OrthoSolutions
Group

Consensus of the 7th Round Table

Cardiff, September 2017

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Aspects of Foot and Ankle Surgery

Consensus of the 7th Round Table

Cardiff, 13th to 15th September 2017

Course Convener:

Dishan Singh

Chairpersons:

Nick Cullen

Sunil Dhar

Andy Goldberg

Fred Robinson

Rhys Thomas

Hosted by:

OrthoSolutions Group

Distilled in this document are the thoughts and opinions, with consensus where possible, of 30 Orthopaedic Foot and Ankle Consultant Surgeons who gathered from across the United Kingdom and Europe. Though eminence rather than true evidenced based medicine, this represents the concepts of over 200 years of combined experience. A basis of invited lectures introduced open and frank discussion from which consensus was sought. The statements herein only represent those of individuals and no claim is made that they are irrefutable. All the percentage figures quoted represent the proportion of the surgeons present who voted on the subject in discussion.

Preface

The 1st Round Table meeting was held in Padua in June 2011, followed by annual meetings in Paris, Barcelona, Budapest, Edinburgh and Munich. The 7th Round Table in Cardiff has once again not followed the usual orthopaedic meeting format where faculty members lecture to delegates. As always, the meeting is unique in that all participants have an equal input to review the literature and present their individual experience on a topic - with ample time for an informal discussion of the subject in a relaxed setting. We then attempt where possible to reach a consensus to guide us.

This year, the chairpersons have selected topics with a loose theme of recent advances in foot and ankle surgery and the topic of randomised controlled trials.

Karan Malhotra, Sally Wright and Lucky Jeyaseelan were responsible for recording opinions and capturing the essence of the debates. I am particularly grateful to Karan, who has spent a lot of time designing the layout. This booklet collates the literature review and the views of all those who participated.

This booklet does not represent Level I evidence derived from prospective randomized controlled trials but represents the compilation of the combined experience of 30 British and European orthopaedic surgeons.

We have selected a short list of references in order to keep the booklet small and easily readable.

I hope that you will find something of use and relevant to your own practice.

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Summary of Sessions

Session 1 - Ankle & Hindfoot Trauma **Chair: Rhys Thomas**

Session 2 - Devices & Biomaterials **Chair: Nick Cullen**

Session 3 - Randomised Controlled Trials **Chair: Fred Robinson**

Session 4 - Tissue Regeneration **Chair: Andy Goldberg**

Session 5 - Adjuvant Medical Therapy **Chair: Dishan Singh**

Session 6 - Total Ankle Replacements **Chair: Sunil Dhar**

Session 1: Ankle & Hindfoot Trauma

1.1 – Posterior Malleolar Fractures (Lyndon Mason)

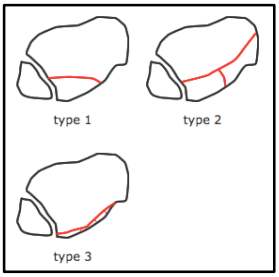
There is a general acceptance that the clinical outcomes following posterior malleolar fractures are less than satisfactory. The most recent systematic review by Odak *et al.* found the outcomes of ankle fractures with posterior malleolar involvement were poor. A recent UK based multicentre study (Roberts *et al.*) compared post-operative Olerud–Molander Ankle Scores (OMAS): 79 for unimalleolar, 65 of bimalleolar, and 54 for trimalleolar fractures.

Effect of Fragment Size:

- Classical teaching is to fix posterior malleolar fragments > 30% articular surface
- Drijfhout van Hooff *et al.* – size of fragment not correlated with functional outcome
- Meijer *et al.* – size of fragment underestimated without CT (Fracture line often oblique to planes of standard AP & lateral radiographs)

Classifications:

The Haraguchi classification describes the fracture patterns but does not address the mechanism.



Haraguchi classification:

- Type 1 - Wedge shaped & related to PTFL (65%)
- Type 2 - Transverse, extends to medial malleolus (20%)
- Type 3 - Small posterior shell fragments (15%)

Mason *et al.* have proposed an alternative classification system based on fracture mechanics:

Type 1	Type 2	Type 3
Unloaded Talus + Plantar Flexion + Rotation	Loaded Talus + Ext Rotation	Loaded Talus + Plantar Flexion
Shell fragment: PITFL avulsion	**Postero-lateral wedge:** Rotational pilon *(Type 2A)* **If it continues rotating:** Separate posteromedial fragment *(Type 2B)*	**True posterior Pilon:** Vertical shear of the posterior plafond
Syndesmotic injury = 75%	Syndesmotic injury = 50%	Syndesmotic injury = 20%
Deltoid injury = 27%	Deltoid injury = 18%	Post-Oblique Fragments = 64%

Management:
The Aintree team have formulated a treatment algorithm for posterior malleolar fractures, based on their classification system (Mason).

Aintree Treatment Algorithm

Classification	Treatment	Approach
1	Syndesmotic fixation	
2A	ORIF	PL
2B	ORIF – posteromedial fragment first	PM or PL + MPM
3	ORIF	PM

Trying to address the syndesmosis without reduction & stabilisation of the posterior malleolus, often results in a syndesmotic mal-reduction.

In a cadaveric model, Gardner *et al.* demonstrated that posterior malleolar fixation restored 70% of syndesmosis stability compared with 40% after syndesmotic screw insertion. Miller *et al.* found syndesmotic reduction was more accurate with fixation of the posterior malleolus.

A current study of PROMS data of 50 patients with at least 1 year follow up has shown an improvement of OMAS by approximately 20 points across all types using the Aintree Algorithm (type 1 to 75.9, type 2A to 75.0, type 2B to 74.0 and type 3 to 70.5). Compared to their previous work (Roberts *et al.* and Mason *et al.*), this analysis has demonstrated a functional outcome equivalent to what would be expected from unimalleolar fractures with this approach.

Summary:

- Historically posterior malleolar fractures have had poor outcomes.
- Size is not an indicator for fixation in itself
- It is suggested that a CT scan be performed in all patients with a posterior malleolar fracture
- Surgical planning is determined by the deforming forces, with particular attention to the syndesmosis, and the medial extension of the fragmentation
- There is further to go regarding the learning curve for understanding these injuries and optimally treating them

Consensus / Discussion:

1. **Should all patients with a posterior malleolar fracture be imaged with a CT?**

Yes	26 (87%)
No	4 (13%)

2. **Should all "fixable" posterior malleolar fractures be fixed?**

Yes	26 (87%)
No	1 (4%)
Unsure	3 (10%)

3. **Who would fix a 10% articular posterior malleolar fracture?**

Yes	10 (33%)
No	20 (66%)

Those answering 'No' felt that the fragment was too small for internal fixation

References:

Drijfhout van Hooff CC, Verhage SM, Hoogendoorn JM. Influence of fragment size and postoperative joint congruency on long-term outcome of posterior malleolar fractures. *Foot Ankle Int*. 2015; 36(6): 673-678.

Gardner MJ, Brodsky A, Briggs SM, Nielson JH, Lorich DG. Fixation of posterior malleolar fractures provides greater syndesmotic stability. *Clin Orthop Rel Res.* 2006; 447: 165-171.

Haraguchi N, Haruyama H, Toga H, Kato F. Pathoanatomy of Posterior Malleolar Fractures of the Ankle. *J Bone Joint Surg Am*. 2006; 88(5): 1085-1092.

Mason LW, Marlow WJ, Widnall J, Molloy AP. Pathoanatomy and Associated Injuries of Posterior Malleolus Fracture of the Ankle. *Foot Ankle Int*. 2017:1071100717719533. [Epub ahead of print]

Meijer DT, Doornberg JN, Sierevelt IN, Mallee WH, van Dijk CN, Kerkhoffs GM, et al. Guestimation of posterior malleolar fractures on lateral plain radiographs. *Injury*. 2015; 46(10): 2024-2029.

Miller AN, Carroll EA, Parker RJ, Boraiah S, Helfet DL, Lorich DG. Direct visualization for syndesmotic stabilization of ankle fractures. *Foot Ankle Int*. 2009; 30(5): 419-426.

Odak S, Ahluwalia R, Unnikrishnan P, Hennessy M, Platt S. Management of Posterior Malleolar Fractures: A Systematic Review. *Journal of Foot and Ankle Surgery*. 2015; 55(1): 140-145.

Roberts V, Mason LW, Harrison E, Molloy A, Mangwani J. Mid-term functional outcomes of reduced and malreduced fractures in two university teaching hospitals. *Bone & Joint Journal*. 2016; 98-B (SUPP 19): 16.

1.2 – Acute Osteochondral Defects (Bob Carter)

Osteochondral defects (OCD) of the talus are a common cause of *chronic* ankle pain and disability. However, there is limited literature regarding treatment and prognosis of *acute* ankle lesions (no Level I studies). Associated injuries accompanying an acute OCD include ankle fractures and ligamentous injuries (lateral ligament complex, syndesmosis, deltoid).

A lesion is generally considered acute if it is within 3 weeks of injury, but there is no consensus on time scale in the literature. This is largely related to presentation delay within the general population, due to misdiagnosis, non-specialist management, and investigation waiting time.

There is more literature regarding acute knee articular cartilage injuries. Application of the literature on knee injuries to the ankle is problematic, however, as the joint biomechanics and articular cartilage itself are quite different.

Investigations:

- Plain radiographs miss 50% of OCDs
- MRI scan to look at bone oedema, the cartilage lesion itself, and associated soft tissue injuries.
- CT scan or CT arthrogram can be useful to look at bony morphology and assessment of a surface cartilage defect.
- Video replay (athletes) can be very helpful to understand the mechanism of injury
- 60% are posteromedial + 40% anterolateral in the talus.

Management:

The literature does not guide the orthopaedic surgeon on *acute* lesion management. Therefore, techniques utilised in *chronic* talar OCD or *knee* OCD are frequently reported in the acute setting. Many reports focus on elite level athletes where diagnosis is usually rapid and the option for acute surgical intervention available.

Acute Fixation:

- Absorbable pin or headless compression screw either open or arthroscopic.
- Often performed in displaced lesions

Debridement & Microfracture (Based on Chronic Lesions):

- These techniques produce results through bone marrow stimulation
- Debate still exists regarding prognosis
- Lesions <150mm do well
- 80% overall success rate: fibrocartilage formation and outcome maintained over time
- A higher grade lesion, associated cyst, and shoulder lesions have a poorer outcome in some studies

Osteochondral Reconstruction & Replacement (Based on Chronic Lesions):

- Include AMIC, Resurfacing, ACI / MACI, Mosaicplasty
- Can be utilised with either plafondoplasty or medial malleolar osteotomy
- Donor site & malleolar osteotomy morbidity
- Performed for failed debridement
- Can be expensive
- Mixed results

Treatment options utilised need to be cognisant of the equipment available and financial implications of the treatment strategies. Arthroscopy equipment is often not available or of sufficient quality in trauma hospitals. Many health care providers have challenged the indications for the use of expensive techniques and have been reluctant to authorise funding.

Rehabilitation traditionally centres on a period of non-weight bearing with early range of movement exercises dependent of the treatment strategy employed and the associated injuries.

Summary:

- Very sparse literature on acute osteochondral lesions in the ankle
- Further imaging (MRI / CT) vital for assessment
- Displaced lesions of sufficient size should be fixed back to their origin using a bioabsorbable pin, either arthroscopically or open
- Undisplaced lesions can be observed
- Chronic symptomatic lesions should be offered arthroscopic debridement & microfracture
- Reconstructive options are available, but they are often expensive and more experimental

Consensus / Discussion:

1. **If an OCD is seen on a plain radiograph how many surgeons would request a CT?**

Yes	30 (100%)
No	0

2. **How many surgeons would routinely proceed directly to surgery in a symptomatic patient with on OCD seen on imaging?**

Yes	1 (3%)
No	29 (97%)

3. If an OCD is deemed "fixable," how many surgeons would use a bioabsorbable pin?

Yes	26 (87%)
No	0
Unsure	4 (13%)

4. How many surgeons would limit weight-bearing post-operatively?

Yes	26 (87%)
No	0
Unsure	4 (13%)

5. **In the case of an isolated acute undisplaced OCD, who would immobilise in a POP?**

Yes	8 (27%)
No	9 (30%)
Unsure	13 (43%)

References:

Barnes CJ & Ferkel RD. Arthroscopic debridement and drilling of osteochondral lesions of the talus. *Foot & Ankle Clinics*. 2003; 8 (2): 243-257.

Choi WJ, Park KK & Kim BS. Osteochondral Lesion of the Talus. Is there a Critical Defect Size for Poor Outcome?. *Am J Sports Med*. 2009; 37 (10): 1974-1980.

Labib S, Magill M, Slone H. Ankle Arthroscopy for Ankle Fracture Care. *Tech in Foot and Ankle Surgery*. 2015; 14(1): 21-24.

van Bergen CJ, Kox LS, Maas M, Sierevelt IN, Kerkhoffs GM, van Dijk CN. Arthroscopic treatment of osteochondral defects of the talus: outcomes at eight to twenty years follow-up. *J Bone Joint Surg Am*. 2013; 95 (6): 519-525.

1.3 – High Ankle Sprains (Fraser Harrold)

High Ankle Sprains:

- Occur in up to 16% of ankle sprains
- Associated with injury to the AITFL
- May be associated with a fracture (Weber B in 30%, Weber C in 70%)
- Contact stress increases by 42% with 1mm talar translation
- Long term prognosis is determined by instability and mal-reduction

In this session fractures have been excluded, but deltoid ligament injury included.

Components of the Syndesmosis:

- AITFL – 35% of diastasis control
  (Limits fibula external rotation)
- PIFL – 45% diastasis control
  (Limits posterior translation)
- IOL – 20% diastasis control
  (Limits pure diastasis)

West Point Classification:

- Grade 1 – Mild Sprain of AITFL
  No instability / diastasis
- Grade 2 – AITFL & partial IOL tear
  Slight instability, no frank diastasis
- Grade 3 – Complete injury
  Frank instability and diastasis

Diagnosis:

Several clinical tests are described e.g. pain at rest, palpation, Cotton's test, squeeze test, ER test, DF test. However, they exhibit poor sensitivity, poor specificity, low PPV, high NPV, and only moderate inter-observer correlation. Therefore, have a high index of suspicion, and utilise investigations which include: plain radiographs, stress views, CT, MRI, USS and arthroscopy.

