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The Wild West of Forefoot Surgery

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Orthopaedic Surgery, Foot and Ankle Surgery

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Learning Objectives

At the end of this session, participants should be able to...



1

Explain the increased demand for forefoot surgery and growth in the market

2

Explain the difference in the traditional forefoot surgeries and newer procedural techniques and devices

3

Use information learned to have meaningful conversations for streamlining supply in the area of forefoot surgery

Normal Anatomy of the Foot

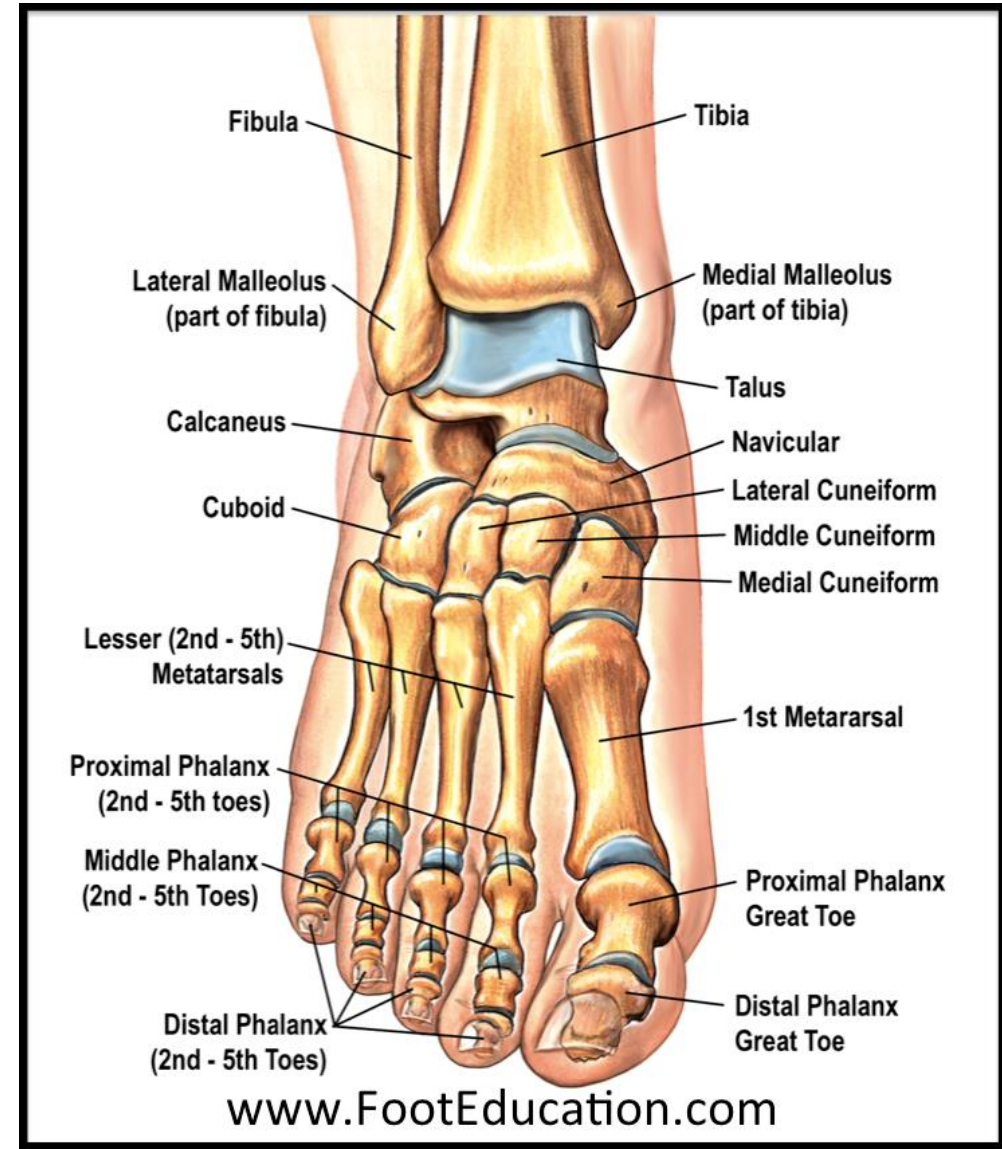
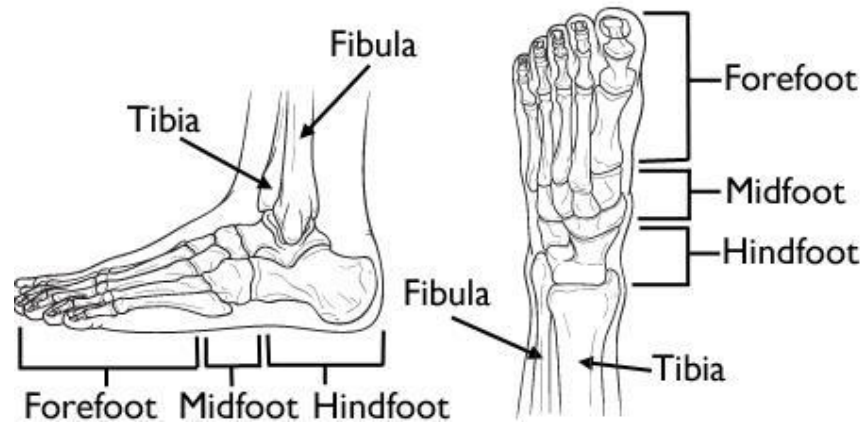


