Exclusively foot & ankle

Paragon 28®

Proximal Rotational Metatarsal Osteotomy (PROMO™)

Technical Monograph

PROMO®

PROXIMAL ROTATIONAL METATARSAL OSTEOTOMY

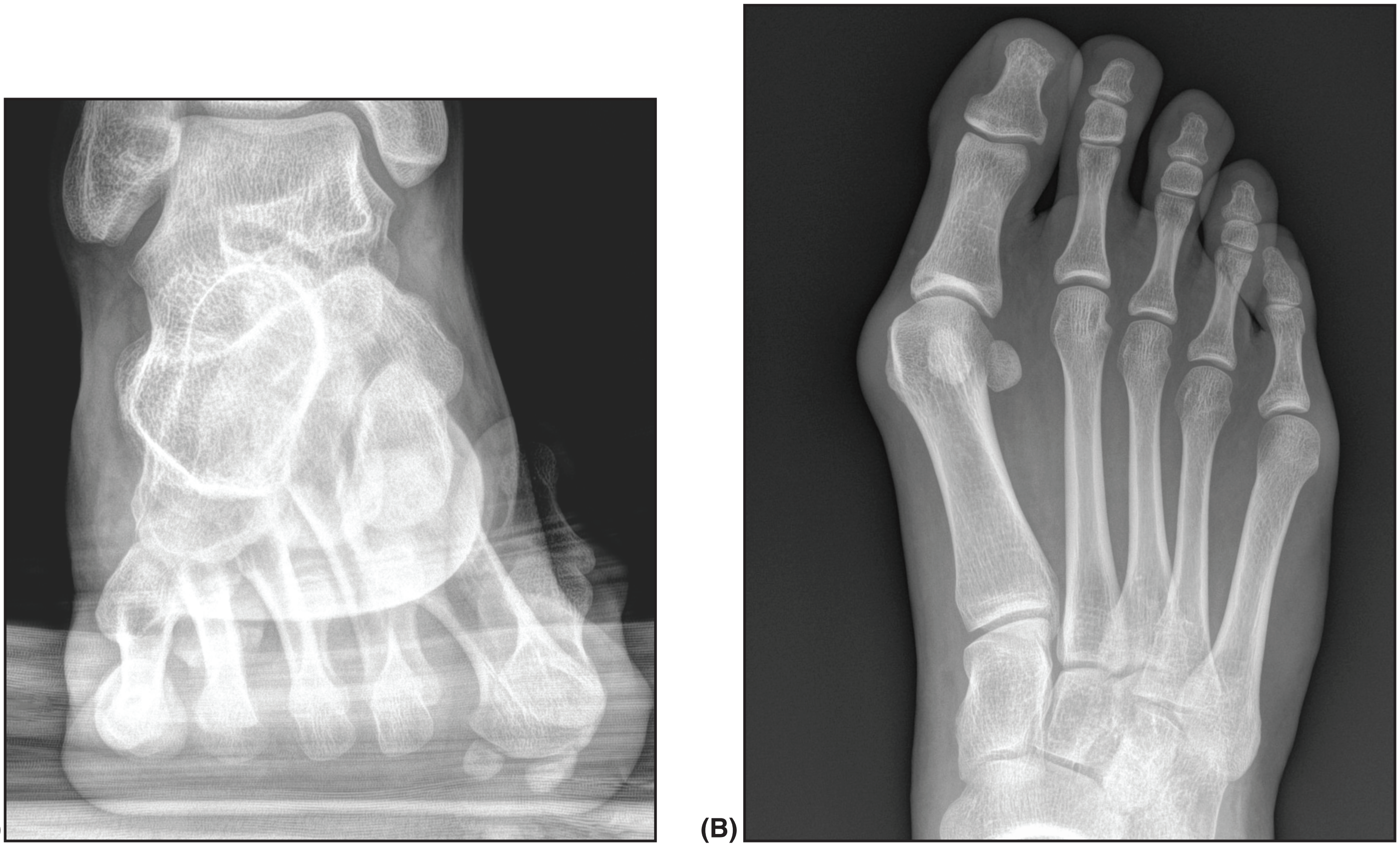
It is widely known that there are over one hundred ways to surgically treat hallux valgus ranging from simply removing the medial eminence to complex treatments such as endoscopy-assisted procedures.[1,2] Each procedure addresses the hallux valgus deformity in its own way; each with its own set of benefits, drawbacks and challenges. It is paramount that the choice of treatment matches the needs of each specific patient. There is no *one size fits all* cure to such a complex confluence of soft tissue and bone.[3-6]

When choosing a hallux valgus procedure, it is important to match the procedure to the severity and type of deformity, while taking into account patient factors such as medical co-morbidities, adjacent joint arthritis, age and activity level. An underpowered correction may not fully correct the deformity and a heavy-handed approach could unnecessarily sacrifice healthy tissue and bone. Improper choice of procedure could lead to under correction, recurrence, complications or altered biomechanics of the foot.[7]

It is paramount that the choice of hallux valgus treatment matches the needs of each specific patient.

In order to properly correct a hallux valgus deformity, a thorough understanding of the deformity is required. Over the years, the collective understanding of hallux valgus and subsequent treatment has progressively morphed as better insight of the problem has emerged. We no longer think of hallux valgus as a simple "turnip" like we once did. Similarly, new evidence has shed light on the rotational aspect of the deformity that can occur in some hallux valgus patients. An example of hallux valgus with a rotational deformity is shown below (Figure 1). Advanced treatments that incorporate frontal plane rotational correction of the 1st metatarsal should be used when necessary.

(A)



(B)

Figure 1: Sesamoid axial radiograph with a rotational deformity (A). AP radiograph with a hallux valgus deformity (B).

Frontal plane rotation of the 1st metatarsal in conjunction with hallux valgus correction has been documented in literature since the 1950s (Figure 2).[8] Since then, researchers have undertaken various studies to quantitatively analyze frontal plane rotation of the 1st metatarsal head in hallux valgus patients. In 1980, Scranton and Rutkowski studied 35 cadaveric specimens and found that the average frontal plane rotation of the 1st metatarsal head in hallux valgus specimens was 14.5° (± 4°) compared to 3.1° (± 3°) for normal feet.[9] In vivo studies have shown that the average frontal plane rotation of the 1st metatarsal in hallux valgus subjects ranges from 5.7° to 22.1°, although it should be noted that measurement technique and subject positioning vary from study to study (Table 1).[10–15] It has also been shown that 87% of hallux valgus deformities have abnormal rotation of the 1st metatarsal head.[12]

Figure 2: The frontal plane in relation to the foot.

