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\*Not currently available in all states.

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# Complications of Orthopedic Implants & Hardware

John V. Vanore  
Steven R. Carter

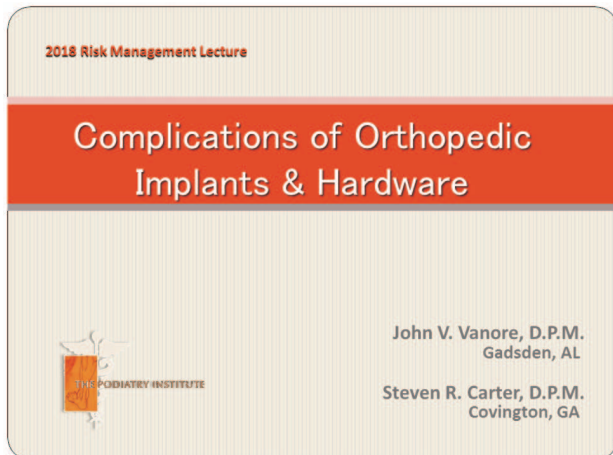


Figure 1.

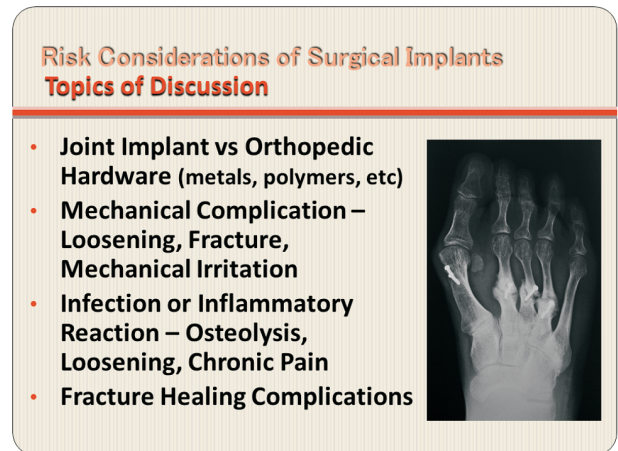


Figure 2.

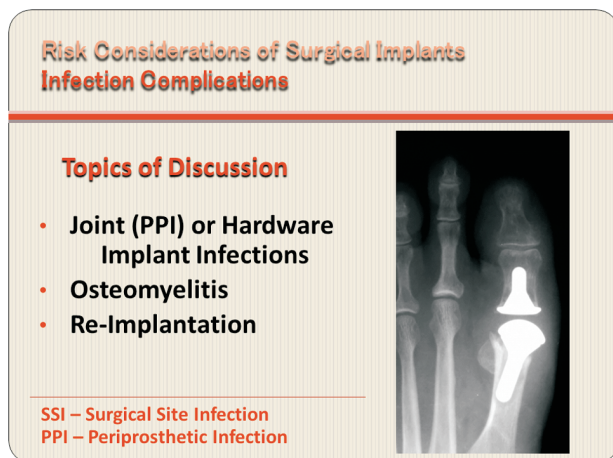


Figure 3.

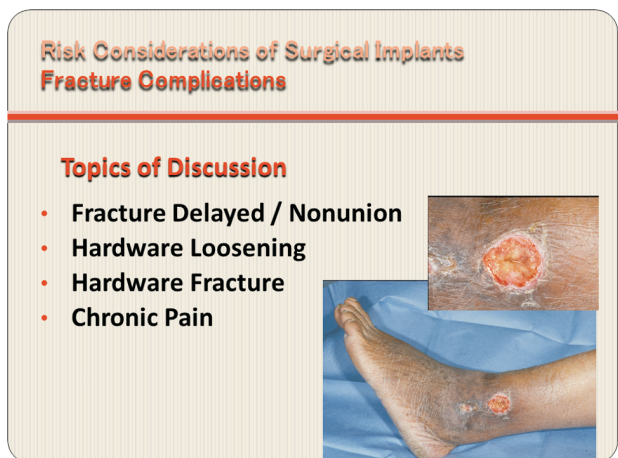


Figure 4.

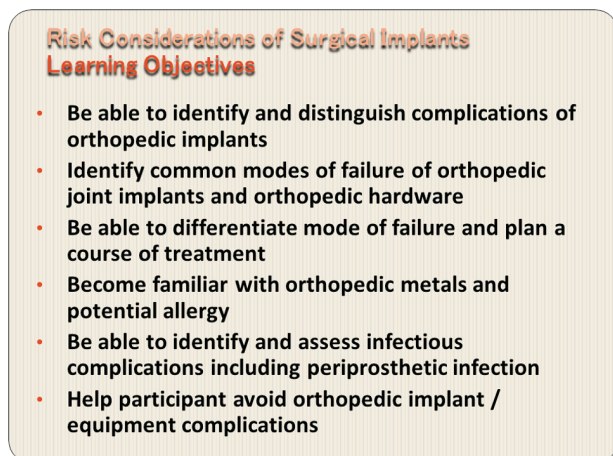


Figure 5.