Image Source: Weatherford BM, OrthoInfo: Rheumatoid Arthritis of the Foot and Ankle. *American Academy of Orthopedic Surgeons*; 2017: Available at: <https://orthoinfo.aaos.org/en/diseases-conditions/rheumatoid-arthritis-of-the-foot-and-ankle> Accessed 5.5.2021

Pinney, S, Foot & Ankle Orthopedia: *The Bone and Joint Initiative: The Codman Group*: Available at: <https://orthopaedia.com/page/Anatomy-of-the-Foot-Ankle> Accessed 5.10.2021

Joints of the Forefoot

- **Abbreviations:**
 - Interphalangeal (IP)
 - Distal Interphalangeal (DIP)
 - Proximal Interphalangeal (PIP)
 - Metatarsalphalangeal (MTP)
 - Tarsometatarsal (TMT)

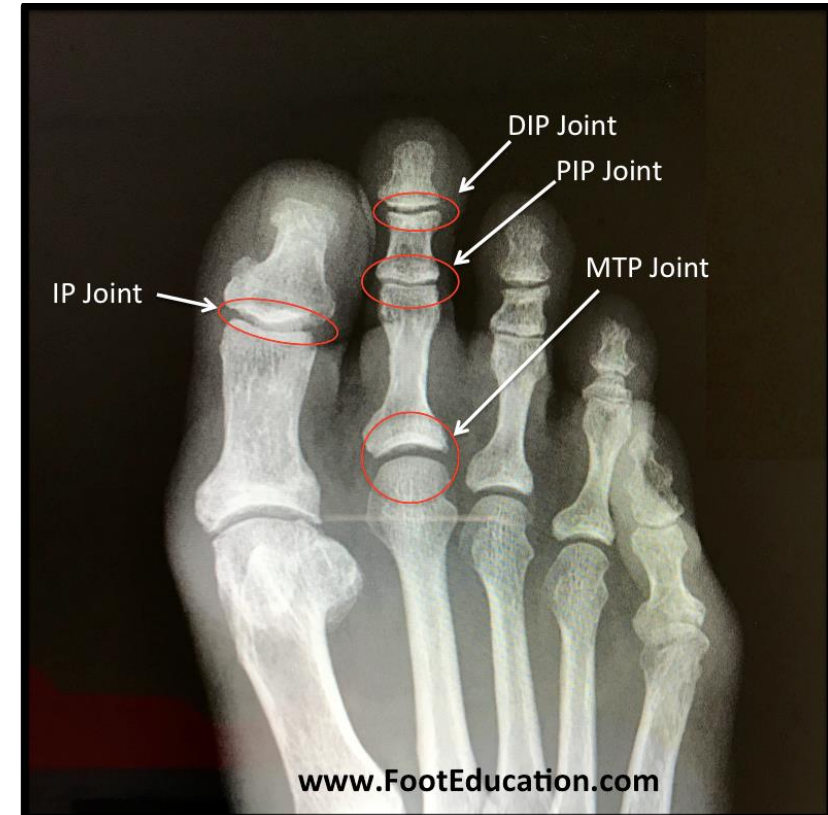


Image Source: Pinney, S, Foot & Ankle Orthopedics: *The Bone and Joint Initiative: The Codman Group*: Available at: <https://orthopaedia.com/page/Anatomy-of-the-Foot-Ankle> Accessed 5.10.2021.