It has been shown that 87% of hallux valgus deformities have abnormal frontal plane rotation of the 1st metatarsal head ranging from an average of 5.7° to 22.1°.

Research has also drawn attention to several key findings that are fundamental to understanding frontal plane rotation:

- Increased frontal plane rotation is generally associated with an increased 1-2 IMA. However, on a case-by-case basis, there is not a consistent 1:1 relationship between IMA and frontal plane rotation of the 1st metatarsal.[10–16]
- Meaningful frontal plane rotation of the 1st metatarsal does not exist in every hallux valgus case.[5,10,12–16]
- A lesser degree of frontal plane rotation is commonly seen in people without hallux valgus.[10,12,13,15]
- Sesamoid rotation does not always equal the rotation of the metatarsal head—sesamoids can be subluxed or dislocated from the metatarsal head.[9,12,14]

Study	Number of HV Feet	FPR		1-2 IMA		Method	WB	MTP DF
		Avg (°)	SD (°)	Avg (°)	SD (°)			
Puccinelli (2017)	30	18.9	9.3	15.3	3.2	Standing CT	Yes	No
Dayton (2016)	36	22.1	5.2	13.4	3.3	Intra-Operative Protractor	No	No
Kim (2015)	166	21.9	6.0	15.0	NR	Supine Traditional CT	Semi	No
Collan (2013)	19	8.0	2.0	17.0	1.0	Standing CT	Yes	No
Mortier (2012)	100	12.7	7.7	15.0	4.2	Standing Bernard X-ray	Yes	Yes
Saltzman (1996)	30	5.7	7.1	NR	NR	Standing Sesamoid View X-ray	Yes	Yes

Table 1: Average frontal plane rotation of the 1st metatarsal in subjects with hallux valgus. All studies measured rotation at the head of the metatarsal except for Dayton et al., who measured the amount of rotation applied to the metatarsal intraoperatively during arthrodesis at the 1st tarsometatarsal (TMT) joint.

Definitions: hallux valgus (HV), frontal plane rotation (FPR), intermetatarsal angle (IMA), weight-bearing (WB), metatarsophalangeal (MTP), DF (dorsiflexion), standard deviation (SD), computed tomography (CT), not reported (NR)

Bone is a highly adaptive tissue and is in a constant state of remodeling.[17] Mechanical loading can alter the composition of bone as well as the physical size and shape of the bone.[17] This concept is better known as *Wolff's Law*. Thus, osseous adaptation due to repetitive loading is a common area of study.[17-23] Studies involving athletes have found that repetitive loading can alter the torsion angle (rotation angle about its long axis) of the humerus.[21,23]

The femur and tibia can also experience torsional abnormalities. Derotational osteotomies can be used to restore proper alignment.[24-28]

The phenomena of torsional deformation has also been explored in the foot and there is a building body of evidence that torsion, or the twisting of the metatarsal about its long axis, can occur in the 1st metatarsal (Figure 3).

Mortier and colleagues authored the paper *Axial rotation of the first metatarsal head in a normal population and hallux valgus patients* and concluded that "*…diaphyseal torsion could impact the axial positioning of the M1 (1st metatarsal) head.*"[14] Mortier goes on to say that "*… the study nevertheless showed that metatarsal head pronation can occur without cuneometatarsal instability.*" They further speculate that this could be morphological adaptation or a response to early hereditary hallux valgus.

A portion of the "rotational" deformity may actually be attributed to torsion within the metatarsal.

In 2017, Ota et al. used CT imaging to create three-dimensional models of the 1st metatarsal from hallux valgus and non-hallux valgus feet.[29] This study showed that there was a significant difference in the torsion angle between the hallux valgus and control groups (17.6° vs 4.7°, $p<0.01$).

Maruyama et al. analyzed CT scans from 182 feet and found a significant difference in torsion angles between the hallux valgus and non-hallux valgus groups.[30]

Kitashiro et al. looked at torsion angles in all five metatarsals in subjects without hallux valgus. They showed that the average 1st metatarsal torsion angle for men and women was around 12°, ranging from slightly supinated to nearly 25° of pronation.[31]

These studies indicate that, in some patients, a portion of the "rotational" deformity may actually be attributed to torsion within the metatarsal.

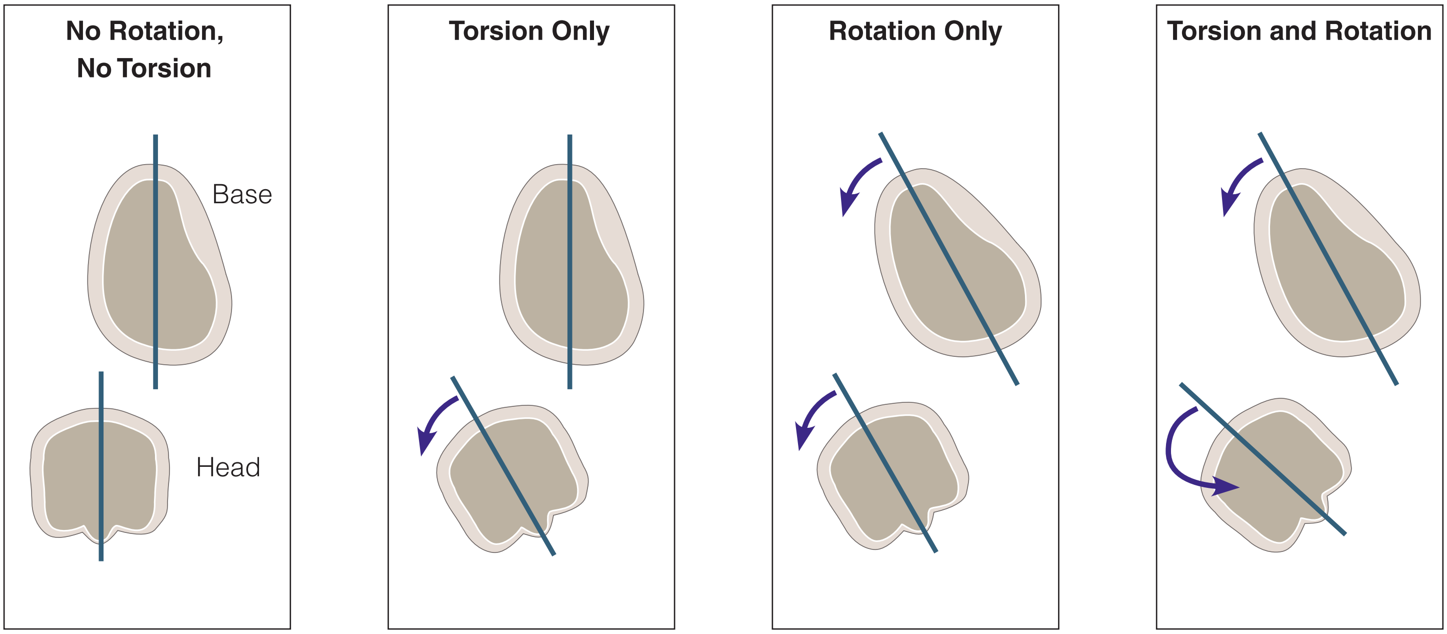


Figure 3: Angle of the 1st metatarsal base in relation to the 1st metatarsal head for combinations of rotation and torsion.

