BIOMECHANICAL EVALUATION OF CITREFIX™ A NEXT GENERATION REGENERATIVE SUTURE ANCHOR SYSTEM

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ABSTRACT

The purpose of this study was to evaluate CITREFIX, a next generation regenerative Suture Anchor System. The CITREFIX device was designed with elastomeric features, which improve fixation by allowing the anchor barbs to elastically rebound after implantation allowing for better engagement in the bone socket compared to currently marketed polylactic acid based (PLDLA) biocomposite anchors. The pull-out strength and resorption rate of CITREFIX anchors was compared to PLDLA biocomposite anchors using 20 PCF foam blocks at T=0 and after 26 weeks of degradation *in vitro*. CITREFIX anchors displayed pull-out strengths (293 N @ T=0 and 297 N @ T=26) when compared to PLDLA anchors (181 N @ T=0 and 155 N @ T=26). *In vitro* accelerated degradation results show that CITREFIX anchors display a controlled resorption over time without bulk degradation or acid dumping, which are associated with chronic inflammation and osteolysis.

Key words: citrate, regeneration, pull-out strength, suture anchor, tendon reattachment, internal brace

INTRODUCTION

Suture anchors are broadly used for attaching soft tissue (e.g., tendons, ligaments, and meniscus) to bone and have become essential devices during reconstruction of damaged or attenuated tissues. For example, suture anchors are predominantly used to reattached tendons and restore more normal movement to a foot and ankle that has lost function and balance of soft tissue forces. Suture anchor techniques in foot and ankle procedures are commonly utilized for ankle lateral ligament repair or realignment procedures. Developed utilizing CITREGEN, a novel citrate-based biodegradable elastomer that replicates the native bone extracellular matrix chemistry, the CITREFIX Suture Anchor System was designed with elastic biomechanical and metabolic characteristics to address unmet needs in tendon/ligament reconstruction procedures.

In contrast to thermoplastic lactic acid-based materials, CITREGEN leverages the citrate molecule to provide the following advantages: 1) a completely amorphous polymer structure to prevent chronic inflammation and osteolysis associated with lactic-acid based materials, 2) polymer chain crosslinking to mimic the elastic structure-property relationships found in the native extracellular matrix, 3) bioceramic interactions allowing for the incorporation of 60 wt.-% bioceramic to match the native bone content without embrittlement, 4) the release of citrate, a metabolic molecule inherent to bone anatomy and physiology.

METHODS AND MATERIALS

Suture Anchors:

All implants examined were 4.5 mm x 18.5 mm in size (Figure 1) anchors designed with faceted barbs that provide an interference fit within a bone socket. A cannula extends through the central axis to impact the implant into position.

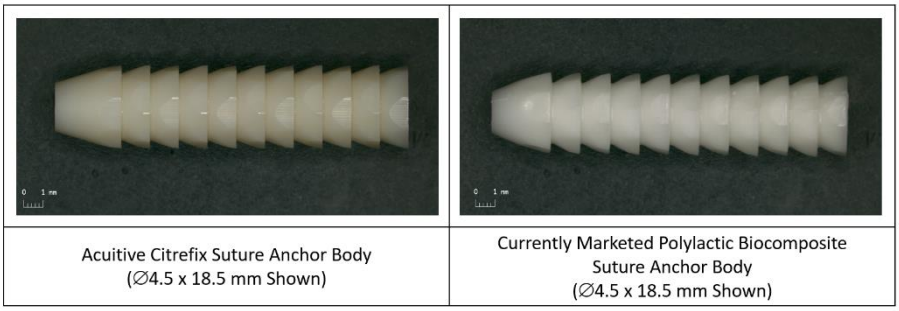

Figure 1: Experimental devices

Biomechanical Pull-out Procedure

4.5 mm diameter suture anchors were inserted into 20 pound per cubic foot (PCF) foam blocks obtained from Sawbones USA (A Pacific Research Company, Vashon Island, Washington). The 20 PCF blocks were first cut into 60 mm x 60mm x 40mm blocks with a predrilled 3.8mm hole as per the suture anchor system's operative technique. All suture anchors were loaded with #2 UHMWPE braided suture and impacted into the 3.8mm hole. Next, test samples were mounted into a mechanical testing frame (Admet eXpert 8613, Admet Inc, Norwood, MA) immediately after insertion as shown in Figure 2. All samples were loaded in the same approximate normal (90 Degrees) orientation with respect to foam block. The ultimate pullout strength of each suture anchor was measured in dry conditions by applying a tensile force to the sutures at a rate of 60 mm/min until failure occurred. Testing was performed at 2 time points, T=0 immediately after implanting the suture anchors and T=26 Weeks of simulated real time aging. For the Simulated real time aging, following implantation, separate foam blocks were placed in individual jars filled with phosphate buffer saline (PBS; pH 7.4) and maintained at 37°C. The PBS solution was changed weekly to ensure a neutral pH was maintained. After 26 weeks (T=26), the ultimate pullout strength was recorded as described above.

