Biomechanical Properties of Gryphon® BR Suture Anchors Using an in vivo Ovine Model

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OBJECTIVE

The successful use of BIOCRYL® RAPIDE™ Biocomposite Material in interference screws and suture anchors has been well described in the clinical literature [Barber *Arthroscopy* 2011; Frosch *Strategies Trauma Limb Reconstr* 2009; Van Klunen *AJSM* 2012], but to the best of our knowledge, the *in vivo* biomechanical properties have not been described. Given the clinical failures of other osteoconductive materials [Bourke *Arthroscopy* 2013], we sought to understand how well the biomechanical properties of BIOCRYL RAPIDE Biocomposite Material are maintained over the course of the healing period.

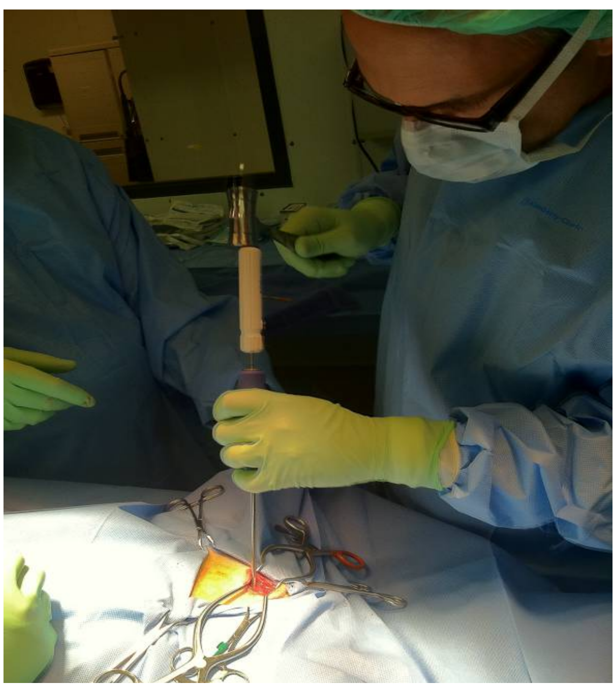

Figure 1: *Surgical exposure and placement for insertion of suture anchors.*

METHODS

Following approval of the protocol by the Institutional Animal Care and Use Committee (IACUC), a total of 12 sheep were enrolled in this study. Both humeri of each sheep were inserted with GRYPHON P BR anchors following the *Mitek Sports Medicine* Instructions for Use. Two experienced orthopedic surgeons (AM and JS) performed all device insertions. Anchors were inserted into the humeral tuberosity and the ORTHOCORD® High Strength Orthopaedic Suture coiled and placed intramuscularly rather than being used to perform a repair. Sterile techniques were used for all anchor insertions on sheep (Figure 1) in the six week (n=4), 12 week (n=4), and alternate groups (n=2). For the two sheep that were going to be sacrificed immediately (zero time point), both humeri received anchors. For the ten sheep that were not going to be sacrificed immediately, the left humerus received an anchor immediately but the right humerus received an anchor after sacrifice and just prior to biomechanical testing. The two alternates were sacrificed at 12 weeks because they were not needed to substitute for a sheep at another time point (i.e. no sheep dropped out of the study).

Following sacrifice, humeral disarticulation was performed with significant effort made to preserve the integrity of the suture, despite it being embedded in fibrous tissue. Tensile loading to failure along the long axis of the anchor was performed after both sutures had been tied together to form a loop around a 25.4 mm diameter mandrel. The anchors were pulled to failure at 24.5 mm/min.

Maximum load, stiffness, and load to 3 mm displacement were calculated and statistically compared across the three time points. A level of significance of 95% was set *a priori*.

RESULTS

The average maximum load, load to 3 mm of displacement (Figure 2), and stiffness (Figure 3) all held roughly constant over the 12 week time period studied (differences were not statistically significant). The average maximum load was 184 N ± 22 N at time zero, 237 N ± 53 N at 6 weeks, and 168 N ± 19 N at 12 weeks and therefore remained 8-10 times above the clinically relevant loads expected of these anchors following labral repair [Oliashirazi *AJSM* 1999; Spenciner *Internal Mitek data* 2010]. The mode of failure was 50% anchor pull out and 50% anchor bridge break for time zero, but then shifted to 100% bridge break for the six and 12 week time points.

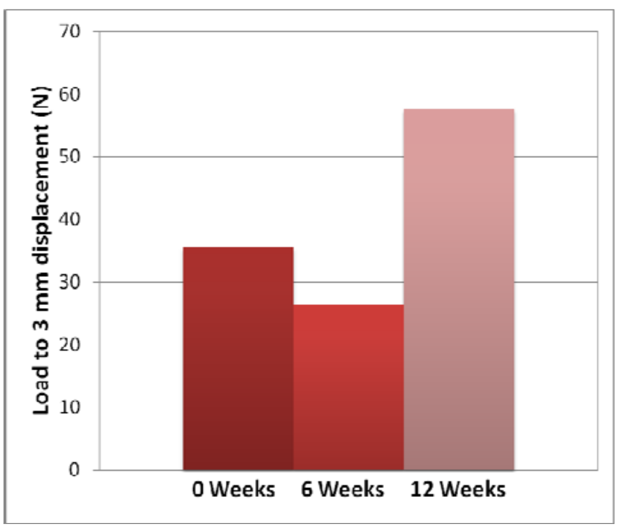

Figure 2: *Average load to 3 mm displacement at all three time points.*

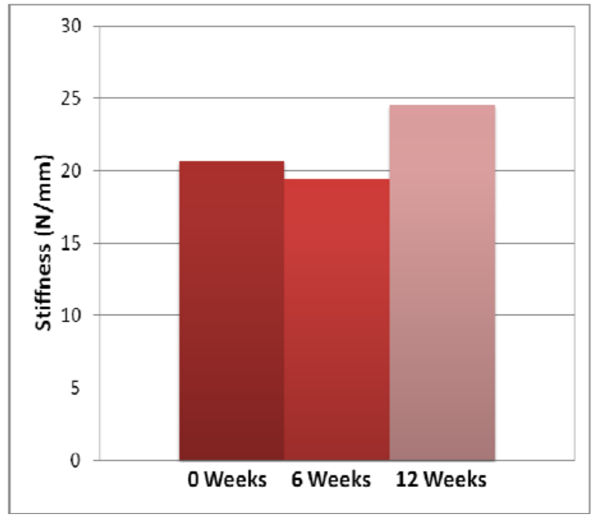

Figure 3: *Average stiffness at all three time points.*

CONCLUSION

At least in this *in vivo* ovine model, the GRYPHON BR anchors with ORTHOCORD High Strength Orthopaedic Suture clearly supported many times the clinically relevant loads even out to 12 weeks post-operatively. The ovine humerus model has been shown to produce maximum pull-out loads for suture anchors almost identical to “healthy” human humeri (i.e. from cadavers with high bone mineral densities) [Pietschmann *JOB* 2010].

Interestingly, there seemed to be a trend toward the average maximum load increasing between the time zero and six week data. Similarly, the average load to 3 mm displacement showed a trend toward increasing over time, with the highest value at 12 weeks (58 N ± 20 N). Stiffness followed this same pattern, but with more moderate gains at 12 weeks. Clinically, this potential for increased repair strength over the healing period could support the use of more aggressive rehabilitation protocols.