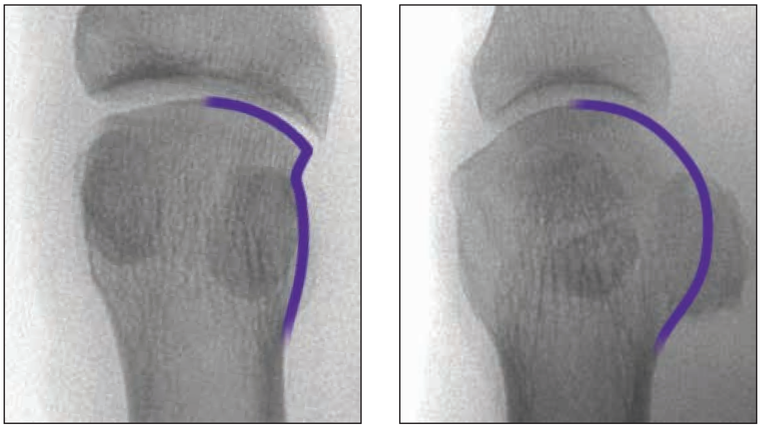
Recurrence rates of hallux valgus vary widely from study to study and by procedure, but have been reported to be as high as 78% (Table 2). Comparison of these rates are complicated by the lack of consistency in the definition of recurrence, differing lengths of follow-up and, in most cases, the retrospective nature of the studies.

Okuda et al. conducted a retrospective review of 60 normal feet and 60 hallux valgus feet aimed at analyzing the radiographic appearance of the head of the 1st metatarsal (Figure 4).[55] They concluded that those who had a positive lateral round sign at their early post-operative exam had 12.7 times greater risk for hallux valgus recurrence than those without. Only 1 of 60 feet from the control group exhibited a positive round sign.

In a CT study, Yamaguchi et al. were able to quantify the effect of rotation and inclination of the 1st metatarsal on the shape of the lateral edge of the 1st metatarsal head.[56] This study concluded that the positive round sign originally described by Okuda was indeed significantly associated with increased pronation and that a negative round sign (a sharp lateral edge) could be used as an indicator of effective correction of 1st metatarsal pronation during hallux valgus surgery.

"Up to three structural alignment deformities may therefore be present in the bunion. Hallux valgus, metatarsus primus varus, and first metatarsal pronation must each be evaluated and corrected or there may be recurrence."

– Scranton and Rutkowski, 1980



(A) **(B)**

Figure 4: AP view of right 1st metatarsal heads showing a sharp lateral edge shape (A) and a positive lateral round sign (B).

Procedure	Recurrence Rates
Chevron Osteotomy[32–34]	10% - 73%
Scarf Osteotomy[33,35–37]	6%- 78%
Crescentic Osteotomy[38–40]	1% - 13%
Hohmann Osteotomy[41,42]	9% - 10%
Proximal Opening Wedge Osteotomy[43,44]	65% - 67%
Lapidus Arthrodesis[4,41,45–48]	3% - 16%
Proximal Supination Osteotomy[49,50]	0% - 4%
Wilson Osteotomy[42,51]	3% - 10%
Mitchell Osteotomy[51,52]	0% - 47%
PROMO[53, 54]	0%

Table 2: A sample of reported hallux valgus recurrence rates for various corrective procedures.

The common understanding of the biomechanics of the 1st ray revolves around the windlass mechanism where the medial arch height increases with dorsiflexion of the hallux. Simultaneously, the plantar fascia shortens the distance between the calcaneus and the metatarsal head. In order for this mechanism to function appropriately, motion is essential in each joint of the medial column. Furthermore, proper alignment of the sesamoids, hallux and 1st metatarsal are required for efficiency of the windlass mechanism.[57]

When a vertical load is applied to the foot, the length and width of the foot increases and arch height decreases.[12, 58]

Lundgren et al. conducted an in vivo gait study on six adult male volunteers using bone pins.[59] They found that, on average, the total range of motion between the 1st metatarsal and the medial cuneiform was 5.3°, 5.4° and 6.1° in the sagittal, frontal and transverse planes, respectively (Figure 5). This tri-planar motion of the 1st metatarsal was also seen by Whittaker et al., who measured motion of the of the 1st metatarsal with respect to the medial cuneiform using a robotic gait simulator.[60]

The 1st TMT joint experiences rotation in the frontal, sagittal and transverse planes during daily activities.

Arndt et al. used bone pins to investigate kinematics during the stance phase of slow running. They found that the 1st metatarsal rotates 4.9°, 5.3° and 4.3° in the sagittal, frontal and transverse planes, respectively, relative to the medial cuneiform.[61]

The motion of the 1st metatarsal relative to the medial cuneiform during more physically challenging activities, such as normal running or step-climbing, is not well understood at this time.

In hallux valgus cases where the IMA is large or the 1st TMT joint is unstable, hypermobile, damaged or diseased, fusion via Lapidus arthrodesis may be required to correct the problem at hand. In cases with a healthy 1st TMT, prematurely sacrificing this joint may limit motion of the 1st ray and thus disrupt the windlass mechanism and overall biomechanics of the foot. Furthermore, prematurely sacrificing the 1st TMT may increase the biomechanical burden on adjacent joints, which may lend itself to degeneration of these joints.

