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Original Research

Defining the Cortical Purchase Zone in New Minimally Invasive Bunion Surgery. A Retrospective Study of 638 Cases.

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Introduction

The stability of the screws in the cortical purchase zone (CPZ) with new minimally invasive bunion surgery (MIBS) is of utmost importance in creating a stable construct for maintaining position and providing a scaffold for bone healing. The distance between the osteotomy and where the screw(s) exit the lateral cortex (a distance we herein coin the "Cortical Runway") within the CPZ has yet to be studied, and is the focus of this retrospective study.

Methods

A retrospective review was preformed of a single surgeons first and consecutive cases of patients who had undergone MIBS from January 2018 to November 2022. The CPZ measurement was obtained on early postoperative radiographs. The CPZ was divided into five stability regions using the statistical empirical rule to define the boundaries of each of the regions.

Results

We included 427 patients and 638 feet in this study. Radiographic measurements were performed at an average 20.7±24.2 days (95% CI, 15.3–15.8 days) from surgery. The mean age of the patients was 46.5±15.0 years (95% CI, 45.3–47.6 years). There were 330 (51.7%) right feet and 308 (48.3%) left feet. Of the 427 patients, 211 (49.4%) had surgery on both feet, with 97 (46%) having both feet operated on the same day. A 1-screw construct was performed in 526 feet (82.4%) and a 2-screw construct in 112 feet (17.6%) of the total 638 feet. The mean anchor screw (primary screw) distance was 10.4±3.7mm (95% CI, 10.1-10.7mm). The mean collateral screw (secondary screw) distance was 1.2±2.0mm (95% CI, 0.8-1.5) and the mean cortical bridge (distance between the two screws) was 10.3±3.2mm (95% CI, 9.7-10.9), in 112 feet. We were able to define the CPZ stability region boundaries, which are: danger (< 2.9mm), vulnerable (3.0 - 6.6mm), standard (6.6 - 14.1mm), safety (14.2 - 17.8mm) and the security (> 17.9mm).

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Conclusion

These CPZ boundaries and newly delineated stability regions will serve not only as an intraoperative visual tool for surgeons to perform MIBS successfully, but will also provide a much more stable and safer construct, thus minimizing risks and complications.

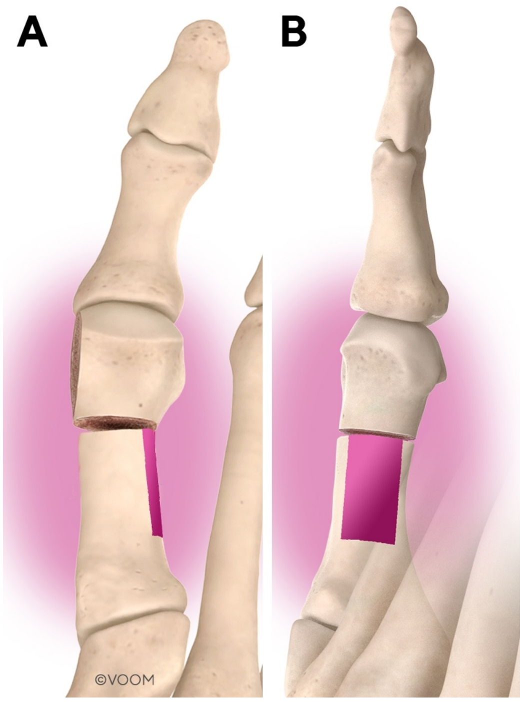

Figure 1. Rendering demonstrating the Cortical Purchase Zone (CPZ).

The CPZ is the available region of cortical bone of the lateral metatarsal shaft (proximal to the osteotomy) where the minimally invasive screw(s) exit. Top-down view (A) and view of the lateral first metatarsal (B).

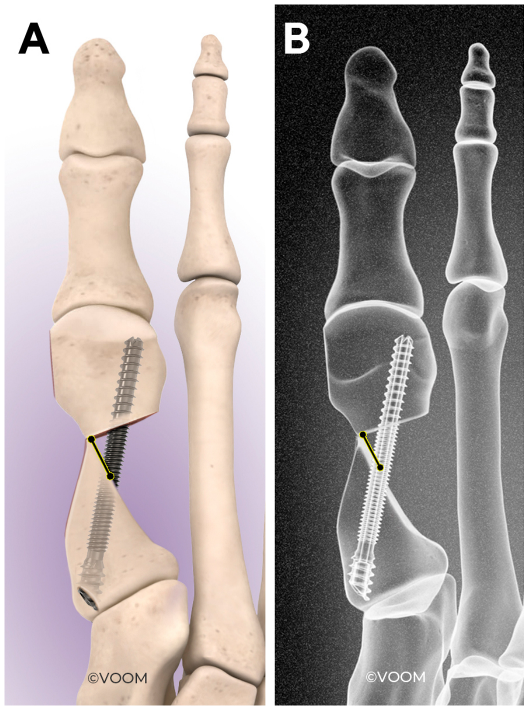

Figure 2. Renderings demonstrating the cortical runway distance of a single MI screw (anchor screw) fixation construct.

The cortical runway is measured as the distance between the distal most point of the lateral metatarsal cortex at the osteotomy and the center point where the screw(s) exit the lateral cortex. Rendering (A) and radiographic illustration (B) demonstrating the cortical runway.

INTRODUCTION

New modern minimally invasive bunion surgery (MIBS) is gaining worldwide interest and is in its infancy.[1-9] The unorthodox extreme shifts of this distal first metatarsal realignment osteotomy create a large void between bony segments that is bridged by one or two minimally invasive (MI) stabilizing screws, forming a metallic scaffold for callus formation in a newly corrected position. The stability of this construct, in part, comes from where the screw(s) engage the cortical bone of the lateral first metatarsal shaft, a region we previously described as the cortical purchase zone (CPZ) (Figure 1).[10,11] The optimal location of the screw(s) within the CPZ remains ill-defined and when placed in close proximity to the osteotomy may lead to fixation instability, signifying the importance of ample cortical real estate surrounding the hardware. The distance between the osteotomy and where the screw(s) exit the lateral cortex (a distance we herein coin the "Cortical Runway") within the CPZ has yet to be studied, and is the focus of this investigation (Figure 2).

METHODS

The authors conducted a retrospective review of the senior author (N.M.B.), first and consecutive cases of patients who had undergone MIBS from January 2018 to November 2022. Medical databases, charts, and radiographs were reviewed. To be included in the cohort required having undergone MIBS with or without other non-fusion procedures of the first ray, with an early posteroperaitve radiograph available. Patients who underwent MIBS in conjunction with other procedures that did not focus on the first pedal ray were excluded. Also excluded were patients who were lost to follow up (unavailable radiographs), had previous osteotomy bunion and/or first ray osseous surgery of any kind, and/or short-term postoperative complications (involving infection requiring incision & drainage, fixation failure and/or metatarsal explosion, and/or requiring additional surgery). The following data was collected: age, sex, laterality, bilateral surgery on same day or different day, anchor screw distance, collateral screw distance, bridge distance between anchor screw and collateral screw, preoperative and postoperative postoperative intermetatarsal angle (IMA) and hallux valgus angle (HVA), as well as time between surgery and first X-ray.

Radiographic angles, measurements and number of metatarsal screws were obtained, Radiographic assessments and measurements were performed with a digital imaging system (20/20 Imaging, Konica Minolta Americas, Inc., Crystal Lake, IL). A single measurement was taken for each radiographic variable, by a single investigator. The anteroposterior view was used for all measurements. All cortical runway measurements were obtained at the first available postoperative radiograph after the date of surgery.

A cortical runway was measured as the distance between the distal most point of the lateral metatarsal cortex at the osteotomy and the point where the screw(s) exited the lateral cortex (Figure 2). When two screws were used, a runway measurement was obtained for each screw.

The dominant screw in the fixation construct, known as the "anchor screw", and its cortical runway is termed the anchor screw runway.[10] If a second screw was used, we term this screw as the "collateral screw", and its cortical runway is termed the collateral screw runway.[10] We used the central aspect of the screw(s) core as the point where the measurement was taken. If any portion of the anchor or collateral screw was in continuity with the osteotomy, then the measurement was counted as a zero cortical runway. When double metatarsal MI screws (anchor and collateral) pierced the lateral cortex, then we additionally calculated this distance between the two screws. The cortical runway distance between the MI screws we term the "cortical bridge."

STATISTICAL ANALYSES

Statistical analyses were performed using Excel and Statistica® 13.1, and a two-sided $P < 0.05$ was considered significant in all analyses. Continuous variables were reported as mean ± standard deviation (SD) with 95% Confidence Interval (CI). Categorical variables were reported as numbers and percentages. Shapiro-Wilk test was used to assess data distribution and the choice of parametric vs non-parametric tests. Comparisons between groups were performed using a T-test, U-Mann–Whitney test, Kruskal-Wallis ANOVA, Wilcoxon matched pairs test, and chi-square, as appropriate. The correlation analysis was performed with Pearson or Spearman-rank test, as appropriate. The univariate binary regression was performed to understand the impact of surgery date on CPZ region security.

