The surgical outcomes of Diabetic Foot Osteomyelitis treated with antibiotic loaded Bio-Composites

A single centre cohort study

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Diabetic foot osteomyelitis

DFO ~20% of those with DFU which may precede amputation (Edmonds et al, 2021) (Mutluoglu et al., 2013)

Major Amputation carries a ~ 50% / 5 year mortality risk (Armstrong et al., 2020)

Diagnosed with combination of clinical, radiological and serological investigations (+ve PTB test, plain radiographs, serum biomarkers +/- advanced imaging) (Senneville et al., 2023)

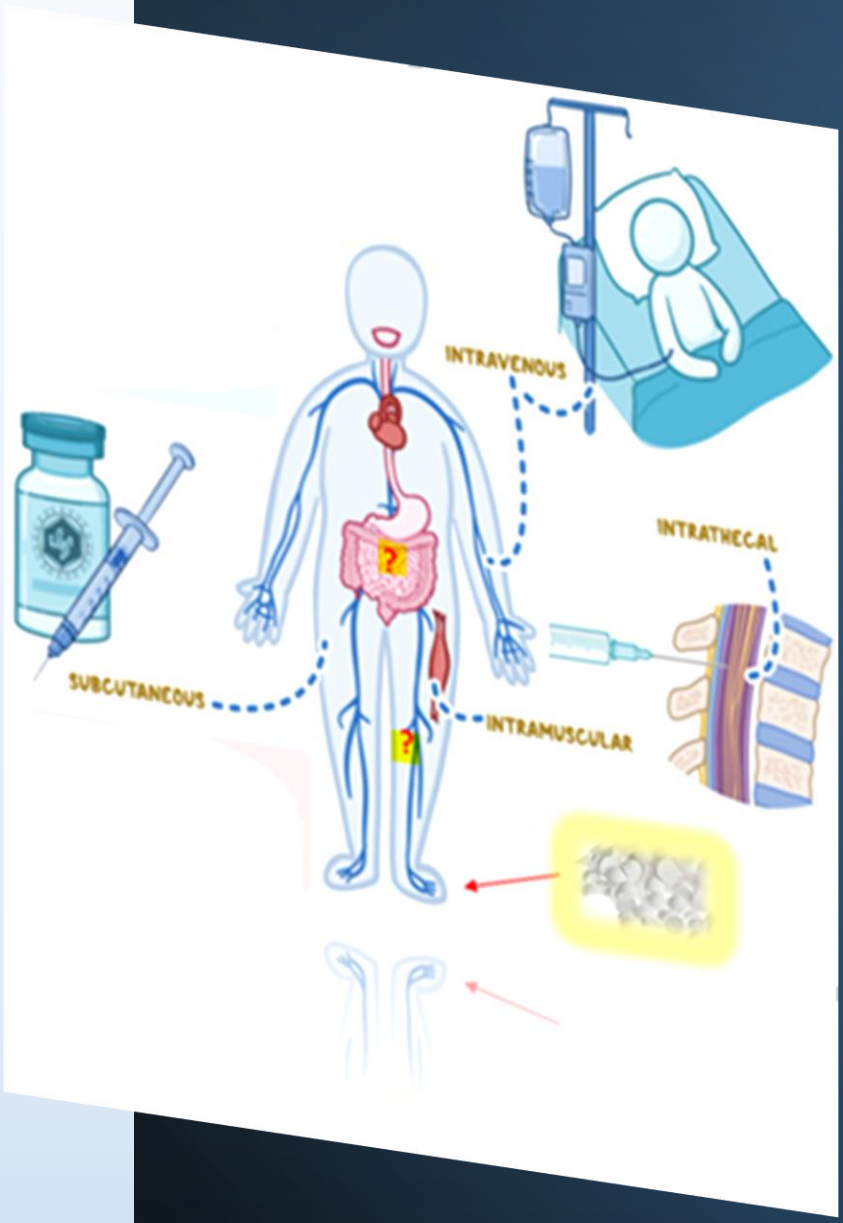
Typically managed with oral/pareneteral antibiotic therapy over 6/52 period (Wukich et al, 2016)

GWH management

- Potential benefits of local antibiotics:
    - Direct high concentrations to infectious material > MIC (Lin et al., 2022)
    - Sustained release ++> MIC high enough to be effective vs mature biofilm (Price et al., 2016)
    - Decreased reliance on systemic delivery
    - Avoid deleterious effects (CDAD, organ toxicity) (Tamma et al., 2017)
    - Potential to help control antibiotic resistance

- Local antibiotic impregnated Bio-Composite material *+/-* systemic antibiotic therapy ≅ 6 weeks

1. Cerament® Vancomycin or Gentamycin
2. Stimulan RapidCure® Vancomycin/Gentamycin
3. Collatamp Gentamycin



Standard practice or fools gold ?