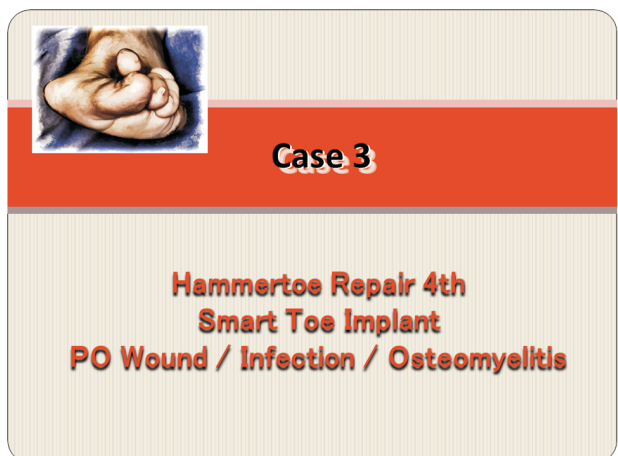


Figure 6.



**Case 3  
Presenting Complaints**

- 25 yo female, non-smoker
- Unremarkable medical history
- Allergies: NKDA
- Complaint – Painful wart & “hammertoe”  
soft corn – lateral PIPJ 4<sup>th</sup>, medial DIPJ 5<sup>th</sup> right foot

Figure 7.

**Case 3 – Physicians Notes**

- Rigid 4<sup>th</sup> toe
- Adductovarus 5<sup>th</sup>
- Soft corn
- “Does not want pin sticking out of toe”

**Impression: Hammertoe, corn**

**Plan: Discusses Surgery**

**HT c K-wire vs Smart Toe**

(Smart Toe will add 2-4 wks of off-loading)

Figure 8.

**Case 3  
Hammertoe- Surgery #1**

**Pre & PO Dx: Hammertoe  
DOS: 5/22/2012**

- PIPJ arthrodesis c implant  
(10° Smart Toe) 4<sup>th</sup> toe
- PIPJ arthroplasty 5<sup>th</sup> right toe
- “Correction of deformity was assessed at  
this time and noted to be excellent”

Figure 9.

**Case 3 – Hammertoe  
PO Course Surgery**

**5/24/2012 – 2 days PO**

- Dressing change – unremarkable
- Cast dry & intact
- Continue with Surgical shoe & crutches

**5/31/2012 – 9 days PO**

**6/7/2012 – 16 days PO**

- Dressing change – unremarkable
- Continue NWB with Sx shoe & crutches
- Pt needs to wear heels for wedding pics AMA

Figure 10.

**Case 3 – Hammertoe  
PO Course Surgery**

**6/11/2012 – 20 days PO**

**Pt wore heels at wedding & danced AMA**

- Rx Keflex, went to ER – XRs, released
- Wound medial aspect 4<sup>th</sup> toe  
Serosanguinous drainage – culture: MSSA
- WBC 7500, CRP <.3
- Crutches, surgical shoe

Figure 11.

**Case 3 – Hammertoe Implant Complication  
PO Course – DOS 5/22/2012**

**6/14/2012 – 23 days PO**

- MSSA, WBC 5.8, afebrile
- Necrotic wound Rx Santyl
- Continue with Sx shoe & crutches

**6/18, 6/22/2012**

**6/26/2012 – OP Sx – Wound debridement**

**DX ? : Gangrene**

- Culture: MSSA, Staph coagulase negative

Figure 12.

**Case 3 – Hammertoe Implant Complication**  
**PO Course – DOS 5/22/2012; Debridement 6/26/2012**

**6/29/2012 – OV**

- Looking good but Pt going on vacation
- “seems the skin is trying to recover from vascular insult of Staph infection”
- Pt on Bactrim x 6 weeks

**7/6/2012– OV – back from vacation**

- Rx Santyl dressings
- “stimulate granulation tissue & graft”
- Another wedding tomorrow

Figure 13.

**Case 3 – Hammertoe Implant Complication**  
**PO Course – DOS 5/22/2012; Debridement 6/26/2012**

**7/11/2012 – 40 days PO**

**Pt went to another wedding & danced AMA**

- Serosanguinous drainage
- Wound exposed flexor tendon 4<sup>th</sup> toe
- Admitted for I&D - **7/12/2012 (3<sup>rd</sup> surgery)**
  - I&D, wound & bone debridement, removal Smart Toe, cultures Enterococcus sp (ABX preOP)
  - Pulsed lavage
  - Application of Apligraf
- ID Consult – 6 wks Cubicin Coag –ve & MSSA

Figure 14.