Hallux Valgus or Bunion Deformities



- **23% of adults aged 18-65 years have Hallux Valgus (HV)**
 - Bunion or angulation of the great toe
- **Causes pain with closed toed footwear**
 - Cosmetic concerns for some
- **Prevalence increases with age and is higher in females. Strong hereditary component.**
 - 30% of females and 13% of males affected
- **>200,000 annual cases of HV correction in the United States (U.S.)**
 - Growth with aging population.
 - Increased awareness and marketing

Source: Nix S, Smith M, & Vicenzino B. Prevalence of hallux valgus in the general population: a systemic review and meta-analysis. *J Foot Ankle Res.* 2010;3(21): doi: [10.1186/1757-1146-3-21](https://doi.org/10.1186/1757-1146-3-21)

Accessed 4.26.2021.

Image source: Pinney, S, Foot & Ankle Orthopaedia: *The Bone and Joint Initiative: The Codman Group*: Available at: <https://orthopaedia.com/page/Anatomy-of-the-Foot-Ankle> Accessed 5.10.2021.

Hammertoe Deformities

- **Hammertoe is a flexion deformity of lesser toes**
 - Pain with foot wear and leads to ulcers
 - Pain at dorsal proximal interphalangeal (PIP) joint or plantar metatarsal head
 - Often associated with Hallux Valgus
 - Can involve multiple toes on same foot
 - Often bilateral involvement
- **>600,000 annual surgical cases for hammertoes**
 - However, 60 million U.S. population is affected
- **Market expands due to aging population with increased awareness and educational resources**

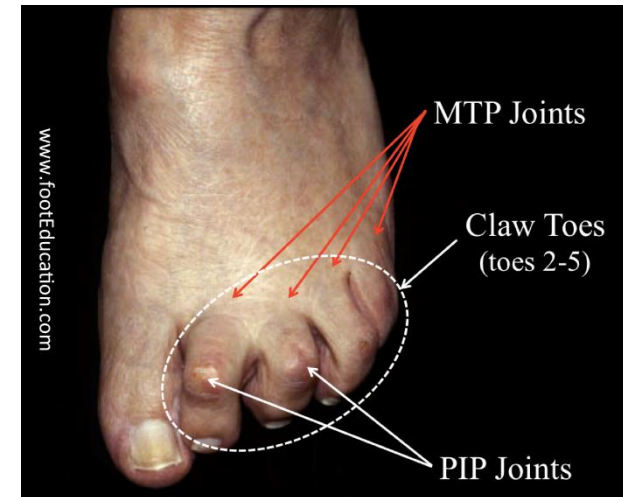
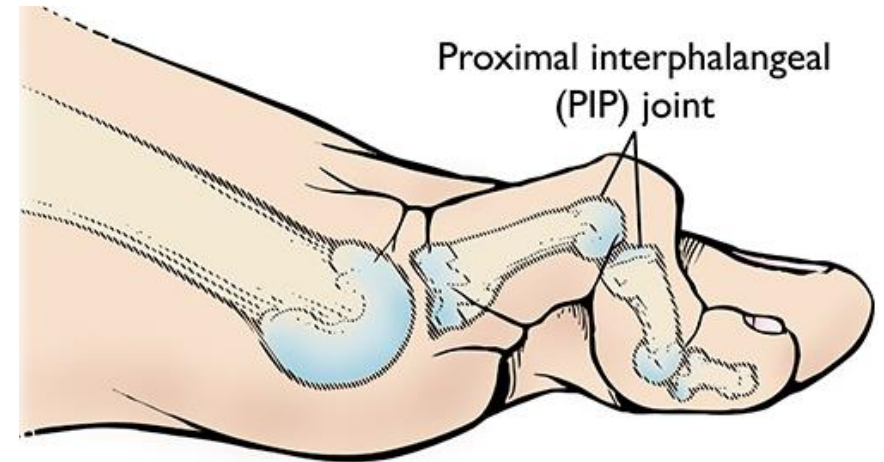


Image Source: Weatherford BM, OrthoInfo:Hammer Toe. *American Academy of Orthopedic Surgeons*; 2020: Available at: <https://orthoinfo.aaos.org/en/diseases--conditions/hammer-toe/> Accessed 5.5.2021.
Pinney, S, Foot & Ankle Orthopedia: *The Bone and Joint Initiative: The Codman Group*: Available at: <https://orthopaedia.com/page/Anatomy-of-the-Foot-Ankle> Accessed 5.10.2021