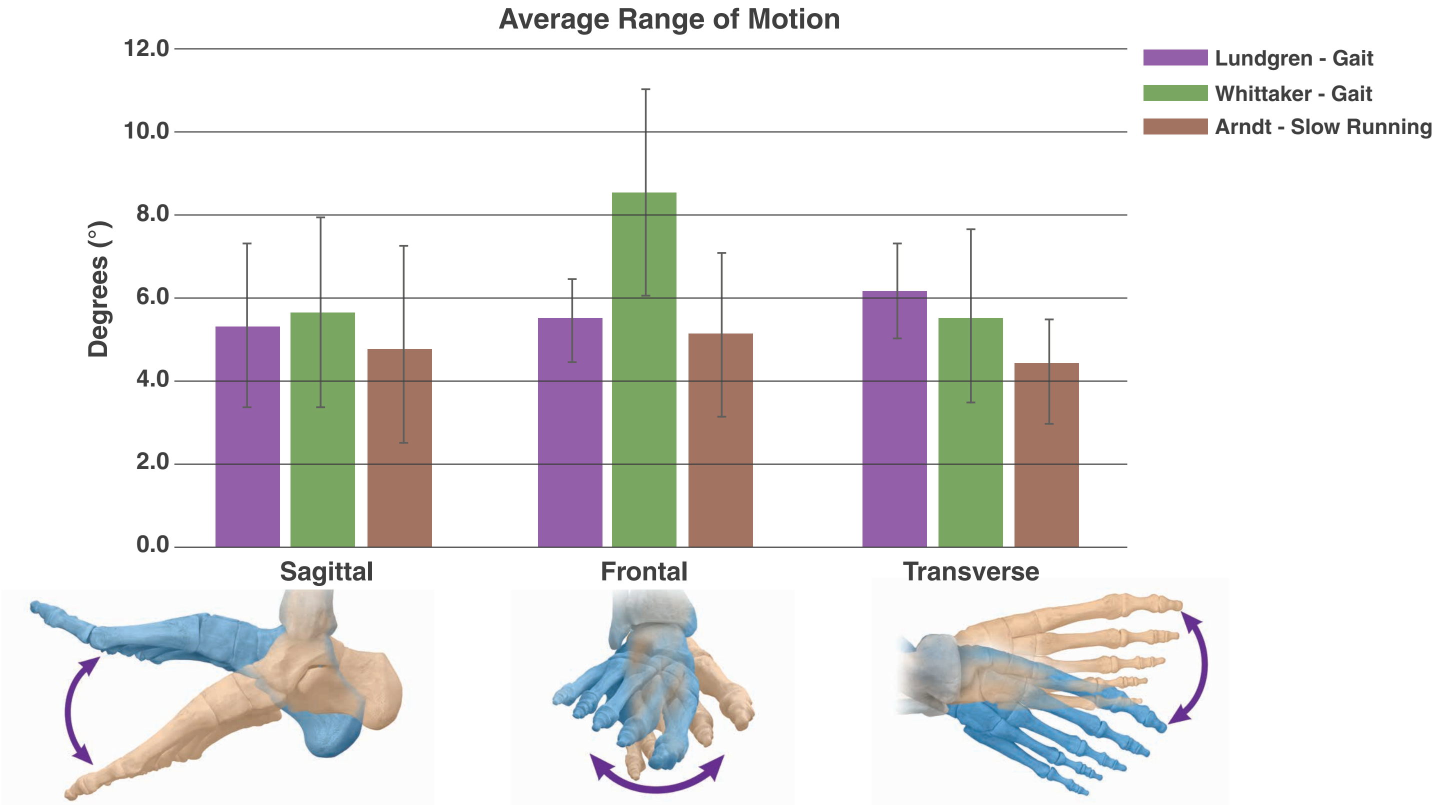


Figure 5: Tri-planar rotation of the 1st metatarsal relative to the medial cuneiform.

The center of rotation of angulation, or CORA, has been used in skeletal deformity correction for years. In 2002, Paley detailed the CORA concept and the three governing osteotomy rules that support it.[62]

As it relates to hallux valgus, LaPorta, et al. stated that the CORA lies in the proximal tarsus while Dayton et al. believe that the CORA lies at the 1st metatarsal cuneiform joint (Figure 6).[63, 64] Mashima et al. detailed the use of a two CORA methodology to treating hallux valgus; where one CORA lies proximal to the 1st TMT and the other near the center of the metatarsal head.[65] Wagner et al. identify that the most important CORA in hallux valgus is the intersection of the 1st and second metatarsals; typically located in the area of the navicular and medial cuneiform.[66]

Osteotomy Rules (adapted from Paley)

Rule 1: The osteotomy passes through the CORA and fully corrects the deformity only through osteotomy angulation without translation.

Rule 2: The osteotomy is performed away from the CORA but achieves complete deformity correction through osteotomy angulation and translation.

Rule 3: An osteotomy partially corrects the deformity given that only angulation and no translation is performed through the bone cut.