Radiographs: Sensitivity 43%, specificity 100%. Detects frank diastasis but unreliable in occult injury.

MRI: Sensitivity and specificity of almost 100%. In chronic injuries, gadolinium enhanced, fat supressed images are more sensitive and specific than routine imaging. "Ring of fire" = visualisation of fluid around the tibia (75% of circumference); it can differentiate lateral ligament injury from syndesmotic injury (present only in latter), and represents interosseous membrane rupture.

CT: Bilateral CT may prove to be a more accurate tool in assessing mal-positioning (Axial slice assessment), and dynamic assessment of instability in WB scans.

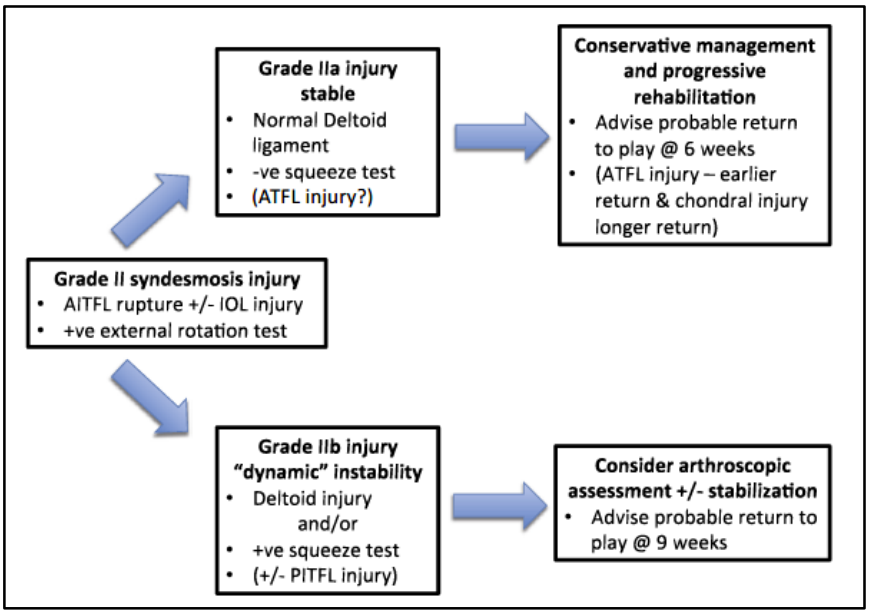
Dynamic USS: is also gaining popularity for accurate functional assessment of the AITFL, but is very operator dependent.

Arthroscopy: has been validated by Calder *et al.*, but no normal range / location of arthroscopic tests has been defined. "Drive through" into medial gutter & accessing the "syndesmotic recess".

Management:

- **Grade I:** RICE, non or protected weight bearing in boot or cast for 1-4 weeks, then converted to a brace
- **Grade II:** Debatable management. Based on stability assessment *(See below)*
- **Grade III:** Surgical stabilisation. ESSKA-AFAS recommend that surgery should include repair of the syndesmotic ligaments + deltoid ligament + stabilisation of the syndesmosis

Calder *et al.* attempted to resolve the issue of Grade II injuries. They divided them into IIa (stable) and IIb (unstable) injuries. They combined clinical assessment, MRI, and arthroscopic assessment. They advocated stabilising the injuries classified as IIb (unstable).



Treatment algorithm for Grade II syndesmotic injuries, Calder et al. 2015

Patient Population:

In the NHS, patients present later due to ongoing symptoms, and thereby self-selection of symptomatic Grade 2s occurs. Elite athletes present early, and there is a greater incentive for patient and surgeon to treat unstable and potentially unstable injuries surgically, to reduce time off play.

Surgical issues that remain unresolved:

- Device choice: Screw *versus* suture button (tightrope).
- Device size, number, position, orientation, number of cortices, and whether or not to remove.

Summary:

- Natural history is unknown and not an uncommon problem
- Better classification may help guide treatment for Grade II injuries (Calder *et al.*)
- Debate continues regarding device, positioning, removal, rehabilitation
- ? Over-treatment better than under-treatment

Consensus / Discussion:

1. **Is arthroscopy the gold standard investigation for a syndesmotic injury?**

Yes	6 (20%)
No	3 (10%)
Unsure	18 (70%)

2. **Is there an optimal radiological investigation for a syndesmotic injury?**

Yes	0
No	23 (77%)
Unsure	7 (23%)

3. **In the case of an unstable syndesmosis with no fracture what is the preferred method of stabilisation?**

Screw	12 (40%)
Tightrope	16 (53%)
Unsure / Other	2 (7%)

4. **If a screw were used, how many surgeons offer routine removal?**

Yes	1 (3%)
No	29 (97%)

References:

Calder JD, Bamford R, Petrie A, McCollum GA. Stable versus Unstable Grade II High Ankle Sprains: A Prospective Study Predicting the Need for Surgical Stabilisation and Time to Return to Sports. *Arthroscopy*. 2015; 32: 634-642.

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Naqvi GA, Shafqat A, Awan N. Tightrope fixation of ankle syndesmosis injuries: clinical outcome, complications and technique modification. *Injury*. 2012; 43 (6): 838-842.

Sman AD, Hiller CE, Rae K, Linklater J, Black DA, Nicholson LL, et al. Diagnostic Accuracy of clinical tests for ankle syndesmosis injury. *Br J Sports Med*. 2013; 49: 323-329.

van Dijk CN, Longo UG, Loppini M, Florio P, Maltese L, Ciufreda M, et al. Classification and diagnosis of acute isolated syndesmotic injuries. ESSKA-AFAS consensus & guidelines. *Knee Surg Sports Traumatol Arthrosc*. 2015; 24: 1200-1216.

1.4 – Deltoid Ligament Injury in Ankle Fractures (Lee Parker)

Acute isolated deltoid injury is rare, comprising 2-3% of all ankle sprains. Most settle with adequate immobilisation followed by physiotherapy. Reconstruction is performed for chronic medial instability, Posterior Tibial Tendon Dysfunction (PTTD) and in balancing Total Ankle Replacement (TAR).

Superficial Deltoid:

- Restricts hindfoot eversion
- 4 components: Tibio-navicular, tibio-spring, tibio-calcaneal, superficial tibio-talar

Deep Deltoid:

- Restricts talar external rotation
- 2 components: Deep anterior tibio-talar, Deep posterior tibio-talar

Diagnosis of Deltoid Injury:

Medial ankle injury occurs with all Pronation-Abduction (PAB) and Pronation-External Rotation (PER) fractures, which *begin* on the medial side, and Supination External Rotation (SER) Type 4 ankle fractures which *finish* on the medial side.

Importance of differentiating stable SER-2 from unstable ligamentous SER-4 injury (Gougoulias *et al.)*:

- Rate of lateral ankle OA in non-operated Type 2 SER injuries = 2.8% at 18 years
- Rate of lateral ankle OA in non-operated Type 4 SER injuries = 65.6% at 6.8 years
- Operating on Type 4 SER injuries reduces the rate of OA to 20% at 5.5 years.

Pre-operative physical signs and X-rays do not always exclude deltoid injury. In uncertain cases a gravity stress or weight-bearing X-ray can be helpful in determining ankle stability when a fibular fracture might otherwise be managed non-operatively. MRI is highly sensitive and specific for deltoid ligament injury, but is not dynamic.

Intra-operatively, the external rotation test is the gold standard. This is done following fibular fixation by turning the heel into varus (unlocks the hindfoot) and then externally rotating the talus. Medial clear space widening or talar tilt indicate an unstable injury.

Classification:

Type	Location	Ligaments Involved	Incidence
I	***Proximal tear:*** Avulsion	Tibionavicular & Tibiospring	72%
II	***Intermediate:*** Deep part remains attached distally Superficial part remains attached proximally	Tibionavicular & Tibiospring	9%
III	***Distal tear:*** Avulsion	Tibionavicular & Spring	19%

Hintermann Classification of Medial ankle instability / deltoid injury

Surgical Treatment of Deltoid Ligament Injuries:

Lateral Malleolar fracture

- Removing interposed deltoid ligament from medial gutter (not repair)
- Exploration not indicated if fibula & mortise reduced + negative ER test
- Low medial malleolar fractures are combined osseous-ligamentous injuries and need careful assessment of stability (osseous fixation insufficient in 25%)

Syndesmotic disruption: Impart stability to the reconstruction

Chronic medial instability: Usually superficial deltoid insufficiency. Rare, but beneficial in high demand patients

Injury with deformity: Combined with calcaneal osteotomy +/- arthroereisis screw in valgus hindfoot

Elective: Ligament balancing in TAR / Adjunct to PTTD reconstruction

Surgical Reconstruction of the Deltoid Ligament:

Arthroscopy allows a thorough assessment of the lateral ankle and syndesmosis, treatment of osteochondral lesions, and the staging of the instability according to Hintermann's classification. It is advisable to treat moderate and severe grades of instability according to injury type (tear location).

Grade (Hintermann)	Arthroscopic findings	Treatment
I	<2mm medial diastasis (minor)	Reattach proximally with suture anchors to the anterior colliculus
II	5mm arthroscope admitted to medial gutter (moderate)	Deep part reattached proximally, superficial part reattached distally with suture anchors
III	Traction allows visualization to the back of the ankle (severe)	Distal deltoid and spring ligament reattached to the navicular +/- distal stump of tibialis posterior tendon overlay

In addition, there are reinforcement techniques using suture augmentation devices and techniques using autogenous tendon graft (plantaris, FDL, hamstring) where there is little remaining native ligament. There are few reports in the medical literature to support one technique over another.

Summary:

- Isolated injuries are rare
- Commonly seen as part of ankle fractures PAB / PER (injury starts medially), or SER4 (injury starts laterally)
- Unstable ankle fractures have high progression to lateral ankle OA
- WB X-rays are useful to assess stability (SER2 *versus* SER4)
- Exploration of the medial side not indicated if ankle reduced & stable
- Deltoid often repaired / reconstructed in conjunction with other procedures

Consensus / Discussion:

1. **When performing a lateral ligament repair, how many surgeons scope the ankle following stabilisation of the lateral side to assess for medial instability?**

Yes	0
No	30 (100%)

2. **Regarding assessment of a syndesmotic injury, how many surgeons think the dorsiflexion test in an awake patient is a reliable test?**

Yes	0
No	30 (100%)

3. **Regarding assessment of a syndesmotic injury, how many surgeons think the dorsiflexion test in an anaesthetised patient is a reliable test?**

Yes	10 (33%)
No	7 (23%)
Unsure	13 (43%)

4. **How many surgeons would routinely open the medial side in an ankle fracture fixation?**

Yes	0
No	27 (90%)
Low threshold	3 (10%)

References:

Crim JR, Beals TC, Nickisch F. Deltoid ligament abnormalities in chronic lateral ankle instability. *Foot Ankle Int*. 2011; 32 (9): 873–8.

Gougoulias N, Khanna A, Sakellariou A. Supination-external rotation ankle fractures: stability a key issue. *Clin Orthop Relat Res*. 2010; 468 (1): 243=251.

Hintermann B. Medial ankle instability. *Foot & Ankle Clin*. 2003; 8 (4): 723-738.

Tornetta P. Competence of the deltoid ligament in bimalleolar ankle fractures after medial malleolar fixation. J *Bone Joint Surg Am* .2000; 82: 843–8.

Session 2: Devices & Biomaterials

2.1 – Biologics: What & When (Katarina Stanekova)

Orthobiologics can be defined as biological substances used therapeutically for their beneficial effects on bone and soft tissue injuries or defects. They augment the efficacy of other implants or surgical techniques and may reduce the need for open surgery.

Biologics consist of:

- Allografts
- Bone substitutes
- Growth factors
- Chondral scaffolds

Properties of the ideal biologic / graft:

- Osteoinductive
- Osteoconductive
- Osteogenic
- Provides structural support
- Available in sufficient quantities
- Good biocompatibility
- Radio-opaque for in-vivo monitoring
- Minimal side effects / morbidity

Autografts – The 'Gold Standard':

These are osteogenic, osteoconductive, osteoinductive, and can provide structural support. It is most commonly used in Foot & Ankle surgery and surveys of orthopaedic surgeons suggest that its routine use is in part due to perceived lower risk of non-union. The complications of autograft are donor site morbidity (pain, fracture, cosmesis) and lack of availability for larger defects. Baumhauer *et al.* demonstrated residual pain at donor sites of up to 18% in the proximal tibia at 1 year.

Volumes available for harvest (Miller *et al.*):

Iliac crest	=	20-55 cm^3
Proximal Tibia	=	25-40 cm^3
Distal Tibia	=	5-15 cm^3
Calcaneus	=	3-5 cm^3

Allograft:

Numerous instances of Level II-IV evidence but no Level I evidence for the use of allograft in Foot & Ankle surgery. Most published literature is for the use of allograft is in primary fusion surgery in well-vascularised sites. In this setting favourable results have been demonstrated with fusion rates and time to fusion comparable to, and complication rates lower than the use of autograft. However, sample sizes are often small and a variety of surgical sites / procedures and graft types are reported.

Limitations:

- Rejection
- Slower incorporation
- Disease transmission
- Reduced osteogenicity / inductivity
- Processing reduces structural and inductive properties

Available as:

- Cortical graft
- Cancellous graft
- Cortico-cancellous graft
- Fresh-frozen
- Freeze-dried
- De-mineralised bone graft

Demineralised bone matrix preparations may have considerable variability in osteoinductive potential. It is available as a gel, powder or chips and provides limited structural support. There is evidence to support its use in hindfoot fusions (Thordarson *et al.*).

Bone Substitutes:

Synthetic or biological substances used as alternatives to autografts / allografts. Avoid some problems associated with allografts: host *versus* graft reaction, disease transmission, and availability. Drawbacks include: lack of osteogenic / osteoinductive potential. Main types include: Calcium sulphate, Calcium phosphate, Tricalcium phosphate, and composites.