The CPZ was divided into 5 regions where screw stability might be delineated based on distance from the osteotomy, a classification system we herein coin as the CPZ stability regions. We used the statistical empirical rule to define the boundaries of each of the CPZ stability regions (Table 1, Figure 3). The bordering values between adjacent stability regions were rounded to the lower value to avoid a value that spans two regions, creating a distinct demarcation line between regions. The regions closest to the osteotomy carry a higher risk for screw instability whereas screw(s) furthest from the osteotomy have less risk. The five stability regions are color coded and depicted in relation to each other with first closest to osteotomy and the last furthest from the osteotomy.

New Cortical Purchase Zone Stability Regions (5 Regions)

1. *Danger Region ($X < \mu-2\sigma$):* The highest risk for MI screw instability as the MI screw is substantially within the osteotomy (Figure 4).
2. *Vulnerable Region ($\mu-2\sigma \leqslant X < \mu-1\sigma$):* Increased risk for MI screw instability as a small portion of the MI screw may be in continuity with the osteotomy or there is a shallow cortical rim between the MI screw and the osteotomy (very short runway) (Figure 5).
3. *Standard Region ($\mu-2\sigma \leqslant X \leqslant \mu-1\sigma$):* The region where a majority of MI screws exit the lateral cortex, and would be considered to have 'enough' or 'ample' cortical runway to minimize risk of MI screw instability (Figure 6).
4. *Safety Region ($\mu+1\sigma < X \leqslant \mu+2\sigma$):* A long cortical runway that would be considered a 'safe' distance from the osteotomy where MI screw instability would be less likely (Figure 7).
5. *Security Region ($\mu+2\sigma < X$):* The longest cortical runway and, theoretically, a more secure fixation location. The MI screw is furthest from the osteotomy and most proximal location on the metatarsal carrying the least risk for instability (Figure 8).

Bunion severity was classified (Table 5) according to a slightly modified version of Lewis and Gordon's classification used in their outcome study on 3rd generation MIBS.[12] In this study, the classification is as follows: mild bunion (HVA < 20°, and/or IMA <14°), moderate (HVA ⩾ 20° to < 40°, and/or IMA ⩾ 14° to < 20°) and severe (HVA ⩾ 40°, and/or IMA ⩾ 20°). The difference that we employed was for mild bunions to eliminate the range, and instead have the upper value threshold.

SURGICAL PROCEDURE

All patients underwent a minimally invasive subcapital metatarsal realignment osteotomy with percutaneous screw fixation using modified third generation minimally invasive approach.[1,11,13-15] This involves a subcapital distal first metatarsal osteotomy using a Shannon bur combined with percutaneous first generation minimally invasive bone screw fixation by placing 1 to 2 screws across the osteotomy site.[1,11,13-15] Anesthesia was either general or monitored anesthesia care along with an ankle block using Lidocaine. Cases were performed with and without a tourniquet. Intraoperative fluoroscopic imaging was used throughout the case. The method and technique was modified for some patients using proprietary methods of the senior author (N.M.B) in some of the cases.

Osseous and joint landmarks are identified and marked with the use of the mini C-arm.[1,11,13-15] Two skin incisions were created. The first incision was made at the medial neck of the first metatarsal. A second incision was made at the medial base of the first tarsometatarsal joint. Dissection of these incisions were bluntly performed to gain access to the bone.

Table 1. New cortical purchase zone stability regions based on empirical rule

Stability Region	Borders Formula	Description
Danger	$X < \mu-2\sigma$	The highest risk for MI screw instability as the MI screw is substantially within the osteotomy (Figure 4).
Vulnerable	$\mu-2\sigma \le X < \mu-1\sigma$	Increased risk for MI screw instability as a small portion of the MI screw may be in continuity with the osteotomy or there is a shallow cortical rim between the MI screw and the osteotomy (very short runway) (Figure 5).
Standard	$\mu-1\sigma \le X \le \mu+1\sigma$	The region where a majority of MI screws exit the lateral cortex, and would be considered to have 'enough' or 'ample' cortical runway to minimize risk of MI screw instability (Figure 6).
Safety	$\mu+1\sigma < X \le \mu+2\sigma$	A long cortical runway that would be considered a 'safe' distance from the osteotomy where MI screw instability would be less likely (Figure 7).
Security	$\mu+2\sigma < X$	The longest cortical runway and, theoretically, a more secure fixation location. The MI screw is furthest from the osteotomy and most proximal location on the metatarsal carrying the least risk for instability (Figure 8).

Table 2. A statistical description of the case series (n = 638 feet in 427 patients).

		Overall	1-screw	2-screw	P-value
Number of Procedures [n (%)]		638	526 (82.4)	112 (17.6)	
Age [mean±SD (95%CI)]		46.5±15.0 (45.3–47.6)	46.0±14.4 (44.8-47.3)	48.4±17.1 (45.2-51.6)	0.1369
Sex [n (%)]					
	Female **Male**	597 (93.6) 41 (6.4)	493 (93.7) 33 (6.3)	104 (92.9) 8 (7.1)	0.7334
Laterality [n (%)]					
	Right **Left**	330 (51.7) 308 (48.3)	270 (51.3) 256 (48.7)	60 (53.6) 52 (46.4)	0.666
Bilaterality [n (%)]					
	Unilateral **Bilateral**	216 (33.8) 422 (66.2)	172 (32.7) 354 (67.3)	44 (39.3) 68 (60.7)	0.1811
	Bilateral Same Day **Bilateral Different Day**	194 (46.0) 228 (63.0)	155 (43.8) 199 (56.2)	39 (57.4) 29 (42.6)	0.0398
Anchor Screw Distance (mm) [mean±SD (95%CI)]		10.4±3.7 (10.1-10.7)	10.2±3.7 (9.8-10.5)	11.5±4.0 (10.8-12.3)	0.0005
Collateral Screw Distance (mm) [mean±SD (95%CI)]		1.2±2.0 (0.8-1.5)	NA	1.2±2.0 (0.8-1.5)	NA
Bridge Distance (mm) [mean±SD (95%CI)]		10.3±3.2 (9.7-10.9)	NA	10.3±3.2 (9.7-10.9)	NA
Time Between Surgery & CPZ Measurement (Days) [mean±SD (95%CI)]		20.7±24.2 (18.8-22.5)	19.9±23.8 (17.8-21.9)	24.4±25.5 (19.7-29.3)	0.0657
Preoperative IMA [mean±SD (95%CI)]		15.5±3.4 (15.3-15.8)	15.4±3.4 (15.1-15.7)	16.2±3.4 (15.6-16.9)	0.0156
Preoperative HVA [mean±SD (95%CI)]		31.3±9.8 (30.5-32.0)	30.8±9.3 (30.0-31.6)	33.4±11.4 (31.3-35.5)	0.0109

IMA: Intermetatarsal Angle; HVA: Hallux Valgus Angle

Attention was first directed at the distal incision where a periosteal elevator is used to create a plane between the bone of the first metatarsal neck and dorsal soft tissue structures. The subcapital osteotomy is performed with a rotary 2.0 mm shannon burr under fluoroscopic guidance and irrigation. A through-and-through extra-capsular osteotomy was made from medial to lateral and dorsal to plantar.[1,11,13-15] Either a transverse, modified chevron/chevron type, or proprietary Transveron™ osteotomy was performed.[11]

The lateral translation of the first metatarsal head was performed with an elevator or hemostat placed into the

Table 3. Boundaries of each cortical purchase zone stability regions (n = 638, mean = 10.4, σ = 3.7)

Stability Region	Cortical Runway (mm)
Danger	<2.9
Vulnerable	3.0 - 6.6
Standard	6.7-14.1
Safety	14.2-17.8
Security	>17.9

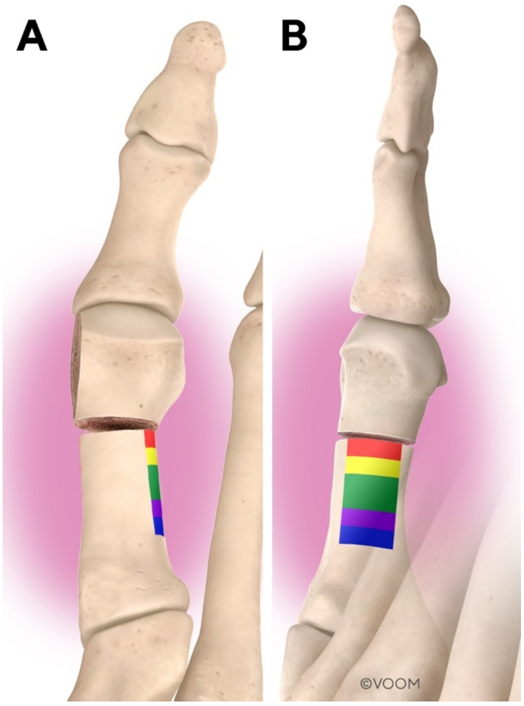

Figure 3. Rendering demonstrating the new CPZ stability region classification system (boundaries defined by the statistical empirical rule) where stability might be delineated based on distance from the osteotomy.

