BIOMECHANICAL & BIOCHEMICAL EVALUATION OF CITRELOCK™ A NEXT GENERATION REGENERATIVE TENDON FIXATION SYSTEM

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ABSTRACT

The purpose of this study was to evaluate a next generation regenerative biocomposite material, Citregen™ which is utilized in the Citrelock Tendon Fixation Implant System. The Citrelock device was designed with unique mechanical design features and elastomeric material characteristics. These features intend to protect the tendon during insertion while maintaining comparable tendon fixation strength to currently marketed polylactic acid based (PLDLA) biocomposite screws. This study demonstrated the pull-out strength of the implant utilizing ovine bone and long digital extensor tendon in an ACL model comparing Citrelock devices to PLDLA biocomposite screws, which measured 344 N and 167 N, respectively. Additionally, Citrelock devices displayed controlled resorption over time through accelerated degradation testing without bulk degradation or acid dumping, which are associated with chronic inflammation.

Key words: citrate, regeneration, pull-out strength, ACL, tendon transfers, tendon laceration

INTRODUCTION

Tendon fixation systems are commonly utilized devices in orthopedic procedures for tendon transfers, whereby a tendon is moved from its normal, anatomic location to another area of the body. Tendons typically are transferred to restore more normal movement to a foot and ankle that has lost function. Tendon transfer techniques in the Foot & Ankle are commonly utilized for foot drop or realignment procedures. The Citrelock Tendon Fixation System was designed with physical and biochemical characteristics utilizing Citregen to address unmet needs in tendon transfer procedures. Citregen, a new biomaterial used for musculoskeletal repair and disease, is a homogeneous biocomposite comprised of 60 wt.-% unsintered hydroxyapatite (HA) and 40 wt.-% polymer. Citregen's polymer component is a citrate-based polyester network of completely amorphous polymer chains crosslinked together to form an elastomeric material. As water penetrates the device, surface erosion of the polymer constituent occurs through hydrolysis releasing essential molecules to assist in healing: Citrate, Phosphate and Calcium.

METHODS AND MATERIALS

Interference devices:

The implants examined were all 7 mm x 23 mm in size (Figure 1). The external surface of the PLDLA biocomposite screw implant presents a traditional screw thread form with a rounded head for engaging soft tissue and providing an interference fit within a bone tunnel or cavity. An insertion drive feature extends through the central axis to torque the implant into position. The Citrelock device is designed with multi-lead, large pitch angle protrusions to engage the tendon and bone within the prepared socket. The large pitch angle eliminates rotation of the tendon during placement, and the large radius of the protrusions mitigate laceration of the fixated tendon commonly seen with traditional thread design screws.

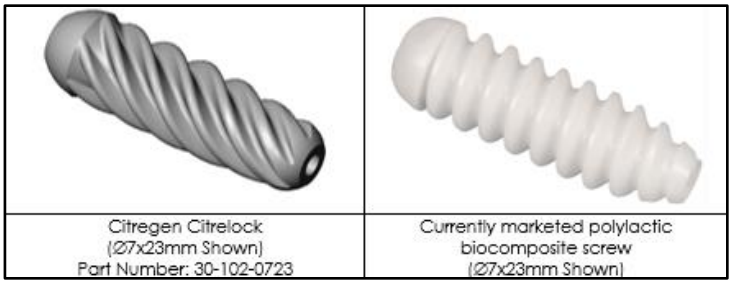

Figure 1: Experimental devices

Biomechanical Pull-out Procedure

Sheep “Ovis Aries” cadavers were utilized for the study. The sheep were skeletally mature (3+ years of age) and between 70-90 kg. The long digital extensor (LDE) tendon was harvested and served as the actual graft to replace the ACL ligament. A lateral parapatellar arthrotomy was performed to access the knee. The fat pad of the knee as well as the ACL was located, transected, and completely removed. A tibial tunnel was created at the location of the tibial attachment of the ACL, and a femoral tunnel was located as far lateral as possible relative to the posterior cruciate ligament (PCL). The LDE Tendon Graft was placed within the femoral tunnel and fixed in position with an interference screw. The graft was pulled down through the tibial tunnel and a second interference screw was placed to fix the tibial aspect of the graft (Figure 2, 3).