Calcium Sulphates:

- Osteoconductive
- Rapidly absorbed over 6 weeks
- Reabsorption may outpace new bone formation
- Copious 'white' discharge often seen
- Pellets, powder, or injectable paste
- No mechanical strength
- Can be mixed with Abx (Stimulan)
- Used to fill defects / treat osteomyelitis
- Safety and efficacy well documented

Calcium Phosphates:

- Osteoconductive
- Resorption over 26 to 86 weeks
- Sufficient time for new bone formation
- Bioabsorbable cement paste
- Isothermic reaction - no thermal necrosis
- x4-10 stronger than cancellous bone
- Can fill bone voids providing interim structural support
- Can improve the purchase of surgical fixation devices

There is Level II evidence for the use of Calcium sulphates and Level I evidence for the use of Calcium phosphates in ORIF of calcaneal fractures. Multiple studies have demonstrated the efficacy of Calcium sulphates and phosphates in the Foot & Ankle setting with no increase in complications.

Other Bone Substitutes:

Tricalcium phosphates are biocompatible and integrate within 6 months. There is limited Level IV evidence for their use in non-unions and bony defects. Composite grafts are a combination of Calcium sulphates and phosphates. A number of case series have demonstrated good radiological and clinical outcomes with no significant increase in complication rate. They have been shown to increase screw purchase and pull out strength by up to 200% in osteoporotic bone.

Summary:

- Limited but consistent Level II-IV evidence for the use of allograft in the primary fusion setting in well vascularised sites.
- Grade B recommendation can be made for the use of allograft
- Evidence for bone substitutes less well documented as there a multitude of options and few good quality clinical trials.
- Grade B recommendation can be made for the use of Calcium sulphates and phosphates in the management of calcaneal fractures
- Grade C recommendation for the use of Tricalcium phosphates.
- Insufficient data for composites

Consensus / Discussion:

1. **What factors would inform decision to use Calcium sulphate *versus* Calcium phosphate as a bone substitute?**
   - Where early weight-bearing is required: Calcium phosphate is preferred
   - Where structural support in a large cavity is required: Calcium phosphate is preferred

2. **Of surgeons who routinely perform primary lateral column lengthening procedures, how many would use the following graft options:**

Autograft	5 (36%)
Allograft	3 (21%)
Both / Either	3 (21%)
Synthetic bone substitute	3 (21%)

3. **When performing a curettage and grafting of a calcaneal cyst, how many surgeons use the following graft options:**

Autograft	5 (17%)
Allograft	5 (17%)
Both / Either	0
Synthetic bone substitute	20 (67%)

4. **How many surgeons routinely use bone graft for primary fusion cases?**

Yes	3 (10%)
No	27 (90%)

All 3 cases where answered 'yes,' were in cases of subtalar joint fusion.

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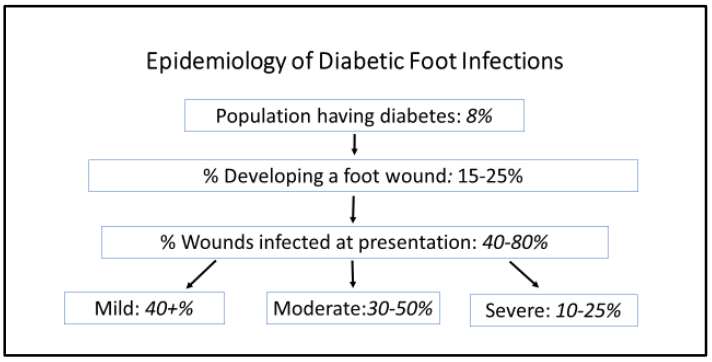
2.2 – Biomaterials in the Diabetic Foot (Anand Pillai)



Managing infection in diabetic feet appropriately is of paramount importance. Resistance may develop over time and antibiotic monotherapy is often inadequate.

Organisms in Diabetic Foot Infections:

- Early = Gram Positive
- Mid-term = Poly-Microbial
- Late = Anaerobic

Goals of Treatment:

- Control of infection
- Healing of wounds / ulcers
- Functional, shoe-able foot
- Prevent future breakdown

The contaminated wound must be debrided to a clean wound: surgical decontamination is often at the expense of function and cosmesis. Radical debridement / amputation changes the mechanics of the foot and therefore there is an associated risk of point loading and further ulceration. Tissue / bone preserving surgery would therefore be preferred.

Antibiotic Carriers:

Vectors to deliver high local concentrations of antibiotics (up to x1000 the minimum inhibitory concentrations for resistant bacteria). Traditionally PMMA was used, but is non-absorbable and may form a nidus for resistant bacteria. Modern alternatives include Stimulan (Calcium sulphate) and Cerament (60% Calcium sulphate + 40% hydroxyapatite + Abx). Composite carriers may also be used.

Features of an ideal antibiotic carrier:

- Deliver high local Abx concentration
- Deliver Abx for sufficient duration
- Non-toxic
- Bioabsorbable
- Structural integrity
- Easy to use

When to use antibiotic carriers:

- As an adjunct to debridement
- As an adjunct to systemic Abx
- Not a substitute for appropriate decision making
- Part of multi-disciplinary approach
- May allow bone / tissue preservation

Stimulan:

- Stimulan may be used as beads
- Variety of Abx may be added 'off-label'
- Rapid breakdown so Abx duration not prolonged
- Associated with copious discharge

Cerament:

- Cerament is injectable
- Comes premixed with vancomycin or gentamicin
- Persists for longer than Stimulan
- May be replaced by bone as absorbed

Choice of Antibiotic Carriers:

When there is poor soft tissue coverage, beads may not remain in the correct position, and in this situation injection of the carrier into the medullary canal of a metatarsal or into drill holes in the calcaneus ('antibiotic silos') may be preferred. In the case of injected Cerament the filled cavity may fill with new bone as the Cerament is absorbed. Where necessary both products may be used.

Vivostat:

This is an autologous platelet concentrate, in a fibrin sealant matrix. It is used as a spray pen over an ulcer after debridement. It undergoes very rapid polymerisation and has excellent adhesive properties. It creates a local environment rich in platelets and growth factors and encourages angiogenesis and healing. Early results are encouraging but it does not work on exposed bone or in presence of infection. Consensus on its use is outstanding.

Summary:

- There is significant interest in antibiotic carriers
- Many carriers are currently available and there is a lack of comparative trials
- Important to perform adequate debridement and target Abx based on culture results
- Many delivery systems show promise but it is likely that those which both: provide a scaffold, and stimulate new bone formation (composite carriers) may have a significant role to play in Foot & Ankle surgery
- More research is required in this area.

Consensus / Discussion:

1. **How many surgeons use Stimulan mixed with antibiotics in their practice?**

Yes	17 (57%)
No	13 (43%)

This is an off-label use. Pre-mixed antibiotic preparations are available in the form of Cerament – however these are either Gentamicin or Vancomycin. Although very high local concentrations are delivered if the organism is highly resistant / secondary resistance has developed and alternative antibiotics are required Stimulan can be used.

2. **For an infected diabetic foot ulcer over the plantar aspect of a rocker bottom deformity which has failed non-operative measures, what is your preferred method of management?**

Debride to bleeding bone, then Total contact Cast	17 (57%)
Debride + Stimulan with Abx, then Total contact Cast	7 (23%)
Unsure / Other	6 (20%)

A negative pressure dressing can be applied post-debridement, even after Stimulan beads have been used. However, Stimulan will be absorbed faster but there will still be adequate concentrations of antibiotics whilst Stimulan is still present. Further Stimulan may be required.

3. **Relative indications of Stimulan vs Cerament:**
   - Cerament is injectable and slower to be degraded, therefore it may be used where a longer term solution is required or the goal is for it to be replaced by bone (e.g. within a cavity)
   - If a shorter term solution with soft tissue elution is required, Stimulan may be preferred. The 2 products can be mixed.

4. **Post-debridement of a diabetic foot ulcer with Stimulan + Abx, are intravenous Abx required?**
   During debridement, marginal samples should be taken and if these demonstrate no organisms then systemic Abx should not be required. If they do culture organisms, then there may have been inadequate debridement and further Abx / procedures may be indicated.

5. **Healing of diabetic foot ulcers using a total contact cast**
   Optimising vascularity is key. Debridement and Abx (local / systemic) are then required. Finally offloading using a total contact / other reinforced cast may be used.

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2.3 – Scaffolds & 3D Printing (Gurbinder Nandhara)

The use of scaffolds & 3D printing is a developing field of tissue engineering. When used for cartilage repair scaffolds provide a 3D environment that allows chondrocytes to proliferate. Scaffolds aim to mimic the extracellular matrix and may be native biological or synthetic polymeric materials.

Properties of an ideal scaffold:

- Biocompatible
- Bioabsorbable
- High porosity
- Suitable for cell attachment, proliferation and differentiation
- Nontoxic
- Non-antigenic
- Flexible and elastic (can be moulded)

Native biological materials include:

- Collagen (biocompatible, non-toxic, absorbed without inflammation)
- Fibrin (good chondrocyte adherence but weak mechanical properties and unsuitable degradation rate)
- Tendons & Ligaments
- Muscle
- Fat

The majority of commercially available synthetic materials include are composed of either:

- Poly-lactic-co-glycolic acid (PLGA)
- Polymer of lactic acid (PLA)

The use of Scaffolds in Foot & Ankle Surgery:

The management of Osteochondral defects (OCD) of the talus is still under debate. Human articular cartilage is highly susceptible to damage and has limited self-repair and regeneration potential. Small lesions have had good success with curettage and microfracture. However, larger lesions require more invasive methods such as autologous osteochondral transplantation (OATS). These procedures may be associated with donor site morbidity.

Cell-based strategies to engineer cartilage tissue offer a promising solution to repair articular cartilage. The use of scaffolds with Autologous Matrix Induced Chondrogenesis (AMIC) was intended to provide a simple technique for securely retaining the fragile blood clot and cells in larger defects within the collagen matrix and to possibly enhance the chondrogenesis of mesenchymal stem cells. This usually requires a medial malleolar osteotomy but allows for a single stage procedure.

Although the majority of the orthopaedic literature on chondral scaffolds looks at the knee, results for AMIC in the treatment of talar OCD have been encouraging. Multiple studies have demonstrated improved function at mid-term follow-up with few failures of treatment.

3D Printing in Foot & Ankle Surgery:

3D printing in Foot and Ankle surgery is relatively new. There is a paucity of data with majority of published literature in the form of case studies and technical guides. One apparent advantage is the ability to plan and perform surgery on a 3D printed model prior to the actual procedure. Another is

the use of patient matched components and patient specific instrumentation. 3D printers have become more compact, accessible, and affordable.

Summary:

- Research is ongoing into the use of chondral scaffolds in Foot & Ankle surgery
- Results are not significantly superior to microfracture in the primary setting
- More comparative studies are required to achieve consensus on its indications and efficacy
- 3D printing in surgery is still in its infancy but may come to play a significant role in both trauma and elective surgery in foot and ankle

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2.4 – Biomaterials in TAR: Bearing Surfaces (Vivek Dhukaram)

A major reason for failure of Total Ankle Replacements (TAR) is aseptic loosening of components secondary to mechanical, biological and patient related factors. Biological causes relate to the implant coating and polyethylene wear. Mechanical factors include high forces being transmitted over a small surface area and anatomical constraints. Patient factors include the individual immunological response to polyethylene (UHMWPE) debris.

Mobile-bearing Implants + dual coat:

- Zenith
- Box
- Salto
- STAR

Fixed-bearing Implants + single Ti coat:

- Infinity
- Salto Talaris
- Inbone

Bone-Implant Interface:

Sealing the bone-implant interface prevents UHMWPE particles entering interface. This relies on good component fit, minimisation of micro-motion, and may be influenced by the nature of the design and implant coating. Designs with multiple keels / pegs which anchor in better quality bone reduce micromotion at the bone implant interface, allowing better integration.

Nature of Implant Coating – single *versus* dual coat:

Implants may have either a single coat composed of hydroxyapatite (HPA) or Titanium (Ti) or a dual coat composed of both.

Singh *et al.* studied the retrieved tissue from 71 revision implants which have used single hydroxyapatite coating. Nearly 40% of those prosthesis failed by ballooning osteolysis. Cysts were surrounded by an area of avascular necrotic with high lymphocyte expression but it is unclear whether this was the cause of loosening. Barg *et al.* found implants with a single HPA coat had a x15 increase in rate of loosening, but it is unclear whether this is due to the design of the older generation implants or the coating. The AES implant was withdrawn due to failure secondary to peri-implant osteolysis: the osteolysis risk was x3 greater with the mono-block, dual-coated implant compared to its previous design.

It is therefore unclear how much the implant coat contributes to failure over other design factors. The primary fixation of the TAR prosthesis relies on implant design with secondary fixation affected by the implant coating. It has been proposed that delamination of the coating and foreign-body reaction to wear particles are related to insufficient primary fixation.

Polyethylene Inlay:

Fractures of the polyethylene inlay were relatively common (10%) indicating the potential for design improvement. Possible reasons included a thin insert, malalignment, and weakening of polyethylene

during the sterilisation process. There is no consensus on the ideal thickness for the polyethylene inlay in TAR. With modern sterilisation techniques the incidence of inlay fractures is reduced.

Stress Shielding:

Stress shielding may result in bone loss with the risk of opening the interface to joint fluid and wear particles, risking secondary periprosthetic osteolysis. Titanium has modulus of elasticity closer to bone which may reduce the effect of stress shielding. Apart from the Infinity and Inbone tibial plates, most of our commonly used prosthesis are composed of Cobalt-Chromium alloys.

Mobile-Bearing TAR Design:

- Lower shear at bone-implant interface
- Susceptible to bearing subluxation
- Possible impingement

Fixed-Bearing TAR Design:

- Improved centering of talar component
- Can use smaller metallic components.
- Theoretically higher implant stresses

A multicentre retrospective study was conducted to compare matched cases of fixed-bearing and mobile-bearing TAR (Gaudot *et al.*). There was no statistical difference between results of the 2 groups in terms of accuracy of positioning, clinical and radiographic mobility, and morbidity. The postoperative AOFAS scores were higher for the fixed-bearing group than for the mobile-bearing group. Radiolucent lines and subchondral cysts were observed with higher frequency in mobile-bearing implants.

Experimental models of bone implant interfacial stress between fixed-bearing, mobile-centred and mobile-eccentric position show higher interfacial stress in the mobile-bearing groups.

