Mechanical response of femoral cortical bone from soft cure and fresh frozen specimens

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ABSTRACT INTRODUCTION:

Medical education, especially in the field of surgery, leads to increased demand for cadaveric tissue with extended preservation time. While using fresh frozen (FF) tissue is a common practice, it is associated with rapid biological breakdown (while parts are being thawed) and high storage/maintenance cost. An alternative method is soft cure (SC) embalming, which minimizes breakdown and storage related costs and maximizes preservation time and educational use. Other advantages include lower odor and constant availability to the trainee due to lack of freezing/thawing. The SC solution was developed to allow for the preservation of cadaveric material without distortion or fixation of the tissues as experienced in traditional formalin/phenol solution-based embalming. The SC technique can preserve components harvested from FF whole cadavers [1] and it worked successfully in an intact FF whole body specimen that was cryogenically suspended for more than three years [2]. It is critical that the material properties between FF and SC body parts are the same, especially when practicing orthopedic surgery techniques, such as fracture fixation or implant placement. Biofidelity in SC specimens compared to FF would also allow biomechanical testing without the challenge of thawing and degradation. It is known that embalming solutions similar to SC can alter the material properties of soft tissue [3]. However, how the embalming process affects the hard tissue (bone) remains a question. As a result, a study that would quantify mechanical properties of FF vs SC specimens is needed. The main objective of this paper is to quantify the tensile properties of the femoral cortical bone preserved with the SC solution and compare them to the mechanical properties of an FF femur.

METHODS:

Dog bone-shaped coupons (Fig. 1) that were 25.4-mm long, 2.5-mm wide in the gage area, and 0.5 mm thick were machined from the left and right femoral shaft (from its cortical bone) of a 68 year-old male donor using a method that has been previously described in detail [4]. The donor was obtained and treated in accordance with the ethical guidelines established by the United States National Highway Traffic Safety Administration, and all testing and handling procedures were reviewed and approved by an institutional review board at the University of Virginia. The specimen was unilaterally embalmed (right side of the body) using standard techniques with the SC solution. The left side of the body was kept frozen other than thawing for specimen harvest. The first group of coupons from the SC femur was machined after 59 days from the embalming date, the second group after 80 days, and the last, third group, after 94 days. Three groups of FF coupons were harvested and machined at the same time points. All machined coupons were tested in load-control tension, under the same conditions, at a loading and unloading rate of 4 N/sec: from 0 N to 60 N and then back to 0 N. Force and displacement of the clamp holding the coupons were measured. Based on the test data force-displacement (FD) curves were built and compared qualitatively between the coupon groups and all tested coupons were found to exhibit a non-linear FD response at the beginning of the loading phase and at the end of the unloading phase (Fig. 2). As a result, a loading phase stiffness (K1; for a toe region with less than 20 N load) and an effective stiffness (K2; linear region above 20 N load) were calculated for each coupon. To characterize the viscoelastic behavior of the samples energy absorption was found by integrating the FD curves. The Shapiro–Wilk test was performed for all sample sub-groups and two combined groups, containing all coupons of the same type. The toe region stiffness, effective stiffness and amount of energy absorption were then statistically assessed using one-way ANOVA (between groups of the same preservation technique) to evaluate the effect of time since embalming. 2-sample t-test between the SC group (all SC coupons grouped together) and FF group (all FF coupons) was used to evaluate the effect of SC fixation. To better characterize the structural response of the bone coupons from the third SC and FF groups, an optical system (Aramis, GOM mbH, Braunschweig, Germany) was utilized to measure the 3D displacement and strain on the outermost coupon surface (Fig. 3). The maximum Y-strains measured by Aramis were also assessed statistically between the SC and FF group using the 2-sample t-test.

RESULTS SECTION:

In total, 24 FF [group (g) 1: 6 samples, g2: 8, g3: 10] and 22 SC (g1: 6, g2: 9, g3: 7) coupons were subjected to the tensile loading/unloading condition (n=46). No significant difference was found in K1 or energy absorption between and within groups. No significant difference was found in K2 for any individual comparisons, but significant difference (7%, $p<0.05$) was found between SC and FF data, when all 24 FF coupons were compared to all 22 SC coupons grouped together. The FF samples were slightly stiffer (675 N/mm vs. 626 N/mm). No material parameters showed any significant variations when comparing time since soft curing. For the third group of the SC and FF coupons no statistically significant difference was found for the maximum Y-strain data measured by Aramis.

DISCUSSION:

While previous use of SC bone tissue in orthopaedic training has suggested that it generally retains properties similar to FF bone for the first 2 months after embalming, but degrades and softens between months 2 and 3 resulting in less realistic material properties thereafter, it was found that soft cure did not change properties over time. Both, the toe region and the linear region were similar, though a small but significant difference (7%) was found between FF and SC groups. This difference indicates also that there were not enough specimens in each group to reach statistical significance in individual comparisons. It should be noted that this study investigates tensile testing only. To better understand the influence of the SC solution on the bone behavior, other types of tests (such as compression, bending, torsion, etc.) should be considered.

SIGNIFICANCE:

This study aims to inform the orthopedic community of biofidelity in SC cadaver bone specimens compared to the gold standard of FF specimens. The results demonstrate that there is only a small difference in the material properties overall between the FF and SC, which suggests that SC tissue is not only appropriate for orthopaedic training, but could be used as a surrogate for biomechanical analyses performed in the first 3 months after fixation. Future studies should target evaluation of the compressive material properties and failure properties before implementation of SC bone in biomechanical testing.

REFERENCES:

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Fig. 1 Machining of bone-shaped tensile coupons

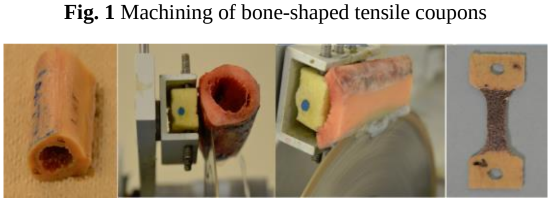


Fig. 2 Sample force-displacement responses

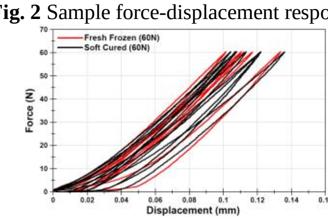
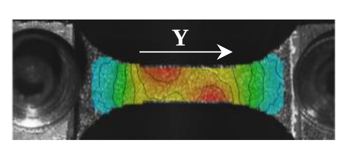


Fig. 3 Y-strain map from Aramis



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