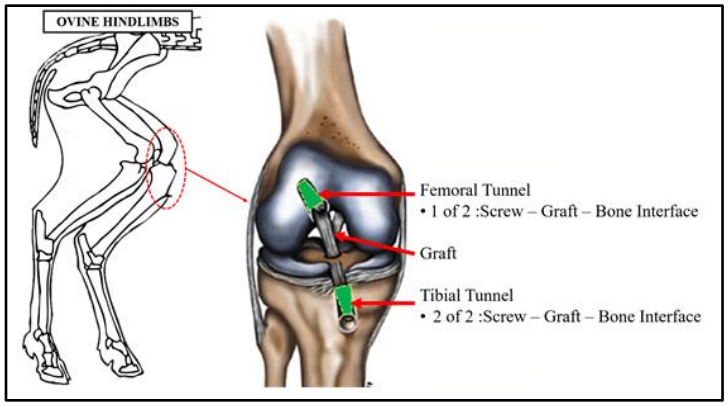

Figure 2: Ovine ACL Model tendon placement

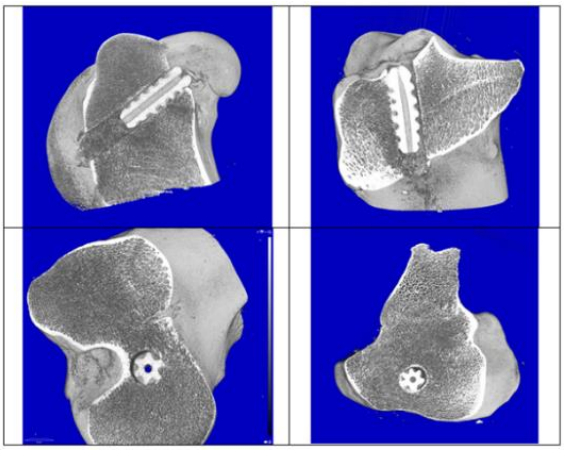
Figure 3: Micro CT illustrating the position of the Citrelock device in the ovine femur.

Following cadaver surgeries, right treated knees were harvested, skinned, and delivered to the Orthopaedic Bioengineering Research Laboratory, Colorado State University (CSU). The surgically treated knee joint was trimmed at the proximal end of the femur and the distal tibia, leaving the LDE Tendon Graft across the joint. For samples allocated to destructive biomechanics, the bone of interest was potted within a polyvinyl chloride (PVC) sleeve, using a two-part epoxy resin (Smooth Cast 321, Smooth-on Inc. Easton, Pennsylvania). Prior to potting, several screws were drilled into the bones to increase their purchase within the potting sleeve.

Specimens were mounted into the testing frame (Mini Bionix 858, MTS Systems, Eden Prairie, MN) using specially designed fixtures attached to a 5000 Newton (N) capacity force transducer (Figure 4). Solid carbon dioxide was laid around the clamp, lowering the temperature to at least -10^{o}C, converting it into a cryo-clamp to prevent tissue slippage during testing. Specimen hydration was maintained during testing via ambient temperature physiologic saline spray.

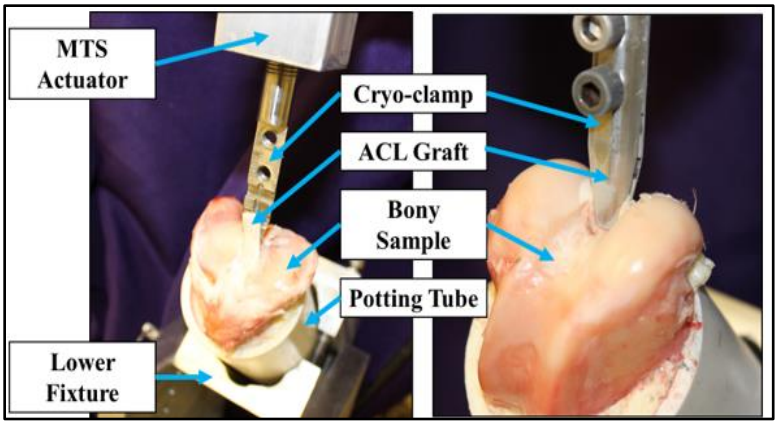

Figure 4: Digital image showing mechanical testing fixture. Components of Interest have been highlighted.