**Case 3 – Hammertoe Implant Complication**  
**DOS 5/22/2012; Debridement 6/26/2012, 7/11/2012**

**7/18/2012 – 6 days PO 3<sup>rd</sup> surgery**

- Wound clean & granular
- No pain, no edema
- IV antibiotics (ID ?)

**7/23/2012 – IV ABX switched to daptomycin**  
**8/3/2012, 8/9/2012 – healing but floppy toe**  
**MRI ordered – negative**  
**Followed Pt several more months**

Figure 15.

**Case 3 – Infected Hammertoe**

**Allegations:**

- Negligent Tx resulting in postoperative infection
- 
- Noncompliant patient who directly contributed to the PO complication

**Case Dismissed**

Figure 16.

**Case 3 – Osteomyelitis Infected Hammertoe**  
**Assessment & Questions**

- Was treatment appropriate ? ... was hammertoe repair necessary?
- Appropriateness of hammertoe implants ?
- Doc did good job documenting patient’s noncompliance
- Vascular embarrassment > digital procedure in young healthy patient?

Figure 17.

**Case 3 – Osteomyelitis Infected Hammertoe**  
**Assessment & Questions**

- I&D hold antibiotics until cultures obtained
  - Chronic infection
    - ... remove implant, culture wound, bone, implant
  - ID consult, don’t manage alone
  - Perspective ... sometimes recommend waiting on elective procedures
- Informed Consent: ... disability considerations**

Figure 18.



**Case 4**

**Pes valgus Repair  
Hardware Removal**

Figure 19.

**Case 4**  
**30 yo female**

9/3/2010 – Surgery LEFT FOOT

- Excision mass / Bunion c osteotomy
- 6 weeks later – Removal K-wire

12/20/2010 – Surgery RIGHT FOOT

- “Obvious pes planus flatfoot...”
- Uncompensated rearfoot valgus

Figure 20.

**Case 4 Pes Valgus**

- Symptomatic / pathologic pes planovalgus
- Rearfoot equinus
- Calcaneal valgus
- Attenuation/posterior tibial tendosynovitis




Figure 21.

**Case 4**  
**Surgery RIGHT Foot 12/20/2010**

- (1) Gastrocnemius recession
- (2) retrocalcaneal displacement osteotomy
- (3) Kidner procedure / posterior tibial tendon advancements with tenodesis screw
- (4) Cotton procedure, i.e., opening wedge osteotomy with plate fixation dorsally of medial cuneiform, right foot;
- (5) dorsal talonavicular exostectomy
- (6) plantar medial hallux IPJ exostectomy

Figure 22.

**12/24/10 (OV)**

- No Post-Op X-rays
- No Post-Op Note

**12/29/10 (OV)**

- Minimal handwritten note

**1/19/11 (OV) – PO Week 4**

- Removal of calcaneal fixation pins in office
- CAM walker

Figure 23.

**Case 4**  
**3-29-2011 (3 mos PO)**

- In pain and distress /using crutches
- Relates falling earlier in the day “afraid she may have broken something”
- OV / X-ray note: osteotomy had moved approximately 8-10 mm.
- Plan: To OR for ORIF with 6.5 mm screw

Figure 24.

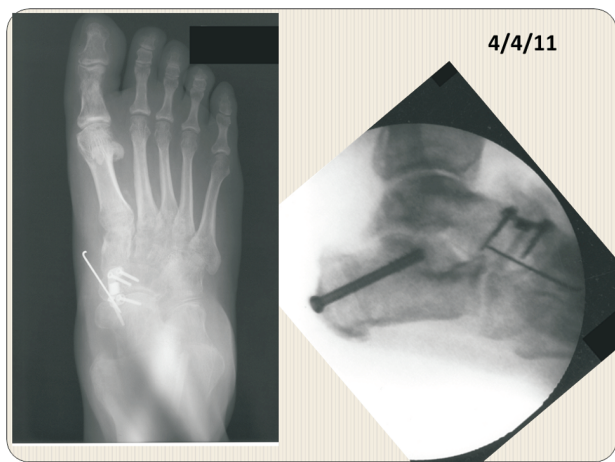


Figure 25.

#### Case 4 9 mos PO – 9/16/2011

- Pt not doing well
- Generalized pain / walked with a limp
- Exam: “discomfort primarily over the lateral right ankle and rear foot, specifically the region of the subtalar joint”
- Re-Order Physical Therapy

Figure 26.

#### Case 4 2 years PO – 4/29/2013

- Rearfoot pain
- Dorsal navicular spur
- Pain over the “midtarsus fixation plate”

##### Plan:

- Apply supportive strapping
- May consider surgery (removal of all hardware and excision of the navicular spur)

Figure 27.