"There remains uncertainty regarding its proven efficacy and long term effects" SR* (Marson et al., 2018)

"Conditional: low evidence base" (Senneville et al., 2023)

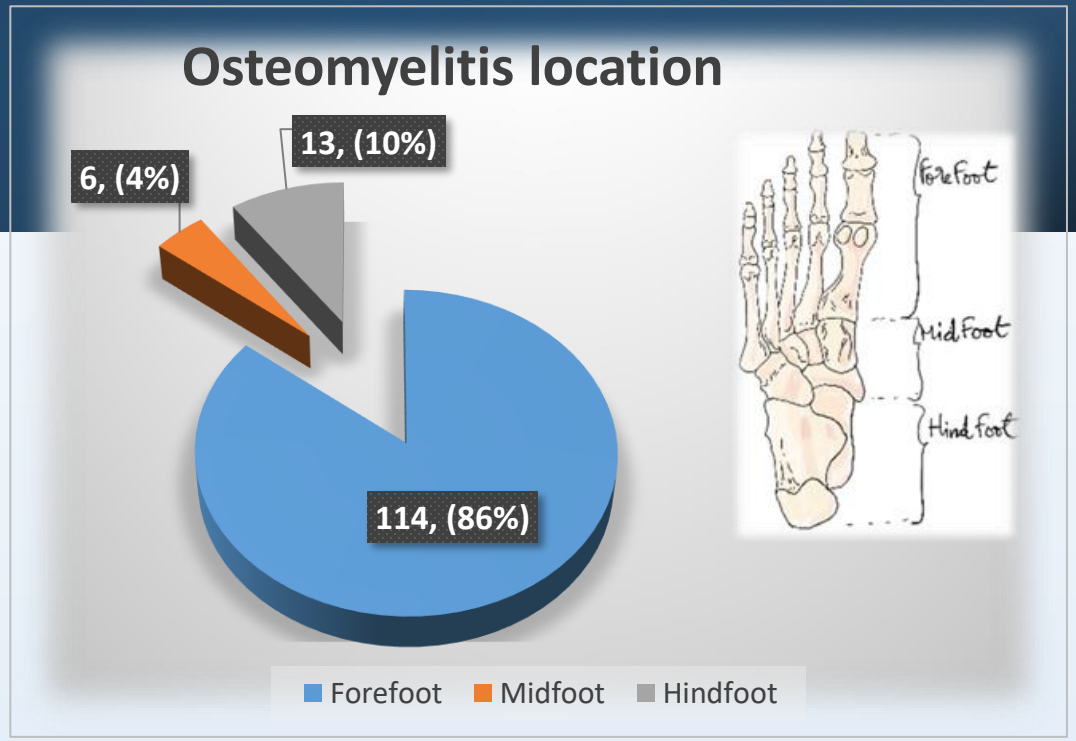
- To determine the efficacy of surgical intervention on diabetic foot osteomyelitis (DFO) treated with antibiotic impregnated Bio-composite(s)

- Primary outcomes – direct/indirect reoperation rates / 1 year
- Secondary outcomes – reinfection rates, limb salvage / 1 year