Summary:

- It is unclear whether the type of implant coat plays a significant role in failure of TAR
- Better implant design could improve primary stability and reduce micromotion, allowing better bony integration
- Limited evidence to favour implants with a titanium single coat, and a fixed-bearing prosthesis
- Further clinical studies with long term data are required

Consensus / Discussion:

1. **Why not use cement in the talus during total ankle replacements?**
   - Difficult to cut and secure talus for cementation process
   - Cannot get good compression of cement (hard bone, poor porosity)
   - Biomechanics of ankle not the same as the knee
   - Cannot generalise principles from TKR to TAR

2. **Fixed *versus* Mobile-bearing consensus**
   - Unclear as laboratory and clinical findings do not match
   - Problems seen with medial gutter pain, but unclear whether this is due to impingement due to subluxation of mobile bearing, or other reasons
   - No consensus reached
   - More research is needed

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Session 3: Randomised Controlled Trials

3.1 – Are RCTs just for Physicians? (Matt Welck)

Randomised controlled trials are considered the 'gold standard' of scientific evidence. They are designed to minimise bias and confounding factors through techniques such as allocation concealment, randomisation, and blinding. This allows researchers to conclude that observed differences in outcome are indeed due to difference in treatment. Sacks *et al.* demonstrated the treatment effect was greater in trials that were *not* randomised i.e. bias increases the treatment size effect and should be eliminated from trials.

Level of Evidence in Orthopaedics:

"Higher quality" evidence is produced from randomised controlled trials and analysis of data from national registries. Over the last 5 years 1156 articles were published in the BJJ. Only 8% of these were Level I RCTs, and of these, 75% were in either hip, knee, or trauma.

Recent / Ongoing RCTs in Foot & Ankle include:

- Calcaneal fracture study: Griffin *et al.* BMJ 2014
- TARVA: Goldberg *et al.* BMJ 2016
- Cartiva: Baumhauer *et al.* FAI 2016
- Cast *versus* surgery for unstable ankle fractures: Willits *et al.* JAMA 2016

RCTs in Medicine *versus* Surgery:

Whereas the introduction of a new medication requires robust clinical evidence and Phase 3 studies to be conducted, the same rigor is not applied to introduction of surgical procedures:

- There are no standardised rules
- RCTs not required, frequently only case series are published
- Have to demonstrate equivalence to existing device only

Surgical RCTs are, in general, of lower quality than medical trials: 33% of studies are of high quality in surgery *versus* 75% in medicine. Over 90% surgical of studies are underpowered and 40-50% lack concealment, blinding, and randomisation. Additionally, the average sample size in orthopaedic trials is 90 patients and it is difficult to make policy changes based on small numbers.

Challenges faced in Orthopaedic RCTs:

Recruitment:

- Anxiety for new procedure
- Preference for one treatment (patient and surgeon)
- Ability to get treatment outside of trial

Sample size:

- Cost: avoid implant funding, NHS environment
- Time
- Low numbers of operations performed
- Insufficient numbers / power create Type 2 (Beta) error (false negative, not finding a difference where one does exist)
- Sub-group analysis creates Type 1 (Alpha) error (false positive, finding a difference where none exist)

Blinding:

- Cannot blind the surgeon to operate, can blind for injections
- Ethics behind "sham" operations (placebo)
- Subconscious bias if randomised to other than their preferred treatment arm

Randomisation & Concealment:

- Blinding can be lost if randomised in advance, but need notice for equipment
- ? Outsource to conceal

Variation:

- Type of anaesthesia used
- Surgeon technique / experience
- Hospital factors in multicentre trials
- Post-operative regimen

Follow-up:

- Patients lost to follow-up threaten the validity of the trial
- One hit phenomenon of surgery reduces incentive for patients to return for review

Due to the difficulties mentioned, interpretation of surgical RCTs needs to be done with caution. A well designed observational study may produce better conclusions than a poorly designed RCT. Involvement of a statistician early is sensible to plan power and recruitment. Pragmatic trials compare non-inferiority to existing treatment, rather than placebo.

With legal implications from evidence-based medicine, the quality of trials and interpretation should be considered during design. For example, whether or not to fix calcaneal fractures: if the surgeon gets a complication, the evidence may not support the decision to operate.

Summary:

- Surgical RCTs pose multiple challenges: Recruitment, sample size, blinding, randomisation, concealment, variation, follow-up
- A well-designed observational study may be better than a poorly designed RCT?
- There are legal implications to the conclusions of surgical trials

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3.2– Calcaneal Fractures (Rajesh Kakwani)

The aims of calcaneal fracture fixation are anatomical congruity of subtalar joint and restoration of the calcaneal height, pitch, Bohler's angle, and heel width. A critical appraisal of 2 randomised controlled trials and a meta-analysis follows, attempting to answer the following 2 questions:

- Whether to operate or not?
- Which surgical approach to use if we do operate?

Buckley *et al*. JBJS 2002. Operative compared with non-operative treatment of displaced intra-articular calcaneal fractures: a prospective randomized controlled multicentre trial:

Study Findings:

- Large, multicenter trial with good follow-up
- Similar functional results (without sub-stratification) of calcaneal fractures treated operatively *versus* non-operatively
- More favourable outcomes in patients without worker's compensation, women, and younger patients

Study Critique:

- Randomised before allocation
- Smoking and co-morbidities not accounted for
- Limited number of surgeons so difficult to generalise findings
- Sub-stratification appeared to be done retrospectively after no difference found between groups

Griffin *et al.* BMJ 2014. Operative *versus* non-operative treatment for closed, displaced, intra-articular fractures of the calcaneus. "UK Heel Fracture Trial":

This study appeared on the cover page of the BMJ with a tabloid-type heading 'Calcaneal fracture: surgery provides no benefit'. This statement has received a lot of criticism by generalising management of all calcaneal fractures.

Study Findings:

- Prospective, multicentre trial (22 centres), parallel groups, assessor blinded with 95% follow-up
- Extended lateral approach for surgery
- Gross deformity excluded (fibular impingement)
- No difference at 2 years (in either PROMs or symptoms)
- Operative group had 20% wound complication rate

Study Critique:

- 500 eligible patients, but only 151 enrolled – potential bias?
- 27 surgeons, 2-7 cases over 2 years – what was the surgeon expertise?
- Follow-up of 2 years only – longer term studies have shown difference in subtalar fusion rates between groups at 10 years

In a regional survey 77% of Foot & Ankle surgeons in the North of England said the UK Heel trial made no difference to their decision making regarding calcaneal fracture management.

Zhang *et al*. ANZ J Surg 2017. Meta-analysis of two surgical approaches for calcaneal fractures: sinus tarsi versus extensile lateral approach:

- Meta-analysis of 8 studies, 564 patients
- Sinus tarsi approach had decreased overall complication rate (odds ratio 0.14) and wound complication rate (odds ratio 0.16)
- No difference in anatomical reduction
- Supports sinus tarsi approach for calcaneal fracture fixation

Surgical Approaches for fixation of calcaneal fractures:

- Extended lateral became the gold standard, propagated by Prof Atkins in 1992
- Gives good access for fixation, but 16-25% wound problems reported.
- 62% of surgeons in the UK still use the extended lateral approach.
- Sinus tarsi approach is the most popular of the MIS approaches; it permits access to the subtalar joint, but is non-extensile.
- Arthroscopic fixation is technically difficult, but can have good results with a low infection rate

Summary:

- 3 large studies have not answered the questions posed
- Challenges: Fracture type, soft tissues, variety of surgical techniques
- Fractures included in the RCTs: make up the minority of fractures we see in our practice, exclude those where surgery is indicated, and generalise a group of injuries that shouldn't all be treated the same
- Legal and cost implications of conclusions of calcaneal trials if complications occur
- Trust involvement in clinical decision making based on RCTs, by non-clinicians and non-specialist orthopaedic surgeons may pose a problem

Consensus / Discussion:

1. **35-year old professional, BMI 25, non-smoker, with a displaced, intra-articular calcaneal fracture after a fall from 6 feet. How many surgeons would perform surgical fixation?**

Yes	28 (93%)
No	2 (7%)

2. **If you did perform fixation, what approach would you use?**

Extended Lateral	21 (70%)
MIS	7 (23%)
Arthroscopic	2 (7%)

3. **How many surgeons operate on fewer calcaneal fractures now?**

Yes	25 (83%)
No	5 (17%)

It was noted that this is due to a number of reasons, including: reduced number of referral, fewer injuries seen, more Foot & Ankle surgeons, and an increased number managed non-operatively

4. **How many surgeons have received guidance from their trust not to operate on calcaneal fractures following the BMJ article?**

Yes	2 (7%)
No	28 (93%)

5. **How many surgeons regularly see and treat calcaneal fractures?**

Yes	27 (90%)
No	3 (10%)

6. **How many surgeons still fix calcaneal fractures?**

Yes	24 (80%)
No	6 (20%)

7. **How many surgeons would opt to have their calcaneal fracture fixed by a Foot & Ankle Surgeon?**

Yes	24 (80%)
No	6 (20%)

8. **How many surgeons feel that one of the aims of fixation is to improve the shape of the hind-foot / subtalar joint to aid in / improve outcome of future subtalar fusion?**

Yes	30 (100%)
No	0

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3.3 – Unstable Ankle Fractures (Billy Jowett)

Willett *et al.* JAMA 2016. Close Contact Casting Vs Surgery for Initial Treatment of Unstable Ankle Fractures in Older Adults: A Randomized Clinical Trial:

This was an equivalence study comparing close contact casting with open reduction and internal fixation for overtly unstable ankle fractures in patients older than 60 years old. Recruitment was based on patients presenting with acute malleolar fracture(s) and an unstable ankle joint on the initial radiograph, who would normally have been offered surgery.

Patient Selection:

- 24 institutions, 40 months
- 2015 patients screened
- 959 excluded, 620 randomised
- 309 surgical group, 311 casting group

Outcomes assessed (6 months):

- Mal-union / non-union
- Olerud-Molander Ankle Score, SF-12, EQ-5D-3L
- XRs missing: 8% surgical, 10% casting

Casting group (n=311):

- 34 did not have casting as could not obtain adequate reduction in a cast (*not* analysed in per-protocol analysis)
- 62 of the remaining patient were abandoned: 52 had an ORIF, 10 had re-MUA and casting (were included in the casting group for analysis)

Surgical group (n=309)

- 7 out of 309 the surgery group did not receive surgery because of soft tissue problems

Results:

- No difference in OMAS score at 6 months, nor any of the secondary outcomes
- Mal-union: 15% in the casting group *versus* 3% in the surgical group
- Infection / wound breakdown: 1% in the casting group *versus* 10% for the surgical group

The authors concluded that Close Contact Casting reduced the number of patients needing surgery and that the clinical outcomes were equivalent.

Critique of the study:

Defining Stability:

- 'Unstable fracture' not defined in the study: fractures may look unstable i.e. widened medial clear space on an equinus X Ray taken in A & E which may not in fact be unstable
- Gougoulias and Sakellariou have shown that gravity stress views over diagnose ankle instability due to ankle equinus relaxing the deep deltoid, and a weight bearing view is better at diagnosis. This alone has reduced the number of patients requiring ORIF from 45% to 3.7%. Patients requiring a WB view were excluded in this study.
- Unstable fractures should have been defined, for example, 'a fracture where the ankle joint can be displaced when subjected to normal forces'

Short Follow up:

- The assessment of clinical equivalence of outcome at 6 months is too early. Development of degenerative change can take over 24 months.

Acceptability of Mal-Union:

- A 15% mal-union rate in the casting group is not acceptable. The surgical mal-union rate could be improved by appropriate grade of surgeon performing the operation (not given).

Rate of Surgical Infection:

- Choosing cast rather than surgery because of the wound complication rate with surgery of 10% in this paper, this needs to be set against recent evidence that showed 0% infection rate for fibula nail fixation with 2% malunion rate (White *et al.)*.

Cost Analysis of Interventions:

- Casting group had an MUA under anaesthetic in theatre and required much closer outpatient monitoring for loss of position. A cost analysis may not be so advantageous.

Summary:

- The paper discussed has some good design features, but has some significant flaws in its methodology and conclusions
- A 15% mal-union rate for casting group is not acceptable
- Better surgical technique and robust diagnosis of unstable injuries will improve outcomes, such as infection rate and progression to degenerative joint disease

Consensus / Discussion:

1. Should we perform ORIF in unstable ankle fractures in patients >60 years of age, with no general contraindications?

Yes	30 (100%)
No	0

2. What is your standard method of fixation for an ankle fracture?

Standard ORIF	30 (100%)
Fibular Nail	0

3. What investigation would you use to assess stability of an ankle fracture?

Gravity Stress Radiograph	4 (13%)
Weight Bearing Radiograph	26 (87%)

4.	**Is the Willett study fundamentally flawed and unhelpful for practice?**	
	Yes	30 (100%)
	No	0

References:

Gougoulias N, Sakellariou A. When is a simple fracture of the lateral malleolus not so simple? *BJJ*. 2017; 99-B (7): 851-855.

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3.4 – Cartiva® Synthetic Cartilage Implant (Simon Clint)

We all see patients with significant 1st MTPJ arthritis who, for various reasons, do not like the idea of an arthrodesis. Most arthroplasties for the first MTPJ have a poor track record with early failure. For some patients, maintaining motion is paramount.

Baumhauer *et al.* FAI 2016 (Cartiva Motion Study Group):

- Prospective randomised trial, 12 centres in Canada & UK
- Cartiva *versus* arthrodesis, Non-inferiority design
- Outcomes = VAS, FAAM, motion, secondary procedures
- Good follow up of 2 years (202 patients / 236 initially enrolled)
- Power calculation performed

Conclusion of paper:

- Equivalent pain relief and functional outcomes
- Synthetic implant is an alternative to arthrodesis in patients who wish to maintain motion of the the first MTPJ
- Secondary procedures were similar in both groups
- < 10% of the implant group required revision to arthrodesis at 2 years

Critique of the Study:

- Recruitment: Intention to treat modified and 'Training patients' included to increase numbers
- Secondary surgery: Failure of implant in Cartiva *versus* removal of metalwork in arthrodesis
- Unusual design of non-inferiority study (all other measures not inferior, in motion it is better)
- Paper was done to get FDA approval for the implant
- ROM in Cartiva group had large variance; arthrodesis group had movement – unclear accuracy
- FAAM scores reduced in arthrodesis group due to immobilisation, and Cartiva group very close to being statistically worse at 6 months
- "Loss of dorsiflexion after arthrodesis limits running and jumping sports and footwear choice." Paper does not examine footwear and no evidence in this patient population that the sporting function of the patient (as measured by the FAAM) is restricted by an arthrodesis.