Principles of Hallux Valgus Surgeries

- **Remove prominent bone medially**
 - Saw resection of medial eminence
- **Realign the metatarsal and phalanx**
 - Osteotomy of metatarsal and/or phalanx
 - Can be at base or more distally in metatarsal
- **Fusion of Tarsometatarsal (TMT) joint in midfoot (Lapidus)**
 - Larger intermetatarsal angles (>15 degrees)
 - Can allow rotational correction as well
- **Fusion of the Great toe metatarsophalangeal (MTP) joint**
 - Loss of motion is concern but no recurrence

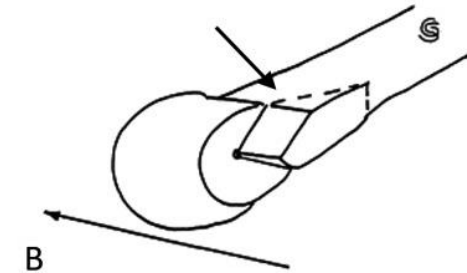


Image Source: Haggstrom M, Z-ray of hammertoe. *Radlines Radiology Guidelines*; 2019; Available at: https://radlines.org/X-ray_of_hammer_toe Accessed 5.5.2021.

Hallux valgus: a minimally invasive surgery corrects the position of the big toe. *Glenn-Klink Orthopedic Hospital*; 2019; Available at: https://www.joint-surgeon.com/orthopedic-services/foot-and-ankle/hallux-valgus-hallux-rigidus-bunion-surgery.html#what_is Accessed 5.5.2021.

Image Source: Baig MN, Usman B, Tarig A & Din R, A prospective study of distal metatarsal chevron osteotomies with K-wire fixations to treat hallux valgus deformities. *Cureus*. 2017;9(9). doi: [10.7759/cureus.1704](https://doi.org/10.7759/cureus.1704) Accessed 5.5.2021.

Lapidus Procedure

- **Lapidus procedure (1st TMT joint arthrodesis)**
 - Corrects larger deformities
 - IM angle >15deg
 - Unstable midfoot or flatfoot
 - Can allow rotational correction of metatarsal
- **Fixation options**
 - Crossed screws
 - Plates
 - Intramedullary nails
- **Concerns**
 - Nonunion (2-10%)
 - Tissue irritation from implants
 - Nerve injury, stiffness
 - Recurrence



This pre-op photo shows the foot of a 56-year-old female before undergoing a modified Lapidus arthrodesis.



Here is the post-op view of the modified Lapidus arthrodesis. The surgeon has placed a third screw from the medial aspect of the first metatarsal to the intermediate cuneiform.



In this pre-op view, one can see the foot of a 19-year-old male before undergoing a modified Lapidus arthrodesis.



As one can see, the surgeon has placed a third screw from the medial aspect of the first metatarsal to the base of the second metatarsal.

Source: Chaparro F, Cardenas PA, Butterl A et. al. Minimally invasive technique with intramedullary nail for treatment of severe hallux valgus: clinical results and surgical technique. *Foot & Ankle*. 2020; 14(1):3-8
Available at: <https://ifootankle.com/JournalFootAnkle/article/view/1158> Accessed 5.5.2021.

Image source: Hamilton, Sautter TL & Ford LA, Current concepts with the lapidus bunionectomy. *Podiatry Today*; 2008;21(12):34-44. Available at: . <https://www.podiatrytoday.com/current-concepts-with-the-lapidus-bunionectomy> Accessed 5.10.2021.

Great Toe Metatarsophalangeal (MTP) Arthrodesis

- **Great toe MTP arthrodesis (fusion)**
 - Used for deformities with arthritis
 - Less risk of recurrence
 - Lose range of motion of great toe
- **Fixation options**
 - Crossed screws (less common now)
 - Plate and screws (gold standard)
- **Concerns**
 - Nonunion (5%)
 - Adjacent joint arthritis-interphalangeal (IP) or tarsometatarsal joints (TMT)
 - Loss of motion



Source: Roukis T, Nonunion after arthrodesis of the first metatarsal-phalangeal joint: A systematic review. *J. Foot Ankle Surg.* 2011;50(6):710-13 Available at: <https://pubmed.ncbi.nlm.nih.gov/21840737/> Accessed 5.10.2021.

Image Source: Onodera T, Nakano H, Homan K, et.al. Preoperative radiographic and clinical factors associated with postoperative floating of the lesser toes after resection arthroplasty for rheumatoid forefoot deformity. (2019);20(87)

Available at: <https://bmcmusculoskeletdisord.biomedcentral.com/articles/10.1186/s12891-019-2462-y#Fig1> Accessed 5.6.2021.