IWGDF Guidelines

Cohort

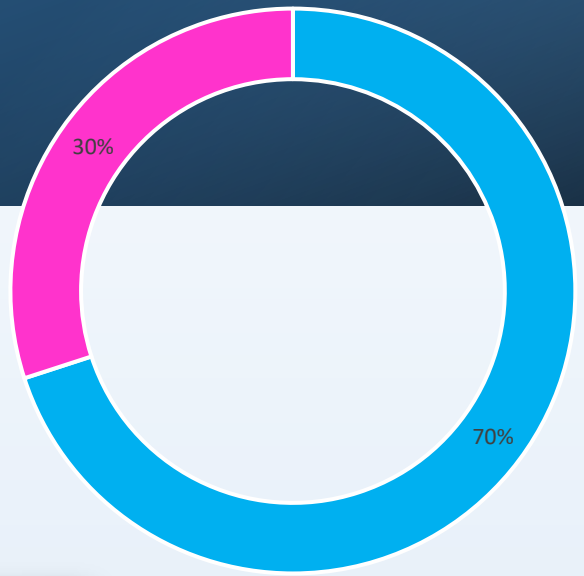
- 133 Consecutive DFO cases/5 years
- Range of conservative & ablative procedures included (debridment/amputation/washout)
- All involved biocomposite implantation (Cerement G/V, Stimulan G/V, Collotamp G +/- systemic antibiotics)
- Range of techniques: Capping, Silo infiltration, Packing, Interposition arthroplasty



Amputation 2 rays +	11	8.27%
Amputation single ray	53	39.85%
Calcanectomy	1	0.75%
Chopart	1	0.75%
Debridement/washout	31	23.31%
Drill & fill	18	13.53%
TMA	18	13.53%
Grand Total	133	100.00%

Cohort

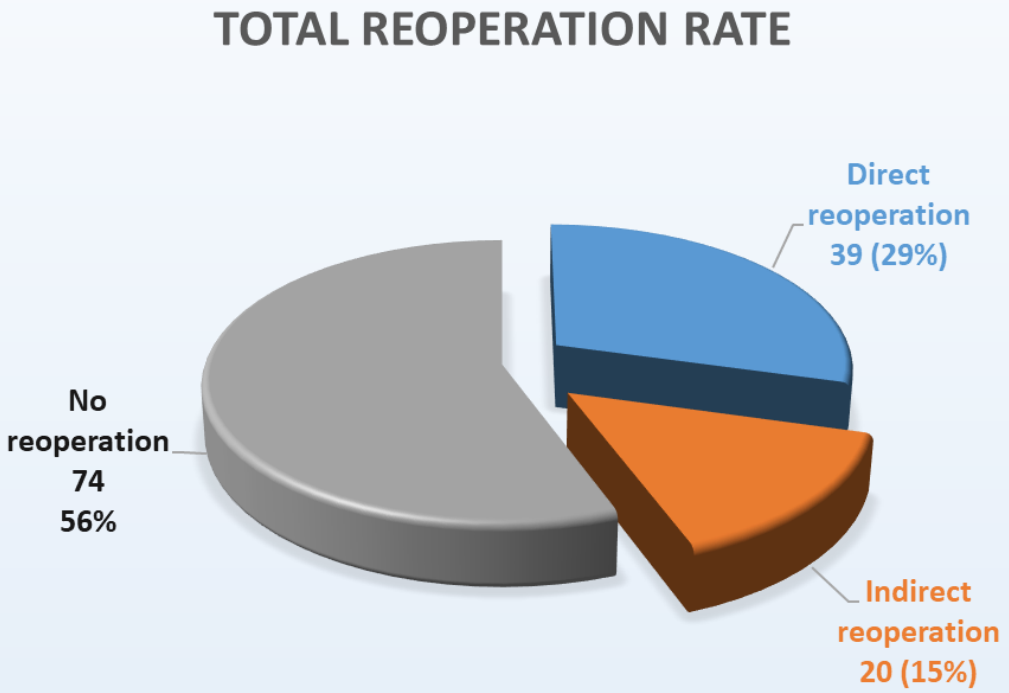
- Male 2:1 female
- Min/max 1 year follow up
- DFO cases confirmed by +ve histo/micro findings in all cases
- Additional variables: indirect (adjacent) reoperations; Proportion of susceptible organisms to implanted material, Diabetes, Vascular, Nutritional status