Summary:

- Cartiva maintains motion, but probably does not increase it
- Improves pain, but not quite as well as a fusion
- Allows prompt initial return to ADLs, but longer to gain full benefit
- A proportion do not work and need a fusion in the short term
- 5 year results expected shortly, and 10 year results agreed to be done

References:

Baumhauer J, Singh D, Glazebrook M, Blundell C, De Vries G, Le IL, et al. Prospective, Randomised, Multi-Centered Clinical Trial Assessing Safety and Efficacy of a Synthetic Cartilage Implant versus Metatarsophalangeal Arthrodesis in Advanced Hallux Rigidus. *Foot Ankle Int*. 2016; 37 (5): 457-469.

Session 4: Tissue Regeneration

4.1 – Chondrocytes in Cartilage Repair (Howard Davies)

Zones of Articular Cartilage:

- Superficial zone – flattened cells and collagen fibres parallel to the articular surface
- Middle zone – more rounded cells and fibres more oblique
- Deep zone –chondrocytes in columns and collagen perpendicular to articular surface
- Tidemark – boundary between deep zone and calcified cartilage

It is composed of extracellular matrix, Type II collagen and chondrocytes. Articular cartilage is predominantly hyaline cartilage and has limited reparative ability. Superficial lesions which do not cross the tidemark do not undergo repair. The principle behind microfracture is to create a deeper lesion which crosses the tidemark, thereby stimulating repair, although this occurs with fibrocartilage (Type I collagen) rather than hyaline cartilage.

Lateral Talar OCD (85% of lesions):

- Traumatic
- Small / Superficial
- Anterior / Central

Medial Talar OCD (15% of lesions):

- Can be atraumatic
- Larger / Deeper
- Posterior

The treatment of Osteochondral Defects (OCDs) consists of:

- Microfracture
- Structural autograft
- Synthetic implants
- Autologous chondrocyte implantation (ACI)
- Stem cells

Microfracture:

This is a minimally invasive technique which is often considered the first line of surgical treatment. It is minimally invasive and consists of a number of holes being drilled through the tidemark to stimulate formation of fibrocartilage. It is used for smaller defects (< 1.5-2 cm^2) although it has been used for larger defect in the Knee literature. It has predictable results and long term durability with minimal associated morbidity.

Autograft:

Hyaline cartilage is usually taken from the medial femoral condyle and implanted in the defect. This is a salvage procedure and requires a medial malleolar osteotomy. Medium term results at 5 years are comparable to microfracture results, but it is associated with donor site morbidity at the knee.

Autologous chondrocyte implantation (ACI):

This aims to produce hyaline cartilage. Chondrocytes are harvested from a donor site and cultured. In the 1st generation, they were implanted under a periosteal patch. The 2nd generation introduced a collagen membrane (composed of Types I & III collagen) to better contain chondrocytes (MACI). The early literature was of use of ACI in the knee with multiple case series but few prospective studies. Bentley *et al.* randomised 100 patients to 1st generation ACI vs mosaicplasty and at 10-year follow-up there was an 83% survivorship of ACI. Horas *et al.* looked at 40 patients and found that at 2 years there was no difference between ACI and mosaicplasty clinically. However, they did note that although mosaicplasty produced predominantly hyaline cartilage, ACI produced mainly fibrocartilage. A number of case series of athletes treated with ACI have demonstrated good to excellent results in 72-91%, however, a third of patients in these studies did not return to sport.

There have been randomised controlled trials comparing 2nd generation MACI to ACI in the knee literature – these demonstrated no clinical or histological benefit of one over the other in the short-term. However, there was reduced donor site morbidity in MACI. Basad *et al.* compared MACI to microfracture in the knee and at 2 years found that cartilage repair was better in the MACI group.

Treatment of OCD in the talus:

There are 2 case series with medium term follow-up looking at the treatment of talar OCD treated with OCI (Anders *et al.* and Giannini *et al.*). Over 5 to 7-year follow-up these have demonstrated significant improvement in AOFAS scores. The failures in these cases were analysed and demonstrated formation of fibrocartilage rather than hyaline cartilage.

Zengerink *et al.* performed a review of literature from 1966 to 2006 and found 1 randomised controlled trial comparing various treatment modalities. They found 65 treatment groups in 54 studies and they concluded that microfracture, mosaicplasty and ACI were all acceptable forms of treatment with comparable results. However, due to donor site morbidity and increased cost associated with other procedures, they recommended that microfracture should be used primarily in the treatment of OCD of the talus.

Summary:

- A number of treatment modalities are available for management of cartilage defects
- Despite the perceived advantage of producing hyaline cartilage with techniques such as ACI and MACI, studies have not demonstrated any clinical or histological difference compared to other techniques
- There is a paucity of Foot & Ankle literature to guide treatment and indications
- The available evidence suggests that no procedure offers superior results to microfracture in the primary setting

Consensus / Discussion:

1. **Preferred first line of treatment for a symptomatic medial talar OCD in a young / middle-aged, active patient who has failed physiotherapy:**

Micro-fracture / Debridement	30 (100%)
Other technique (ACI / MACI) without medial malleolar osteotomy	0
Other technique (ACI / MACI) with medial malleolar osteotomy	0

It was discussed that not all OCDs are symptomatic and that decision to proceed to surgical treatment would depend on symptoms compatible with lesion.

2. **How many surgeons would proceed to micro-fracture in a symptomatic patient if an OCD was present on CT scan but during arthroscopy it was noted that the overlying cartilage was completely intact?**

Proceed to debridement and micro-fracture	10 (33%)
Leave cartilage undisturbed	20 (67%)

It was noted that in a symptomatic patient with a significant OCD it is very unusual to have completely intact overlying cartilage. MR or CT arthrogram may help determine pre-operatively if the cartilage is intact or not but is not a substitute for arthroscopic assessment.

References:

Anders S, Goetz J, Schubert T, Grifka J, Schaumburger J. Treatment of deep articular talus lesions by matrix associated autologous chondrocyte implantation--results at five years. *Int Orthop*. 2012;36(11):2279-85.

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Zengerink M, Struijs PA, Tol JL, van Dijk CN. Treatment of osteochondral lesions of the talus: a systematic review. *Knee Surg Sports Traumatol Arthrosc*. 2010;18(2):238-46.

4.2 – Platelet Rich Plasma (Ashok Acharya)

Platelet Rich Plasma (PRP) was first used to aid in wound healing in 1987 after cardiac bypass surgery. In 1998 it was used to enhance bone repair in mandibular defects by maxillofacial surgeons with good results. The first use in orthopaedics was in 2003 for the treatment of recalcitrant tennis elbow. It has since been used for a wide variety of conditions and indications.

Production and Mechanism of PRP:

There have been varying definitions of what constitutes PRP. Therapeutic levels of >1,250,000/mm^3 promote an endothelial response and levels >1,500,000/mm^3 promote angiogenesis. There are a variety of types of PRP but the most commonly used in orthopaedics are Pure PRP (P-PRP) which does not contain leucocytes, and Leucocyte-rich PRP (L-PRP) which contains leucocytes.

Steps in Preparing PRP:

- 15-20 ml autologous blood extracted
- Mixed with an anticoagulant – usually Citrate Dextrose
- Centrifuged at an acceleration >1000g for 15-20 minutes
- This may be repeated x1 or x2

Common conditions where PRP is used:

- Achilles tendinopathy
- Achilles Tendon repair
- Plantar fasciitis
- Ankle cartilage pathology
- Foot & Ankle fusions
- Foot & Ankle wounds

PRP is thought to contain alpha granules which promote adherence of platelets to exposed endothelium. This causes release of a variety of growth factors which encourage a localised inflammatory response with migration of leucocytes and a subsequent fibroblastic response.

PRP in Foot & Ankle:

In plantar fasciitis, Aksahin *et al.* performed a randomised controlled trial with a double-blind comparison of PRP *versus* steroid injection and found a comparable improvement in both groups. A systematic review (Franceschi *et al.*) noted that although in most series a significant improvement in symptoms occurred and there were no major complications, most studies did not have a control or placebo group for comparison.

PRP in Achilles Tendinopathy:

- RCT: PRP *versus* Placebo – No difference at 1 year (de Jone *et al.*)
- PRP *versus* high volume injection (HVI) – HVI superior in short term (Boesen *et al.*)
- Systematic review – evidence for single USS guided PRP injection (Fitzpatrick *et al.*)

PRP in Achilles Tendon Repair:

- Case series - faster functional recovery in the PRP group compared to historical results (Sanchez *et al.*)
- PRP + Repair *versus* Repair only - No difference in biomechanical tests at 12 months (Schepull *et al.*)

In ankle osteoarthritis PRP is inserted as a gel accompanied by a scaffold of mesenchymal stem cells and compared to traditional procedures such as ACI. PRP has shown favourable outcomes. Studies comparing PRP injection to hyaluronic acid injections have also reported improved pain and function in the PRP group (Mei-Dan *et al.*). Guney *et al.* compared microfracture and PRP to microfracture alone and reported better function with addition of PRP over 16 months. A systematic review of the aforementioned literature concluded that overall the results of PRP in ankle cartilage disorders was good, and there were no major adverse effects noted.

Case series comparing PRP in ankle fusions to historical controls suggest lower non-union rates. A randomised controlled trial of 117 diabetic ulcers treated with or without application of a PRP gel reported significant improvement in wound healing in the PRP group. A Cochrane review {Martinez-Zapatta *et al.*) comparing PRP with placebo in the management of chronic wounds, however, found no evidence to suggest value of PRP due to a high level of bias in studies.

Vannini *et al.* performed a systematic review of all literature looking at the use of PRP in Foot & Ankle across all pathologies. They concluded that there was no clear indication for the use of PRP. NICE states that there are no safety concerns with the use of PRP, but there is insufficient evidence regarding efficacy and no difference between use of PRP and autologous blood injections.

Summary:

- Consensus that there are few adverse effects associated with PRP
- No consensus on which preparation / composition of PRP should be used
- Unclear effect of therapeutic protocols and associated procedures
- No clear evidence to support use of PRP in Foot & Ankle conditions
- Despite lack of evidence the use of PRP is increasing
- Any clinician offering PRP should do so within a clinical governance framework

Consensus / Discussion:

1. **Preferred first line of treatment for a symptomatic, middle-aged patient with a raised BMI with a 3-month history of pain secondary to proven plantar fasciitis with a positive Silfverskiöld test:**

Aircast boot	0
Calf Stretches	30 (100%)
Night Splints	20 (67%)
Shockwave Treatment	14 (47%)
PRP Injection	0
Steroid Injection	6 (20%)
Medial Proximal Gastrocnemius Release	0
Plantar Fascia Release	0

2. **Who has performed / performs plantar fascia releases?**

Yes	18 (60%)
No	12 (40%)

3. **Of those who have performed plantar fascia releases, how many have got good results?**

Yes	9 (50%)
No	9 (50%)

It was agreed that plantar fascia release was a last resort after an extended period of unsuccessful treatment.

4. **Preferred first line treatment for non-insertional Achilles Tendinopathy in a middle-aged runner with symptoms for 6 months, refractory to physiotherapy:**

PRP	0
Shockwave Therapy	24 (80%)
Dry Needling	1 (3%)
High Volume Injection +/- Steroid	6 (20%)
Steroid Injection	0
Medial Proximal Gastrocnemius Release	2 (7%)
Sclerosant Therapy	0

It was noted that shockwave is not available in all trusts / units with only 15 (50%) of participants having access in the NHS setting.

5. **How many surgeons routinely place patients into a cast / boot after high volume injection +/- steroid or dry needling to reduce risk of Achilles tendon rupture**

Yes	1 (3%)
No	29 (97%)

It was discussed that whilst it was not negligent to give a steroid injection around a tendon it should be given with caution and not injected into a tendon.

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4.3 – Stem Cell Therapy (Jim Carmichael)

Stem cells are cells that have the potential to develop into many different cell types in the body. This potential has led to an explosion of research into their use in a wide range of medical conditions. Recently, stem cells have generated interest in the treatment of orthopaedic conditions.

Use of Stem Cells in Orthopaedics:

- Osteoarthritis
- Articular cartilage Disorders
- Tendinopathies
- Tendon Ruptures
- Fracture non-union

Types of Stem Cells:

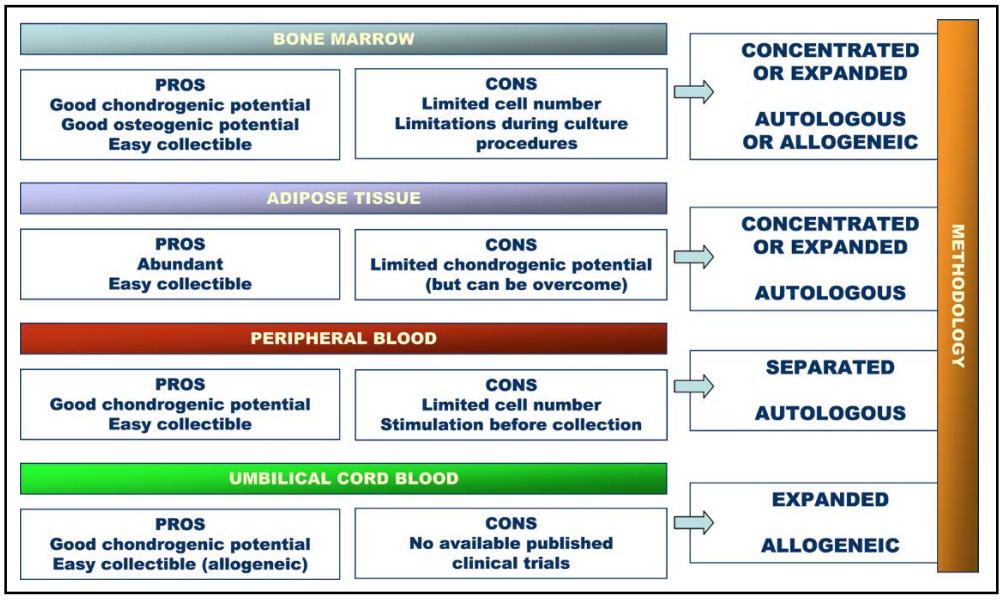
- Pluripotent – divide into any cell type
- Multipotent (mesenchymal stem cells) – divide into specific cell lines only
- Induced pluripotent cells –theoretical risk of neoplastic change

Types of Stem Cells:

Pluripotent Stem cells are only found in embryonic sources or through manipulation of adult cell types (Induced pluripotent cells). Multipotent mesenchymal stem cells (MSCs) are, however, ubiquitous in the adult body and common sites for harvest include subcutaneous fat and bone marrow. MSCs have a limited differentiation ability but remain an attractive option in the treatment of orthopaedic conditions. They may enhance the repair process through their immunomodulatory and anti-inflammatory properties and their action as "growth factor pharmacies".