Visser, HJ, Day JP & Sills-Powell JD, First MPJ arthrodesis: what the evidence reveals. *Podiatry Today*(2013):26(9): 34-42: Available at <https://www.podiatrytoday.com/first-mpj-arthrodesis-what-evidence-reveals> Accessed 5.6.2021.

Principles of Hammertoe Correction

- **Proximal Interphalangeal (PIP) arthrodesis**
 - Resect bone at the PIP joint to realign toe
 - May need MTP capsulotomy and extensor tendon lengthening
 - May need a metatarsal osteotomy
- **Fixation options**
 - K-wire
 - Metallic implant
 - Bioabsorbable pin
- **Concerns**
 - Nonunion and recurrent deformity
 - Stiffness
 - Implant removal
 - Infection, digital ischemia



Professional Society Guidance

American Orthopaedic Foot & Ankle Society

Position Statement

- Avoid surgery for purely cosmetic deformities
- Should have pain or problems with function
- Difficult to predict footwear changes postop

Conclusion

Studies have shown that the shape of a foot is a poor predictor of function.^{17,14} Operative procedures carry inherent risks which should be considered carefully prior to embarking potentially unnecessary surgery. The AOFAS questions the practice of cosmetic foot and ankle surgery because there lacks medical evidence on safety and efficacy, especially in asymptomatic individuals.

Source: Position Statement: Cosmetic Foot and Ankle Surgery. *American Orthopaedic Foot & Ankle Society*;2015; Available at: .
https://www.aofas.org/docs/default-source/research-and-policy/position-statement-cosmetic-foot-and-ankle-surgery.pdf?sfvrsn=c416380b_4
Accessed 4.27.2021

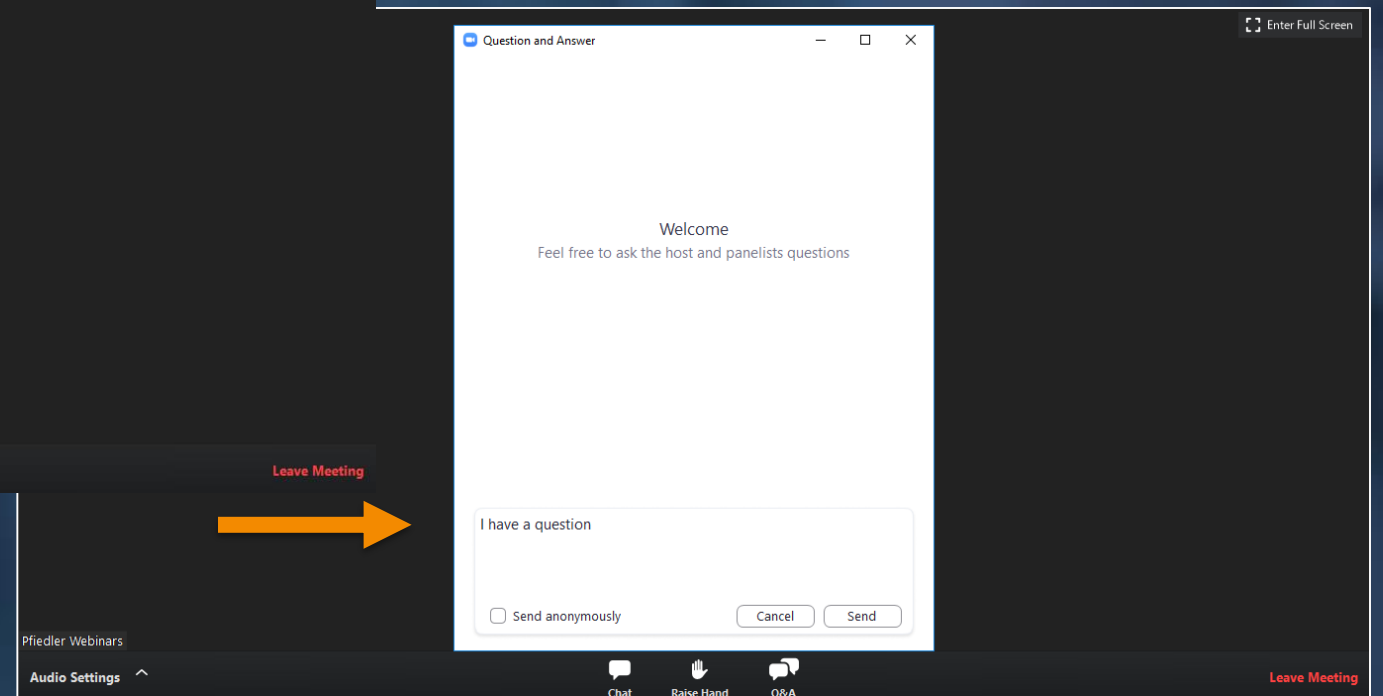


Dynamic. Decisive. Dedicated.