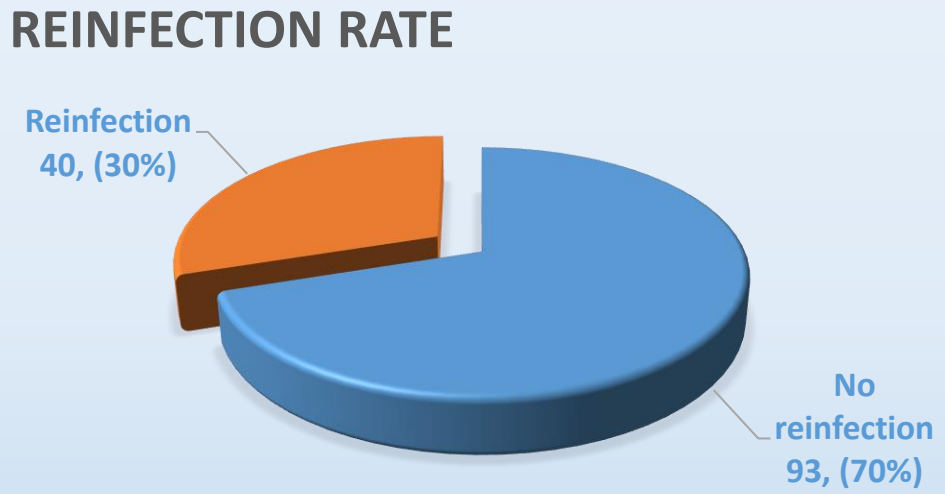


Results

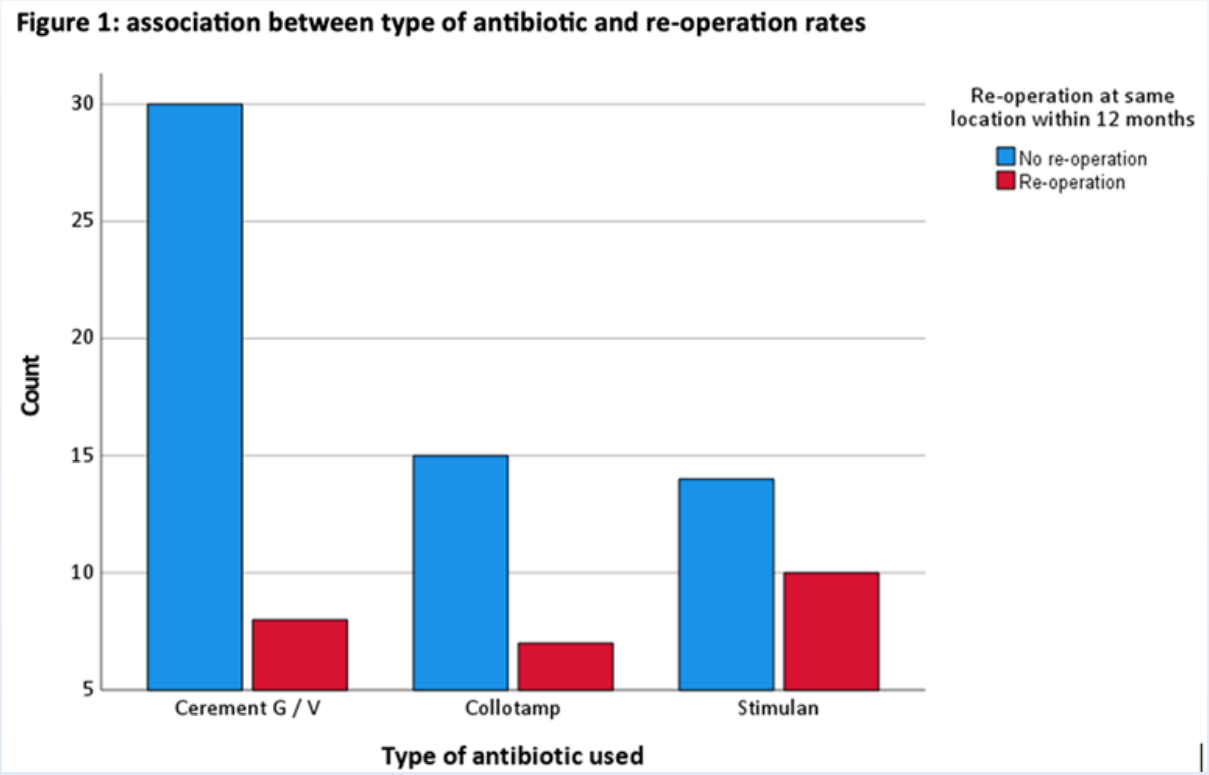
- Reinfection rate 30.1% (95% CI 22.3 - 37.9%)
- Reoperation rate (Directly related) 29.3% (95% CI, 20-39.5%)