Harvest of Stem Cells:

The development of viable treatment options for disorders of articular cartilage through the use of stem cells faces numerous challenges. Although easily harvested and concentrated from fat or bone marrow aspirate, the proportion of MSCs in these preparations is small and variable. However, the use of these preparation techniques is commercially attractive as it allows for single stage procedures.



In order to increase the number of cells and more reliably predict the cell type and dosage for therapeutic purposes, cell expansion techniques have been developed. This approach unfortunately necessitates a 2 stage approach, is more invasive and has a greater cost. Furthermore, the need for extensive cell manipulation transforms expanded cells into an "advanced therapy medicinal product" which demands more rigorous regulatory requirements for use in clinical practice.

The desire to combine the advantages of the single stage procedures possible through concentrated MSC harvest, with the reproducibility of cell numbers and purity of cell type of the expanded cell techniques has led to interest in the use of embryonic or allograft MSC products from cell banks. Although obvious concerns exist regarding use of cellular allograft, MSCs are non-immunogenic due to their low expression of antigen presenting molecules. Even though this property is not shared with the differentiated cell lines, preliminary preclinical and clinical trials suggest this may be a safe and effective option.

Goal of Treatment of Articular Defects:

- Regenerate Hyaline Cartilage
- Mechanically identical to cartilage
- Histologically identical to cartilage
- Integrated into surrounding tissue
- Single Stage procedure
- Financially viable

Methods of Delivery of Stem Cells:

- Injection – injection of MSCs into degenerative joint space to reverse / prevent degenerative joint disease
- Surgical – application of gels to augment microfracture

Use of Stem Cells:

Currently available techniques include microfracture, OATS, and ACI / MACI. Microfracture has been successfully used in primary and revision settings but has limited utility in larger defects and produces only fibrocartilage. ACI and MACI are more invasive procedures which may require 2 stages and are associated with donor sit morbidity. It is hoped that Stem cells can be used to combine the strengths of all of the above options.

Injective therapy is aimed to preventing progression of degenerative joint disease. Most evidence for its use comes from animal studies, but a few series in knee arthritis have suggested some success with improved appearance of articular cartilage on MRI and improvement in functional scores. Phase 1 trials have suggested that injective treatment is safe, and cell dosage appears to be an important factor. Phase 2 trials are currently being commenced to investigate this further.

Surgical therapy uses MSCs to augment existing surgical techniques. There is poor evidence for its use in Foot & Ankle thus far but it does appear to be safe. A systematic review of animal trials suggests a beneficial effect but significant paucity of data.

Summary:

- The use of stem cell therapy in orthopaedics remains in its infancy
- There is a growing amount of research but evidence in the treatment of ankle pathology is sparse
- The use of stem cells in the treatment of ankle cartilage injury has promise but further data is required on optimal harvesting and delivery techniques
- Long term follow-up data is required comparing stem cells with standard therapy

Consensus / Discussion:

1. **Preferred first line treatment for a middle-aged patient with moderate ankle osteoarthritis with symptoms affecting quality of life but continuing to go to the gym and requesting stem cell therapy:**

Offer Stem Cell Treatment	0
PRP	0
Advise Steroid Injection	28 (93%)
Arthroscopy	2 (7%)
Recommend fusion / TAR	0
Gene Therapy	0
HA Injection	0

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4.4 – Gene Therapy (Mike Karski)

Gene therapy aims to treat genetic disease at the molecular level. The basis for gene therapy is the introduction of genetic material into a cell to produce a specific protein.

Aims of Gene Therapy:

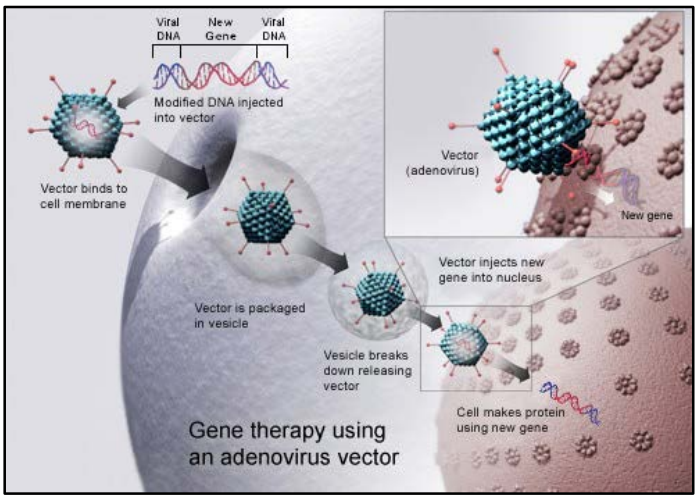
- Production of normal protein to compensation for host deficiency
- Production of therapeutic substance
- Function within target cell / tissue
- Function long term
- No adverse effects to host

Early Results of Gene Therapy:

- 1500 clinical trials since 1990
- Success in some areas - leukaemia, immune deficiencies
- Early complications: severe host reaction; secondary leukaemia
- 2017: first FDA approved gene therapy - for treatment of leukaemia

Vectors in gene therapy:

In order to introduce the desired gene into the target cell a vector is required. Translocation of the graft DNA / RNA into the existing host cell nucleus / chromosomes results in a high level of sustained transgene expression and is therefore desirable, although not always achievable. Viruses are ideal vectors as their cellular machinery is designed to introduce foreign DNA / RNA into host cells for transcription. Majority of clinical trials have therefore looked at viruses as vectors.



There have been some concerns with viral vectors such as a significant host immune response which can be fatal. If the viral / graft DNA incorporates into the host chromosome it can predispose to mutation and subsequent neoplastic transformation. Gene therapy is also extremely expensive to research and produce and therefore the costs of treatments are prohibitive. To mitigate these issues research has been undertaken into non-viral vectors such as DNA plasmids. These are often cheaper than viral vectors but the transgene expression is often short-lived and therefore the use of non-viral vectors has been limited.

Steps in Preparing a Vector:

- Genetic engineering to remove part of genome causing disease
- Replace with desired gene
- Maintain infectivity to allow uptake
- Remove proteins triggering host response

Delivery of Vector:

- In-vivo – vector is directly injected into host cells / target tissues
- Ex-vivo – autologous / allogenic cells are extracted and vector introduced. Re-implantation directly or with scaffold

Gene Therapy in Orthopaedics:

Intra-articular gene therapy has shown some efficacy in animal models using both viral and non-viral vectors. Transgenes coding for Etanercept and TGF-β have been studied in patients with rheumatoid arthritis and there are currently phase 3 clinical trials being conducted. During phase 2 trials no significant benefit in pain score was noted at 12-weeks post-intervention. Animal trials have also been conducted treating OCDs in the femoral condyle with a 'gene plug'.

Summary:

- Gene therapy is a field very much in its infancy
- Orthopaedic treatments still in phase 2/3 or animal trials
- Concerns of patient safety: immune response to vectors and secondary neoplasms
- Research and treatment costs prohibitively expensive

References:

Evans CH, Ghivizzani SC, Robbins PD. Arthritis gene therapy and its tortuous path into the clinic. *Transl Res*. 2013;161(4):205-16.

Evans CH, Huard J. Gene therapy approaches to regenerating the musculoskeletal system. *Nat Rev Rheumatol*. 2015;11(4):234-42.

Hacein-Bey-Abina S, Von Kalle C, Schmidt M, McCormack MP, Wulffraat N, Leboulch P, et al. LMO2-associated clonal T cell proliferation in two patients after gene therapy for SCID-X1. *Science*. 2003;302(5644):415-9.

Mease PJ, Wei N, Fudman EJ, Kivitz AJ, Schechtman J, Trapp RG, et al. Safety, tolerability, and clinical outcomes after intraarticular injection of a recombinant adeno-associated vector containing a tumor necrosis factor antagonist gene: results of a phase 1/2 Study. *J Rheumatol*. 2010;37(4):692-703.

Pascher A, Palmer GD, Steinert A, Oligino T, Gouze E, Gouze JN, et al. Gene delivery to cartilage defects using coagulated bone marrow aspirate. *Gene Ther*. 2004;11(2):133-41.

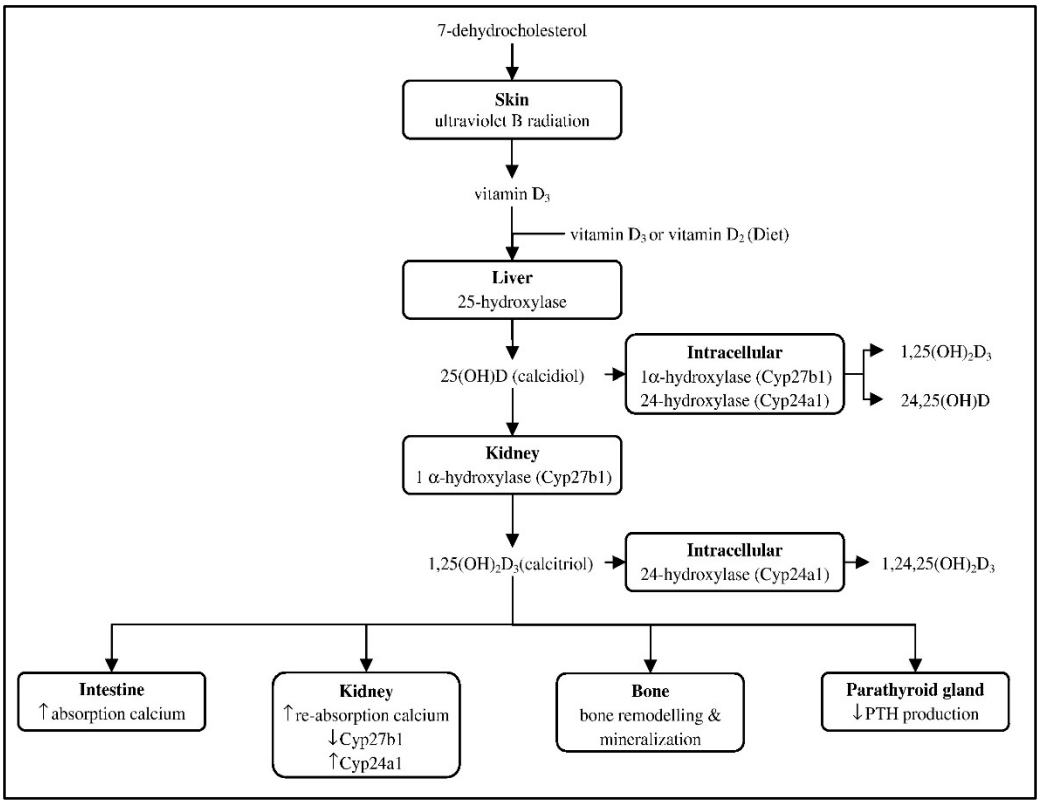
Session 5: Adjuvant Medical Therapy

5.1 – Vitamin D & Calcium for Bone Healing (John Grice)

Benefits of Vitamin D:

- Increases calcium levels
- Reduces non-vertebral fracture rates by at least 20% (Eschle *et al.*)
- Reduces risk of falling and increases muscle strength (Holick *et al.*)

Metabolism of Vitamin D:



Vitamin D metabolism adapted from Gorter et al.

Review of Literature:

Estimated levels of Vitamin D_3 required to reduce fractures in the elderly is 75nmol/l and supplementation of 800 to 1000iu per day should achieve this level. There is a paucity of evidence in humans to support supplementation following foot and ankle fractures. However, evidence suggests greater deficiency in those who suffer fractures of the foot and ankle and there is a correlation between Vitamin D deficiency and poorer outcome scores following ankle fracture fixation (Warner *et al.*). There is also a high prevalence of Vitamin D deficiency (84%) in patients with bone marrow oedema syndrome of the foot and ankle (Horas *et al.*).

Vitamin D supplementation alone may not reduce fracture risk with a randomised double blind, placebo controlled trial of 10000 participants failing to demonstrate a reduced risk of hip/wrist/vertebral fractures (Bernhard *et al*.). Calcium and Vitamin D deficiency has been shown to marginally impair fracture healing in mice, but significantly increase PTH levels and posttraumatic bone loss from the rest of the skeleton.

Summary:

- Combined Vitamin D and Calcium supplementation in those who are deficient may reduce the risk of fractures and may also improve healing if fracture occurs
- Testing / supplementation may be appropriate in high risk patients
- A cost / benefit analysis is required before considering routine testing
- The effect of Vitamin D deficiency on Foot & Ankle surgery has yet to be determined

Consensus / Discussion

1. **How many surgeons would test pre-operative Vitamin D level in a planned elective hindfoot fusion?**

Yes	15 (50%)
No	15 (50%)

2. **How many surgeons currently advise pre-operative Vitamin D / Calcium supplementation prior to any elective foot and ankle procedure?**

Yes	8 (27%)
No	22 (73%)

3. **Following the Round Table Meeting, how many surgeons would now advise pre-operative Vitamin D / Calcium supplementation prior to any elective foot and ankle procedure?**

Yes	15 (50%)
No	15 (50%)

4. **How many of the participants would be taking Vitamin D supplementation this autumn / winter as per Public Health England guidelines?**

Yes	28 (93%)
No	2 (7%)

References:

Bernhard A, Matuk J. Vitamin D in foot and ankle fractures healing: A literature review and research design. Foot Ankle Spec. 2015;8(5):397-405.

Clutton J, Perera A. Vitamin D insufficiency in patients with fractures of the fifth metatarsal. Foot. 2016;27:50-2.

Dawson-Hughes B, Heaney RP, Holick MF et al. Estimates of optimal vitamin D status. Osteoporos Int. 2005;16:713-6.

Fischer V, Haffner-Luntzer M, Prystaz et al. Calcium and vitamin D deficiency marginally impairs fracture but aggravates posttraumatic bone loss in osteoporotic mice. Sci Rep. 2017;7:7223.