The regions closest to the osteotomy carry a higher risk for screw instability whereas screws furthest from the osteotomy have less risk. The five stability regions (color coded) are depicted in relation to each other with first closest to osteotomy and the last furthest from the osteotomy: Danger region (red), Vulnerable region (yellow), Standard region (green), Safety region (purple), and the Security region (blue). Top down (A) and medial views (B).

proximal metatarsal shaft, using the diaphyseal cortex as fulcrum for translation. The metatarsal head was laterally translated to reduce intermetatarsal angle, and the head rotated to restore the frontal plane position of the sesamoids as deemed necessary.[1,11,13-15]

Fixation of the metatarsal head was achieved by placing a first generation MI bone screw through the proximal incision. Minimally invasive chevron akin screw fixation (Stryker Corp, Kalamazoo, MI) was used. The screw(s) was placed over a guidewire, which was placed using fluoroscopic assistance. In all cases, a 4.0mm screw was placed obliquely within the first metatarsal, originating from the flare of the medial base of the first metatarsal into the capital fragment, while engaging the lateral diaphyseal cortex of the first metatarsal. In some cases, an additional point of fixation was placed using an additional 4.0mm screw or a 3.0mm screw just distal and parallel or divergent to the first screw. This screw was either placed through the same proximal incision or through an ancillary percutaneous incision, also using intraoperative fluoroscopic assistance.

The overhanging redundant bone shelf of the proximal medial metatarsal shaft was resected with a burr. The bone fragment(s) were either removed or pushed into the metatarsal canal as bone graft. A percutaneous adductor release was performed if needed using a beaver blade under fluoroscopic guidance.[1,11,13-15]

RESULTS

The results are tabulated in Table 2. A total of 638 feet in 427 patients fulfilled the inclusion criteria. Forty-one patients (6.4%) were male and 597 (93.6%) were female. The mean age of the patients at the time of surgery was 46.5±15.0 years (95% CI, 45.3–47.6). There were 330 (51.7%) right feet and 308 (48.3%) left feet. Of the 427 patients, 211 (49.4%) had surgery on both feet, with 97 (46%) having both feet operated on the same day and 114 (54%) having surgery on different days. A 1-screw construct was performed in 526 feet (82.4%) and a 2-screw construct in 112 feet (17.6%) of the total 638 feet.

The mean CPZ measurement was obtained at 20.7±24.2 days (95% CI, 15.3–15.8) from the date of surgery. The mean anchor screw runway distance was 10.4±3.7mm (95% CI, 10.1-10.7). The mean anchor screw runway for a 1-screw construct was 10.2±3.7mm (95% CI, 9.8-10.5) and the mean anchor screw runway for 2-screw construct was 11.5±4.0mm (95% CI, 10.8-12.3), demonstrating statistical significance (p=0.0005). The mean preoperative IMA was 15.5±3.4° (95% CI, 15.3-15.8). The mean pre-op IMA for 1-screw construct was 15.4±3.4° (95% CI, 15.1-15.7) and the mean pre-op IMA for 2-screw construct was 16.2±3.4° (95% CI, 15.6-16.9), demonstrating statistical significance (p=0.0156). The mean preoperative HVA was 31.3±9.8° (95% CI, 30.5-32.0). The mean pre-op HVA for 1-screw construct was 30.8±9.3° (95% CI, 30.0-31.6) and the mean pre-op HVA for 2-screw construct was 33.4±11.4° (95% CI, 31.3-35.5), demonstrating statistical significance (p=0.0109). The mean collateral screw distance was 1.2±2.0mm (95% CI, 0.8-1.5) in 112 feet. The mean cortical bridge (distance between the anchor and collateral screw) was 10.3±3.2mm (95% CI, 9.7-10.9).

The CPZ stability region boundaries were calculated (with the anchor screw as the template) using the statistical empirical rule as follows: Danger Region (< 2.9mm), Vulnerable Region (3.0 - 6.6mm), Standard Region (6.6 - 14.1mm), Safety Region (14.2 - 17.8mm) and the Security Region (> 17.9mm) (Table 3 & Figure 9).

With regard to a 2-screw construct, there was a moderate positive correlation between CPZ region and collateral screw runway (r=0.51, p<0.05) and a strong positive correlation between CPZ region and bridge distance (r=0.75, p<0.05). (Figure 10 & 11).

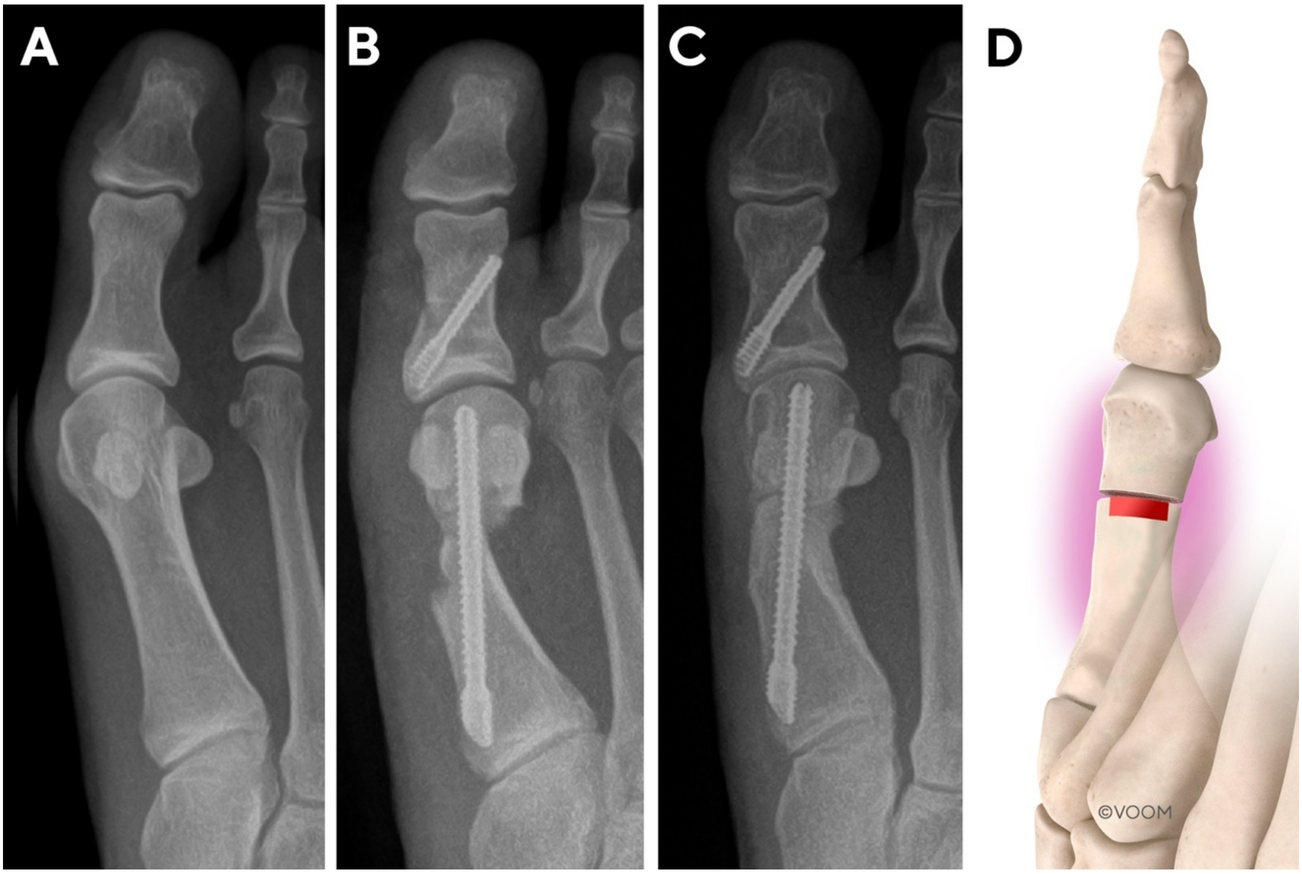

Figure 4. Radiographic example of a cortical runway within the CPZ Danger region (red).

The Danger region carries the highest risk for MI screw instability as the MI screw is substantially within the osteotomy. (A) Preoperative anteroposterior radiograph demonstrating a moderate bunion deformity. (B) Postoperative anteroposterior radiograph 9 days after single MI anchor screw MIBS. The cortical runway is zero. The MI anchor screw is substantially within the osteotomy. (C) Postoperative anteroposterior radiograph at 180 days demonstrating a healed realigned regenerated osteotomy. (D) Rendering illustrating the CPZ Danger region (red).

