POLY-L-LACTIC/CO-GLYCOLIC ACID (PLGA) BIORESORBABLE SCREWS FOR THE FIXATION OF FIRST RAY OSTEOTOMIES: A MULTI-CENTER PROSPECTIVE STUDY.

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My disclosure is in the Final AOFAS Program Book

I have a potential conflict with this presentation due to:

This clinical study was funded by Tornier
I am the Primary Investigator
I am on the Speakers Bureau for Tornier

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I have no potential conflicts with this presentation.
Bioresorbable implants are used for the fixation of fractures and osteotomies

- Early implants had high rates of complications
  - Peri-implant osteolysis
  - Localized inflammation
  - Sinus formation.
- Newer implants have improved strength, smoother degradation, and decreased incidences of complications which approaches those of metallic implants.

The purpose of this study is to provide high level evidence that bioresorbable PLGA (85/15) screws are a safe and effective means to fixate osteotomies of the first ray.
This is a prospective multicenter central IRB approved clinical trial. PLGA (85/15) bioresorbable screws were used for the fixation of first ray procedures in 40 consecutive patients. Patients were evaluated clinically and radiographically at 6 weeks, 12 weeks, 9-12 months, and 18-24 months postoperatively. At each study follow up interval patients were assessed for:
- Boney union
- The presence of complications associated with absorbable fixation
  - abscess formation
  - sinus tract formation
  - abnormal erythema or edema
  - osteolysis in the area of screw placement

The authors hypothesized that the use of PLGA (85/15) screws would have similar rates of bony unions when compared to metallic fixation devices and minimal complications.

Poly-L-Lactic/Co-Glycolic Acid (85/15)
Methods

- **Forty bunionectomies** were performed using PLGA (85/15) screws and standard technique, i.e., Osteotomy, reduction, drill, over-drill, measure, tap, and screw insertion.

- Bunionectomies included in this study:
  - Chevron osteotomies
  - Phalangeal osteotomies
  - Closing base wedge osteotomies.
All 40 osteotomies healed

- No non-unions or delayed unions.
- No complications related to the absorbable fixation
  - No osteolysis
  - No abnormal edema / erythema
  - No sinus tract formation
  - No abscess formation

One SAE

- Unrelated to bunionectomy
  - Concurrent hammertoe surgery
    - Developed osteomyelitis
CASE STUDY

- 40 year old female with painful bunion
- Chevron osteotomy and hallux osteotomy were performed.
- Osteotomies fixated with 2 bioresorbable RFS screws.
- Achieved union of the osteotomies by 6 weeks
- No complications associated with bioresorbable fixation.

The above radiographs show the patient preoperatively, 6 weeks post-operatively, 9 months post-operatively, and 18 months post-operatively.
Compared to other forms of metallic fixation, newer bioresorbable implants used in fixation of the 1st metatarsal osteotomy have similar:

- Correction of the IM angle
- Rates of bone healing
- Rates of complications

Bioresorbable implants are best used in situations associated with:

- Low load
- Anticipation of rapid healing
- Fixation of small bone fragments.

**Advantages of bioresorbable implants:**

- Reduced need for hardware removal
- Gradual load transfer to the healing bone
- Radiolucency
- Bacteriostatic
This study has demonstrated in a prospective model in 40 consecutive bunionectomies:

- No complication associated with the resorbable PLGA (85-15) screws
  - This suggests that the prior history of complications associated with the older resorbable fixation implant are not occurring in this new generation of implant
- All patients healed their osteotomies with no delayed or non unions
  - This suggests that the newer generation of resorbable implants lead to high rates of union as would be expected with standard metallic fixation

The foot and ankle specialist should consider bioresorbable fixation and the RFS 85/15 PLGA screw as an effective means of fixation of osteotomies of the first ray.