Gorter EA, Hamdy NAT, Appelman-Dijkstra NM, Schipper IB. The role of vitamin D in human fracture healing: a systematic review of the literature. Bone. 2014;64:288-297.

Holick MF. The role of vitamin D for bone health and fracture prevention. Current osteoporosis reports. 2006;4:96-102.

Horas K, Fraissler L, Maier G et al. High Prevalence of Vitamin D Deficiency in Patients With Bone Marrow Edema Syndrome of the Foot and Ankle. FAI. 2017;38(7):760-6.

Moran DS, Heled Y, Arbel T et al. Dietary intake and stress fractures among elite male combat recruits. J Int Soc Sports Nutr. 2012;9:6-13.

Public Health England. The Scientific Advisory Committee on Nutrition (SACN) recommendations on vitamin D. https://www.gov.uk/government/publications/sacn-vitamin-d-and-health-report (date last accessed 14/09/2017).

Smith JT, Halim K, Palms DA et al. Prevalence of vitamin D deficiency in patients with foot and ankle injuries. Foot Ankle Int. 2014;35(1):8-13.

Warner SJ, Garner MR, Nguyen JT, Lorich DG. Perioperative vitamin D levels correlate with clinical outcome after ankle fracture fixation. Arch Orthop Trauma Surg. 2016;136(3):339-44.

5.2 – Vitamin C & CRPS (Martin Raglan)

Complex Regional Pain Syndrome (CRPS) is a significant problem for both patients and surgeons. It has a varied and dynamic presentation whose chief feature is pain out of proportion to the precipitating event, without an obvious underlying organic cause. The pain often follows a non-dermatomal distribution and there is a constellation of symptoms and signs that makes accurate diagnosis and subsequent management tricky. The literature uses several diagnostic criteria, which makes accurate comparison of prevalence of CRPS in the foot and ankle population difficult.

Properties of Vitamin C:

- Essential, water soluble vitamin
- Readily available from citrus and vegetables
- Co-factor in enzymatic reactions
- Physiological antioxidant
- Immune enhancement
- Absorption of iron

Therapeutic Effects:

- Accelerates fracture healing (animal models)
- Reduction of skeletal muscle injury
- Mitigates effects of mechanical allodynia
- Reduces free-radicles and inflammatory mediators

Randomised Controlled Trials (RCTs) for use of Vitamin C:

In humans there are currently three RCTs looking at the effects of Vitamin C in CRPS and these are all in distal radial fractures. In these RCTs the control groups were given a placebo and the intervention group was given various doses of Vitamin C at the time of their fracture, both groups were then assessed at 6 weeks and 1 year.

Placebo Controlled RCT	Placebo controlled RCT	Results
Erkol *et al.* 2014 252 Non-op 84 Surgery	Grp I - 167 pts (Placebo) Grp II - 169 pts (Vit C 500mg/50days)	CRPS 42% 6 weeks (16% at 1 yr) CRPS 42% 6 weeks (16% at 1 yr)
Zollinger *et al.* 2007 *(Multi centre)* 291 Non op 37 Surgery	Grp I - 99 pts (Placebo) Grp II - 96 pts (200mg Vit C) Grp II - 144 pts (500mg Vit C) Grp III - 118 pts (1.5g Vit C)	CRPS 10% at 1 Year CRPS 4% CRPS 2% CRPS 2%
Zollinger *et al.* 1999 All Non-Op	Grp I - 63 pts (Placebo) Grp II - 95 pts (500mg Vit C /50 days)	22% CRPS 7% CRPS 1 yr f/u

Only the work by Zollinger *et al*. supports the use of Vitamin C, but the study has several flaws, which limits the validity of their conclusion. These limitations include; high drop-out rate (30%), poor compliance with treatment (80%), no difference in CRPS at 6 weeks between the treatment groups and at one year very wide confidence intervals which limits interpretation of the results. Another RCT

by Erkol *et al.* was more robust in its methodology and subsequently failed to find any difference in CRPS rate and vitamin C prophylaxis.

Three subsequent meta-analyses have been carried out: 2 in favour and 1 against giving vitamin C. Interestingly, all the meta-analyses were carried out on the same RCTs, suggesting their results should be interpreted with caution.

There is only one study in Foot & Ankle (Besse *et al.*), which found in favour of giving Vitamin C in Foot & Ankle surgery patients. However, this was a 'before and after' quasi-experimental study design and due to its methodology the findings have to be interpreted with caution.

Summary:

- Vitamin C is an essential co-factor in multiple enzymatic reactions
- There is evidence in animal models of it being able to mitigate the effects of CRPS
- Human studies have shown mixed results
- However, given it has few side effects at the recommended doses it is worth considering as an adjunct in selected patients in Foot & Ankle practice

Consensus / Discussion

1. **How many participants currently take vitamin C supplementation?**

Yes	3 (10%)
No	27 (90%)

2. **How many surgeons currently advise vitamin C supplementation in elective foot and ankle surgery?**

Yes	4 (13%)
No	26 (87%)

3. **Following this Round Table Meeting, how many surgeons will advise Vitamin C supplementation in elective foot and ankle surgery?**

Yes	17 (57%)
No	13 (43%)

It was discussed that all studies suggest commencing vitamin C on the day of surgery, for a period of between 45 and 60 days. Differences seen are at one-year incidence of CRPS, with no changes at 6 weeks.

References:

Yilmaz C, Erdemli E, Selek H, Kinik H, Arikan M, Erdemli B. The contribution of vitamin C to healing of experimental fractures. Arch Orthop Trauma Surgery 2001; Jul 12197);426-8.

Keams SR, Daly AF, Shehan K, Murray P, Kelly C, Bouchier-Hayes D. Oral vitamin C reduces the injury to skeletal muscle caused by compartment syndrome. J Bone Joint surg Br. 2004 Aug;(86(6):906-11.

Keams SR, Moneley D, Murray P, Kelly c, Daly AF. Oral vitamin C attenuates acute ischaemic-reperfusion injury in skeletal muscle. J Bone Joint Surgery Br. 2001 Nov; 83(8):1202-6

Alcantara-Martos T, Delgado-Martinez AD, Vega MS, Carrascal MT, Munuera-MartinezL L. Effect of Vitamin C on fracture healing in elderly Osteogenesis disorder Shionogi rats. J Bone Joint Surg Br. 2007 Mar;89(3):402-7.

Besse JL, Gadeyne S, Galand-Desme S, Lerat JL, Moyen B. Effect of vitamin C on prevention of complex regional pain syndrome type 1 in foot and ankle surgery. Foot and Ankle Surgery 15(2009) 179-182.

Ekrol I, Duckworth A, Ralston S, Court-Brown C, McQueen M. The influence of Vitamin C on the Outcomes of Distal radial fractures. J Bone Joint Surg Am. 2014;96:1451-9.

5.3 – Bisphosphonates in Charcot Arthropathy (Natasha Hossain)

Charcot neuropathic osteoarthropathy (CNO) is a non-infectious destructive process affecting the bone and joint structures that results from significant peripheral neuropathy of almost any aetiology. It leads to dramatic deformities and recurrent ulceration that can lead to amputation.

Pathogenesis of Charcot Neuropathic Osteoarthropathy:

- Controversial and not completed understood
- Neurotraumatic *versus* neurovascular
- Bone resorption and osteoclastic hyperactivity are major early features

Although there is currently no proven pharmacological treatment, administration of bone resorption inhibiting agents like bisphosphonates have been thought to be a reasonable pharmacological agent for its treatment.

Evidence for Bisphosphonates:

Majority of the published papers provide low grade evidence for the usage of bisphosphonates in acute CNO. Out of 4 clinical trials published only 3 were RCTs. Taking into account the problems with the trials, overall bisphosphonates appear to be associated with a rapid decrease in the skin temperature but this effect does not appear to be sustained and it is unclear if it results in an improvement in pain.

All studies, however, demonstrated a reduction in bone turnover markers in the bisphosphonate groups. All studies consistently demonstrated a decrease in the serum ALP level, a marker for osteoblastic rather than osteoclastic activity. Although bisphosphonates may have a clinical benefit, the results published to date have been inconclusive, and long-term outcomes are not available. In some cases, the use of bisphosphonates appeared to be detrimental to the resolution time of the acute stage.

Summary:

- At present, there is little evidence to support the routine use of bisphosphonates in patients with acute Charcot Neuropathic Osteoarthropathy
- NICE does not recommend the routine use of bisphosphonates outside the setting of a clinical trial
- Based on the available evidence this recommendation is justified and further research in this area is required

Consensus / Discussion

1. **How many surgeons would commence bisphosphonates in diabetic patients or refer to an endocrinologist for consideration of bisphosphonates?**

Yes	0
No	30 (100%)

References:

Richard JL, Almasri M, Schuldiner S. Treatment of acute Charcot foot with bisphosphonates: a systematic review of the literature. Diabetologia. 2012 May;55(5):1258-64.

Anderson JJ, Woelffer Ke, Holtzman JJ, Jacobs AM. Bisphosphonates in the treatment of Charcot Neuroarthropathy. J Foot and Ankle Surgery. 2004 Sept-Oct; 43(5):285-9.

Jude EB, Selby PL, Burgess J, Lilleystone P, Mawer EB, Page SR, et al. Bisphosphonates in the treatment of Charcot neuroathropathy; a double-blind randomised controlled trial. Diabetologia. 2001 Nov;44(11):2032-7.

National Institute for Health and Care Excellence. Diabetic foot problems: prevention and management. https://www.nice.org.uk/guidance/ng19 (date last accessed 14/09/2017).

Pitocco D, Ruotolo V, Caputo S, Mancini L, Collina CM, et al. Six-month treatment with alendronate in acute Charcot neuroarthropathy: a randomized controlled trial. Diabetes Care. 2005 May;28(5):1214-5.

Pakarinen TK, Laine HJ, Maenpaa H, Mattila P, Lahtela J. The effect of Zoledroic acid on the clinical resolution of Charcot neuroarthropathy. Diabetes Care 2011; 34:1514-1516.

Bharath R, Bal A, Sundaram S, Unnikrishnan AG, Praveen VP, Bhavani N, et al. A comparative study of zoledronic acid and once weekly Alendronate in the management of acute Charcot arthropathy of foot in patients with diabetes mellitus. Indian J Endocrinol Metab. 2013 Jan;17(1):110-6.

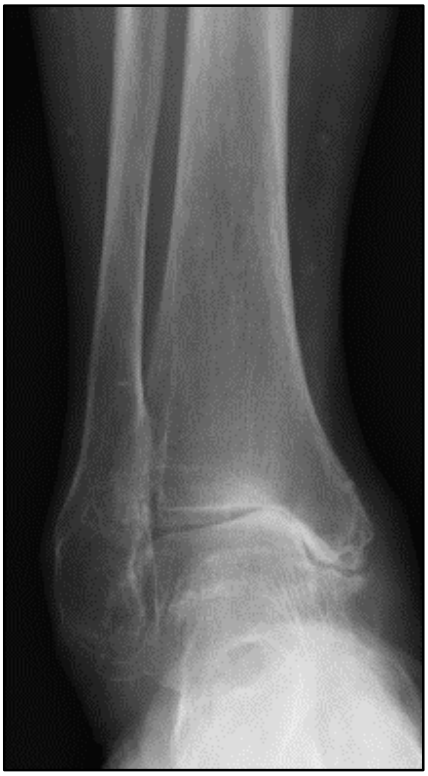
Session 6: Ankle Replacements

6.1 – Varus Ankle, Medial Osteoarthritis (Robert Clayton)

Traditional teaching has it that significant coronal deformity is a contraindication to TAR. Cut-off values of 10 or 20 degrees of varus have been proposed. While this seems intuitive, there is little evidence to support this. Various case series to support TAR in high degrees of varus have been published. However, only short term follow-up for these patients has been reported and it is not clear how applicable these results are to the wider foot and ankle community.

Varus deformity is either intra-articular, extra-articular or both. The steps in the correction of intra-articular varus are:

- Soft tissue correction
- Bony correction



Steps in Soft Tissue Correction:

- Deltoid release
- Ensuring CFL is not interposed in lateral gutter
- Excision of lateral gutter osteophytes

Steps in Bony Correction:

- Tibial resection to correct medial soft tissue tension
- Correction of rotation deformity (varus often associated with increased external rotation)

Adjunctive procedures are considered for correction of extra-articular (supra or infra-malleolar) deformity. In a varus heel, a Dwyer osteotomy of the calcaneus can be performed. If there is a cavus foot deformity, then elevation of the first ray and other adjunctive procedures may be added. In more extreme deformity, or the presence of arthritis in other joints, a triple fusion can be carried out instead.

Supramalleolar osteotomy in conjunction with TAR has been described by some surgeons. It is essential to ascertain that the deformity truly does arise above the ankle rather than from differential wear in the ankle, or both. In cases of severe lateral soft tissue laxity, reconstructive options include a simple Brostrom, an anatomical ligament reconstruction or a peroneus longus to brevis transfer.

Summary:

- Significant varus deformity has traditionally been thought of as a contraindication to Total Ankle Replacement
- There is some evidence that good results can be obtained in the short term even in the face of significant deformity
- In order to tackle these complex cases, the surgeon should take into account the location of the primary and associated deformities and perform the required soft tissue, bony, and adjunctive procedures

References:

Nieuwe Weme RA, van Solinge G, N Doornberg J, Sierevelt I, Haverkamp D, Doets HC. Total ankle replacement for posttraumatic arthritis. Similar outcome in postfracture and instability arthritis: a comparison of 90 ankles. Acta Orthop. 2015;86(4):401-6.

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Hobson SA, Karantana A, Dhar S. Total ankle replacement in patients with significant pre-operative deformity of the hindfoot. J Bone Joint Surg Br. 2009 Apr;91(4):481-6.

Kim BS, Choi WJ, Kim YS, Lee JW. Total ankle replacement in moderate to severe varus deformity of the ankle. J Bone Joint Surg Br. 2009 Sep;91(9):1183-90.

Mayich DJ, Daniels TR. Total ankle replacement in ankle arthritis with varus talar deformity: pathophysiology, evaluation, and management principles. Foot Ankle Clin. 2012 Mar;17(1):127-39.

Trajkovski T, Pinsker E, Cadden A, Daniels T. Outcomes of ankle arthroplasty with preoperative coronal-plane varus deformity of 10° or greater. J Bone Joint Surg Am. 2013 Aug 7;95(15):1382-8.