Questions?



This screenshot shows a Zoom meeting window. In the center, there is a white square containing the Pfiedler Education logo, which consists of a cluster of colorful dots (yellow, orange, blue) above the text "PFIEDLER" in blue and "education" in orange. At the bottom of the window is a dark toolbar with several icons: "Audio Settings", "Chat", "Raise Hand", and "Q&A". An orange arrow points from the "Q&A" icon to the right.



This screenshot shows the "Question and Answer" dialog box that appears when the Q&A button is clicked. The dialog has a white background and a dark border. It contains the text "Welcome" and "Feel free to ask the host and panelists questions". Below this is a text input field with the placeholder text "I have a question". At the bottom left of the input field is a checkbox labeled "Send anonymously". At the bottom right are two buttons: "Cancel" and "Send". An orange arrow points from the "Q&A" button in the previous screenshot to this dialog box.

K Wire

- Low cost
- Easily removable
- 5% recurrence
- Similar complication rate to implants
- More difficult for patient to navigate ambulation and slower time to footwear



Image Source: Vanore JV, The case against the use of new technologies for hammertoe repair. *Podiatry Institute*; 2013: Chapter 12; Available at: http://www.podiatryinstitute.com/pdfs/Update_2013/2013-12.pdf Accessed 5.5.2021.

Stainless Steel: One Piece System

Serrated distally and threaded proximally

- Higher cost
- Even higher cost if multiple toes
- Doesn't address MTP joint deformity
- Can cut out of bone if fusion isn't solid
- Difficult to remove if revision surgery needed
- Easier on patient (quicker to shoes) and possibly earlier return to function/work
- Best for solitary hammertoe without MTP deformity



Image Source: Hyer CF & Scott RT, Current and emerging insights on hammertoe correction. *Podiatry Today*. (2012);25(2):34-40. Available at <https://www.podiatrytoday.com/current-and-emerging-insights-hammertoe-correction> Accessed 5.5.2021

Other Options by Various Suppliers

Multiple Options

- **Bioabsorbable pins**
 - Technically challenging
 - Flexible
- **Polyetheretherketone (PEEK) dart implant**
- **Nitinol dynamic fixation**
 - Newest
 - Cost/ lack of studies
- **Allograft bone dart**



Lapidus Plates

- Plates designed to provide stabilization and fixation during arthrodesis of the metatarsal-cuneiform joint
- Most are constructed of titanium alloy
- Plates and screws
- Various features: Locking, non locking, cannulated, non cannulated, fixed angle, variable angle

Lapiplasty

- New name for different approach to same procedure (Lapidus)
- Double plate fixation increases costs
- No comparative studies
- Offers guides for cutting and correcting in 3 planes. Can be done traditionally as well
- May have a role in very difficult deformity cases or revision hallux valgus surgery

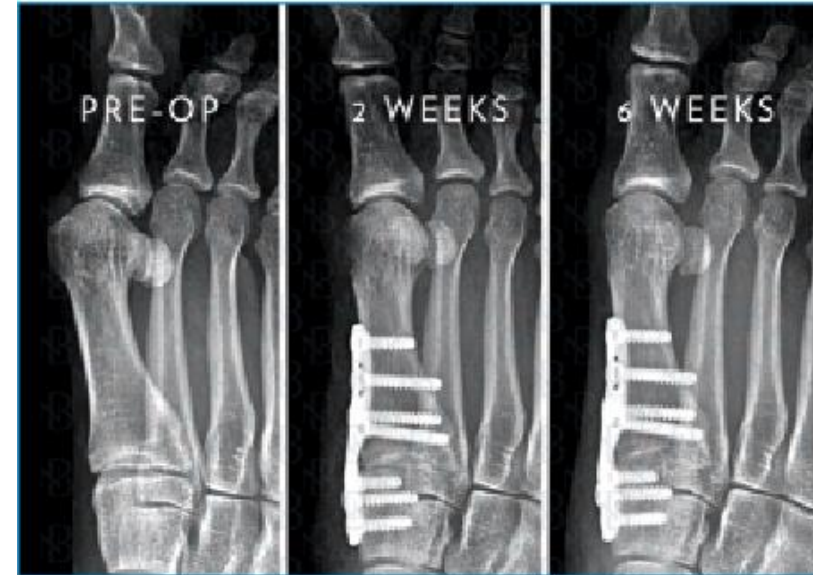


Image Source: PodiBlitz NM, Emerging concepts with post-lapidus bunionectomy weightbearing; *Podiatry Today*; 2012;25(9):58-66. Available at:

<https://www.podiatrytoday.com/emerging-concepts-post-lapidus-bunionectomy-weightbearing> Accessed 5.5.2021.