Destructive biomechanical testing included two phases: preconditioning and ramp to failure. Ramp to failure was a destructive test and was performed last in the evaluation sequence. All loads imparted on the samples were applied quasi-statically and aligned collinear to the physiologic loading direction of the tendon. All samples were loaded in the same approximate orientation with respect to bone and tendon orientation. To minimize the viscoelastic effects on the measured biomechanical response, five (n=5) tensile loading cycles ranging between 0 and 2% strain were applied for the purpose of preconditioning the tendon. The preconditioning phase was preceded by a ~2-minute preload phase. A static preload of 10 N was applied to all specimens for ~2 minutes or until the specimen was fully relaxed. To characterize structural and material properties of the repaired tissue, the specimens were quasi-statically loaded to failure at a rate of 0.5% strain/sec.

Degradation Life Cycle pH Stability

Accelerated degradation of Citrelock devices were conducted in 50 mL of phosphate buffered saline (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. It was noted that during insertion the Citrelock implants did not twist or wind the tendons unlike the polylactic acid based (PLDLA) biocomposite screws which required approximately 7 revolutions to seat the implant and dragged the tendon around the bone tunnel. Tendon pull out testing performed on the ovine ACL reconstruction demonstrated that the mean ultimate load of the Citrelock device withstood 344 Newtons compared to 167 Newtons for the currently marketed polylactic acid based (PLDLA) biocomposite screws. (Figure 5)

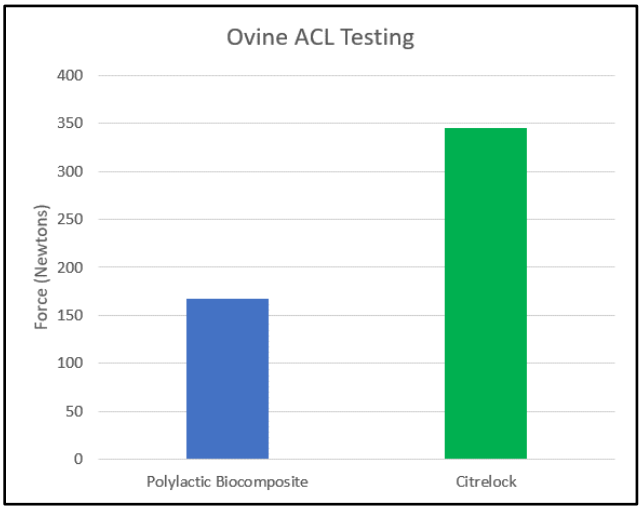

Figure 5: Tendon Pull out Strength Testing

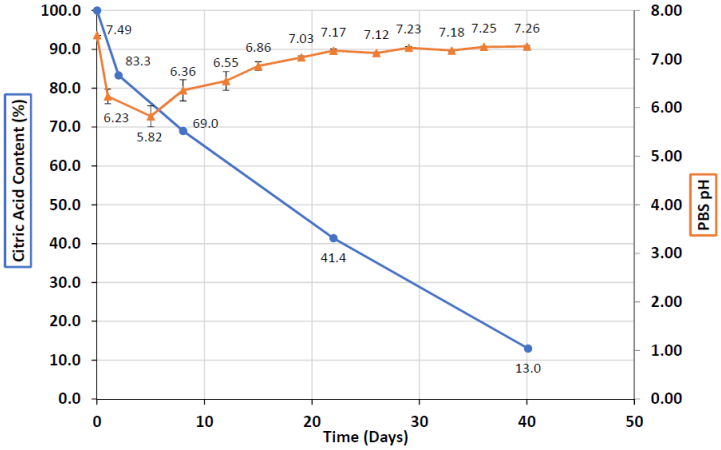

Figure 6: Citregen pH stability over accelerated lifecycle

Material Characteristics – Compressive Strength & Modulus:

Compression testing of PLDLA vs Citregen (6mm x 12mm test cylinders) demonstrates that PLDLA is 10 times stiffer than Citregen, 2,905 MPa vs 284 MPa, respectively (Figure 7). Citregen test cylinders had a maximum compressive strength of 7,365 Newtons, which was significantly higher than PLDLA test samples 3,442 Newtons. Citregen samples were two times stronger than PLDLA due to the material's ability to withstand high compressive forces and high strains. These material properties allow the Citrelock implants to withstand a great amount of compressive deformation without failure.

Degradation Life Cycle pH Stability

The hydrolysis rate of Citrelock devices was linear and controlled throughout the study and absent of any signs of rapid degradation at later time points. Although the pH of the degradation media was initially acidic, the pH stabilized after 21 days and did not drop for the remainder of the study indicating that acid dumping does not occur at late stages of the polymer lifecycle, as has been reported for polylactic and glycolic based thermoplastic materials (Figure 6).

