Clinical and Patient-Reported Outcomes Following Low Intensity Pulsed Ultrasound (Exogen) For Established Post-traumatic and Post-surgical Nonunion in the Foot and Ankle

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BACKGROUND

- Surgery for nonunion can achieve 68%-96% union rates but is associated with its inherent risks, is technically difficult and may still fail in some cases due to multiple reasons.
- Biophysical methods including LIPUS are being used as alternate to surgery.
- LIPUS is well-documented to enhance the healing rate of fractures and post-surgical nonunions, however variable results exist in the literature.

AIMS & OBJECTIVES

- To prospectively review the clinical and patient-reported outcomes of the patients treated with LIPUS (Exogen, Bioventus, UK) following post-traumatic and post-surgical nonunion in the foot and ankle.

METHODOLOGY

- 50 consecutive patients with established nonunions over 3 years period.
- Choice of revision surgery and LIPUS treatment discussed with patients.
- High-frequency LIPUS self-administered by the patients to the nonunion site for 20 minutes everyday.

- MOXFQ, EQ-5D and VAS data collected on regular follow-up visits.
- Plain X-rays and/or CT scans used for assessment of union.

- Patients divided in to 3 groups:

  A : Fractures (Tibia/Ankle) – n=15
  B: Hindfoot procedures (ankle fusion /subtalar fusion/tibio-talo-calcaneal (TTC) – n=15
  C: Midfoot and forefoot procedures (talonavicular/tarsometatarsal/ metatarsal) – n=20

- No patients lost to follow-up.

RESULTS

- Female 22: Male 28
- Average age: 56.6 years (23 to 76)
- Average time from fracture/surgery to start of Exogen: 16 months (4 to 50)
- Average duration Exogen used: 5.9 months (3 to 15)

- Atrophic nonuions: 38 (11,11,16)
- Hypertrophic nonunions: 12 (4,4,4)
- Diabetics: 13 (2,3,8)
- Smokers: 6 (4,2,0)

- Union achieved (Clinical and/or radiological): **80% - 40 patients** (14,10,16)

- Group A: 93% (14/15)
- Group B: 67% (10/15)
- Group C: 80% (16/20)
- **10** Patients failed treatment; 4 refused surgery due to manageable pain.

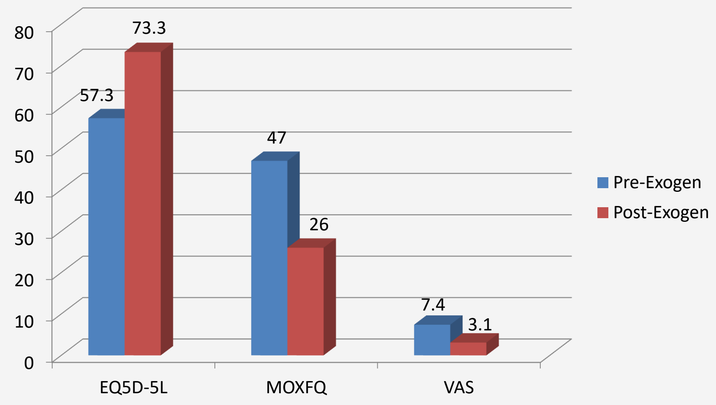
Diagnoses of fractures and surgical procedures

Diagnosis	No
Fracture Nonunions	
Tibia	7
Ankle (medial=1, lateral=3)	4
Talar body	2
Navicular	2
Metatarsal (not 5th)	9
5th Metatarsal base (avulsion=3, Jones fracture=1, distal shaft=1)	5
Post-Surgical Nonunions	
Tibio-talo-calcaneal Fusion	8
Ankle Fusion	5
Subtalar Fusion	2
Medial Midfoot Fusion	3
Metatarsal Osteotomy	2
1st MTP Joint Fusion	1

Patients who failed LIPUS treatment **(6/50)**

Diagnosis	Revision Surgery Performed
Talar body fracture dislocation – Failed primary fixation due to collapse and avascular necrosis	Hindfoot fusion with TTC nail and bone graft
Base of 2nd metatarsal fracture	Fusion 2nd and 3rd Tarsometatarsal joints
Subtalar fusion – Failed primary surgery	Revision subtalar fusion and bone graft
2nd metatarsal fracture	Open reduction and internal fixation with bone graft
Open ankle fusion	Revision open ankle fusion
2nd metatarsal base fracture	Open reduction and internal fixation with bone graft

Functional Results
(significantly improved, $p < 0.05$)



Cost Analysis

- Cost of Exogen treatment per patient: £2300.
- Potential cost of revision surgery based on individual diagnoses: £3611 to £5370 (as per HRG coding).
- Significant potential cost savings with the use of Exogen ($p < 0.05$).

DISCUSSION

- Higher union rates in fracture group at an average use of Exogen for 6.3 months (93%) ($p > 0.05$).
- Quicker union time in midfoot/forefoot group (5.1 months) vs 6.3 (A) and 6.9 (B) months.
- More unions in hypertrophic group (11/12) than in atrophic group (30/38) ($p > 0.05$).
- Current literature reports union rates of 64% to 88% with LIPUS.
- Zura et al – 767 cases – 86.2% union.
- Nolte et al – 29 cases – 80% union.
- Syed et al – 13 cases – 84.6% union.

CONCLUSION

- Overall, 80% patients improved (clinically and/or radiographically) without the need for further intervention.

- Significant improvements in PROMS.

- Better results in fracture group and relatively poor results in hindfoot fusion group.

- Better results in hypertrophic nonunions.

- Exogen for established nonunion in the foot and ankle is a safe, valuable and economically viable clinical option as an alternative to revision surgery.

- No conflict of interest.
- No funding received to conduct the study.

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REFERENCES

• Zura, R., et al., *Treatment of chronic (>1 year) fracture nonunion: heal rate in a cohort of 767 patients treated with low-intensity pulsed ultrasound (LIPUS).* Injury, 2015. **46**(10): p. 2036-41.
• Nolte, P.A., et al., *Low-intensity pulsed ultrasound in the treatment of nonunions.* J Trauma, 2001. **51**(4): p. 693-702; discussion 702-3.
• Schofer, M.D., et al., *Improved healing response in delayed unions of the tibia with low-intensity pulsed ultrasound: results of a randomized sham-controlled trial.* BMC Musculoskelet Disord, 2010. **11**: p. 229.
• Satter Syed, A., et al., *Pulsed electromagnetic fields for the treatment of bone fractures.* Bangladesh Med Res Counc Bull, 1999. **25**(1): p. 6-10.
• Moghaddam, A., et al., *Low intensity pulsed ultrasound in the treatment of long bone nonunions: Evaluation of cytokine expression as a tool for objectifying nonunion therapy.* J Orthop, 2016. **13**(4): p. 306-12.