#### Case 4 Pes Valgus

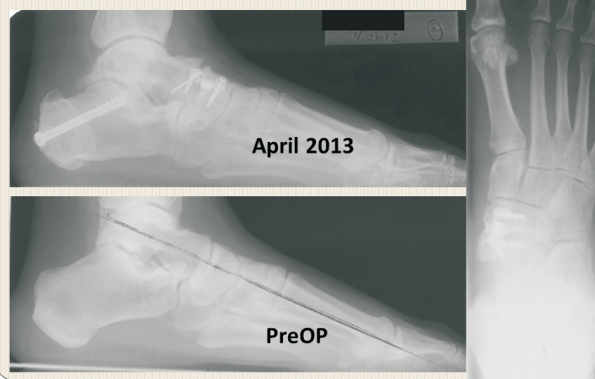


Figure 28.

#### Case 4 Recommendations – 5/7/2013

- Decision to remove all hardware and dorsal TN spur
- “*would need special equipment consisting of screwdrivers and he would need to look at the old operative report identifying the screw type used in the prior surgery*”

Figure 29.

#### Case 4 Surgery– 6/7/2013

- Removal of calcaneal screw
- “Attempted” removal of dorsal plate and screws

*“an attempt was made to remove the dorsal plate over the dorsum of the right midfoot, deep dissection exposed to the plate, but Dr. did not have the appropriate tools to back out the fixation screws, so then the decision was made to track down the screw and close the wound, and then bring the patient back to the operating room at a later time”*

Figure 30.



**Case 4**  
**JUN 2013 – PO Removal**  
**Calcaneal Screw**

*The doctor discussed with the patient the fact that unfortunately he did not have the right equipment at the time of surgery to remove the titanium plate. She would discuss it with her neurologist. If necessary, she would return to surgery. It was noted that she was understanding.*

Figure 31.

**Case 4**  
**JUN 2013 – PO Removal**  
**Calcaneal Screw**



Figure 32.

**Case 4**  
**Surgery– 7/1/2013**

- Removal of TN hardware
- (no op report)

---

**8/21/2013**

- Last visit with pod
- Overall doing fine
- Ready to RTW
- Patient discharged

Figure 33.

**Case 4 – Summary**  
**Case History – Right Foot**

- DEC 2010 – Displacement calcaneal osteotomy / Kidner / Cotton
- MAR 2011 – Pt fell → dislodged calcaneal osteotomy
- APR 2011 – ORIF prior calcaneal osteotomy
- MAY 2013 – Pt wanted hardware removed
- JUN 2013 – Hardware removed from heel; did not have instrumentation to remove midfoot hardware
- JUL 2013 – Removal of remaining hardware

Figure 34.

**Case 4**  
**Allegations**

- Multiple allegations regard prior surgeries: long and complicated course, including an infection and movement of the osteotomy
- Need for additional surgery as a result of not having the requisite surgical tools available for removal
- Negligence in failure to ensure that the appropriate instruments were available at the time of surgery
- Notably, there is no allegation by plaintiff that her injuries include a wrong site surgery
- No allegation of failure to disclose complication

Figure 35.

**Orthopedic Equipment Failure**

- Surgery delayed due to missing equipment
- Lack of sterility of equipment
- Equipment not available
- Equipment malfunction
- Equipment sets incomplete
- Additional equipment necessary for completion of case
- Surgeon responsibility for availability of equipment / implants on hand (Hospital vs Surgical Center)

Efficacy of surgical safety checklist: Assessing orthopaedic surgical implant readiness. Thomasson et al. Healthcare (2016) 4:307

Figure 36.

### Surgical Safety Checklist

- Foot/Ankle surgery is a surgical specialty with technically complex instrumentation requirements for the implantation of screws, plates and pins to fix bones.
- Joint replacement involves multi-material implant systems each with multiple procedure specific instrumentation and procedural requirements

Assessing orthopedic equipment readiness preoperatively and its ability to prevent orthopedic equipment failures

Efficacy of surgical safety checklist: Assessing orthopaedic surgical implant readiness.  
Thomasson et al. *Healthcare* (2016) 4:307

Figure 37.

### Case 4 Defense Challenges

- It would not be hard for the plaintiff to successfully argue that a reasonable prudent surgeon would have ensured prior to commencing surgery that he had the correct tools and instruments to perform the surgery.

### OUTCOME

- Case dismissed by plaintiff

Figure 38.



### Case 6

**Hallux Limitus**  
**4 Surgeries – 6 months**  
**Possible Metal Allergy**

Figure 39.

### Case 6 Presenting Complaints

- 42 yo white female
- Relatively unremarkable medical history
- Allergies: PCN, sulfa, latex
- Complaint – Painful left foot bunion

Figure 40.