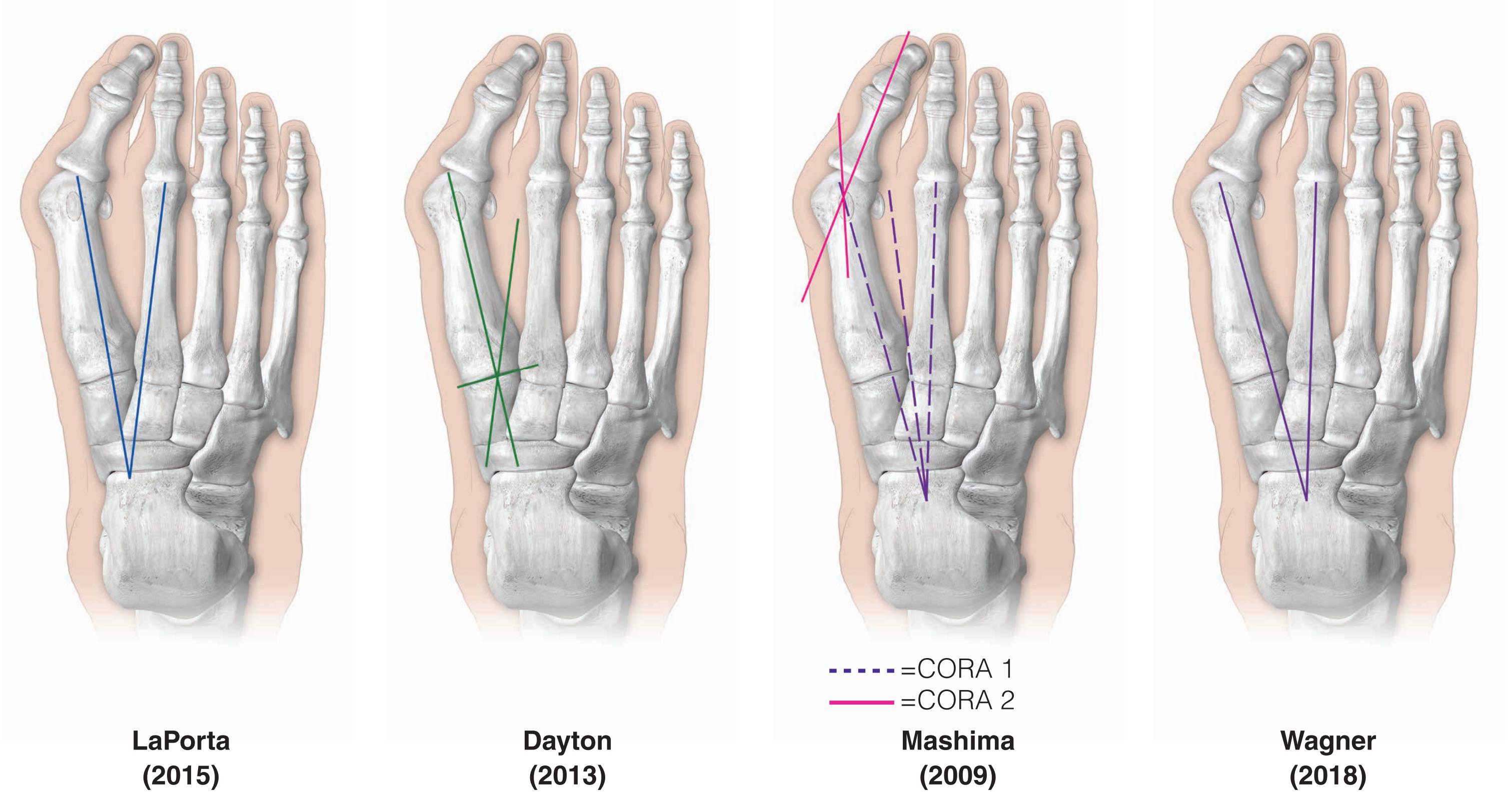


Figure 6: Depictions of varying CORA as described by various authors.

All surgical treatments for hallux valgus alter the existing bone and/or soft tissue; however, the severity, impact and location of the alteration can be controlled. Currently, no one knows the precise anatomic location of the frontal plane deformity associated with hallux valgus.[67] It likely varies from patient to patient, and is comprised of multiple factors such as diaphyseal torsion and rotation that occurs proximal to the 1st metatarsal.

The goal of any hallux valgus procedure should be to maximize deformity correction while minimizing disruption of healthy tissue and bone. Proper hallux valgus procedure selection should also aim to maintain and/or restore the natural biomechanics of the foot; loss or transfer of motion within or away from the medial column should not be taken lightly. It is paramount to correctly identify the deformity at hand in each case.

PROMO allows for simultaneous correction of the IM angle as well as the rotational deformity through a single, guided, oblique osteotomy.

PROMO Design Rationale

As outlined previously, there are many circumstances where a hallux valgus deformity requires multi-plane correction, but arthrodesis of the 1st TMT joint may not be appropriate. In these cases, a procedure such as the Proximal Rotational Metatarsal Osteotomy (PROMO) should be chosen. The PROMO system allows for simultaneous correction of the IM angle as well as the rotational deformity through a single, guided, oblique osteotomy (Figure 7).

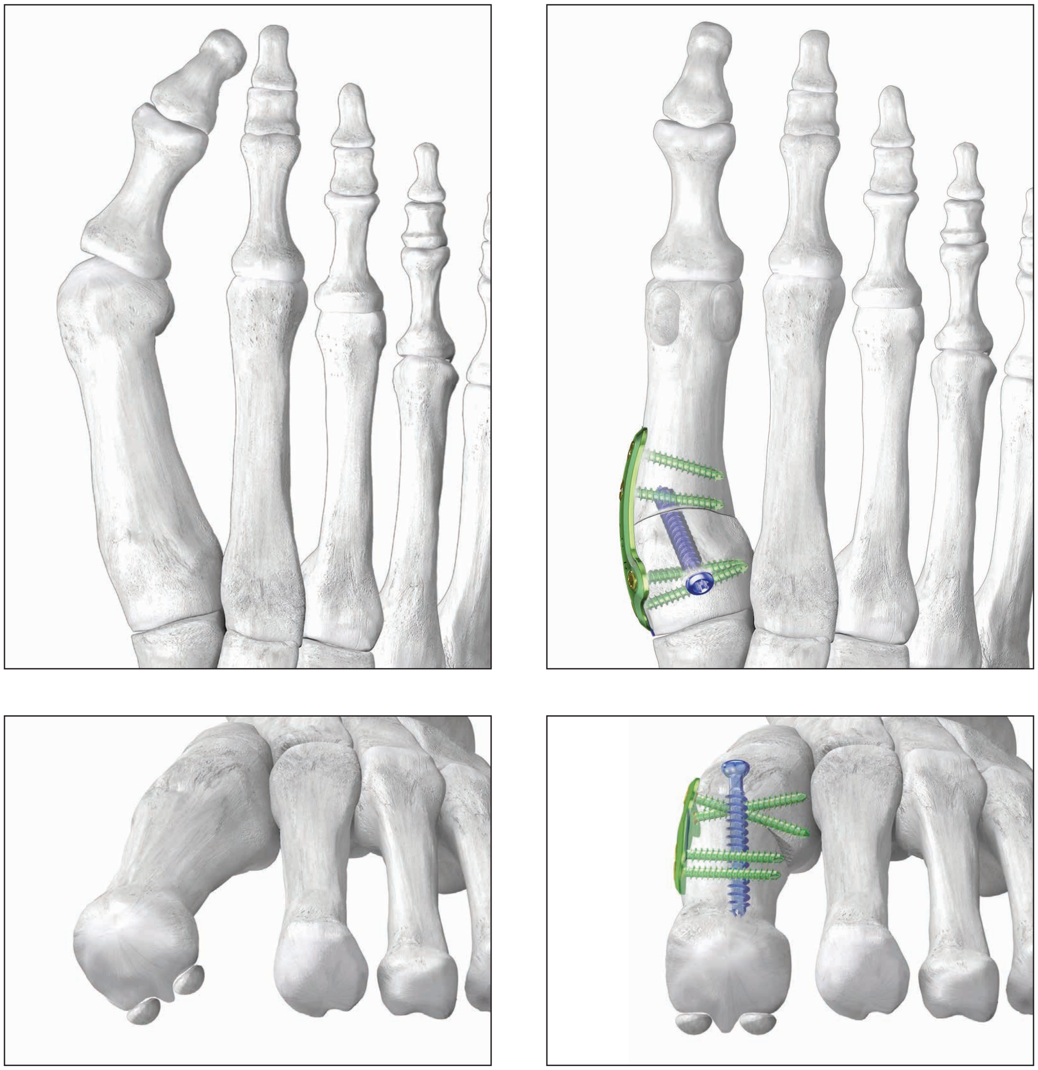


Figure 7: A multi-plane hallux valgus deformity (top left and bottom left) corrected in the transverse plane (top right) and frontal plane (bottom right) utilizing the PROMO system.

