

## Statement of Purpose

Our goal was to create a reproducible, minimally invasive surgical procedure to correct hallux abductovalgus in patient populations with connective tissue disorders or complex soft tissue disorders such as Ehlers-Danlos Syndrome, Diabetes Mellitus, and Rheumatoid patient

## Level of Study

Level IV, Retrospective Analysis

## Introduction

The deformity has been cited for years with the now earliest case of hallux abductovalgus documented in an Egyptian mummy from the necropolis of Sharuna in 2100 BC. The mummified remains of the first ray were identified with a hallux abduction angle of 28° (1). In today's society, hallux abductovalgus has been analyzed in a literature review to have a prevalence estimate of 23% in adults aged 18-65 years, and 35.7% in elderly people aged over 65 with a higher occurrence rate in females as seen within 76 papers with 496,957 participants (2). Biomechanical and structural abnormalities contributing are attributed but not limited to hypermobile first ray, overpronation, equinus, metatarsus adductus, and limb length discrepancies. Medical conditions such as rheumatoid arthritis or connective tissue disorders including Marfan Syndrome or Ehlers-Danlos Syndrome (EDS) can contribute to ligament instability and lead to deformity. These patients are at increased risk due to ligament and soft tissue laxity from their collagen disorders. Throughout history, hallux abductovalgus was described with potential surgical interventions proposed or proven to correct the deformity. In 1934, Dr. Paul Lapidus described a first and second metatarsal fusion. In 1981, Austin and Leventen introduced a 60° osteotomy centered through the head of the first metatarsal. In 1987, Kalish and Bernbach proposed a more acute angle of 55° with a long dorsal armed V-shaped osteotomy through the metaphyseal-diaphysis junction. In 1989, Vogler also introduced a change to the Austin angle to 30° mimicking the long arm dorsal V-shaped osteotomy with success (3). As more and more literature is published, variations to procedures, osteosynthesis, and weight bearing guidelines are introduced.

## Methodology and Procedures

In total, 61 patients and 68 feet were studied during the exam. No patients were lost to follow up. The average follow up from procedure was 41.56 weeks. Within the patient selection, there was no discrimination between age, sex, gender, PMH, prior procedures, or IM angles as the study was fully inclusive. 14 of the 61 patients were EDS patients.

A single, experienced surgeon performed all the procedures. X-Rays were performed pre-operatively and post-operatively including an AP, Medial Oblique, and Lateral views. X-Rays were taken intra-operatively and post-operatively at 1 week and progressively over 3 months, 6 months, and 1 year on average when possible. These images and angles were interpreted by a single physician to avoid compromise of values.

The anchor system used is a variation of a Titanium wedge bone anchors are composed of strands of ForceFiber consisting of UHMWPE (Ultra High Molecular Weight Polyethylene), polypropylene, and nylon with a Titanium anchor attached. Once inserted, the suture ends are untethered from the anchor inserter, and both the inserter and guide are removed. The suture is then tied from the proximal and distal aspects of the respective anchors to realign the hallux to its rectus position.

Every procedure included a traditional lateral release. Once completed, a L-shaped capsulotomy was performed to gain access to the 1<sup>st</sup> metatarsal. Resection of the medial eminence was performed in all cases followed by the traditional V-shaped osteotomy. The capital fragment was displaced for correction while ensuring correction of the sesamoid position was also achieved. Then, following standard AO technique, a single screw was used for osteosynthesis of the osteotomy site. Two anchors were placed with one applied into the base of the proximal phalanx, while directing the anchor distal to the joint, with the second anchor placed proximally and centrally to the V-shaped osteotomy. The fashioned suture material produced a marked medial translocation of the hallux with decrease in the hallux abduction angle. Closure was achieved using 4.0 Monocryl in a running subcuticular fashion and reinforced with simple, non-interlocking running 4.0 Prolene for skin closure.

Patients were weight bearing as tolerated immediately following the procedure in a post-operative shoe and presented with weekly follow ups. Results were measured quantitatively based on the pre-operative and post-operative IM and HAA angles on dorsal plantar images taken in standard weight bearing angle and base of gate. Subjective analysis was confirmed with a variation of the ACFAS Questionnaire to evaluate patient pain, satisfaction, and physical abilities pre versus post-operatively as outlined for the first ray. Statistical analysis was completed via paired t-test analytics with standard deviations also calculated.

## Results

Overall, 61 patients and 68 feet were studied with an average follow up of 41.56 weeks. The average intermetatarsal and hallux abduction angles encountered pre-operatively were 13.27° and 19.88°, respectively, with a decrease observed post-operatively to 8.50° and 8.96°, respectively. X-Rays were recorded at previously described intervals with no statistically significant variance in the IMs upon analysis. The average change across the patients IM angles in their furthest follow up from procedure was documented at 0.45°. Subjective analysis was also analyzed and revealed an overall improvement in aesthetics, pain level, and function by patient's standards from pre to post-operatively. Patients were contacted via telephone and surveyed using an adaption of the ACFAS Score to facilitate telephone data collection. All patients expressed a positive outcome and commented on their desire to have the procedure once more if required. Overall, the patient cohort scored a 45.5 out of 50 for the subjective analysis. When EDS patients were isolated, there was a subjective score of 47 out of 50. The paired t-test values for the intermetatarsal and hallux abduction angles revealed  $P < .0001$  within the 95% confidence intervals. The respective standard deviations for the post-operative angles were 1.22 and 4.70.

Complications included one patient with hallux varus, one patient with hallux valgus, and 3 patients with post-operative infections. None of the infections required additional procedures with symptoms resolved with PO antibiotics. Both the hallux varus and hallux valgus patients underwent revision of their procedure with removal and re-application via a similar correction. The hallux valgus was due to a rupture of the suture material. The hallux varus was attributed to overtightening of the suture material prior to closure. These revisions have been without incident and successful since. None of the required revision procedures were needed in EDS patients as there was 100% union rate without revision or complication along with positive subjective scoring in that patient cohort. Overall, a success rate of 66/68 patients was achieved for 97.1% of satisfactory outcomes.