- Comparable with similar centres:
  - ✓29.4% (Kings College NHSFT) mean f/u 30 months (Kavarthapu et al., 2023)
  - ✓24.7% (Javier Aragón-Sánchez et al., 2013)

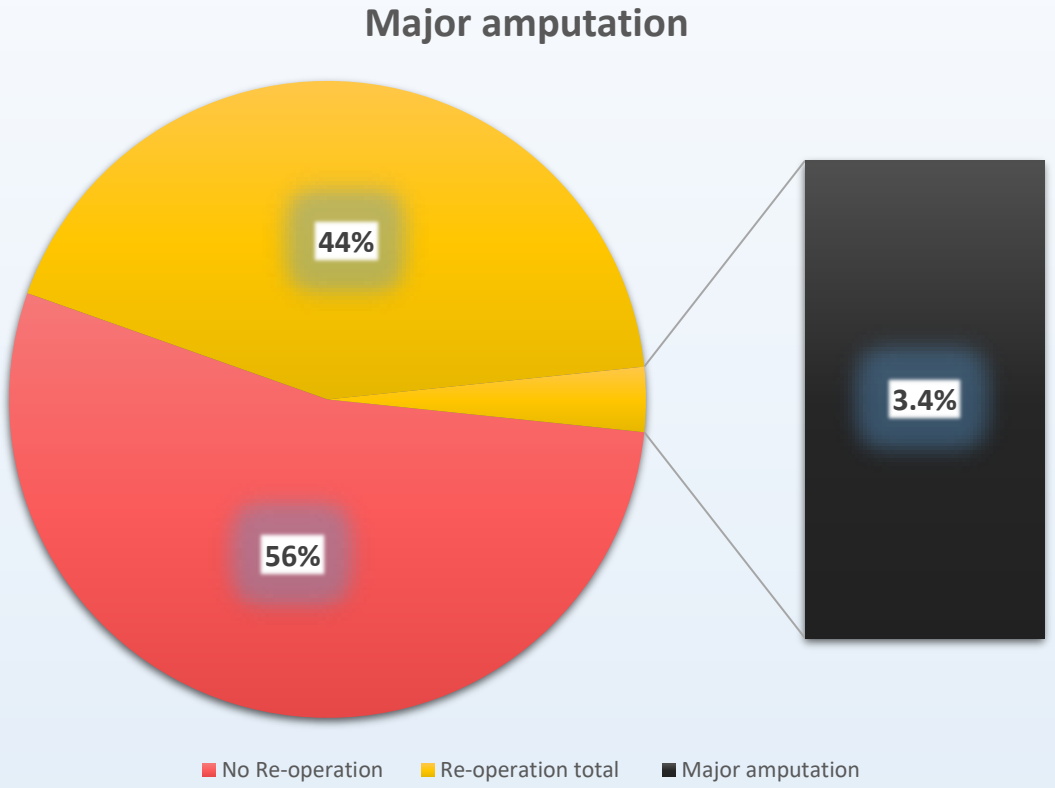




Results



- 84/133 had a (∧ 50%) sensitivity of the micro isolates
- A χ^2 test ($\chi^2_{(2)}$=3.05; p=0.218).

