Background:
Suture anchors and sutureless tacs are gaining wide acceptance as viable options for repair of soft tissue to bone, including repair of torn rotator cuff tendons. The vast majority of performance testing of these devices has been carried out in a manner that does not represent physiologic conditions. Testing is often performed as a single load to failure with the direction of pull perpendicular to the bone surface. Cyclic loading better represents the mechanism by which early failure occurs in vivo, and can answer the question of how early motion in rehabilitation will affect the repair. In addition, many studies explain that early failure of fixation devices is caused by use of anchors in bone with poor bone quality. However, bone quality is often judged on a subjective basis, or with measurement techniques with little clinical applicability. Examples of these measurements include measurement of cortical thickness, radiographs compared to aluminum density gauge, and indentation testing. In contrast, measurement of bone density by DEXA is an accepted and clinically available technique. This study tests three fixation devices by cyclic loading with direction of pull oriented at 30 degrees of arm abduction, at loads representative of that expected in early rehabilitation, and normalizes the results with bone mineral density measured by DEXA. The devices tested are manufactured by Arthrotec (Warsaw, IN): the Harpoon Suture Anchor, the BioPhase II Suture Anchor, and the LactoSorb RC Pop Rivet. The three devices represent a metal anchor, a bioabsorbable anchor, and a sutureless bioabsorbable tac, respectively.

Methods:
Proximal humerus specimens were obtained fresh from unembalmed human cadavers shortly after death, and stored frozen at – 20°C as complete shoulder blocks until the time of testing. At the time of abstract submission, eight specimens of a total of sixteen were tested. The mean age of the specimens was 64.5 years (range 50 – 90 years), from 3 females and 2 males. For testing, specimens were thawed for 24 hours, and stripped of all soft tissue attachments. The humeral neck was prepared as a bone trough by rasping the cortical surface to represent intraoperative preparation prior to rotator cuff repair. The specimens were then potted to allow orientation in a custom holding device at 30 degrees of humeral abduction. The humeral neck was divided into 1 cm square blocks with a marking pen, and each block labeled as a region of interest then underwent bone mineral density analysis by dual x-ray absorptiometry (DEXA) technique on a Lunar DPX system perpendicular to the cortical surface with the specimens held at 30° abduction in the custom holder. Failure strength of each device was determined using a materials testing machine (MTS). The two anchor type devices were loaded through the No. 2 suture with which they were originally manufactured, and the pop rivet through nylon strap to simulate fixation of native tendon. Each device was cyclically loaded beginning at 60N for 100 cycles, and each load was then increased by a 20N increment for an additional 100 cycles, and this incremental process was repeated until failure. Failure was defined as complete loss of tension in the system. Performance of each device was analyzed based on load to failure, failure mode, total number of cycles, and bone mineral density for each device location.

Results:
Performance of the metal and bioabsorbable anchors does not statistically differ. A clear statistically significant difference exists between the suture anchors and the pop rivet (P > 0.003 by Analysis of Variance), with the anchors outperforming the pop rivet. No anchor failed below 100N, whereas 75% of pop rivets failed below 100N. No correlation (r = 0.1) between bone mineral density and failure load was demonstrated for any of the three devices. Mode of failure for the metal anchor was predominantly through suture (62%) over the range of bone mineral density. Mode of failure for the bioabsorbable anchor was largely by anchor failure (88%). Pop rivet pullout occurred unpredictably from 60 to 120N, with no correlation to bone mineral density. Bone mineral density ranged from 0.135 – 0.464 gm/cm².

Conclusion:
The performance of suture anchors compared to pop rivets was far superior over a wide range of bone mineral density. The anchors were tested by cyclic loading, with incremental increases in loading during cycling to represent an accelerated rehabilitation protocol. The load at failure for the anchors was high, and represent loads higher than would be expected in the early phase of rehabilitation prior to tendon healing to bone. In comparison, pop rivet failure occurred at relatively low loads, and therefore may warrant a less aggressive rehabilitation schedule. Metal and bioabsorbable anchors appear to be suitable devices for rotator cuff repair regardless of bone mineral density. The major difference between the two suture anchors tested was mode of failure. Bioabsorbable anchors failed at the anchor, rather than through the suture, much more frequently. If failure is to occur during aggressive rehabilitation, the weak link in the repair is preferably not the anchor device. Metal suture anchors, therefore, may be the device of choice.

**Department of Biomedical Engineering. University of Rochester, Rochester, NY.