Problem: Typically hallux valgus procedures only correct in a single plane (transverse) which may lead to higher rates of recurrence due to neglected frontal plane rotation.

Solution: Create an oblique osteotomy that allows for simultaneous correction of both the frontal and transverse planes with a single osteotomy with no wedge resection.

PROMO provides deformity correction via an oblique osteotomy that is away from the CORA. The unique angulation of the osteotomy allows the metatarsal head to simultaneously translate and rotate upon correction of the capital fragment.

A single-plane osteotomy such as a scarf or Austin/chevron only allows correction in the transverse plane, but generally does not correct a frontal plane deformity.

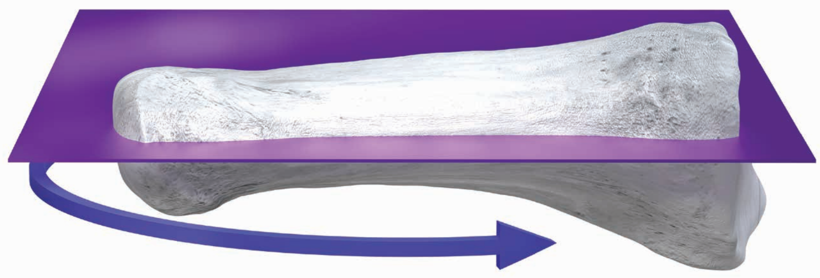


Figure 8: A 1st metatarsal with a horizontal cutting plane (purple).

An osteotomy preformed vertically across the metatarsal would allow for correction of the rotational deformity but would generally not allow correction of the IM angle in the transverse plane.

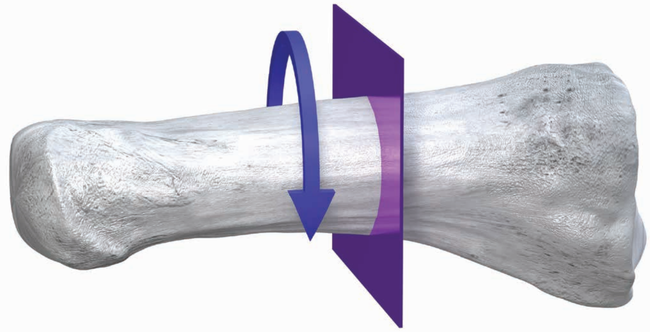


Figure 9: A 1st metatarsal with a vertical cutting plane (purple).

An oblique osteotomy allows for both frontal plane and transverse plane correction.

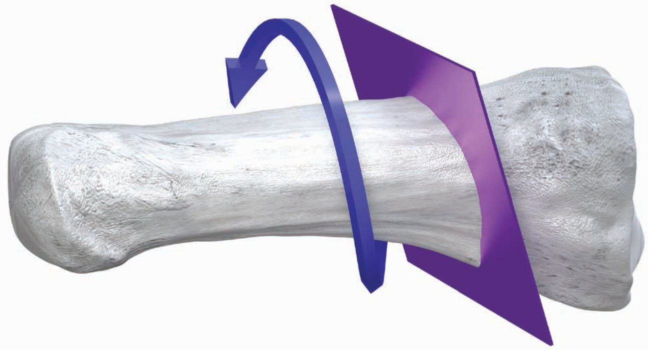


Figure 10: A 1st metatarsal with an oblique osteotomy plane (purple) allowing for both frontal plane and transverse plane correction.

Design Rationale: Deformity Assessment

Problem: A wide range of hallux valgus deformities are "fit" to a single procedure, often unnecessarily sacrificing the 1st TMT joint or failing to address the multi-plane nature of the pathology.

Solution: Tailor the hallux valgus procedure to match the deformity rather than fitting multiple deformities to a single procedure.

PROMO provides the opportunity to correct a wide range of hallux valgus deformities through customization of the osteotomy to the patient specific IM angle and rotational deformity.

Step 1. Measure IM angle using a standard AP radiograph.

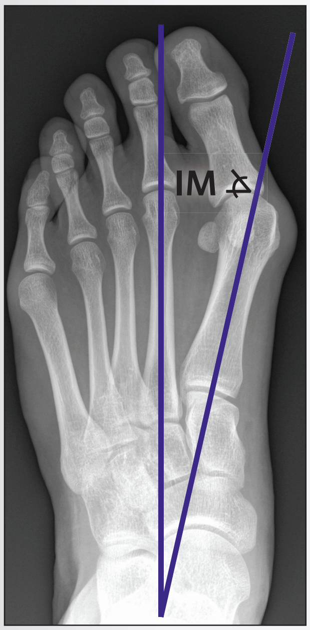


Figure 11: AP radiograph with IM measurement.

Step 2. Determine frontal plane rotation using a standard AP radiograph.

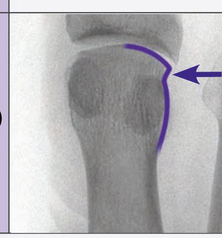
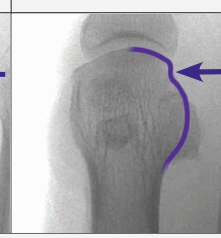
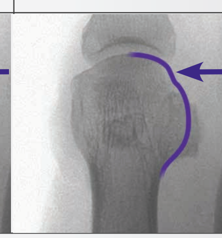
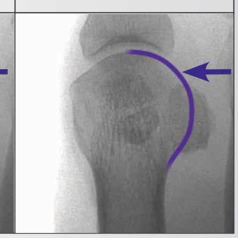
Rotation Range	0°	10°-19°	20°-29°	30°-39°
Lateral Head Shape	Sharp	Irregular	Rounded	Circular
Lateral Condyle Visibility	Not Visible	Notable	Observable	Apparent
Lateral Articular Surface Continuity	None	Step-Off	Notched	Smooth
Image Examples (Right 1st Metatarsal)				

Table 3: Descriptive and visual guidance to determine frontal plane rotation.