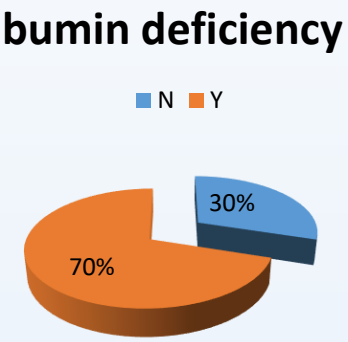


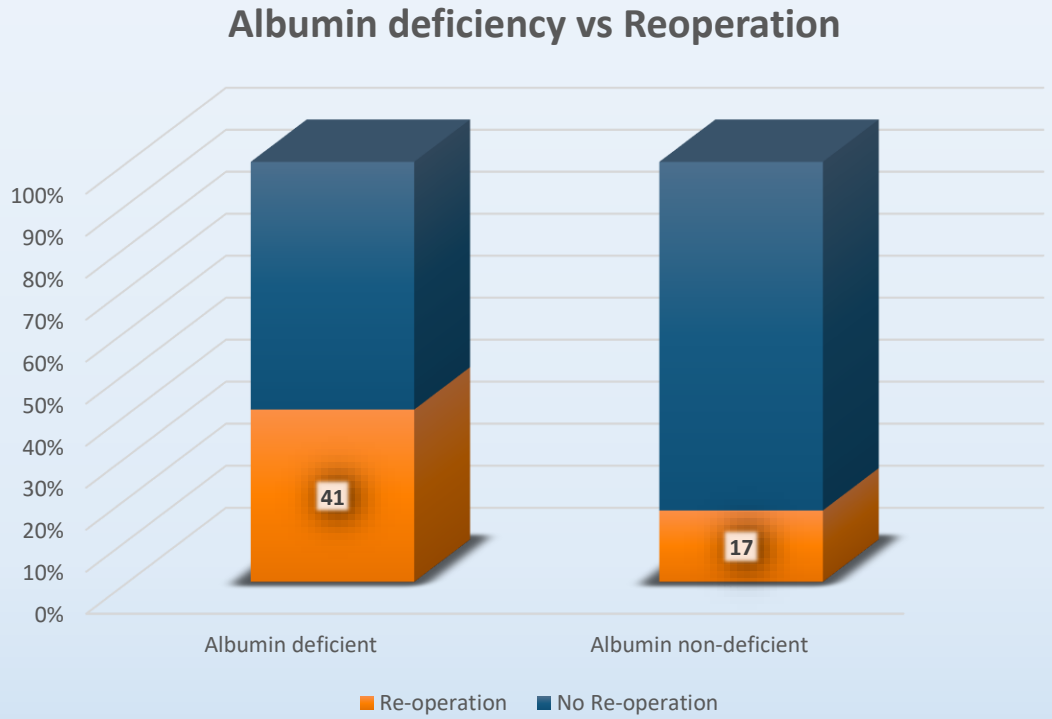
- Major (re) amputation rate 3.4%
- ~8%/47 weeks (Wukich et al., 2016)

- Total cohort limb salvage rate of rate 98.5% / 1 year
- ~ 98.8% (Javier Aragón-Sánchez et al., 2013)