### Case 6 – Physicians Notes

- Painful bunion
- Dorsal Bump
- Limited ROM
- Pain c DF 1<sup>st</sup> MTP joint

Limited Hx & Physical Exam  
No X-rays

**Impression: Hallux Limitus**  
**Plan: Schedule Surgery**

Figure 41.

### Case 6 – PreOP Consult for HAV

X-rays

- Dorsal exostosis
- Long 1<sup>st</sup> metatarsal
- 1<sup>st</sup> MTP joint degeneration



**Proposed surgery:**  
**Osteotomy & screw fixation**

Figure 42.

**Case 6**  
**Hallux Limitus - Surgery #1**

**Pre & PO Dx: Hallux abductovalgus**  
**DOS: 12/27/2012**

- Bunionectomy c osteotomy & screw fixation
- Inverted L capsulotomy, lateral release
- Medial eminence resected
- "Drilled" cartilage defects
- Inverted V osteotomy 1/3 lateral shift
- OP report dictated month > surgery

Figure 43.

**Case 6 - Hallux Limitus**  
**PO Course Surgery #1**

**1/3/2013 - 5 days PO, dressing change**

- Pt on feet a lot
- 1<sup>st</sup> MTP Joint edematous
- Pt "feels crunching"
- Instructed rest but allowed to work 2 hrs/day; limit WB (Surgical Shoe, crutches?)
- Cold laser performed
- Redress

Figure 44.

**Case 6 - Hallux Limitus**  
**PO Course Surgery #1**

**Subsequent OVs - 2, 3, 5 wks PO**

- Pain & limited ROM
- WB & shoe 5 wks
- Cold laser performed ea PO visit
- Medrol dose pack at 3 wks PO

Figure 45.

**Case 6 - Hallux Limitus**  
**PO Course Surgery #1**

**2/14/2013 - 7 wks PO**

- Pt not improving
- XR's healing MT osteotomy lytic bone
- Spurring base proximal phalanx**

**Hemi joint implant recommended at 7 wks**



Figure 46.

**Case 6**  
**Hallux Limitus - Surgery #2**

**Pre & PO Dx: Hallux limitus/rigidus**  
**DOS: 2/21/2013**

- Bunionectomy c hemi implant screw removal
- Degeneration 1<sup>st</sup> MT articular surface
- Biopro hemi implant
- OP report dictated 1 wk > surgery

Figure 47.

**Case 6 - Hallux Limitus**  
**PO Course Surgery #2**

**2/27/2013 - 1 wks PO**

- Dressing change - unremarkable

**3/6/2013 - 2 wks PO**

- Pt "bumped" toe kitchen island
- Dressing change - unremarkable

**Fx 1<sup>st</sup> MT / cartilage damage 2<sup>o</sup> injury**



Figure 48.

**Case 6 – Hallux Limitus  
PO Course Surgery #2**

**3/26/2013 – 1 month PO**

- Continued pain & swelling
- Discuss possible damage 1<sup>st</sup> MT head
- Discussed 3<sup>rd</sup> surgery “to correct damage to 1<sup>st</sup> MT head”

Figure 49.

**Case 6  
Hallux Limitus – Surgery #3**

**Pre & PO Dx: Fracture 1<sup>st</sup> metatarsal  
DOS: 4/5/2013**

- Indications: chronic pain, failed conservative Tx, patient requests surgery
- Findings: Fracturing of surface cartilage with bone degeneration throughout 1<sup>st</sup> MT head
- Debridement / remodeling 1<sup>st</sup> MT head
- OP report dictated 10 days > surgery

Figure 50.

**Case 6 – Hallux Limitus  
PO Course Surgery #3**

**4/16/2013 – XRs 11 days PO**

- Good alignment of hallux & 1<sup>st</sup> MT
- Lysis 1<sup>st</sup> MT osteotomy site



Consider “possible delayed healing”

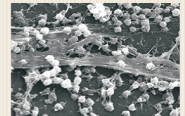


Figure 51.

**Case 6  
Hallux Limitus – Surgery #4**

**Pre & PO Dx: Irritation of hemi-implant  
2° to allergic reaction  
DOS: 6/7/2013**

- Removal / reinsertion Ti hemi
- Remodeling 1<sup>st</sup> head
- Findings: “Biofilm c inflammation”
- No pathology, No culture
- OP report dictated 5 days > surgery



\* Biofilm generally a descriptor of bacteria generated glycoprotein

Figure 52.

**Case 6 – Hallux Limitus  
PO Course Surgery #4**

**1<sup>st</sup> 1-2 mos**

- Unremarkable, symptoms improving

**9/6/2013 – 3 mos PO**

- EHL tendonitis / weakness
- Pain wearing shoes

**9/17/2013 – last OV**

- Pt sent to PT

Figure 53.

