Evaluation of an Orthopedic Screw Retention Device using an in vivo Ovine Metatarsal Fracture

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OBJECTIVES

- Screw failure is the primary cause of revision procedures, which require extensive pre-operative planning, specialized implants and tools, and advanced technical surgical techniques that raise the cost of care for hospitals and contribute to patient morbidity.
- **The objective of this study was to determine if a novel braided sleeve composed of a unique bio-textile inserted into a compromised screw hole would allow for increased fixation/purchase and provide enhanced mechanical strength of the bone/screw fixation.**

METHODS

- 18 sheep (N = 6 samples at each time points of 3, 6 and 12 weeks) were utilized in this IACUC-approved study (Colorado State University, CO).
- One metatarsal in each animal had a 3 mm diaphyseal ostectomy and a 9-hole non-locking plate was used for stabilization (**Figure 1**).
- To simulate the worst case scenario where all screw's acute screw-bone purchase is compromised, **screw holes were over-drilled such that the diameter was equivalent to the outer screw thread diameter.**
  - 3.5 mm for cortical screws and 4.0 mm for cancellous screws.
- Every screw hole had the same surgical treatment:
  - **Screw retention sleeve composed of a unique bio-textile (SRT) (Figure 1)**
- "Negative control" (i.e., over-drilled holes w/ no SRT) treatments were not implemented because pilot work demonstrated that those constructs would fail immediately post surgery

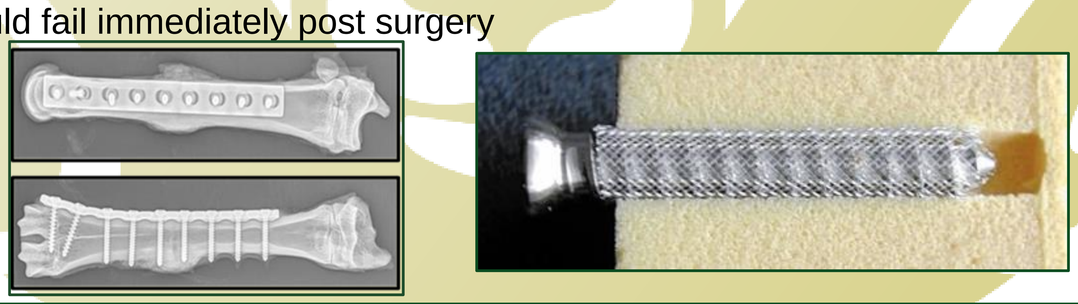

Figure 1: (*Left*) Ovine metatarsal osteotomy model stabilized with 9-hole locking plate. Screw holes were over drilled. (*Right*) Bio-textile screw retention technology (**SRT**) shown around an orthopedic screw placed inside a foam block.

- Screws were quasi-statically pulled out (at 1 mm/sec)
  - Maximum pullout forces (N);
  - Construct stiffnesses (N/mm) were calculated.
- Histology samples were processed using standard undecalcified hard tissue histology techniques (**Figure 2**)
  - Histomorphometric measurements were performed; percent bone, fibrous tissue, implant, and void spaces were calculated.

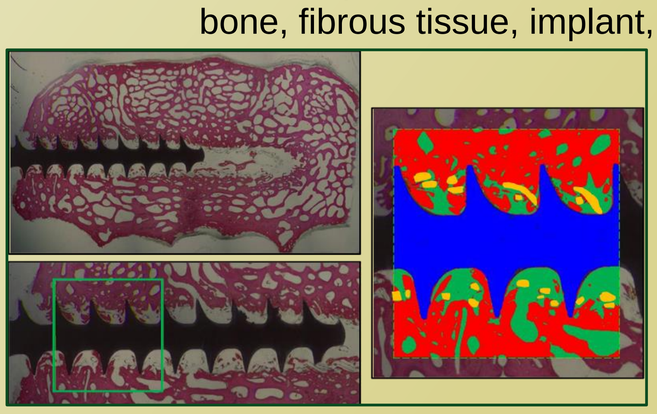

Figure 2: (*Green box*) Example cancellous region of interest (ROI) established for histomorphometric analyses of the screw ROIs at 3-weeks. (*Right*) Each histomorphometric constituent of interest has been highlighted: blue = metal; red = bone; yellow = SRT; green = "void" space; purple (not shown) = fibrous tissue.

- A standard one-way ANOVA was used to determine statistical significance ($p < 0.05$)