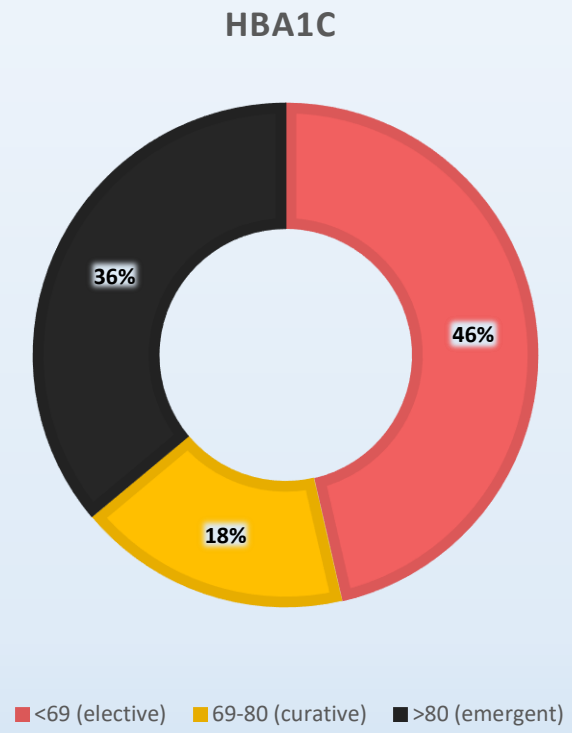
Hypoalbuminemia

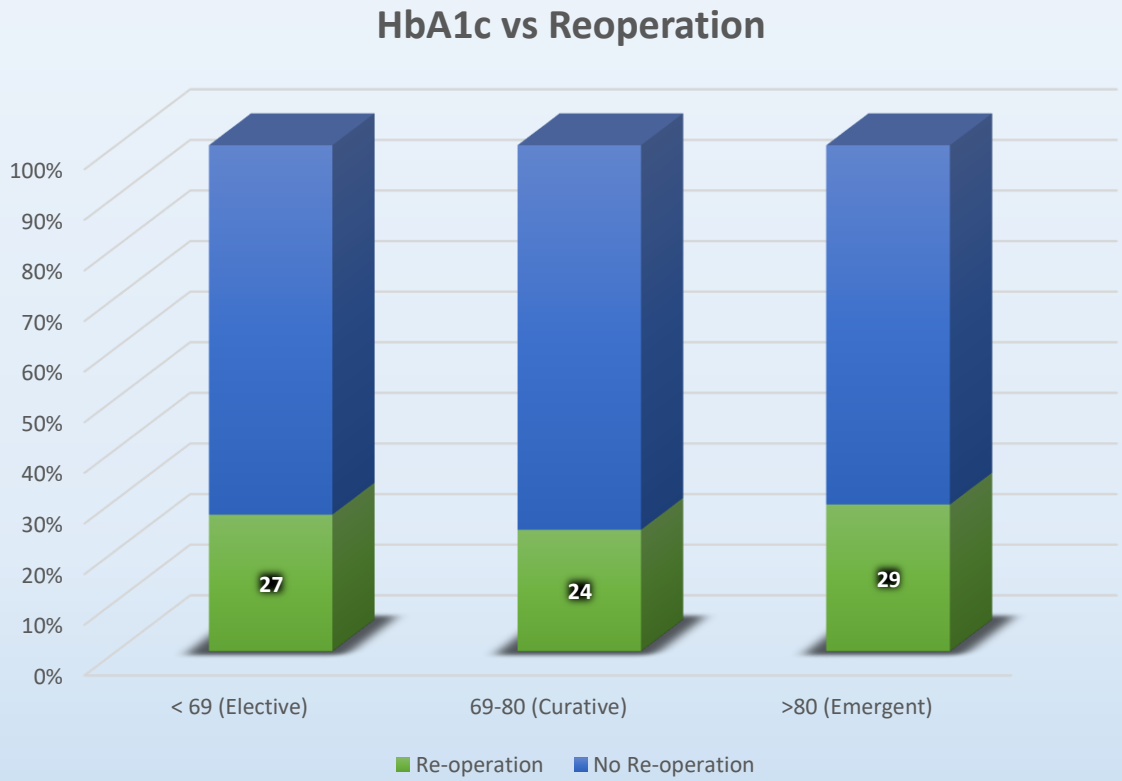
- 70% deficient <3.5g/dl
- 41% of those deficient required reoperation compared with 17% in the non-deficient group
- ∴ patients with albumin deficiency were just under **2.5x** more likely to require reoperation
- An independent risk factor for reoperation and in orthopaedic trauma patients (Wilson et al., 2019)