Out of 211 bilateral surgeries, 115 (55%) had a different CPZ zone, while the remaining had the same. Similarly, among 97 bilateral procedures performed on the same day, 53 (54.6%) had a different CPZ zone and 45.4% had the same.

An analysis of the case series relating to CPZ stability region distributions are tabulated in Table 4. As the cortical runway increased with more proximal anchor screw placement (as a function of more proximal CPZ stability region), so did the mean IMA (p=0.01) and mean HVA (p=0.0002), demonstrating statistical significance. The mean IMA of the regions are as follows: Danger Region 13.8±2.2° (12.6-15.0), Vulnerable Region 14.8±3.0° (14.2-15.4), Standard Region 15.7±3.2° (15.4-16.0), Safety Region 15.9±4.4° (15.0-16.8) and the Security Region 14.0±2.5° (12.6-15.8). The mean HVA of the regions are as follows: Danger Region 27.8±5.9° (24.5-31.0), Vulnerable Region 27.7±8.0° (26.1-29.3), Standard Region 31.5±9.7° (30.6-32.5), Safety Region 34.0±10.7° (31.7-36.1) and the Security Region 35.7±15.3° (24.8-46.7).

Bunion severity and anchor screw CPZ security region results are tabulated in Table 6. Bunion severity distributions were as follows (n=638): mild 53 feet (8.31%), moderate 453 feet (71%), and severe 132 (20.69%). There was statistical significance (p=0.0002) with increasing bunion severity and anchor screw runway distance. Table 6 illustrates bunion severity as it relates to CPZ stability region either proximal or distal to the standard region. When comparing anchor screw runways distances to stability regions either distal (a.k.a., closer to the osteotomy) or proximal (a.k.a., further from the osteotomy) to the standard zone, 24.53% of mild bunions had an anchor screw runway distance distal to the standard zone whereas 25% of severe bunions had anchor screw runway distance proximal to the standard zone.

We performed a time based analysis and the results are illustrated in Figure 9. An ordinal univariate regression revealed a positive association between the date of surgery of individual surgeries and CPZ region (beta=0.12, adjusted R^2 = 0.015, p=0.002). A year-over-year analysis comparing danger versus non-danger stability region placement of the anchor screw is presented in Table 7. There was a decreasing percentage of anchor screw landing into the danger zone over time (statistically significant, p=0.002) with 5/78 (6.41%) screws landing in the danger zone in 2018, 7/134 (5.22%) in 2019, 3/146 (2.1%) in 2020 and 0 (0%) out of 143 and 137 feet undergoing surgery in 2021 and 2022, respectively.

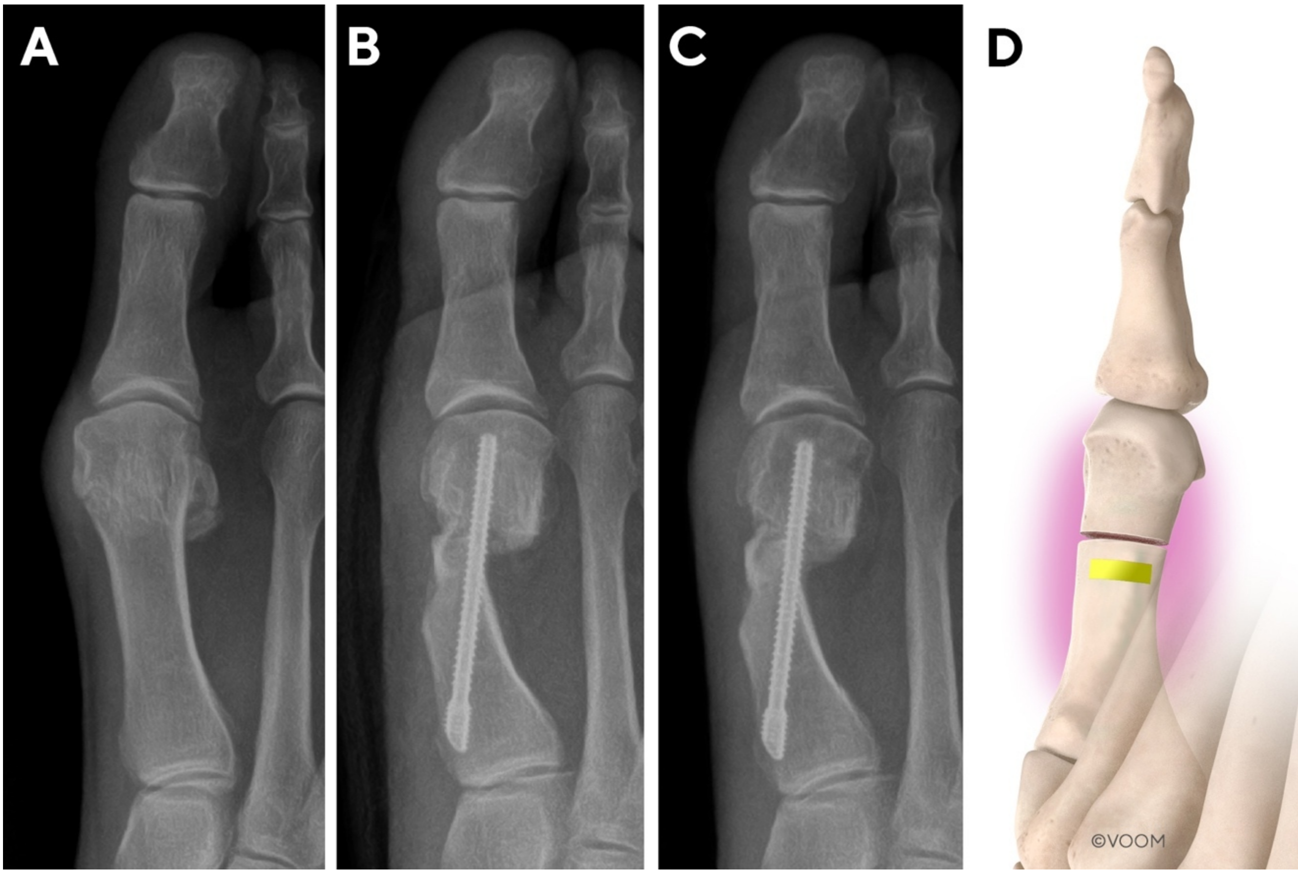

Figure 5. Radiographic example of a cortical runway within the CPZ Vulnerable region (yellow).

In the Vulnerable region, there is increased risk for MI screw instability as a small portion of the MI screw may be in continuity with the osteotomy or have a shallow cortical rim between the MI screw and the osteotomy (very short runway). (A) Preoperative anteroposterior radiograph demonstrating a moderate bunion deformity. (B) Postoperative anteroposterior radiograph 14 days after single MI anchor screw MIBS. The cortical runway is 4.1mm. (C) Postoperative anteroposterior radiograph at 360 days demonstrating a healed (medial healing) realigned osteotomy. (D) Rendering illustrating the CPZ Vulnerable region (yellow).

DISCUSSION

The stability of the MI screws in the CPZ with new MIBS is of utmost importance in creating a stable construct for maintaining position and providing a scaffold for bone healing across an osseous defect. The precise location within the CPZ where the screw(s) should exit the lateral cortex has yet to be defined. Screws strongly engaged in the cortical bone with a wide cortical rim are less likely to become destabilized, which may result in fracture and/or a change in correction.[10] This study identifies the boundaries of the CPZ and provides predictive risk modeling zone classification for the location where the anchor screw exits the lateral cortex, in a large cohort of patients who underwent MIBS.

Current 'best' practices believe that the anchor screw should exit the cortex approximately 1 cm proximal to the osteotomy; however this has been based on clinical experience of founders and early adopters.[13-15] Our study demonstrated a mean anchor screw cortical runway of 10.4±3.7mm, corroborating this value as a sweet spot when targeting the lateral cortex exit point. In addition, we also demonstrated that the runway can be twice as long (over 20mm) than previously thought, creating a potential safeguard against screw instability and/or metatarsal explosion.[10]

In a previous retrospective case series by the authors involving 16 feet (15 patients) with metatarsal explosion after MIBS, we identified that a distally placed screw in the CPZ was present in 75% of all types of explosions.[10] Lewis et al also recognized and described fractures as "metatarsal cutouts" with fixation failure when the screw is in continuity with the osteotomy.[12,16,17] Together these papers, emphasize how important it is to maintain cortical stability within the CPZ with increased cortical real estate, which can be achieved by the MI anchor screw exiting the cortex as far proximal on the lateral metatarsal as feasible or achievable (aka a lengthy cortical runway).

