Ultrasonically Assisted Anchoring of Biodegradable Implants for Chevron Osteotomies

Kai H. Olms, MD
Bernd Robioneck, PhD
Nils Reimers, Dipl. Ing.
Robin Buescher, PhD
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Presenter: Robin Buescher, PhD

My disclosure is in the Final AOFAS Program Book.

I have a potential conflict with this presentation due to:

Employment by Stryker Trauma GmbH
Introduction

• Chevron osteotomies are considered intrinsically stable, current hardware does not show outstanding clinical issues
• Hardware removal burden for healthcare system\(^1\), higher patient satisfaction after metal removal\(^2\)
• Biodegradable implants no hardware removal, no imaging artifacts, gradual load sharing; concerns regarding foreign body reactions and fixation strength
• A new technology is proposed that may provide enhanced anchoring in weak bone with acceptable tissue reactions

1 - Schurr et al., Reimbursement model for Germany, internal analysis
2 – Wadia et al., Metalwork removal in elective foot and ankle practice: Does it make any difference to the patient?, The Foot 2012
Mechanism of Ultrasonic Assisted Anchoring
Material

- PLDLA (70:30 L/LD) LR 706S, Evonik,
- Slow degrading, reduced drop in pH level, no inflammation expected
- Pin 2.2 mm x 22 or 26 mm
- Frequency 30 KHz
- Ultrasonic activation 5 s
- 8 mm liquefies
Ultrasonically assisted Pin (22mm / 26mm) vs. Ti Screws (2mm /3mm) with different threads, indicating comparable pull out strength values.
Polymer is almost completely surrounded by bony tissue

Multinucleated macrophages protrude locally into the polymer

No difference in foreign body reaction CD68 compared to Ti screws

*B. Robioneck, The influence of ultrasound based welding on the bone remodeling process of resorbable pins in a standardized osteotomy of the femoral condyle in a lapine animal model, Giessen 2010
Methods

- 30 consecutive patients enrolled from May 5th to September 11th 2008 with a mild to moderate Hallux valgus deformity
- Single center & single surgeon
- 100% Chevron Osteotomy
- Clinical examination, evaluation of complications & EQ-5D
- Follow up 1 week, 6 weeks, 3 months, 1 year, 2 years, 3 years
- Conducted acc. to ISO 14155 & GCP

Inclusion Criteria:
- Diagnosed mild to moderate hallux valgus deformity
- with or without concomitant forefoot deformities
- > 18 years
- mental ability to give informed consent

Exclusion Criteria
- advanced osteoarthritis
- underlying rheumatic disease
- overweight (BMI>35)
- previous surgical procedures to ipsilateral first ray.
RESULTS

3 months follow up

12 months follow up

24 months follow up

36 months follow up
Conclusion

- PLDLA shows no inflammation up to 3 yrs
- Welded material shows strong implant to bone bonding
- Ultrasonically Assisted Anchoring appears to be a safe and efficient osteosynthesis method for distal bunion osteotomies
- No revision surgeries
- Significant improvement in health related quality of life

Limitation of the present study include sample size, single center, single surgeon study, uncertainty of MRI Images, 3 yrs follow up
References


Schurr; et al, Reimbursement model for Germany, internal analysis.


Wadia, F; et al., Metalwork Removal in elective foot and ankle practice: Does it make any difference to the patient?, The Foot 2012.