of the implant, lateral translation, transverse plane rotation and frontal plane rotation of the first metatarsal head will occur with respect to the first metatarsal shaft based on the original medial eminence resection performed.

Of special note, it is critical to ensure that the flat, medial surface of the first metatarsal head is in direct contact with the flat part of the implant. The implant should never be adjusted to fit against the first metatarsal head. If necessary, the first metatarsal head can be translated dorsally or plantarly at this time to correct any sagittal plane mal-alignment. Once the optimum position of the first metatarsal head is achieved as confirmed under image intensification, the osteotomy is stabilized with a positioning olive wire through the plantar distal hole in flat part of the implant. The plate allows two inferior locking screw hole options in the distal screw cluster. These are pre-drilled using a 1.8mm drill with the screw length being measured directly off the drill/sleeve. Uni-cortical 2.5mm locking screws, between 10 and 26mm in length, are then inserted after which the index 2mm guide-wire is removed.

The compressor and proximal screw targeting guide is attached to the superior locking hole of the implant and secured with the threaded bolt attachment wheel. The final frontal plane positioning of the first metatarsal head is performed at this time by rotating the first metatarsal around the intramedullary stem portion of the implant. Once ideal frontal plane positioning has been assessed under image intensification by verifying proper first metatarsal head sesamoid coverage, a 2mm diameter by 100mm length K-wire is inserted bi-cortical into one of two holes at the proximal end of the compressor and proximal screw targeting guide.

Before setting up the compressor and targeting guide on the implant, the compression wheel must be put in the "start" position. The compression wheel is then rotated clockwise until the desired amount of compression, up to 3mm, is achieved. It is important not to over compress the osteotomy, as this may excessively shorten the metatarsal. Two, bi-cortical 2.0mm non-locking screws are placed through the intramedullary portion of the implant. These screws have a divergence of 8 degrees relative to each other to allow for added stability. To place these, small skin incisions are made using nick and spread technique to the bone followed by pre-drilling the pilot hole using a 1.5mm drill with the screw length being measured directly off the drill/sleeve. Once the screws are fully seated and verified on image intensification, the compressor and proximal screw targeting guide are removed. The residual first metatarsal shaft medial cortical overhang can be resected at an oblique angle if this area remains prominent.

A third 2.5mm locking screw can be inserted into the first metatarsal head through the proximal-superior locking hole within the flat portion of the implant for additional mechanical stability using the same steps as noted above. After final intra-operative image intensification is performed, the surgical site is irrigated to remove osseous debris, the capsule tissue is plicated and the skin incision closed according to the surgeon's preference. Weightbearing as tolerated in a post-operative shoe and return to activities is performed according to the surgeon's preference.

Conclusions

The CENTROLOCK, a rigid intramedullary angle-stable locked plate, was designed to employ a precise targeting system to achieve optimal multi-planar deformity correction through a minimal incision approach without the need for fusion. The guided system allows for precise performance of a Kramer/Bösch transverse first metatarsal head osteotomy that allows for up to 100% lateral displacement, as well as, DMAA correction, sagittal plane translation, frontal plane rotation and axial compression. The rigidity of the CENTROLOCK implant allows full weightbearing immediately post-operative, even when performing bilateral procedures in the same surgical session.







References

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