Having defined geographic boundaries that potentially mitigate screw instability risk as a function of distance from the osteotomy would be an invaluable reference for the surgeon. Rather than arbitrarily assigning these boundaries based on 'theory', we chose to divide the CPZ using actual real-world outcome cortical runway data in a large number of patients who underwent MIBS. We hereby coin this new classification (or demarcation) of the CPZ as "CPZ stability regions" and applied the statistical empirical rule to define: 1) the borders of the CPZ stability regions, 2) the distributions normality, and the 3) upper and lower limits of +/- three standard deviations. Being that an empirical rule dis-

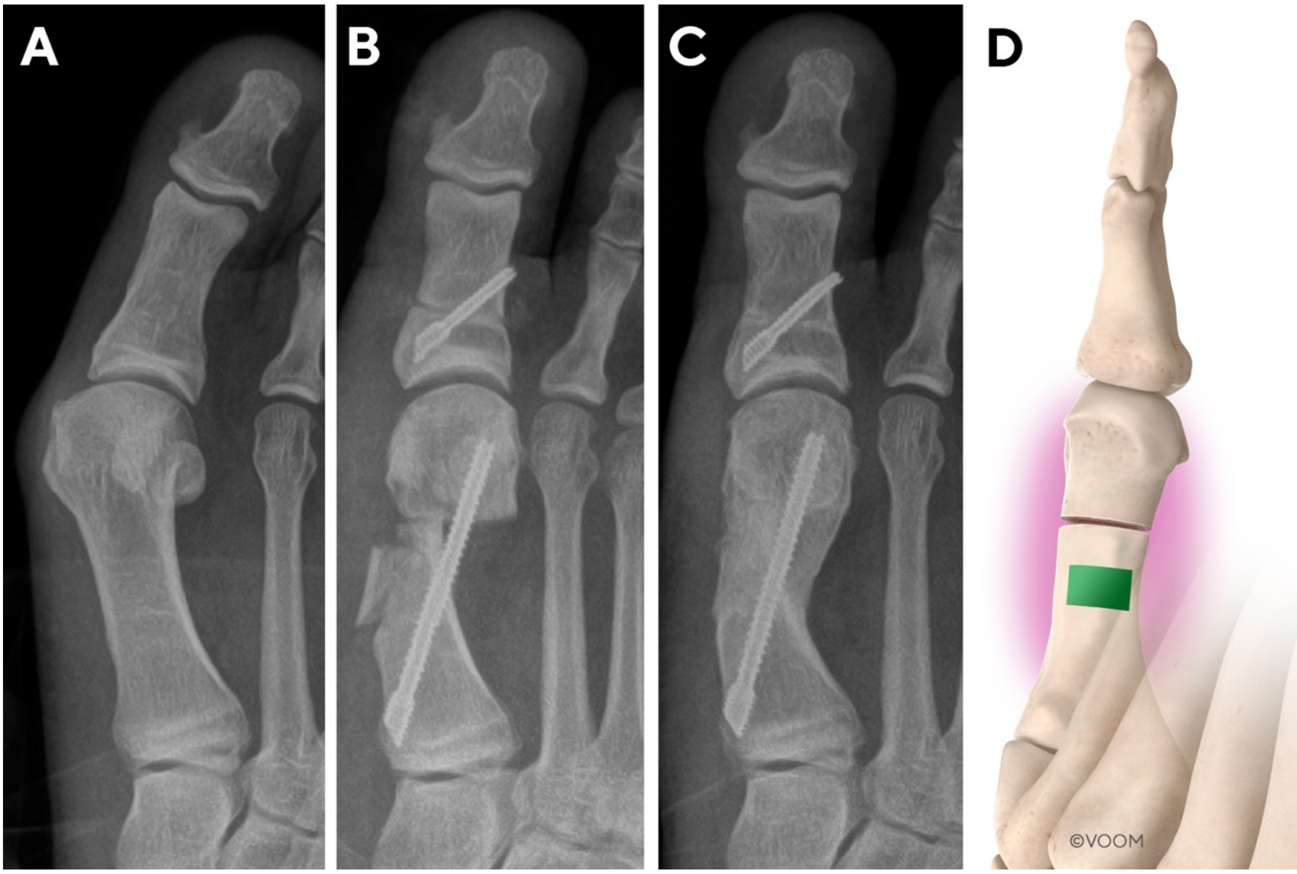

Figure 6. Radiographic example of a cortical runway within the CPZ Standard region (green).

The Standard region is where a majority of the MI anchor screws will exit the lateral cortex, and is considered to have a sizable enough cortical runway to minimize MI screw instability. (A) Preoperative anteroposterior radiograph demonstrating a moderate bunion deformity. (B) Postoperative anteroposterior radiograph 11 days after single MI anchor screw MIBS. The cortical runway is 13.2mm. (C) Postoperative radiograph at 189 days demonstrating a fully regenerated and realigned metatarsal. (D) Rendering illustrating the CPZ Standard region (green).

tribution has five areas (regions) based on three deviations from the mean, we also created five CPZ stability regions. Perhaps three CPZ stability regions (two standard deviations from the mean) would be sufficient, but a millimeter of cortical runway may be the difference between fracture or not, particularly in the stability regions closest to the osteotomy (i.e., danger and vulnerable region), so we decided to use five CPZ stability regions.

While it may be seemingly advantageous to have a longer cortical runway, achieving it can be technically challenging as the intraoperative scenario may force a shorter runway. Factors that seem to contribute to runway length include: bunion size, tarsometatarsal mobility, metatarsal length, metatarsal width, MI screw type, MI screw's medial entry location, MI screw's trajectory, metatarsal head translation, osteotomy location, osteotomy orientation, osteotomy configuration, body habitus, foot architecture and/or surgeon's MIBS experience. A shorter runway with any MI screw in continuity with the osteotomy is in danger for destabilization.[10] A MI screw can be partially within the osteotomy but be completely stable depending on the percentage of screw exposed and the angle that the MI screw crosses the lateral cortex. A screw that is more acutely angled to the lateral cortex will have more threads engaging the cortical bone, which might offer more stability than a screw that has less thread contact. A double metatarsal screw construct with a narrow cortical bridge and/or a collateral screw in close proximity to the osteotomy may also invite fracture. Nonetheless, a stable MI anchor screw regardless of cortical runway length is the ultimate goal.

Overall technique seems to play the largest role in cortical runway length. Toepfer et al advocate a "K-wire first technique" to MIBS, which involves placing the guide wire(s) before osteotomy which seems to lock-in the location of the exit point in hopes of avoiding osteotomy contiguation with the hardware.[18] Industry led jigs for guidewire placement also pre-determine and limit both MI screw trajectory and runway distances. Conversely, we strongly advocate the opposite, a freedhand technique whereby the surgeon can assess the amount of metatarsal head translation and angulate the guidewires trajectory to shorten or lengthen the runway to capture the translated metatarsal head.

Two MI screw MIBS seemingly provides a more stable fixation construct when compared to a single MI anchor screw. In this series, a 2-screw construct (when compared to 1-screw construct) was associated with a statistically significant larger pre-operative IMA and HVA values, as well as anchor screw distance. This suggests a larger bunion has more real estate for placement of two screws. Two MI screws engaging within the CPZ, effectively shortens the anchor's screws runway, but more importantly places the