Step 3. Utilize PROMO angle values table to obtain the vertical inclination angle.

		Rotation Angle (°)		
		10-19	20-29	30-39
IM Angle (°)	8-10	38	28	23
	11-12	47	33	28
	13-14	55	38	33
	15-17	55	42	38
	18-20	55	47	42

Vertical Inclination Angle

Table 4: PROMO angle values table.

Design Rationale: Constructing the Osteotomy

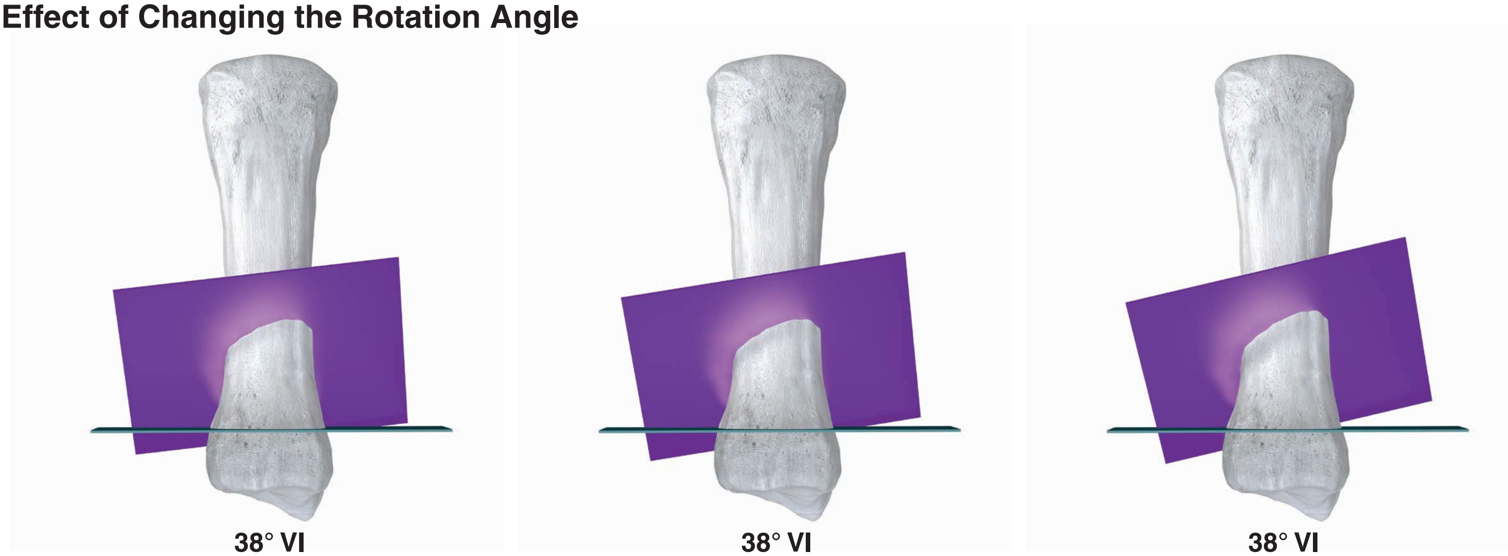
Problem: An arbitrarily defined oblique osteotomy will not obtain adequate correction to address the variances seen in hallux valgus.

Solution: Use simple, guided instrumentation to create an oblique osteotomy that matches the patient's hallux valgus deformity in the frontal and transverse planes.

PROMO provides a guided jig system that allows for a reproducible and accurate construction of an osteotomy that delivers simultaneous correction of both the frontal and transverse planes.

The cutting plane is defined by both the vertical inclination (VI) and the rotation angle category. A positioning jig utilizes the rotation angle category to control the obliquity of the osteotomy in the transverse plane. As the rotation angle category changes, the obliquity of the osteotomy becomes greater (Figure 12). A cutting jig is then used to establish the appropriate vertical inclination in the sagittal plane. As the vertical inclination value increases, the inclination of the osteotomy becomes greater (Figure 13).

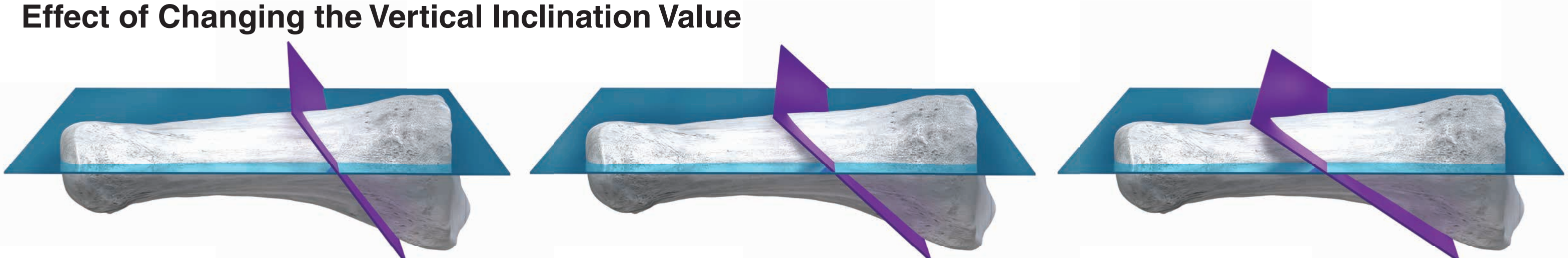
Effect of Changing the Rotation Angle



38° VI 10°-19° Rotation	38° VI 20°-29° Rotation	38° VI 30°-39° Rotation

Figure 12: Depictions of different cutting planes (purple) where the VI is held constant but the rotation category changes. The blue line is a reference line perpendicular to the metatarsal.

Effect of Changing the Vertical Inclination Value



28° VI 20°-29° Rotation	38° VI 20°-29° Rotation	47° VI 20°-29° Rotation

Figure 13: Depictions of different cutting planes (purple) where the VI changes but the rotation category is held constant. The blue plane is a reference plane parallel to the metatarsal.

Problem: Metatarsal shortening and sagittal plane disruption can occur with hallux valgus correction.

Solution: Return the 1st ray to its natural position while maintaining the length and height of the 1st metatarsal.

PROMO provides transverse plane correction that occurs simultaneously with frontal plane rotation through supination of the distal metatarsal fragment. During the course of this rotation, the distal 1st metatarsal head has slight movement in the sagittal plane, but returns to its original sagittal plane position when fully rotated from the measured starting point.