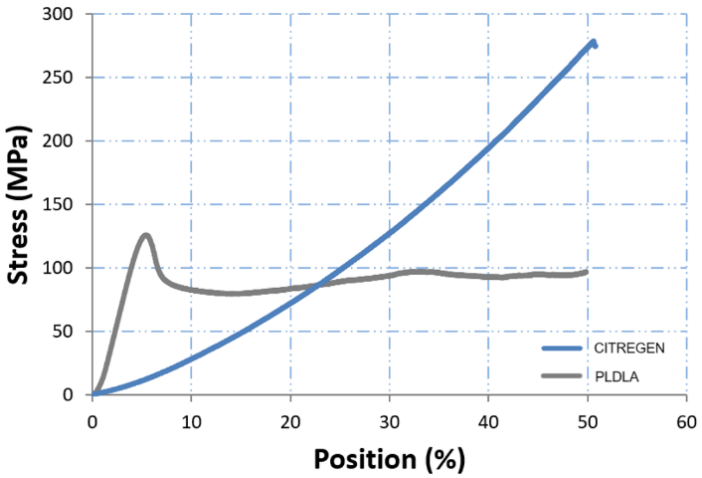

Figure 7: Citregen vs PLDLA Compression Testing

DISCUSSION

The Acuitive Citrelock Tendon Fixation device 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 Citrelock thread form was compared to a currently marketed PLDLA biocomposite screw (control) thread form (both device types were 7mm in diameter). The thread form for Citrelock was designed with a large radius at the major thread crest to distribute stress over a larger area and protect the tendon during insertion (Figure 8). The control screw's smaller radius is sharper and concentrates a greater percent of the radial force over a smaller area, which can crush the tendon in a focal region. The unique Citrelock multi-lead thread design requires only ½ of a rotation to obtain full seating during implantation, whereas the currently marketed control screw requires approximately 7 full rotations to seat the implant. The extra rotations impart increased friction that can cause significant damage to the tendon and contributes to what is clinically termed as tendon winding, where the tendon rotates into an undesirable anatomic location.

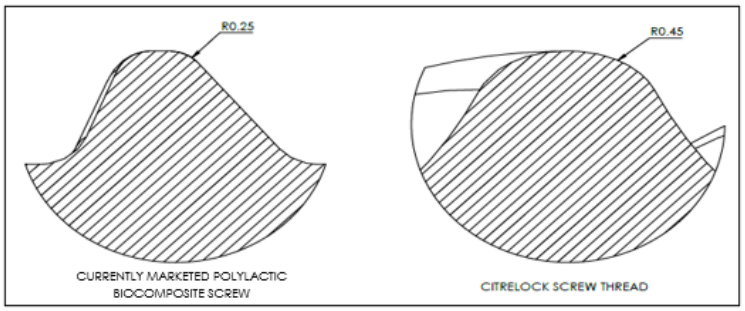

Figure 8: Citrelock vs PLDLA Screw Thread forms

The purposeful design features along with Citregen's low material modulus maximize tendon fixation while minimizing damage to the tendon. In contrast, traditionally designed implants made from higher modulus materials, and designed with sharper thread forms that require multiple turns for full seating, can lacerate the tendon. The Citrelock device combines unique design features and Citregen material properties to provide firm fixation while protecting tendon tissue.

CONCLUSIONS

Cadaveric ovine testing of a reconstructed ACL was conducted at CSU to compare mechanical fixation properties of two tendon interference devices; a current market leading polylactic acid based (PLDLA) biocomposite screw and the Citrelock device. The Citrelock device displayed increased pull-out strength and greater overall mechanical performance compared to the PLDLA biocomposite control screw and maintained good tendon integrity at the tendon-bone interface.

Accelerated degradation testing performed at Acuitive Technologies demonstrated a slow and steady 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 Citrelock screw design is less likely to damage tendons upon insertion since it spreads the load over a greater area, has a lower material modulus and requires less rotations to seat the implant.

The chemical and mechanical properties of Citregen, a next generation elastomeric bioabsorbable material, along with a unique physical design delivers a novel solution for current clinical challenges. This combination of characteristics enables the Citrelock device to preserve tendon integrity while providing secure tendon fixation without the potential of acid dumping as the material resorbs.

REFERENCES

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CSU Citregen Tenodesis Screw (ACL) OBRL Study Identification OBRL AT01-18
CSU Citregen Tenodesis Screw (ACL) OBRL Study Identification OBRL19-01
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