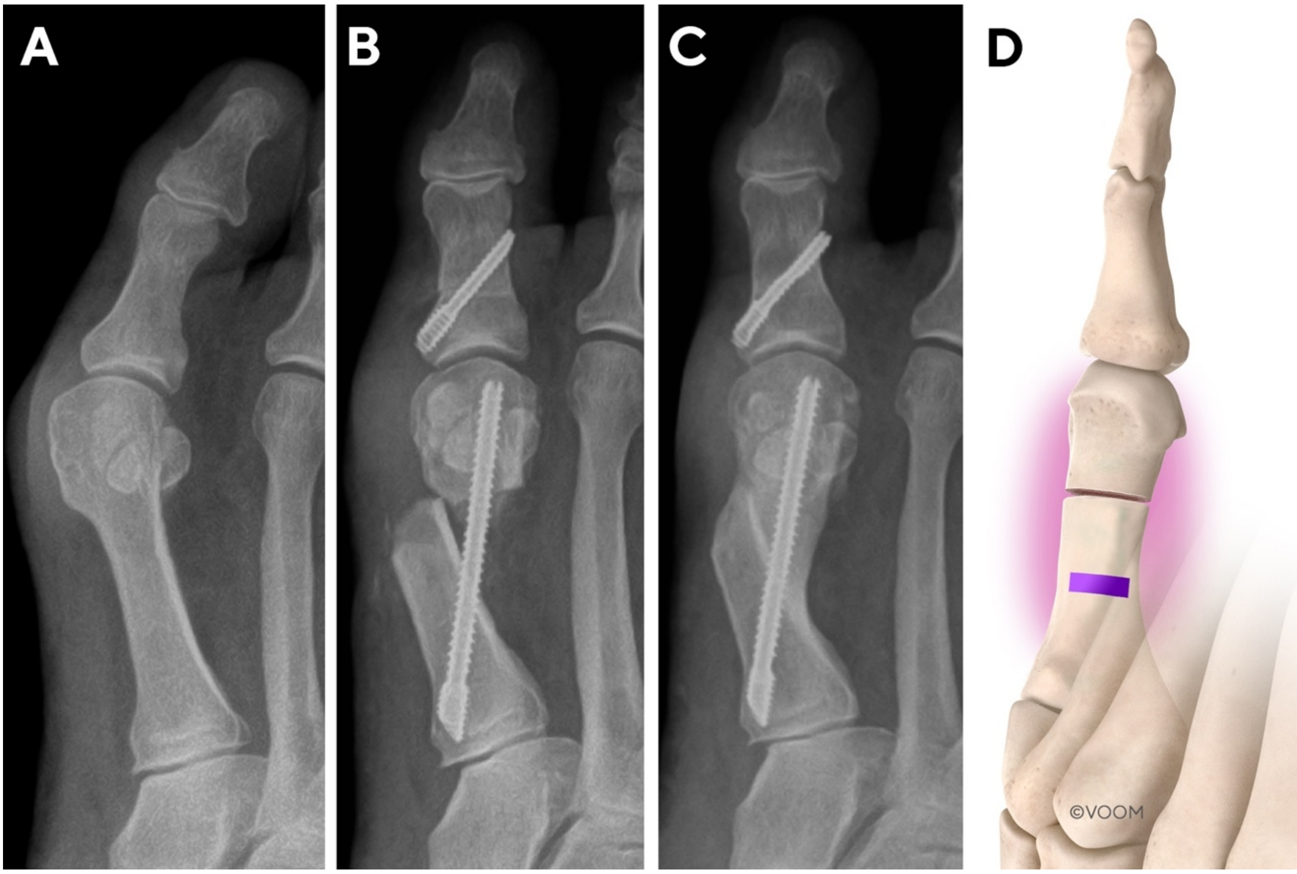

Figure 7. Radiographic example of a cortical runway within the CPZ Safety region (purple).

In the Safety region (with a long cortical runway) the MI anchor screw is considered to be a 'safe' distance from the osteotomy where MI screw instability would be less likely. (A) Preoperative anteroposterior radiograph demonstrating a moderate bunion deformity. (B) Postoperative anteroposterior radiograph 12 days after single MI anchor screw MIBS. The cortical runway is 15.7mm. (C) Postoperative anteroposterior radiograph at 215 days demonstrating a fully regenerated and realigned metatarsal. (D) Rendering illustrating the CPZ Safety region (purple).

collateral screw in closer proximity to the osteotomy, risking fracture. A more proximally located anchor screw allows for increased cortical real estate for increased collateral screw distances. The mean collateral screw runway was 1.2±2.0mm (0.8-1.5). Since the collateral screw is not the main fixation point, it seems having the screw in close proximity to the osteotomy is less problematic compared to an isolated anchor screw in this zone. However, in our previous case series on metatarsal explosions, worse explosions were more likely with two metatarsal MI screws, suggesting that a fracture at the collateral screw interface could extend and destabilize the anchor screw, particularly if the bridge distance between the two screws is shallow.[10] The mean bridge distance in the 122 feet (17.6%) with two MI screws in this series was 10.3±3.2mm (9.7-10.9), indicating that we were mindful to keep ample space between the dual MI screws that engage the lateral cortex. Our data demonstrated a strong correlation between a more proximal CPZ region and increased bridge distance, suggesting a more stable bony bridge between the two MI screws. It's generally our preference to have the collateral screw avoid the lateral cortex altogether and instead place it divergently into the metatarsal canal and head, thereby maximizing the overall runway and also having a potential benefit of a secondary point for the purposes of increased stability and/or anti-rotation. An area for future investigation might be related to construct stability differences between dual MI screw construct versus a single anchor screw distance, with varying runway distances of each screw.

Besides the benefit of mitigating potential fracture by an increased cortical runway between the osteotomy and MI screw, other advantages might be increased construct stability and improved healing potential. Stability of the MIBS construct with MI screw(s) comes from three distinct points of fixation: 1) the fixation stability at the CPZ, 2) anchoring of the MI screw head within the base of the first metatarsal, an area we previously described as the cancellous anchor zone (CAZ), and 3) the docking engagement zone (DEZ) of the MI screw within the metatarsal head.[10] This three point fixation construct that involves intra- and extra osseous segments has yet to be mechanically studied, and the cortical runway seems to be an important component in overall construct stability. And the cortical runway is truly a proxy to infer how well the MI screw threads engage the cortical bone of the CPZ.

The breaching location of the MI anchor screw at the lateral metatarsal cortex may play a role in bone healing and first metatarsal regeneration (FMR).[19] Disruption of the periosteum at the screw's exit at the lateral cortex may signal bone healing initiation, which is radiographically witnessed as early callus formation in this regenerative triangular zone. In another retrospective radiographic review

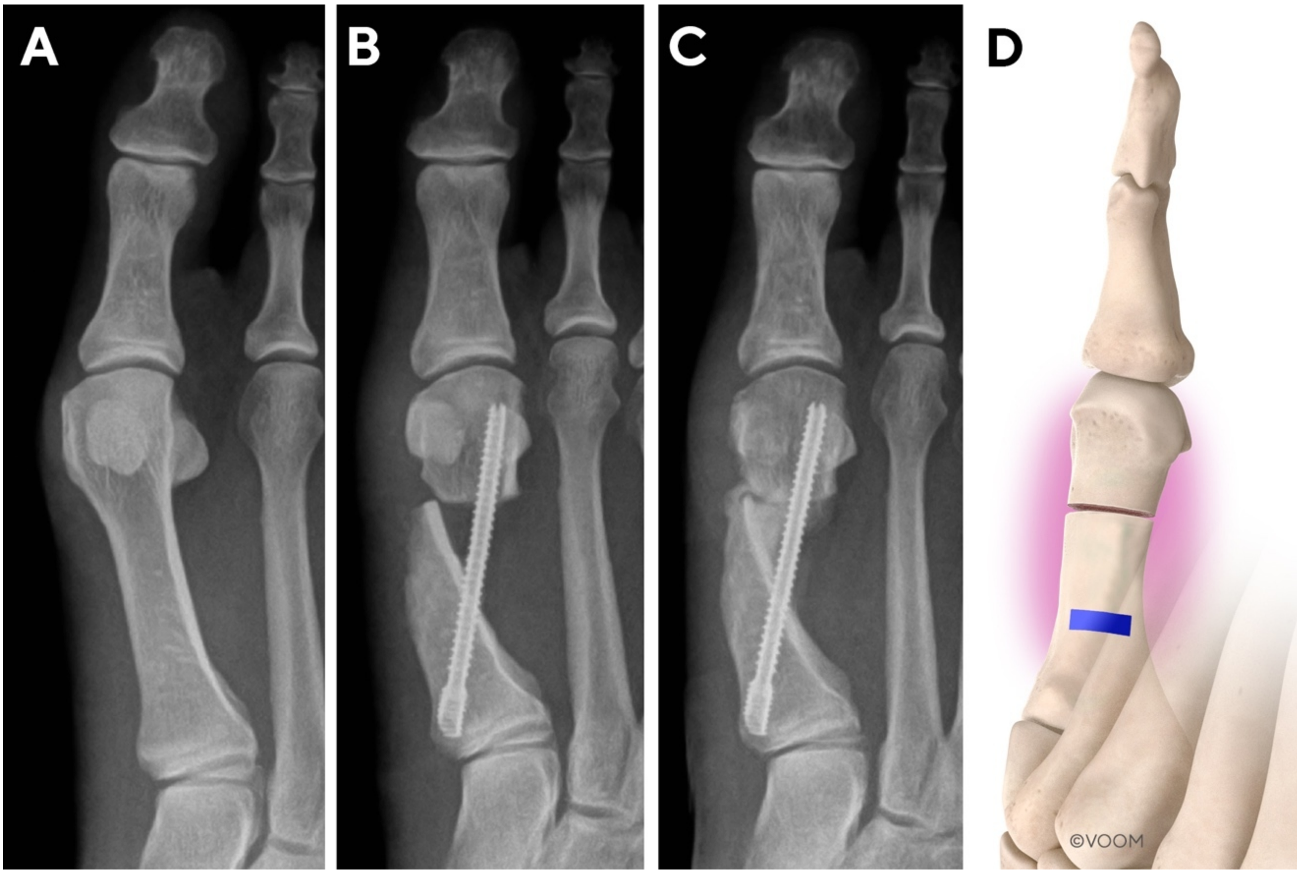

Figure 8. Radiographic example of a cortical runway within the CPZ Security region (blue).