As illustrated in Figure 14, the metatarsal travels in an ellipse in the frontal plane, resulting in translation of the metatarsal head without altering the height when complete rotation is achieved.

Likewise, the anatomic length of the metatarsal is maintained with the exception of bone loss approximately equal to saw blade thickness.

With execution of the PROMO osteotomy and full correction of rotation from pre-operative measured value, the natural position of the 1st metatarsal can be restored.

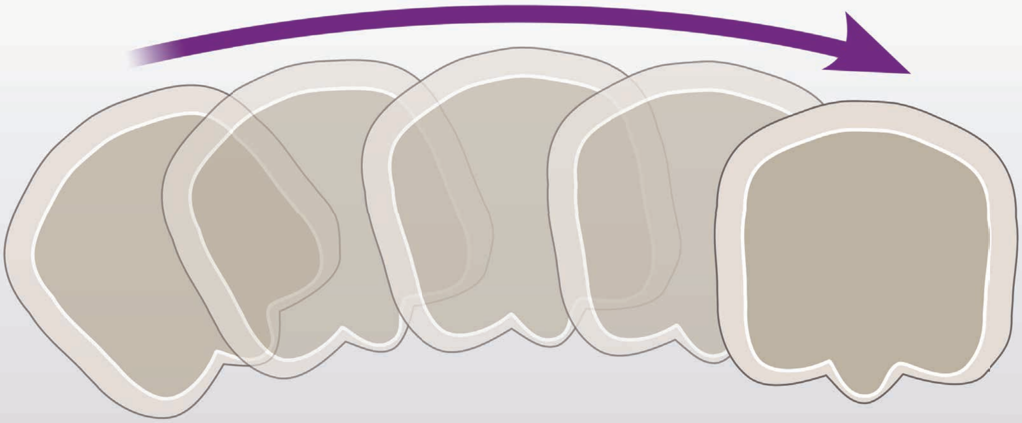


Figure 14: A 1st metatarsal head traveling in an ellipse from an un-corrected position to a fully corrected position.

Thousands of pages have been written about hallux valgus and its associated corrective procedures over the years; the successes and failures, the benefits and drawbacks, the *why does it happen* and the *how do we treat it*. PROMO was born from these findings.

The PROMO system is the result of a collaborative effort between surgeons and engineers; all seeking to create a versatile, joint-sparing, multi-plane solution to hallux valgus. This novel system allows surgeons to tailor the corrective procedure to each patient while minimizing unnecessary tissue disruption.

Surgeons no longer have to choose between ignoring frontal plane rotation and fusing the 1st TMT.

PROMO is the joint-sparing, multi-plane solution to hallux valgus.

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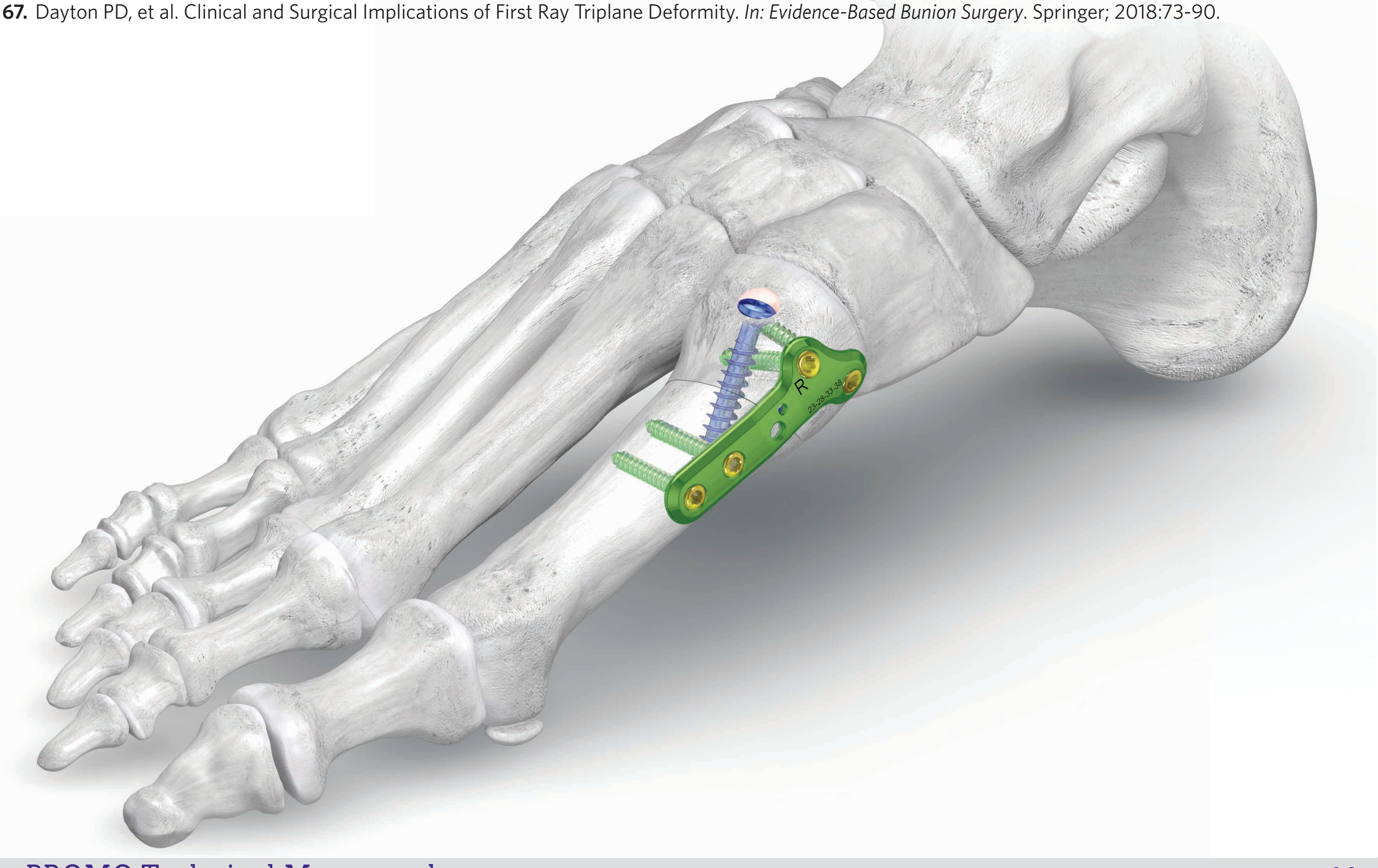

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