Figure 1: A patient's pre-operative image encountered with increase in IM angle and HAA



Figure 2: A patient's post-operative image with reduction in IM angle and HAA with intact hardware

Parameter	Degree	Score
Pain: Over the past month, how much has your foot pain limited your daily activities?		
I have no pain with normal activities		30
I have slight pain but no limitation of activities		22
I have moderate pain limiting some activities		14
I have pain and significant limitation of activities		6
I have severe pain that limits almost all activities		0
Appearance: How would you rate the appearance of your big toe joint?		
I like it very much		5
I mostly like it		4
I'm not sure either way		3
I mostly do not like it		2
I definitely dislike it		0
Functional capacities: How frequently do you have pain wearing shoes or issues working?		
I am able to continuously wear any type of shoe and work		15
I am able to wear any type of shoe and work most of the time		10
I am able to wear only walking, athletic, or casual shoes		5
I am unable to wear shoes or work		0

Figure 3: Variation of the ACFAS Subjective Questionnaire

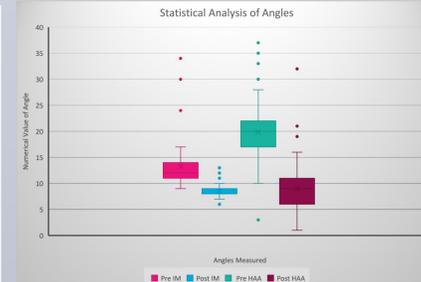


Figure 4: Statistical distribution of data via a Box Plot

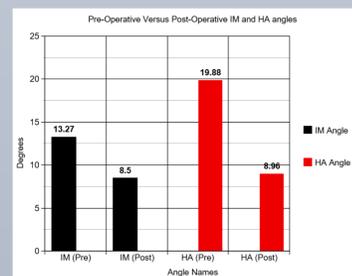


Figure 5: Pre- and Post-operative IM angle and HAA measurements

## Discussion

The bone anchors were chosen for osteosynthesis due to their stability and dependability. They have been documented to have a load to failure in procedures involving the hip and rotator cuff of at least 103.9 N. Their endurance was also tested to show a mean displacement of only 8.4 mm after repetitive stressors under tension at 50 cycles. (5). Traditional anchors may have slightly higher load to failures; however, the anchors chosen are readily available, cheaper, and sufficient for procedures in the lower extremity. The wedge anchors permit reapplication where as those such as barbs have a destructive removal process limiting the surgeon. The anchor strength corresponds with the strength of the medial collateral ligament as Drs. Rabie and Agnew performed a cadaveric study where the failure to load of the ligament via repetitive force was analyzed across 3 specimens. The failure to load of the medial collateral ligament was approximately 22 kg (6).

Bunion recurrence rates have been studied and range from 2.7% to 16.0% across multiple studies. These findings are consistent in the general population, and they are much more prevalent in patients with connective tissue disorders by our observations. These patients demonstrate higher failure rates with increased complications with transfers of instability to adjacent joints.

Within each osteotomy or bunionectomy procedure, additional factors are included such as osteosynthesis techniques. These approaches can include osteosynthesis via a K-wire or screws, cerclage wire, or no osteosynthesis at all as the Austin bunionectomy has been documented as being inherently stable. A study by Crosby analyzed 6 patients with screw osteosynthesis, 7 with K-Wire, and 6 patients with no osteosynthesis. Upon statistical analysis, the patients undergoing screw osteosynthesis has less complications and higher success rates for healing. Screw osteosynthesis and no osteosynthesis revealed the greatest improvement in IM angles as they decreased by 9.5° and 7.1° respectively. Subjective analysis showed no difference between the groups (7).

Akin procedures have been utilized in the past to aid with correction of the IM in hopes of reducing PASA and the HAV angle. This approach, while helpful, comes at quite the cost. Surgeon precision must be high in order to maintain the lateral cortex of the proximal phalanx and ensure no breakage of the hinge. Most importantly, an additional osteotomy presents increased risks due to complications and potentially poor bone quality. A retrospective study has reviewed the Akin procedure revealing 65/132 patients with complications highlighted by 42 patients who experienced compromise of the lateral hinge intra-operatively. The technique presented avoids any of these complications due to the limited invasion and technical application of the suture anchors. This procedure also allows for surgeons to avoid base procedures such as a Lapidus which comes with recurrence rates ranging from 2-12% (8). It also eliminates potential complications or issues arising from questions to the bone stock of patients.

While the 14 patients with EDS encountered is a small sample size, the 100% success rate in patients with EDS with no recurrence was a success by achieving one of the main goals of this study in providing aid to those with connective tissue disorders. The subjective analysis score also revealed a successful outcome with respect to treating connective tissue disorders. In addition, our initial failure rate which includes recurrence and complications of 2.9%. Since these results include recurrences and complications, our actual recurrence rate falls under the lower averages documented yielding promising results. The percutaneous technique also aids with scarring and surgical wound healing in diabetics as well as those with connective tissue disorders.

Limitations to the study are humbly presented to highlight problems encountered. With the history and prevalence of bunions, this study lacks an extensive follow up period. The procedure and imaging studies performed by one individual also allows for interpretational bias which must be acknowledged. Subjective scoring was positive; however, these results are limited to a single procedure. Patients have no idea how they would have felt with a traditional bunion procedure, and there is no comparable subjective data within this cohort. A more significant limitation is the physical cost and availability of the anchors which are used for the procedure.

## References

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