The Security region is the furthest from the osteotomy (most proximal on the metatarsal) with the longest cortical runway and considered to carry the least risk for MI anchor screw instability. (A) Preoperative anteroposterior radiograph demonstrating a mild bunion deformity. (B) Postoperative anteroposterior radiograph 21 days after single MI anchor screw MIBS. The cortical runway of the MI anchor screw is 21mm. (C) Postoperative anteroposterior radiograph at 89 days demonstrating significant callus formation and realigned metatarsal. (D) Rendering illustrating the CPZ Security region (blue).

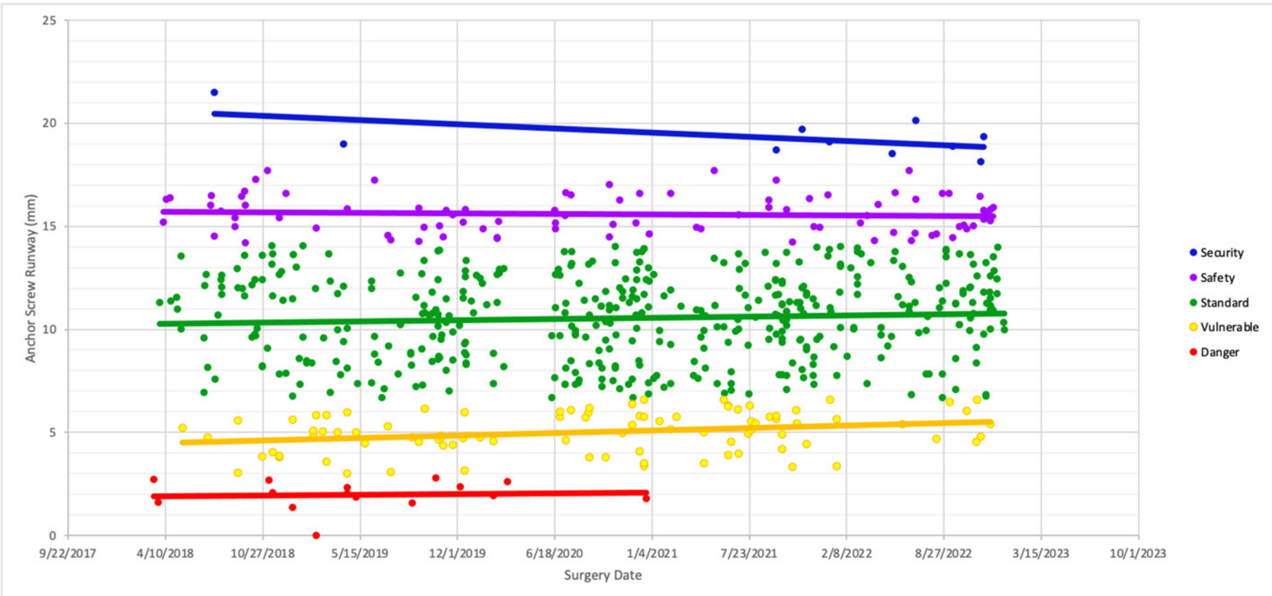

Figure 9. Scatter plot demonstrating anchor screw runway measurements highlighting each stability region of the cohort over time.

Table 4. A statistical description of the case series in relation to the CPZ stability region distributions (n = 638 feet in 427 patients).

	Overall	Danger	Vulnerable	Standard	Safety	Security	P-value
No. of Procedures [n (%)]	638	15 (2.3)	96 (15.0)	424 (66.5)	93 (14.6)	10 (1.6)	
Laterality [n (%)]							
Right	330 (51.7)	7 (2.12)	45 (13.64)	211 (63.94)	58 (17.58)	9 (2.73)	0.019
Left	308 (48.3)	8 (2.6)	(51 (16.16)	213 (69.16)	35 (11.36)	1 (0.32)	
Anchor Screw Distance (mm) [mean±SD (95%CI)]	10.4±3.7 (10.1-10.7)	2.0±0.7 (1.6-2.4)	5.1±1.0 (4.9-5.3)	10.6±2.0 (10.4-10.7)	15.5±1.0 (15.3-15.7)	19.3±1.0 (18.6-20.0)	<0.001
Preoperative IMA [mean±SD (95%CI)]	15.5±3.4 (15.3-15.8)	13.8±2.2 (12.6-15.0)	14.8±3.0 (14.2-15.4)	15.7±3.2 (15.4-16.0)	15.9±4.4 (15.0-16.8)	14.0±2.5 (12.6-15.8)	0.01
Preoperative HVA [mean±SD (95%CI)]	31.3±9.8 (30.5-32.0)	27.8±5.9 (24.5-31.0)	27.7±8.0 (26.1-29.3)	31.5±9.7 (30.6-32.5)	34.0±10.7 (31.7-36.1)	35.7±15.3 (24.8-46.7)	0.0002

by the authors involving 172 feet (122 patients), we classified the extent of FMR (aka bone healing), but did not demonstrate a statistically significant correction with IMA and HVA in bunions of all sizes.[19] This suggests that there are other factors not involving bunion severity and its angular correction (or translation) that might correlate to more robust callus formation. Perhaps there is an optimal cortical runway distance(s) that might be more advantageous for bone healing propensity?

This study illustrated a trend that with surgeon MIBS experience the anchor screw runway distance increases with time. Given that this investigation involves a single surgeon's first and consecutive cases over 5 years in a large cohort study with an evolving mastering (and proprietary) technique, might explain the trend for lengthier cortical runways with experience. The year-over-year analysis demonstrated a statistically significant trend of decreasing percentage of the anchor screw landing into the danger zone. The most striking and important finding observing the trend of anchor screw runways in an early adopter MIBS surgeon's first and consecutive cases clearly identifies a distinct point in time when the anchor runway distances would never breach the vulnerable or danger regions ever again. This "ah-ha" moment occurred 3 years and 352 MIBS procedures after the first case in January 2018. Prior to this moment (or revelation), the invasion of the danger region occurred in 15 cases, accounting for 2.4% (or 4.3% of the total cohort). Though the danger region represents a true demarcation line as to where the "no-go" zone of the anchor screw runway of the CPZ truly lies, and that is less than 3 mm. The fact that there were no breaches of the no-go zone for 2 years confirms that the no-go zone can be avoided despite bunion size/severity. Conversely, the security zone (furthest from the osteotomy) was struck in 10 cases (2% of the cohort), with 8 cases (80%) occurring after the "ah-ha" moment. Clearly, technique changes based on experience resulted in both avoiding the no-go zone and more frequent placement in the security zone (Figure 9 & Table 7). The clinical effect of the anchor screw was not studied and may result in clinically equivalent results, and therefore breaching the no-go zone should not be considered inappropriate, but rather not ideal.

This unique case series also represents that of one of the first Podiatric surgeons to perform MIBS with a subcapital osteotomy and beveled screw(s) construct within the United States, January 2018.[20] At that moment in time (aka newness of MIBS), there was a paucity of information/resources and no "surgical playbook"[21] on the then new and novel 2-screw extra-articular chevron approach (aka, third generation minimally invasive bunion correction) described by Redfern and Vernois.[13-15] The secluded experience by this surgeon in our study resulted in a divergence from the original Redfern-Vernois technique giving rise to new methods, and this CPZ data exemplifies how this unique clinical experience facilitated innovation/change.

One technique divergence is the use of a single point of fixation with an anchor screw, and this is the largest series to report the use, and preference, of a single proximal MI screw (526 feet, 82.4% of this cohort). Our first use of a single screw was on March 2nd, 2018 and was the second case after we first adopted MIBS. We first published this single screw technique in Foot & Ankle Quarterly in 2020.[1] In 2022, Vulcano and colleagues reported the use of single screw fixation within their retrospective outcome study of 274 feet over 2 years; however, they did not provide the frequency or outcomes comparing 1-screw versus 2-screw metatarsal fixation. The authors seemingly attributed the use of a single screw technique as the cause of all their 2.6% bone-healing related complications (nonunion; 2 feet and delayed union; 5 feet).[22] Perhaps construct configuration might have contributed to these bone-healing related complications as figure images demonstrated screws placed distal to the CAZ.

Also in 2022, Harrasser and colleagues provided the first published retrospective comparative analysis with a prospective follow-up study comparing 2-screw versus 1-screw fixation of chevron-MIBS in 50 patients (33 feet with 2-screws, and 22 feet with 1-screw).[23] Their criteria for using dual metatarsal fixation was "the surgeon's perception of stability at the osteotomy site." Harrasser's study demonstrated similar outcomes/results between both

Table 5. Comparison of bunion size category and anchor screw CPZ security region distribution between subgroups.