**Case 6 – Next DOC (#2)  
10/13/2013 – 1 mo following PT\* referral**

- Swelling 1<sup>st</sup> interspace
- Tender medial 1<sup>st</sup> MT head
- Hypersensitivity cicatrix
- +ve Tinel’s plantar PP base  
(exact nerve NOT documented)
- Pain wearing shoes, comfortable 1 hour

\* Physical therapist told patient to go for 2<sup>nd</sup> opinion

Figure 54.



**Case 6 – Hallux Limitus**  
**PO Course – 2<sup>nd</sup> Dec**

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**9 OV over next year**

- Dx Ultrasound
- Periarticular injection
- Padding & strapping
- CBC diff: WBC 8.4, ESR 8
- PT – 20+ sessions
- MRI – soft tissue swelling, EHL entrapment, ferromagnetic artifact
- Medrol dose pak

Figure 55.

**Case 6 – Next DOC #3**  
**12/2/2014 – Continued complaints**

- pain & swelling 1<sup>st</sup> MTP joint
- Difficult WB & wearing closed shoes

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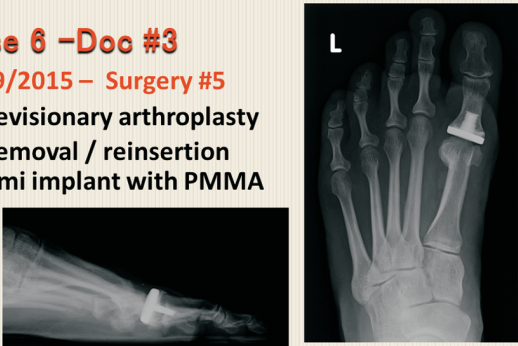
X-rays • Hemi Implant  
 • “changes” at 1<sup>st</sup> MTP Joint

**Proposed surgery:**  
**Revisory arthroplasty**

Figure 56.

**Case 6 –Doc #3**  
**1/29/2015 – Surgery #5**

- Revisory arthroplasty
- Removal / reinsertion hemi implant with PMMA




---

- Followed for 1 year PO with reasonable resolution of symptoms

Figure 57.

**Case 6 – Hallux Limitus**  
**Allegations:**

- Use of an oversized implant
- Failure to inquire about metal allergies
- Improperly removed the metallic implant without verifying the allergy
- Improperly positioned the replacement implant

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**Case resolved prior to trial**

Figure 58.

**Case 6 – Hallux Limitus**  
**Assessment & Questions**

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**1<sup>st</sup> Doc – 4 surgeries, 6 months**

- Was treatment appropriate ?
- Limited exam, evaluation
- Poor documentation
- Quick to bring Pt back to surgery
- Metal allergy ? No screening, No pathology
- Should skin testing be performed ?
- Should patients be screened for metal allergy

Figure 59.

**Infection or Allergy?**  
**Verification ...Patch Testing ?**

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- Cutaneous metal sensitivity 10-15%
- Questionable correlation to hypersensitivity to orthopedic implants
- Patch testing is reliable for investigation of contact dermatitis ...
- But NOT so useful in evaluation of deep tissue metal allergy

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Biant et al: J Arthroplasty 2010

Figure 60.

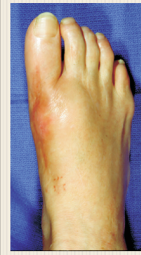
### Making sense of metal allergy and hypersensitivity to Metallic Implants

Currently, there are no clinical practice guidelines from American Academies of Orthopaedic Surgery, Immunology, or Dermatology to help guide diagnosis and management of this hypersensitivity disorder.

Christensen et al: J Hand Surg Am 2017;42:737.

Figure 61.

### Metal Allergy Assessment & Questions



- Any implanted metal may increase metal sensitivity or ..
- Metal sensitivity lead to TJA failure
- Testing recommended (by Allergists) in Pts c Hx of metal sensitivity (Ortho IGNORES)
- Patch testing may be flawed because it may have no bearing on what is occurring happening in deep tissues

AAOS 2012 Annual Meeting Metal Allergy in Joint Replacement. Joshua Jacobs, MD

Figure 62.



### Case 7

### Hindfoot Fusion Osteoarthritis

Figure 63.

### Case 7 Presenting Complaints

- 64 yo obese female (5'4" – 200lb)
- PMH: hypothyroid; prior bunion surgery
- NKDA
- Complaint – foot pain, right > left; swelling right ankle EOD  
Seen other DPMs, told "flat-footed", prescribed inserts that give no relief

Figure 64.