Sung KS, Ahn J, Lee KH, Chun TH. Short-term results of total ankle arthroplasty for end-stage ankle arthritis with severe varus deformity. Foot Ankle Int. 2014 Mar;35(3):225-31.

6.2 – Valgus Ankle Osteoarthritis (Bob Sharp)

Up to 55% of patients having total ankle replacements in the published literature are described as having some pre-operative deformity. Although the vast majority of these are varus deformities, valgus deformities also occur.

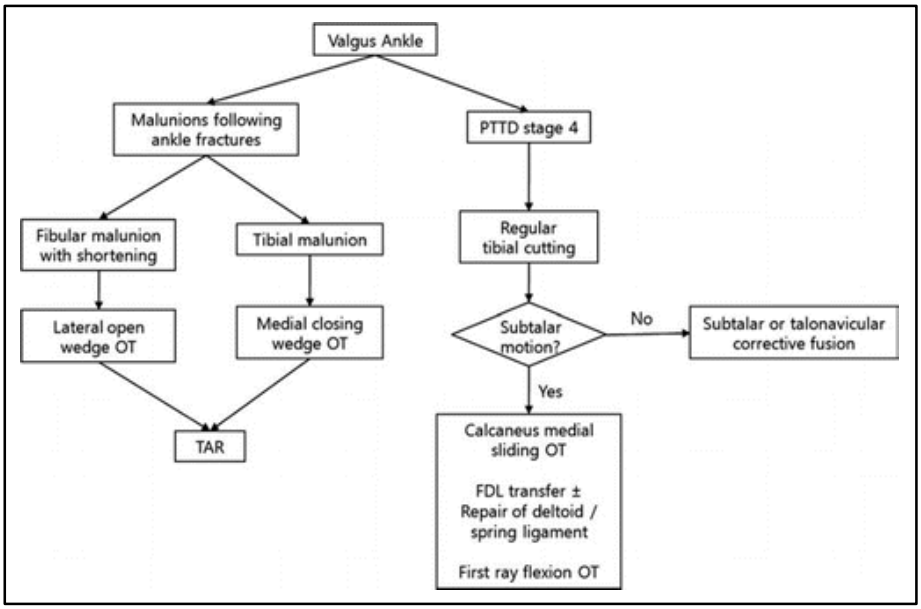
Potential Components of a Valgus Ankle Deformity:

- Alignment of distal tibia
- Abnormality of tibio-talar joint alignment (congruent or incongruent)
- Position and orientation of the hindfoot
- Generally accepted as talar tilt > 5 degrees

Valgus deformities occur most commonly from fibular shortening following an ankle fracture or from advanced tibialis posterior pathology. However, ankle deformities are not simple uniplanar deformities. Coronal deformities are often associated with sagittal as well as rotational deformities. A congruent joint is where the tibial and talar surfaces are both mal-aligned and an incongruent joint is where the talus is mal-aligned within the ankle joint.

The Finnish, Swedish, and Norwegian Registries report significant failure rates of TAR in valgus ankles (up to 39%). Other literature suggests better outcomes are achieved in congruent deformities and where the deformities are fully corrected. One possible reason for the higher failure rate in valgus ankles is the increased contact pressures on the polyethylene inlay. Incomplete deformity correction can lead to lateral shearing of the inlay and talar components.

There is no consensus on the upper limit of acceptable pre-operative valgus deformity. Many papers suggest a cut off of 20-25 degrees but there is evidence to suggest patients with greater degrees of deformity can have good outcomes if reconstructed appropriately. Dhar *et al.* showed no difference in failure rates between <10 degrees and <30 degrees valgus deformity at 4 years.



Multiple techniques have been described to deal with valgus deformity. Schuberth suggests a 2 stage procedure involving correcting deformities and subsequent TAR. Other techniques include larger bone cuts and thicker inlays, and adjunctive procedures such as triple arthrodesis, or calcaneal osteotomy to correct deformities and align the hindfoot. The literature also suggests that there is a learning curve associated with TAR and that surgeon complication rates improve after 30 ankle replacements have been performed.

Summary:

- There are a number of components to a valgus ankle
- All of these must be addressed adequately in severe deformity in order to achieve a good result
- Multiple techniques have been described to address the associated deformities
- These are complex cases which should be performed by surgeons experienced in TAR

Consensus / Discussion (For 6.1 & 6.2)

1. **How many surgeons felt that a weight bearing view of the ankle, with the lower third of the tibia visible would give a reasonable view on which to assess varus/valgus deformities at the ankle?**

Yes	28 (93%)
No	2 (7%)

It was discussed that over one third of patients have differing tibial axis and mechanical axis and that ideally long leg measurement films should be used to fully assess overall limb alignment. This may not be available at all centres and in these cases at least a knee and ankle weight-bearing XR should be obtained for complex cases. It was also discussed that pre-operative CT may be useful in complex cases given the evidence of the high incidence of pre-operative talar cysts. This will also allow the surgeon to assess the torsional profile on the tibia

2. **How many surgeons would be willing to take on a deformity of more than 10 degrees varus?**

Yes	15 (50%)
No	15 (50%)

There is much debate on exact definitions of varus/valgus deformities of the ankle. Overall view is of a much more complex, multi-planar deformity with many adjunct procedures to correct deformity applied extra-articular to the ankle joint. One of the main issues at present is tibial rotational profile and the fact that no designs at present address this issue.

3. **In an osteoarthritic ankle with valgus deformity with an adjacent symptomatic pes planus deformity (Grade II tibialis posterior dysfunction with an intact deltoid), what is your preferred order of correction?**

Pes Planus Correction + TAR at same time	4 (13%)
Staged: TAR first	1 (3%)
Staged: Pes planus first	16 (53%)
Undecided	9 (30%)

4. **Given the extent of adjuvant surgery required and the time restrictions on surgery, how many surgeons would be happy to allow a tourniquet time at 300mmHg of:**

Maximum of 2 hours	11 (37%)
Maximum of 2 ½ hours	16 (53%)
Maximum of 3 hours	3 (10%)

References:

Fukuda T, Haddad SL, Ren Y, Zhang LQ. Impact of talar component rotation on contact pressure after total ankle arthroplasty: a cadaveric study. Foot Ankle Int. 2010 May;31(5):404-11.

Pyevich MT, Saltzman CL, Callaghan JJ, Alvine FG. Total ankle arthroplasty: a unique design. Two to twelve-year follow-up. J Bone Joint Surg Am. 1998 Oct;80(10):1410-20.

Wood PL, Deakin S. Total ankle replacement. The results in 200 ankles. J Bone Joint Surg Br. 2003 Apr;85(3):334-41.

Hobson SA, Karantana A, Dhar S. Total ankle replacement in patients with significant pre-operative deformity of the hindfoot. J Bone Joint Surg Br. 2009 Apr;91(4):481-6.

Kim BS, Choi WJ, Kim YS, Lee JW. Total ankle replacement in moderate to severe varus deformity of the ankle.J Bone Joint Surg Br. 2009 Sep;91(9):1183-90.

Colin F, Bolliger L, Horn Lang T, Knupp M, Hintermann B. Effect of supramalleolar osteotomy and total ankle replacement on talar position in the varus osteoarthritic ankle: a comparative study. Foot Ankle Int. 2014 May;35(5):445-52.

Hobson SA, Karantana A, Dhar S. Total ankle replacement in patients with significant pre-operative deformity of the hindfoot. J Bone Joint Surg Br. 2009 Apr;91(4):481-6.

Shock RP, Christensen JC, Schuberth JM. Total ankle replacement in the varus ankle. J Foot Ankle Surg. 2011 Jan-Feb;50(1):5-10.

6.3 – Revision Total Ankle Replacement (Senthil Kumar)

Revision of a failed TAR to another TAR has only a small evidence base. Mostly case series, with custom implants commonly used. There are only two studies reporting on revision to TAR.

How do TARs Fail?

- Deep infection
- Recurrent deformity and loosening
- Periprosthetic cysts
- Aseptic loosening (subsidence/tilting)
- Unexplained pain

Aseptic loosening / tilting:

- Usually due to poor alignment of components
- Lack of bony integration
- Realignment surgery
- Revision to TAR or fusion

Literature results of Revision of TAR to TAR:

The literature on revision of TAR to TAR is sparse. Majority of the studies are case series using custom implants. There are 2 published larger series.

Hintermann *et al.*

- 83 ankles
- Mean follow-up: 64 months
- Excellent/Good: 69
- Satisfactory: 12
- Fair: 2
- Revisions: 3 (2 TAR, 1 fusion)

Ellington *et al.*

- 53 ankles (41 had follow-up)
- Mean follow-up: 49 months
- 54% had concomitant subtalar fusion
- Custom talar component in majority
- 5 pts converted to fusion,
- 2 pts went on to amputation

Experience of revision TAR at Glasgow Royal Infirmary:

- 18 revision TAR's since 2014 (16 Mobility, 1 STAR, 1 Hintegra)
- All converted to Inbone
- 12 pain-free, 3 moderate pain, 2 significant pain (? Cause: well-fixed prosthesis)
- No further interventions, no infections

Summary:

- Revision of TAR to a further TAR is a viable option
- Patients may prefer it to conversion to a fusion
- Dedicated revision instrumentation is required
- Further studies with long term follow-up are required

Consensus / Discussion

1. **How many Total Ankle Replacements have you revised to another Total Ankle Replacement?**

> 20	1 (3%)
5-20	3 (10%)
< 5	26 (87%)

2. **How many surgeons feel primary TAR should be performed under image intensifier guidance?**

Yes	30 (100%)
No	0

References:

Hintermann B, Barg A, Knupp M. Revision arthroplasty of the ankle joint. Orthopade 2011;40:1000–7.

Ellington JK, Gupta S, Myerson MS. Management of failures of total ankle replacement with the agility total ankle arthroplasty. J Bone Joint Surg Am. 2013 Dec 4;95(23):2112-8.

6.4 – Fusion to Total Ankle Replacement (Tim Clough)

Potential indications for Fusion to TAR include:

- Non-union
- Mal-union
- Ongoing pain (may be due to adjacent joint OA)

Evidence for conversion of Ankle Arthrodesis to TAR:

There is a paucity of evidence of TAR following failed ankle fusion. Hansen *et al.* reported a series of 23 ankles (5 pts with subtalar OA, 2 with non-union, 3 with malunion, and 9 with no cause for pain identified). All were revised to an Agility TAR and 19 were followed-up for a mean of 39 months. Adjunctive procedures were performed in majority of cases and included bony and soft tissue corrective procedures. Intra-operative fractures were sustained in 43% of cases. Revision was required in 5 cases and amputation in 3 cases. The authors concluded that poor results were seen particularly in the group with a previous fibular excision and those with unknown cause for pain.

Hintermann *et al.* reported on 30 conversions with a mean follow-up of 55 months. They used the Hintegra prosthesis and performed subtalar and talonavicular fusions in 13 cases. They sustained intra-operative fractures in 17% of cases. They did not have any amputations and, in contrast to the previous authors, reported good outcomes in all 7 patients who had previous fibular excision. Painful arthrofibrosis was reported in 13% and 1 patient required further revision. They report good outcomes in 5 patients but ongoing pain in 26 (86%).

Nunley *et al.* reported on 23 ankles revised to Inbone (14 pts), STAR (17 pts) or Salto (2 pts). Concomitant fusions were performed in 7 cases. They performed prophylactic malleolar fixations in 16 cases and sustained intra-operative malleolar fractures in 2 cases where they did not perform prophylactic fixation (29%). No patients required amputation and 3 patients required further revision for failure on the talar side. They found, again, that previous fibular excision at time of initial fusion was associated with a poorer outcome.

Further series by Anderson *et al.* and Preis *et al.* looked at 5 and 18 ankles respectively. The smaller series reported no complications and an 80% satisfaction rate (4/5). The larger series reported 2 intra-operative fractures (11%) and 1 patient who required revision. Acceptable results were reported in 16 cases (89%).

Summary:

- Revision of Ankle Fusion to TAR is a technically difficult procedure
- Previous fibular excision is associated with poor outcome
- The rate of intraoperative malleolar fractures is high
- Results are better if a clear cause for the pain / source of pain is identified
- A high rate of adjunctive procedures can be expected
- Expected outcomes from the literature: Good: 15%, Acceptable: 65%, Poor: 20%

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6.5 – Fusion for Failed Total Ankle Replacement (Patricia Allen)

Arthrodesis following failed total ankle replacement presents additional challenges to those encountered in primary arthrodesis. Whilst the overall aims remain the same – to achieve stable bony union in a functional position whilst maintaining the vascularity of the foot, consideration must be given to additional problems that may be encountered.

Challenges of TAR to Fusion:

- Poor soft tissue envelope
- Bone stock loss / avascular bone
- Achieving adequate / stable fixation
- May require staged procedure
- Poor hold of screws / plates
- Eradication of any infection

Planning Surgery:

- Planning approach
- Accommodating for bone loss – if larger than 2cm defect may need interposition arthrodesis
- Choice of graft (autograft / allograft / mesh cages)

Screw fixation of the tibio-talar joint alone provides the most favourable results but is not always feasible in the presence of bone stock loss. In these cases, the subtalar joint must be sacrificed and fixation achieved with an intramedullary nail if possible or a plate. Prolonged non-weight bearing post operatively is generally recommended.

Outcome following arthrodesis for failed total ankle replacement is less favourable than primary arthrodesis. Union rates of 50-90% have been reported with the highest union rates are seen in pure tibio-talar arthrodesis. Kamrad *et al.* reported the outcome of 188 TAR failures from the Swedish registry. 118 were revised to an arthrodesis but although union was achieved in 90% at the first surgery, patient satisfaction scores were low with only 47% being satisfied. The results of arthrodesis however were better than those of revision TAR.

A systematic review of the literature (Gross *et al.*) showed that the overall union rate was 81% at primary surgery with the best results achieved when intercalary bone graft was used or fixation was achieved with a blade plate. Tibio-talo-calcaneal arthrodesis with a cage had the worst results with a 50% union rate, although they may represent a more complex group. The overall complication rate was over 18%.

Summary:

- Arthrodesis for failed TAR is a challenging procedure which needs careful planning
- The complication rate is high
- Even if union is achieved patients may not be satisfied
- Results are better if the subtalar joint is preserved
- Overall satisfaction is lower than primary ankle arthroplasty but superior to revision to further TAR

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