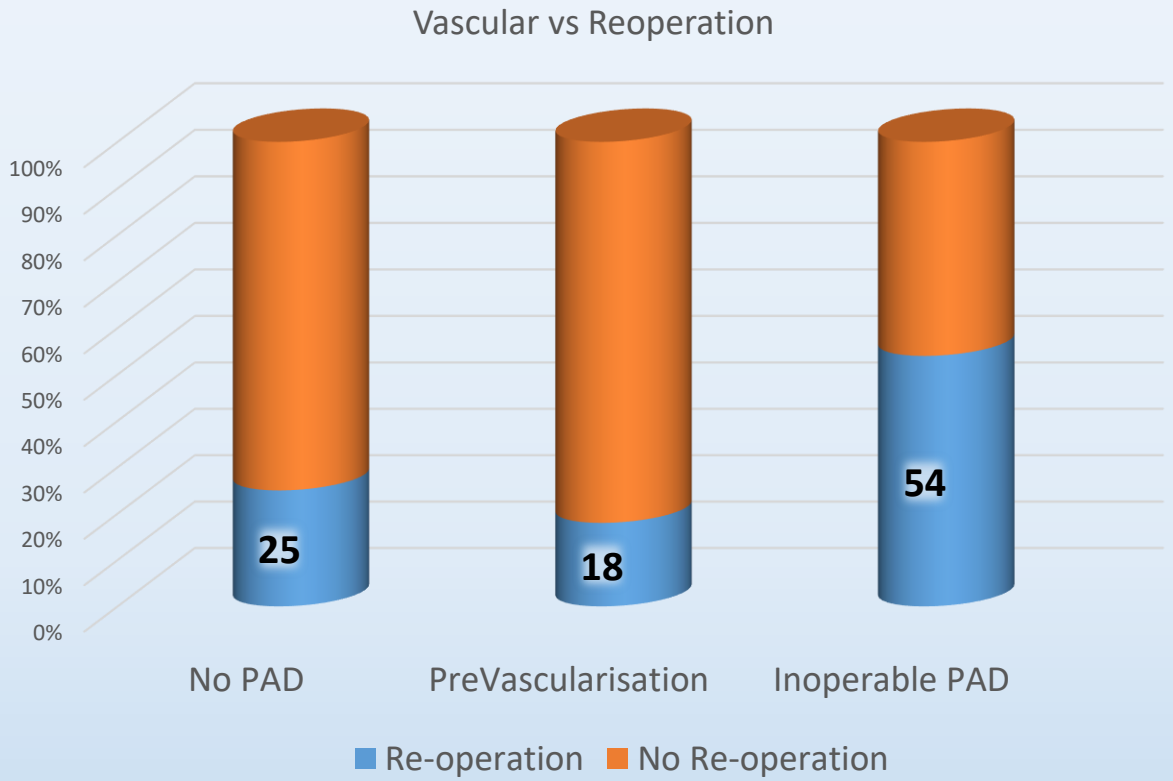


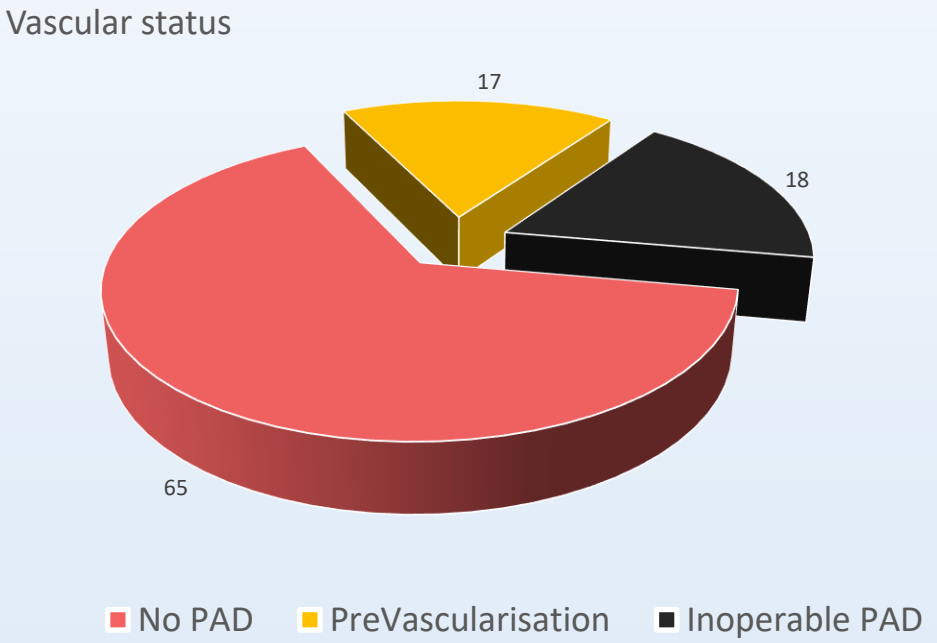
Diabetes (HbA1c) status





Vascular status





Conclusions

Reoperation rates at GWH are comparable with other institutions

The proportion of cases requiring re-operation is highest in patients prescribed Stimulan and lowest in patients prescribed Cerement antibiotics (Irrespective of Vascular/Diabetes status)- *substantive, but not significant

When accounting for additional operative treatment on adjacent areas, this implies that up to 44.4% of patients will require a further operation on their foot in the first 12 months following surgery at our institution

There remains a need to prove safe and effective outcomes when utilising antibiotic loaded biocomposite material to support its growing/widespread use.

Thanks for your time.

- **James Craven**
- Specialist Registrar Podiatric Surgery
- GWH & STH NHSFTs

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