### Case 7 – Physicians Notes

- No exam ?
  - X-rays – No interpretative reading
- Assessment: Localized osteoarthritis, ganglion, limb pain

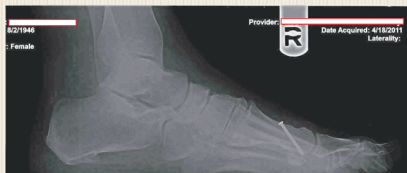


Figure 65.

### Case 7 – IOV Physician Notes

#### Procedure Codes:

- 76942 Ultrasound guided injection
- 20600 Arthrocentesis/injection small joint, RT
- 76881 Ultrasound extremity nonvascular

#### 6/2/2011 – Follow-up

- Had injection sinus tarsi – 100% pain relief
- Exam – unremarkable (limited!)

Poor Documentation  
No XR or ultrasound interpretative reports

Figure 66.

**Case 7 – Hindfoot/ankle pain**  
**PreOP**

---

**6/21/2011 – follow-up**

- Pt requesting another injection
- Exam: midfoot pain on palpation and ROM

**Assessment: Tenosynovitis foot/ankle**

- Ultrasound guided depomedrol injection talonavicular joint RT

Figure 67.

**Case 7 – Hindfoot/ankle pain**  
**PreOP – 9/28/2011**

---

**HPI:**

- Pt has had pain at the lateral ankle/foot now for some time. She has pain 2/2 PTTD w lateral impingement.
- There are some sign of arthritis at CC and 4th, 5th Metatarsal-cuneiform Joints and the midfoot medially on XR.
- She has received steroid injections into STJ in the past which have helped. She would like to discuss her options today.

Figure 68.

**Case 7 – Hindfoot/ankle pain – PTTD**  
**PreOP – 9/28/2011**

---

**A:**

- Acquired flat foot
- Limb pain
- Capsulitis PTTD w/lateral impingement

**Plan:**

- US guided Kenalog injection CCJ & STJ
- Low-Dye strapping

**11/23/2011 – Dispense orthotics**

Figure 69.

**Case 7 – PTTD / OA**  
**11/23/2011, 12/12/2011, 2/27/2012**

- Difficulty with orthotics
- Later bracing

---

**CT – 3/7/2012:**

- There is severe navicular cuneiform osteoarthritis most pronounced between the navicular and the medial and lateral cuneiforms. There is complete loss of joint space, small marginal osteophytes and numerous tiny subchondral cysts. There is less pronounced talonavicular osteoarthritis. Tibiotalar and subtalar joints are preserved

Figure 70.

**Case 6**  
**Hindfoot Fusion – Surgery #1**

---

**OP Report NOT reviewed**  
**DOS: 5/1/2012**

- Navicular-cuneiform fusion
- Talonavicular fusion



**5/29/12**

Figure 71.

**Case 7 – Hindfoot Fusion**  
**JUN – SEP 2012**

- NWB – gradual progression WB c CAM walker
- ... Richie Brace

---

**11/7/2012: 6 mos PO**

- Pt walking on outside border of foot & unable to straighten out foot
- WB in Richie Brace
- XR: one of the screws may be bending; there is not complete radiographic healing
- RTC 3 mos

Figure 72.

**Case 7 – Hindfoot Fusion**  
Last OV JAN 2013 – 9 mos PO

- Continued pain
- NOT wearing brace
- Voltaren gel
- XR – may consider CT to Eval

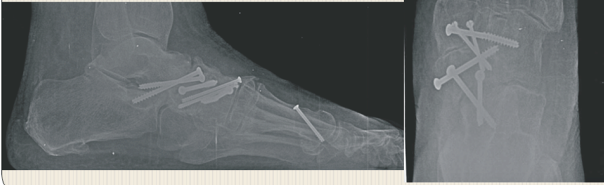


Figure 73.

**Case 7 – Complications of Hindfoot Fusion**

**Sees 2<sup>nd</sup> DOC – DPM**

- “the screws are in such a random placement, it is difficult to really comprehend what the goal of the surgeon was.”

---

**Sees 3<sup>rd</sup> DOC – DPM**

- Fusion had failed at both joints, some of the screws had fractures, and an unnecessary screw was placed between navicular and calcaneus

Figure 74.

**Case 7 – Hindfoot Fusion**

**Sees 3<sup>rd</sup> DOC – Subsequent Surgery**

- Removed all hardware
- Re-fusion TNJ and Navicular-Cuneiform Jt.

---

**3<sup>rd</sup> DOC – 3<sup>rd</sup> Surgery**

- 7 months later, the 3<sup>rd</sup> DPM performs subtalar joint fusion and extensor tendon lengthening great toe, right foot.

Figure 75.