JCMG Podiatry <https://www.icmgpodiatry.com/lapiplasty-3d-bunion-correction-jefferson-city/> Accessed 5.5.2021

Intramedullary Nail

Minimally invasive technique

Intramedullary Nail Fixation

- Theoretically less prominent hardware
- Technically challenging
- Significant cost
- 510K approval by FDA
- No comparison studies
- Role in revision arthrodesis

Retrospective review of ten feet in eight patients

- No soft tissue complications
- One patient required screw removal
- Conclusion: Intramedullary nail for Lapidus arthrodesis with minimally invasive technique showed satisfactory radiographic correction and minimal complications, but further follow up is needed to analyze clinical-radiographic results.



Figure 3. A. Preoperative and B. Postoperative anteroposterior (AP) radiographs demonstrating first tarso-metatarsal arthrodesis with intramedullary nail.

Source: Chaparro F, Cardenas PA, Butterl A et. al. Minimally invasive technique with intramedullary nail for treatment of severe hallux valgus: clinical results and surgical technique. *Foot & Ankle.* 2020; 14(1):3-8 Available at: <https://jfootankle.com/JournalFootAnkle/article/view/1158> Accessed 5.5.2021.



Multicenter Trials

Need for well-designed comparative multi-center outcome studies



Registries

Similar to total joints. Allows to see where some procedures or implants may be outliers



Cost/Benefit

Determine if added cost of implants results in improved patient outcomes



Improving Outcomes

Lower complication rate with similar outcomes

Better outcomes with similar complications

Patient safety



Supply Chain

How to address increasing costs with no change in reimbursement

Need other options for revision surgery



32yr old female who has bilateral hallux valgus deformities

Overview

- Left side has slightly higher intermetatarsal angle
- Both sides have increased angle of the metatarsal articular surface
- Both great toes have valgus deformity between the MTP and IP joints

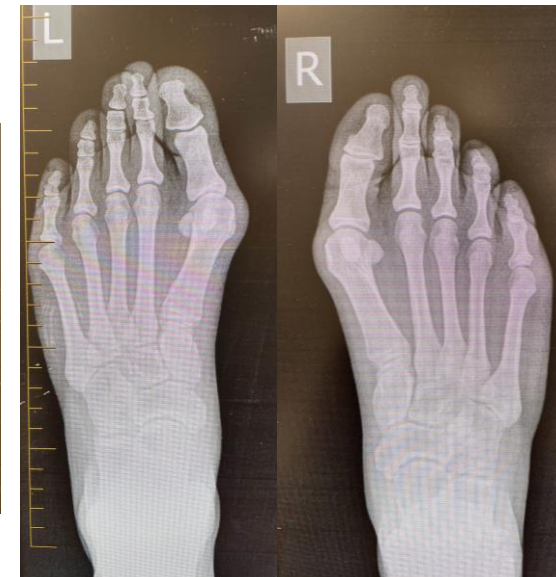
Considerations:

Pes Planus

Time away from work

Time to drive after right foot surgery

Bilateral vs sequential surgery





32yr old female who has bilateral hallux valgus deformities

Overview

- Left side: Lapidus TMT fusion, distal chevron rotational osteotomy, akin proximal phalanx osteotomy
- Right side: Distal chevron rotational osteotomy, akin proximal phalanx osteotomy