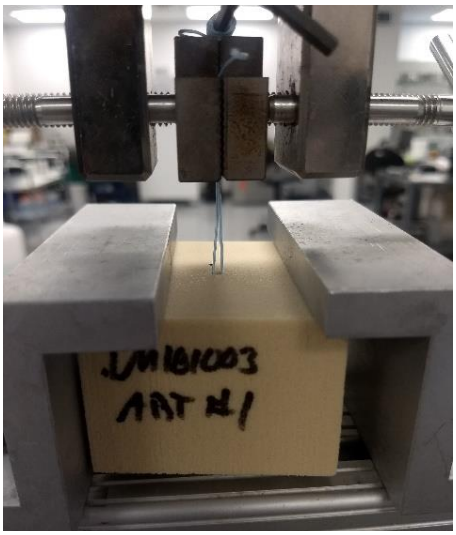

Figure 2: Suture Anchor Pull out set up

Figure 3: Compression Test set up

Material Viscoelastic Compression Properties

6 x 12 mm (diameter x height) PLDLA and CITREGEN compressive plugs were machined, and compression tested in accordance with ASTM D695: Standard Test Method for Compressive Properties of Rigid Plastics. PLDLA and CITREGEN test samples were loaded in compression at a rate of 1.3 mm/min between 2 load platens at room temperature in dry conditions (Figure 3) and compressed to 10, 20, 30, and 40% strain corresponding to 1.2mm, 2.4mm, 3.6mm and 4.8mm of deflection, respectfully. The force was removed, and the height of each sample was remeasured after 24 hours.

In Vitro Degradation Life Cycle pH Stability

Accelerated degradation of CITREGEN samples was conducted in 50 mL of PBS) at 77°C. Since hydroxyapatite does not resorb in PBS, the amount of polymer degradation was determined by measuring the citrate content remaining in the device via high performance liquid chromatography. Throughout the accelerated degradation study, the pH of the PBS was recorded and replaced.

RESULTS

Pull-out testing

All implants were successfully inserted, and testing was performed. Suture tension pull out testing performed on the 20 PCF foam block constructs and the results demonstrated that the mean ultimate load of the CITREFIX device withstood 293±40 N compared to 181±11 N for the currently marketed polylactic acid based biocomposite (PLDLA) suture anchors at T=0. At T=26 weeks, the CITREFIX devices withstood 297±50 N of force before failure compared to 155±16 N for the PLDLA implant demonstrating almost twice the fixation strength (Figure 4).

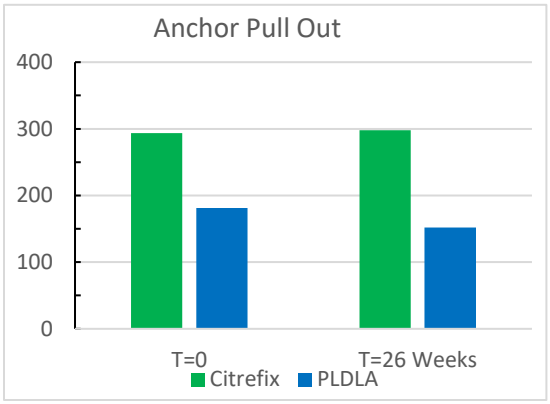

Figure 4: Suture Anchor Pull out Strength Testing

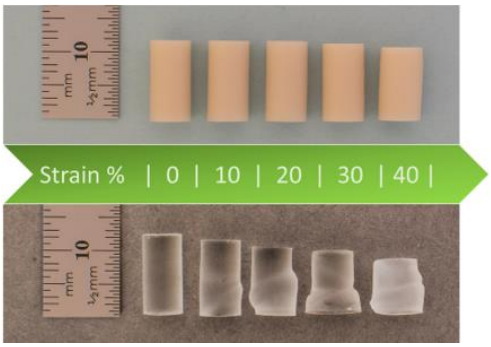

Figure 5: Citregen vs PLDLA Plastic Deformation

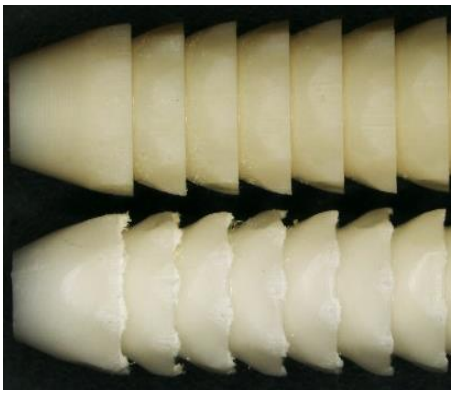

Figure 6: Barb Deformation

Material Characteristics – Compressive Strength & Modulus:

CITREGEN and PLDLA samples were compression tested using 6 x 12mm test cylinders. CITREGEN cylinders achieved a maximum compressive strength of 7,365±282 N, while PLDLA test samples only registered 3,442±162 N. While CITREGEN demonstrated twice (2x) the compressive strength over PLDLA, it also displayed an elastic modulus closer to cancellous bone at 284±3 MPa vs 2,905±139 MPa for PLDLA. CITREGEN demonstrated 2x greater compressive strength, resisting deformation.

CITREGEN cylinders were able to recover nearly 100% of their original height under 40% compressive load (strain), while PLDLA cylinders were permanently deformed after only 10% strain (Figure 5). When translated into implant function, the PLDLA Anchor barbs permanently deflect and deform under compressive load during implant insertion into the bone socket reducing the barb overhang for bone fixation. (Figure 6) Conversely, the elastomeric CITREFIX barbs bend during insertion, but rebound to their original configuration providing greater barb engagement into bone.

Degradation Life Cycle pH Stability

The polymer resorption rate of CITREGEN was linear and controlled throughout the study and absent any signs of bulk degradation at later time points. While the pH degradation media was initially acidic, the pH stabilized early on and maintained near normal pH levels during the remainder of the study. This indicates the absence of acid dumping during late stages of the polymer lifecycle, as has been reported for polylactic and glycolic acid based thermoplastic materials (Figure 7).

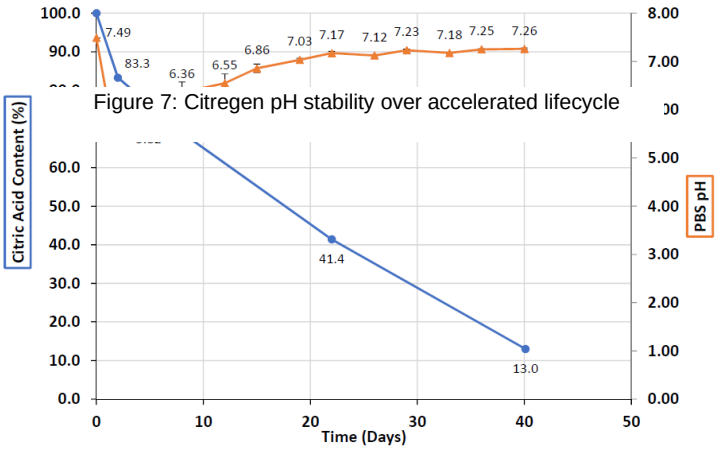

Figure 7: Citregen pH stability over accelerated lifecycle

DISCUSSION

The Acuitive CITREFIX suture anchor is produced from CITREGEN, a thermoset elastomeric polymer composited with hydroxyapatite. This bioceramic material was formulated with a lower modulus of elasticity than commercially available thermoplastic materials (PLLA, PLDLA, PGA, PCL, or combinations thereof).

The CITREFIX suture anchor was mechanically tested and compared to a currently marketed PLDLA biocomposite suture anchor (control). The material was also analyzed with regards to its compression properties and its biological hydrolysis degradation profile. The testing and analysis demonstrate the CITREFIX system manufactured from CITREGEN provides strong fixation strength and structural integrity over the healing phase, and releases citrate, calcium and phosphate as it resorbs over time and is replaced by host tissue.

The purposeful design features along with CITREGEN's low material modulus maximize suture anchor fixation and avoid any potential harm from late-stage acid release.

CONCLUSIONS

Bench top in-vitro biomechanical testing was conducted at ATI to compare mechanical fixation properties of two suture anchors; a current market leading polylactic acid based (PLDLA) biocomposite anchor and the CITREFIX anchor. The CITREFIX suture anchor displayed increased pull-out strength compared to the PLDLA biocomposite control suture anchor and maintained twice (2x) the fixation strength over 26 weeks of simulated aging.

Accelerated degradation testing demonstrated a slow and predictable resorption profile that maintained the pH balance throughout the device lifecycle, mitigating concerns of latent bulk degradation and acid dumping, which are associated with chronic inflammation.

The CITREGEN material properties allow elastic rebound of the suture anchor barbs which contribute to the improvement in pull out testing of the suture anchor.

The chemical and mechanical properties of CITREGEN, a next generation elastomeric bioabsorbable material, along with a proven design delivers a novel solution for current clinical challenges. This combination of characteristics enables the CITREFIX device to provide secure fixation without the potential of acid dumping as the material resorbs.

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