Development of Simulated Osseointegration to Reduce Age and Sex-Based Disparities with In-Vitro Orthopedic Biomechanics Research

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INTRODUCTION: Poor bone quality of some cadaveric specimens, which can be exacerbated in female and elderly specimens, can lead to in vitro biomechanics research not accurately reflecting the patient population of interest. Studies aiming to compare surgical interventions relying on secure fixation of devices into the bone (e.g. suture anchors, buttons, etc.) are often compromised due to fixture loosening, which is rarely observed clinically and can be attributed to poor bone quality in cadavers and lack of device osseointegration. This inhibits the ability to assess the performance of surgical intervention in a clinically meaningful way. A review of relevant in vitro orthopedic biomechanics studies related to fixation at the bone device interface showed that, of the studies reporting gender, nearly 70% preferentially utilized male specimens. This is concerning for studies examining sports injury treatment, such as anterior cruciate ligament (ACL) rupture, because female athletes are significantly more likely to injure their ACL [1]. Additionally, of the studies reporting age, average age of cadaveric specimens was greater than 64 years old. However, peak ACL injuries are understood to occur most frequently in 14- to 25-year-olds [2]. Furthermore, limited availability of young, healthy cadaveric specimens results in utilization of elderly specimens, increasing the likelihood of decreased bone quality. Traditionally, bone cement has been used as an effective remedy in situations where poor bone quality is a concern for the integrity of fixation devices. However, bone cement is expensive and becomes challenging to work with once set, leaving no room for error or any surgical revisions. The primary aim of this study is to evaluate different augmentations for improving effective bone quality in an in vitro model. We hypothesize that one or more cyanoacrylate-based polymer adhesive formulations can be identified to quickly and easily simulate osseointegration and healing through secure device fixation via improved trabecular bone density.

METHODS: Two male fresh frozen matched pair cadaveric knees, with a mean age of 74 years, were utilized to explore the application of two commercially available adhesives. The two adhesives (SB02 and SB150) were cyanoacrylate based and were modified with the addition of silica nanoparticles (1.5 wt%). Each matched pair was utilized to evaluate the performance of a different polymer adhesive, with one side of the pair serving as a control. First, 30mL of the adhesive was applied to the interior of the bone via syringe to the center of the bone. Secondly, drill holes, 4.5mm in diameter and 25mm deep, were placed in clinically relevant sites (three sites on the tibia and four sites on the femur). 3mL of additional adhesive was applied to the pilot holes. After allowing the polymer adhesives to cure for 30 minutes, surrogate PEEK suture anchors were inserted into the bone of all four knees using a digital torque wrench and maximum insertion torque values were recorded. The bones were placed in an adjustable fixture on an Instron MTS 858 to perform anchor pull-out tests. A cable was mechanically attached to the end of the PEEK anchor and pulled in the normal direction with a crosshead speed of 1mm/s, and the failure load was recorded for each pullout test. Failure force was extracted from the data.

RESULTS SECTION: Twenty-eight pullout tests and insertion torque measures (n=14 per donor) were evaluated. The matched pair treated with the polymer adhesive SB02 experienced an average increase of 200N in pullout force across the seven insertion sites compared to the control side (Fig. 1a). The second matched pair, treated with the polymer adhesive SB150, experienced an average increase of 379N in pullout force across the seven insertion sites compared to the control side. Both treatment groups displayed an average 51% increase in maximum insertion torque compared to the matched control (Fig. 1b).

DISCUSSION: From this initial study, cyanoacrylate-based polymer adhesives modified with additives such as silica nanoparticles show potential to be a feasible solution to improve device fixation for in vitro biomechanics testing. Cyanoacrylate glues form strong polymer matrices and provide quick cure times in addition to their low viscosities, allowing them to infiltrate and improve the density of the bone. This is displayed by the increase in both maximum pullout force and maximum insertion torque of PEEK anchors, as insertion torque is known to have a strong correlation with bone mineral density. Future research in this area will focus on evaluating various wt% additions of silica nanoparticles and optimize the application technique to ensure an even and accurate distribution of adhesive throughout the trabecular bone. Additionally, computed tomography will be included to further investigate the relationship of specimen bone mineral density and the performance of the adhesive in the bone.

SIGNIFICANCE/CLINICAL RELEVANCE: There are two major disparities in sex and age representation in cadaveric research studies as compared to the patient populations of interest, both of which are related to the quality of bone observed in some cadaveric specimens. Successful completion of this study will further increase the clinical relevance of in vitro biomechanics research and be more representative of young healthy patient populations (often the target of sports medicine studies) post osseointegration and healing by minimizing age and sex-based disparities.

REFERENCES: [1] Huston, L.J.,et al., *Clin Orthop Relat Res,* 2000, [2] Sanders, T.L., et al., *Am J Sports Med*, 2016.

IMAGES AND TABLES:

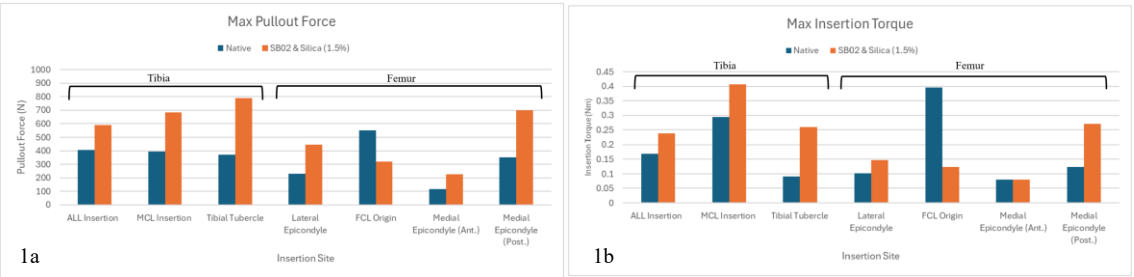

Figure 1a & 1b: Maximum pullout force and insertion torque of the SB02 and Silica (1.5%) adhesive for various insertion sites.