RESULTS - Biomechanics

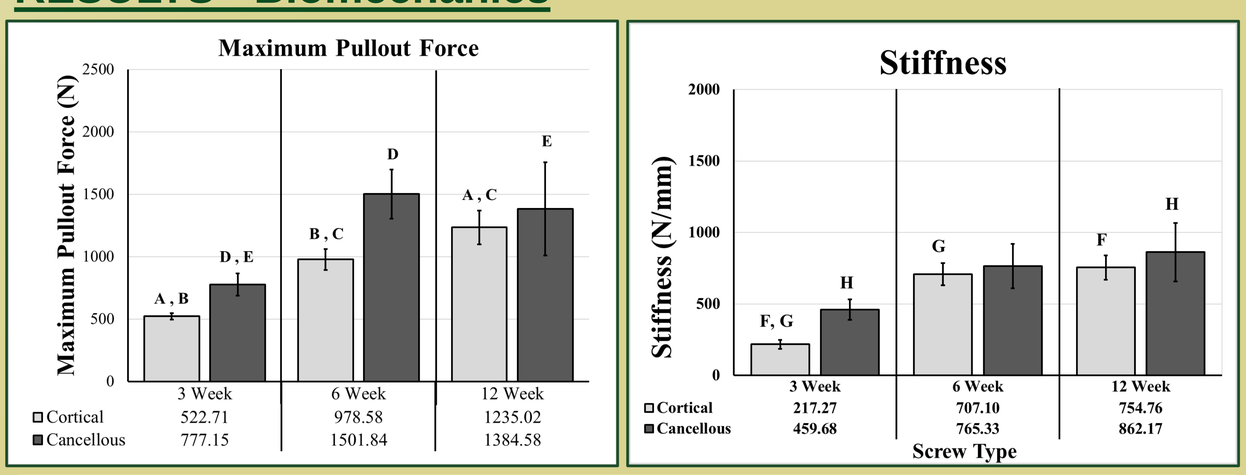

Figure 3: *(Right)* Maximum pullout force across sacrifice time periods. Data means are shown with standard deviation bars. Like letters indicate statistically significant differences: A, B, C, D, E: p-value <0.01. *(Left)* Stiffness measured across sacrifice time period. Data means are shown with standard deviation bars. Like letters indicate statistically significant differences: F, G: p-value <0.01, H p-value=0.014.

RESULTS – Biomechanics Cont.

- The cortical trajectory screws demonstrated increased maximum pullout force as healing progressed from 3 to 6 to 12 weeks (**Figure 3**).
- The cancellous trajectory screws demonstrated an increase in pullout force at 6 and 12 weeks when compared to the 3-week group (**Figure 3**).
- Significant increases in construct stiffness were also observed for the cortical screw trajectory samples at 6 and 12 weeks as compared to the 3 week samples (**Figure 3**).
- Cancellous screw trajectory construct stiffness significantly increased at 12 weeks as compared to the 3 week samples (**Figure 3**).

RESULTS – Histology

- Gross histology demonstrated that the device did not inhibit bone growth through the sleeve and to the threads of the screw.
- Histomorphometry data showed that the percent bone within the screw thread profile increased significantly for both the cortical and cancellous screws at 12 weeks as compared to the 3-week time point (**Figure 4**).
- The percent bone in the cortical screws was significantly increased at 6 weeks when compared to the 3-week group (**Figure 4**).
- Similar significant decreases in percent soft tissue and void space were observed for both the cancellous and cortical screw trajectories at 6 and 12 weeks compared to the 3 week histomorphometry data (**Figure 4)**

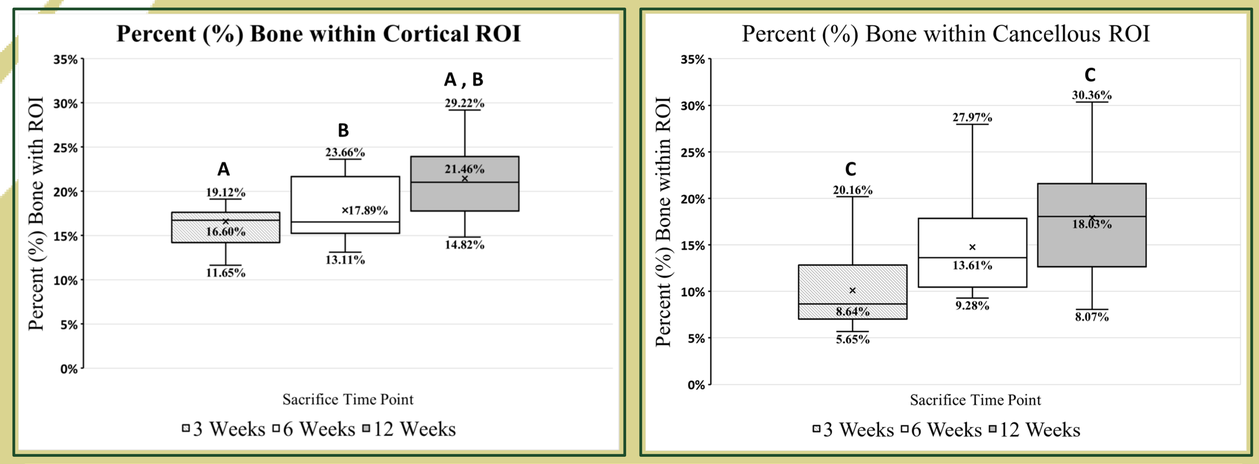

Figure 4: Box and whisker plots of cortical (l*eft*) and cancellous (*right*) percent bone within the screw-SRT device interface. Like letters represent statistically significant differences. A: p-value < 0.01; B: p-value=0.01; C: p-value = 0.03

DISCUSSION

- The increase in stiffness and maximum pullout force measured following healing showed that insertion of the braided sleeve in a worst case compromised screw hole scenario leads to increased biomechanical stability throughout the healing cascade.
- **The biomechanical and histomorphometric data clearly demonstrated enhanced bone ingrowth and biomechanical screw purchase when a screw retention device is used in an acutely over-drilled screw hole.**
- This novel technology holds promise for use in surgeries wherein compromised bone and/or screw purchase is encountered.

SIGNIFICANCE

This study shows that a braided sleeve composed of a unique bio-textile placed within a compromised screw hole can reduce the likelihood of a screw loosening by increasing the biomechanical properties of the screw-bone interface and allow for stabilization of the fracture site and healing of a fracture.

ACKNOWLEDGEMENTS

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REFERENCES

(1) Hirvinen, L.J.M. et al AJVR (2009). (2) Patil, S.S.D. et al. IJO 50(4) (2016) (3) Bone Joint J 2016;98-B:1099-1105.