Bunion Size	Radiographic Criteria	Overall		Danger	Vulnerable	Standard	Safety	Security	P-value
Mild [n (%)]	HVA < 20°, and/or IMA <14°	53 (8.31)	n	**0**	**13**	**30**	**9**	**1**	0.002
			Column (%)	0.00	13.54	7.08	9.68	10.00	
			Row (%)	0.00	24.53	56.6	16.98	1.89	
			Total (%)	0.00	2.04	4.70	1.41	0.16	
Moderate [n (%)]	HVA ≥ 20° to < 40°, and/or IMA ≥ 14° to < 20°	453 (71)	n	**14**	**74**	**305**	**55**	**5**	0.002
			Column (%)	93.33	77.08	71.93	59.14	50.00	
			Row (%)	3.09	16.34	67.33	12.14	1.10	
			Total (%)	2.19	11.60	47.81	8.62	0.78	
Severe [n (%)]	HVA ≥ 40°, and/or IMA ≥ 20°	132 (20.69)	n	**1**	**9**	**89**	**29**	**4**	0.002
			Column (%)	6.67	9.38	20.99	31.18	40.00	
			Row (%)	0.76	6.82	67.42	21.97	3.03	
			Total (%)	0.16	1.41	13.95	4.55	0.63	
Totals [n (%)]		638 (100)		15 (2.35)	96 (15.05)	424 (66.46)	93 (14.58)	10 (1.57)	

HVA: Hallux Valgus Angle; IMA: Intermetatarsal Angle

Table 6. Anchor screw stability region by year, comparing danger versus non-danger stability regions

Year	Overall	Danger	Danger + Vulnerable	Standard, Safety + Security	Safety + Security	Security
2018 [n, (%)]	78	5 (6.4)	14 (17.95)	64 (82.05)	19 (24.36)	1 (1.28)
2019 [n, (%)]	134	7 (5.22)	33 (24.63)	101 (75.37)	16 (11.94)	1 (0.75)
2020 [n, (%)]	146	3 (2.05)	25 (17.12)	121 (82.88)	20 (13.7)	0 (0)
2021 [n, (%)]	143	0 (0)	2 (18.88)	116 (81.12)	16 (11.19)	2 (1.4)
2022 [n, (%)]	137	0 (0)	12 (8.76)	125 (91.24)	32 (23.36)	6 (4.38)
	P-value	0.002	0.015	0.015	0.007	0.04

groups, and statistically more patients were dissatisfied with the implants with the 2-screw fixation than 1-screw (32% versus 3%, respectively).

In our clinical experience, we don't particularly identify worrisome instability with a single screw, rather the decision to add an additional collateral screw is focused more on the amount of metatarsal head shift (greater than 100% shift) and the available real estate to add another point of fixation. In fact, our study demonstrates that we had increasing confidence with single screw fixation as construct stability increased as a function of longer anchor screw cortical runways, and is the focus and importance of our investigation. Our mean anchor screw cortical runway was longer with 1-screw at 11.5±4.0mm (10.8-12.3) compared to 2-screws 10.2±-3.7mm (9.8-10.5), reaching statistical significance (p=0.0005). In the absence of biological bone brittleness, it is our opinion that single screw MIBS originating in the proximal medial first metatarsal base (CAZ) centered within the metatarsal canal with a lengthy cortical runway is the ideal fixation construct. Future studies that compare single versus dual metatarsal screw fixation are the next logical studies to emerge with MIBS.

Evolution in MI screw design now supports a single screw solution with the advent of the dual zone MI screw,[11] whose non-compressive alternating pitch is specifically designed to better capture the dense cortical runway bone and the spongy cancellous bone of the metatarsal base insertion as well as the cancellous bone of the metatarsal head. This current retrospective study only reviewed radiographs with fixation constructs that involved first generation MI bone screws. In short, a first generation MI bone screw is a fully threaded screw with a chamfered head and a shank that is cancellous pitched.[1] A second generation MI bone screw has a cancellous neutral pitched head to match the spongy CAZ insertion of the medial proximal metatarsal base. Lastly, the third generation screw is the dual zone anchor screw as described above. While screw design may impact strength and confidence for a 1-screw solution, it does not particularly impact one's ability to obtain a longer cortical runway but might forgo the desire for a second point of fixation.

Anchor screw distance can also be another metric used to assess surgeon proficiency with MIBS. Current metrics to assess surgeon proficiency are surgery duration and amount of fluoroscopy use (number of images, cumulative dose and radiation exposure).[24] Toepfer et al additionally investigated degree of bunion correction as a proficiency metric during the learning curve but the adequacy of correction was the same despite being "proficient."[24] As such, their idea of proficiency is thought to be achieved after 40 procedures where surgery time is under 45 minutes and less than 100 fluro-exposures. Our CPZ data offers a clinical radiographic metric of proficiency that is easily measured radiographically, and we believe that infrequent no-go zone placement be considered. At a minimum, an acceptable no-go zone occurrence during the first 40 procedures should be less than 18% (matching our overall incidence); though, we believe 2 out of 40 (or 5%) more appropriate. With advanced techniques, it's our current opinion that it's actually easier to free handedly place a more proximal screw. Current jigs often force the placement of the MI screw into a no-go zone and therefore this metric of proficiency would not be effective with the use of a positioning device.

Bunion severity also appears to play a role in the ability to achieve a more proximal CPZ region. Increasing both preoperative IMA and HVA demonstrated a more proximal CPZ region. The takeaway is larger bunions (particularly with increased HVA) have more opportunity for a more proximal anchor screw placement. Mild (smaller) bunions were unable to achieve lengthier runways (distal to standard region) in 25% of cases, whereas the severe bunions were able to achieve the lengthiest runways (proximal to standard region) in 25% of cases. It is our clinical experience that increased tarsometatarsal mobility is a factor in achieving increased cortical runway. It has been documented that MIBS "locks-up" the first tarsometatarsal joint by adducting the proximal metatarsal segment, and this maneuver (we have found) allows for increased cortical runway.[25] The effect of tarsometatarsal mobility on CPZ was not studied as a part of this investigation and an area for future research that might help surgeons plan and perform MIBS.

There are several limitations to this study. Our radiographic data collection was performed by one person (an experienced surgeon). The measurement of CPZ is not complex and there is limited room for subjectivity based on two clearly defined data points, which also removes any inter-rater reliability issues. Another important limitation is that the CPZ measurement relies on the length of the metatarsal as well as the location and angulation of the osteotomy. None of these variables were studied, however given that this study involved a large cohort of a single surgeon's cases provides a level of consistency through the dataset.

An important limitation of this study is that this was a retrospective analysis studying where the anchor screws exited the lateral cortex of the first metatarsal with a MIBS. The surgeon's goal and intent was to place screws that provided a clinically appropriate position, and not try and achieve the absolute best or maximum cortical runway. In other words, if the screws trajectory allowed for a clinically "good enough" or "ample" cortical runway then position was accepted, rather than repeated trying to achieve the extreme lengths as the detriment of the patient with increased operating room time and/or perhaps weakening the bone from many/multiple trajectory attempts. It is important that surgeons heed this message so that cortical runway length does not become a mark or badge of merit or skill set, and surgeons should focus on an achievable "good enough" cortical runway based on the clinical scenario.

This was a retrospective radiographic study that measured the length of the cortical runaway with new MIBS, a measurement that has not been previously investigated. The data provided a new novel system to define and map out (classify) the CPZ stability regions of the lateral cortex of the first metatarsal with MIBS. Understanding the normal and ranges of the cortical runway will help surgeons guide their intraoperative corrections. It is postulated that achieving longer runway distances (aka avoiding the danger zone) might shield from fixation instability and fracture/explosion and perhaps also be an indicator, or metric, of surgeon MIBS proficiency (i.e., avoiding the no-go zone). It's likely that future studies will emerge that specifically measure and correlate cortical runway to healing (FMR type), fixation construct orientation/type, stability, metatarsal explosion and/or other variables that might improve surgical techniques as well as lessen complications and/or improve outcomes.

CONCLUSION

New MIBS and its unique fixation construct that bridges segments of bone that are drastically separated is an unconventional solution to classic bunion surgery principles. The optimal fixation construct and technique continue to evolve as MIBS becomes mainstream. The stability of this MI screw construct to maintain a corrected position is paramount as the first metatarsal regenerates itself in a newly corrected position. Respecting the boundaries of the CPZ and maintaining an adequate cortical runway are seemingly important components of maintaining stability and mitigating positional loss and/or fractures. When proficient, a properly performed MIBS provides surgeons with yet another option to treat bunions of nearly all sizes with a walking recovery.

DISCLOSURE STATEMENT

Neal M. Blitz DPM is the CEO of Voom Medical Devices, Inc and receives compensation for this role. Bogdan Grecea DPM is the Director of Surgeon Onboarding for Voom Medical Devices, Inc and receives compensation for this role. David T. Wong DPM reported no disclosures. Eric S. Baskin DPM is the Director Surgeon Training for Voom Medical Devices, Inc and receives compensation for this role.

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