References

1. Nix S, Smith M, & Vicenzino B. Prevalence of hallux valgus in the general population: a systemic review and meta-analysis. *J Foot Ankle Res.* 2010;3(21): doi: [10.1186/1757-1146-3-21](https://doi.org/10.1186/1757-1146-3-21) Accessed 4.26.2021.
2. Weatherford BM, OrthoInfo: Rheumatoid Arthritis of the Foot and Ankle. *American Academy of Orthopedic Surgeons*; 2017: Available at: <https://orthoinfo.aaos.org/en/diseases--conditions/rheumatoid-arthritis-of-the-foot-and-ankle> Accessed: 5.5.2021
3. Nix S, Smith M, & Vicenzino B. Prevalence of hallux valgus in the general population: a systemic review and meta-analysis. *J Foot Ankle Res.* 2010;3(21): doi: [10.1186/1757-1146-3-21](https://doi.org/10.1186/1757-1146-3-21) Accessed 4.26.2021.
4. Pinney, S, Foot & Ankle Orthopedia: *The Bone and Joint Initiative: The Codman Group*, Available at: <https://orthopaedia.com/page/Anatomy-of-the-Foot-Ankle> Accessed 5.10.2021
5. Weatherford BM, OrthoInfo: Hammer Toe. *American Academy of Orthopedic Surgeons*; 2020: Available at: <https://orthoinfo.aaos.org/en/diseases--conditions/hammer-toe/> Accessed 5.5.2021
6. Haggstrom M, Z-ray of hammertoe. *Radlines Radiology Guidelines*; 2019; Available at: https://radlines.org/X-ray_of_hammer_toe Accessed 5.5.2021.
7. Hallux valgus: a minimally invasive surgery corrects the position of the big toe. *Glenek-Klink Orthopedic Hospital*; 2019; Available at: https://www.joint-surgeon.com/orthopedic-services/foot-and-ankle/hallux-valgus-hallux-rigidus-bunion-surgery.html#what_is Accessed 5.5.2021.
8. Baig MN, Usman B, Tarig A & Din R, A prospective study of distal metatarsal chevron osteotomies with K-wire fixations to treat hallux valgus deformities. *Cureus.* 2017;9(9). doi: [10.7759/cureus.1704](https://doi.org/10.7759/cureus.1704) Accessed 5.5.2021.
9. Chaparro F, Cardenas PA, Butterl A et. al. Minimally invasive technique with intramedullary nail for treatment of severe hallux valgus: clinical results and surgical technique. *Foot & Ankle.* 2020; 14(1):3-8 Available at: <https://jfootankle.com/JournalFootAnkle/article/view/1158> Accessed 5.5.2021.
10. Hamilton, Sautter TL & Ford LA, Current concepts with the lapidus bunionectomy. *Podiatry Today*; 2008;21(12):34-44 Available at: . <https://www.podiatrytoday.com/current-concepts-with-the-lapidus-bunionectomy> Accessed 5.10.2021.
11. Roukis T, Nonunion after arthrodesis of the first metatarsal-phalangeal joint: A systematic review. *J. Foot Ankle Surg.* 2011;50(6):710-13 Available at: <https://pubmed.ncbi.nlm.nih.gov/21840737/> Accessed 5.10.2021.
12. Onodera T, Nakano H, Homan K, et.al. Preoperative radiographic and clinical factors associated with postoperative floating of the lesser toes after resection arthroplasty for rheumatoid forefoot deformity. (2019);20(87) Available at: <https://bmcmusculoskeletdisord.biomedcentral.com/articles/10.1186/s12891-019-2462-y#Fig1> Accessed 5.6.2021
13. Visser, HJ, Day JP & Sills-Powell JD, First MPJ arthrodesis: what the evidence reveals. *Podiatry Today*(2013):26(9): 34-42: Available at <https://www.podiatrytoday.com/first-mpj-arthrodesis-what-evidence-reveals> 5.6.2021
14. Hyer CF & Scott RT, Current and emerging insights on hammertoe correction. *Podiatry Today.* (2012);25(2):34-40. Available at <https://www.podiatrytoday.com/current-and-emerging-insights-hammertoe-correction> Accessed 5.5.2021.
15. Position Statement: Cosmetic Foot and Ankle Surgery. *American Orthopaedic Foot & Ankel Society*;2015; Available at: . https://www.aofas.org/docs/default-source/research-and-policy/position-statement-cosmetic-foot-and-ankle-surgery.pdf?sfvrsn=c416380b_4 Accessed 4.27.2021
16. Vanore JV, The case against the use of new technologies for hammertoe repair. *Podiatry Institute*; 2013: Chapter 12; Available at: http://www.podiatryinstitute.com/pdfs/Update_2013/2013-12.pdf Accessed 5.5.2021.
17. Blitz NM, Emerging concepts with post-lapidus bunionectomy weightbearing; *Podiatry Today*; 2012;25(9):58-66. Available at: <https://www.podiatrytoday.com/emerging-concepts-post-lapidus-bunionectomy-weightbearing> Accessed 5.5.2021
18. JCMG Podiatry <https://www.jcmgpodiatry.com/lapiplasty-3d-bunion-correction-jefferson-city/> Accessed 5.5.2021.

Thank you...

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Questions: *Contact the Clinical Research & Education Team*

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