Orthopedic Fixation of Skeletally Immature Ankle Fractures in Pediatric Populations Using Bio-Integrative Implants

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Statement of Purpose

Explore the outcomes of transitional ankle fractures after operative stabilization with bio-integrative versus metal alloy fixation devices.

Literature Review

- Fracture rates are higher in children due to their skeletal immaturity.[1]
- Most fractures can be treated conservatively; however, some fractures require internal fixation, often performed with metal-alloy fixation devices (e.g., screws).[2,5]
- In children, it is generally recommended to remove metal implants to prevent future device-related complications.[3]
- Removal of hardware requires a second surgery, increasing the immediate risks and burdens for patients.[3]
- Bio-integrative fixation devices may present an alternative to metal alloy fixation devices through minimizing device-related complications and eliminating the need for a second surgery.[3-10]

Hypothesis

Bio-integrative fixation devices will offer comparable rates of fusion and fixation to metal-alloy devices, with fewer complications, reduced operation rates, decreased costs for patients, and improved quality of life.

Methodology

Level of Evidence: III

Study Design: Chart Review

- Retrospective, descriptive, IRB approved, single-center study.
- 35 participants, aged 7 to 16 years, with displaced transitional ankle fractures (i.e., Tillaux and triplane), followed to 52 weeks post-operative.
- 12 treated with bio-integrative OSSIOfiber® 4.0 mm cannulated screws (OSSIO Ltd., Caesarea, Israel)
- 23 treated with metal alloy (stainless steel) 4.0 mm cannulated screws

Inclusion Criteria:

- ≤ 17 years of age
- Surgical candidates requiring ORIF for displaced transitional ankle fractures
- Participants and their authorized legal guardians can understand and follow all study procedures, post-operative care, and attend follow-up visits.

Outcomes:

- Radiographic fracture healing post-procedure
- Nature and rate of device-related complications, including re-operation rates
- Patient cost-efficiency between bio-integrative and metal implants
- Quality of life measures

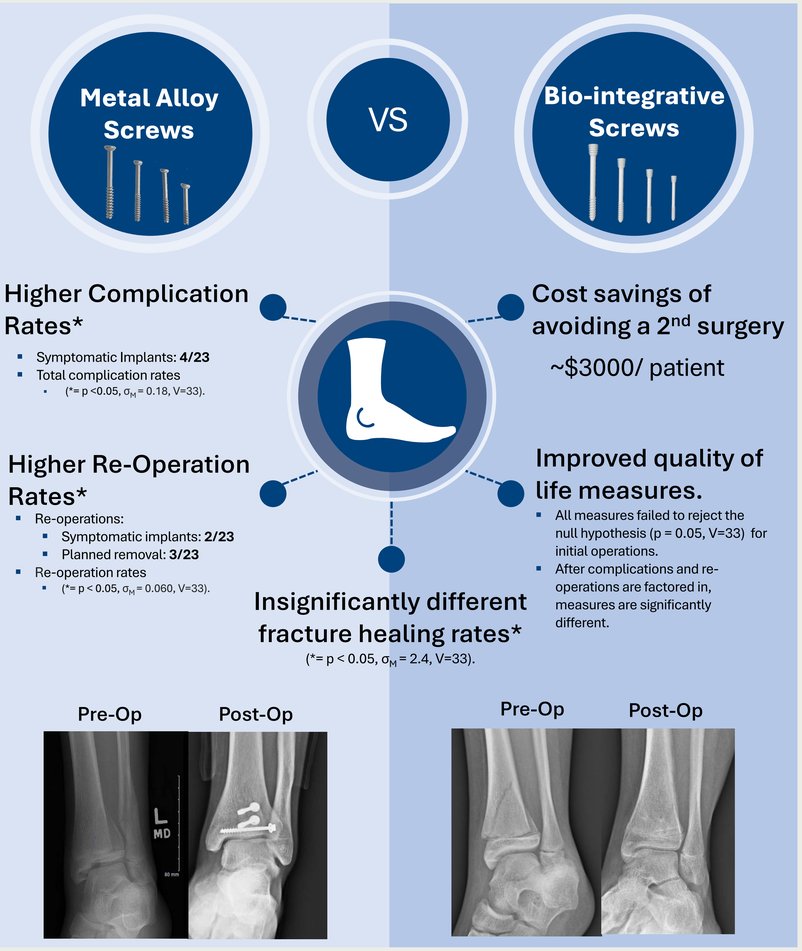
Measurements:

- Radiographs: image quality, implant visibility, bony reactions, hardware failure, and fusion rates
- Device Complications: Clavien-Dindo system [10]
- Cost-efficiency: CPT code billing rates of patient's actual procedure costs averaged across patient populations
- Quality of life measures: amount of time required for patients to regain function of the ankle and return to full activities as well as the rate of post-operative complications and re-operations

Statistical Analysis:

- The two patient populations were compared using un-paired t-tests with a p-value of 0.05.

Results



Discussion

Conclusions:

Preliminary results suggest that bio-integrative fixation devices are comparable to metal-alloy devices in treating transitional ankle fractures, while offering advantages in terms of complication rates, re-operation rates, cost-efficiency for patients, and quality of life.

These findings demonstrate bio-integrative fixation devices' viability as an alternative to metal screws, most significantly, by saving a child from a second surgery.

Limitations:

- Relatively small sample size
- Single-centered study
- Retrospective design
- 52-week follow-up period

A larger, multi-center, prospective, extended study would establish a more comprehensive understanding of the long-term efficacy and safety of bio-integrative devices in this specific population.

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