**Case 7 – Complications of Hindfoot Fusion**

**Complications / Injuries**

- Failed fusion at TNJ and NCJ
  - Required removal of hardware
  - Re-fusion of failed arthrodesis sites
- Continued pain in foot
- Development of back /knee pain
- Multiple falls since surgery
- Development of cold sensitivity in foot

Figure 76.

**Case 7 – Complications of Hindfoot Fusion**

**Allegations**

- The screws inserted during the procedure were randomly and erroneously placed
  - Failure to verify screw positions with C-Arm
  - Unnecessary screws were used in the procedure
- Failure to properly remove cartilage and properly prepare fusion sites
- Refusal to release complete chart
- Negligent retention and/or destruction of portions of plaintiff’s medical records
- \*no plaintiff expert identified

Figure 77.

**Case 7 – Complications of Hindfoot Fusion**

**Defense Challenges**

- The surgical technique was not great...the screws were not well placed to get fixation and compression at the joints, contributing to a nonunion
- The operative report is non-descriptive
- Films did not show arthritis at the talonavicular joint. No justification for a fusion at that joint.
- Subsequent treating podiatrists were not supportive of the insured’s surgery.

Figure 78.



**Case 7 - Complications of Hindfoot Fusion**

**Outcome**

- Resolved through mediation (200k)



Figure 79.



**Case 8**

**Hammertoe Repair**  
**Hx TKR & Titanium Allergy**  
**Plan: PIPJ Arthrodesis with Absorbable Pin**  
**Surgeon Used SS HT Implant**

Figure 80.

**Case 8**  
**Presenting Complaints**

- 68 yo white male
- Medical Hx: OA, gout
- Allergies: Titanium (TKR)
- Complaint – Painful hammertoe

\* PLEASE NOTE:  
 ALLERGIC REACTION TO TITANIUM  
 LT & RT KNEE  
 DIAGNOSED BY 3 ORTHOPEDISTS

LT TKR 2004, TKR REVISION 2006  
 RT TKR 2006  
 \* SYNOVITIS LT & RT KNEE DUE TO  
 ALLERGIC TO TITANIUM PROSTHESIS

Figure 81.

**Case 8 - Physicians Notes**

- "toe pain 2nd digit"
- Hammertoe 2<sup>nd</sup> right
- "Pt admits allergies to reaction to titanium resulting in unspecified"
- Plan: 2<sup>nd</sup> toe PIPJ arthrodesis with absorbable implant



Figure 82.

**Case 8 - PO PV**



Doc: "I explain that better correction was obtain with the stainless steel implant and that I felt we would have a better outcome with the stainless steel implant."

- 3 weeks PO Pt having localized swelling erythema & pain 2<sup>nd</sup> toe

Figure 83.

**Case 8 - 2<sup>nd</sup> Surgery**  
**Remove implant**



- Revisionary arthroplasty with removal of PIPJ implant & placement of absorbable K-wire
- C-arm evaluation
- No labs
- No culture

Figure 84.

### Case 8 – Hammertoe Implant

#### Allegations:

- Knowingly exposed the patient to a hazard or potential hazard likely to cause injury.
- Failure to obtain informed written consent for placement of metal implant during surgical procedure
- Implant of metal without the approval or knowledge of plaintiff.
- Battery against patient performing unwanted surgical procedure without plaintiff's consent.

**Case resolved through mediation**

Figure 85.

### Case 8 – Hammertoe Implant Assessment & Questions



- Doc had preOP discussion acknowledging prior problems with metal implants
- Agreed to use of absorbable & **NOT** use a metal implant
- Doc rationalizes use of metal implant

Figure 86.



What should the Pre-OP discussion include?

### Allergies

The use of the word "allergy" has become a generic term used by the public to describe allergies, sensitivities and intolerances.

**Drug Allergies**  
**Latex**  
**Metals**

Figure 87.

### PreOperative Screening

- Do you have any allergies? ... antibiotics, latex
- Have you ever developed a skin rash to topical antibiotics or iodine based antiseptics?
- Do you have a bleeding disorder? ... excessive bleeding to dental work? ...use blood thinners: Coumadin, warfarin, Eliquis, Plavix, Pradexa, aspirin ?
- Have you ever experienced a blood clot, DVT or pulmonary embolus?
- Do you develop a rash or itching to earrings, necklaces, watchbands or jean snaps?
- Have you had local swelling, pain, or ulcers to dental implants, braces, crowns or dentures?
- Do you have any implanted metals? .. cardiac stents, dental braces, artificial joints, bone fracture fixation implants – screw, plate, etc
- Have you ever had a heart attack, heart surgery or stroke?
- Do get nausea, vomit or sick with anesthesia or pain medication?
- Do you regularly use pain medication? Do you have any substance abuse problems, alcohol or drugs?
- Do you form thick scars or keloids in areas of cuts or surgery ?

Figure 88.