INTRODUCTION:
Anterior cruciate ligament (ACL) reconstructions are among the most common sports medicine procedures performed in the US each year. Different fixation implants for femoral side have been developed to provide initial stability to the knee during rehabilitation and graft healing to the tunnel. The purpose of this study was to evaluate the biomechanical properties of three ACL reconstruction femoral fixation devices in a porcine model using two methods of surgical implantation.

METHODS:
ACL reconstructions with femoral fixation were performed on 48 porcine femurs with one of three femoral fixation devices, Endobutton CL (Endobutton) (Smith & Nephew, Memphis, TN), ToggleLoc with ZipLoop Technology (ToggleLoc) (Biomet Sports Medicine, LLC, Warsaw, Indiana), or EZLoc (Biomet Sports Medicine, LLC, Warsaw, Indiana), as shown in Figure 1.

In 24 specimens (lateral cortical surface group), the femoral tunnel was drilled from the 10:30 surgical position on the femur with an Acufex 5 mm femoral aimer guide (Smith & Nephew, Memphis, TN) from a simulated 8 mm tibia tunnel created in a wooden block with an Acufex ACL guide (Smith & Nephew, Memphis, TN), at 55 degrees in the sagittal plane and 65 degrees in the coronal plane. This placed the fixation device on the lateral cortical surface of the distal porcine femur. In the remaining 24 specimens (anterior cortical surface group), the tunnel was drilled from the 10:30 position to a standardized anterior femoral surface 5 mm from the lateral cortical edge with the Acufex ACL guide at 55 degrees. For both groups, each fixation device was implanted into 8 femur specimens using an 8mm tendon graft composed of 2-4 porcine extensor tendons whip-stitched at the free ends while being held at equal tension. The femurs were secured to an MTS 858 Mini Bionix testing machine (MTS Corp., Eden Prairie, MN) in a custom loading frame that allowed force transfer through the condyles, in line with the bone tunnel, as shown in Figure 2. The tendon bundle was pre-tensioned to 49N in a custom cryo-clamp and secured with a 40mm distance between the clamp edge and the condylar notch of the femur representing the average intratrabecular distance in the knee plus 10mm that is commonly free in the tibial tunnel when an interferon screw is used.

Cyclic testing was performed from 50N to 450N at 1 Hz for 2000 cycles. This simulates the possible forces that could occur in the ACL graft during the initial postoperative rehabilitation phase. Data was collected with the MTS TestStar II software over the entire cyclic protocol, recording the displacement at the valleys and peaks of the applied forces. Total graft elongation (mm) was determined by calculating the graft construct change in displacement at the 50N valley at 2000 cyclic tests. Tendons were kept moist with a spray application of saline solution every five minutes.

After cyclic testing, the cryo-clamp was loaded with dry ice in bays positioned over both sides of the clamp. The tensile failure test was performed when the clamp temperature reached -15 degrees Celsius, and the tendon temperature mid-substance was between 18-19.5 degrees Celsius. The tendon-femur construct was loaded to failure at a 100% intraarticular strain rate of 30mm/sec to simulate an injury mechanism failure. Load vs. displacement curves were generated from the recorded data. Stiffness (N/mm), first failure load (N), and the observed mode of failure, ie. tendon failure or bone device failure (migration, breakage, etc) was determined. Statistical analysis was performed using the ANOVA procedure in PC SAS (Statistical Analysis Software Cary, NC), and Student’s t-test, when appropriate.

RESULTS:
In the lateral cortical surface group, almost every implant tested failed at some point during the cyclic testing. In most cases the implant was pulled into and through the bone tunnel, ripping away the postero-lateral wall of the femur. All EZLoc devices failed during the cyclic testing. Of the other devices, 3 Endobutton and 2 ToggleLoc implants held throughout the cyclic procedure and were then tested to failure. ToggleLoc exhibited a significantly higher (P=0.0001) stiffness (stiffness (304.64 +/- 2.15 N/mm) than the Endobutton (231.21 +/- 11.14 N/mm). Although not significant, the Endobutton exhibited less elongation after 2000 cycles and a higher failure load.

With the standardized anterior cortical surface group, 11 of 24 femurs completed the cyclic protocol and were then tested to failure: 5 Endobutton, 5 ToggleLoc, and 1 EZLoc implant. As seen in Table 1, the ToggleLoc exhibited significantly higher 2000 cycle elongation (P=0.0127) and stiffness (P=0.0002) than the Endobutton. The Endobutton had significantly higher values for failure load (P=0.0066). The most commonly observed mode of failure for the ToggleLoc was the implant pulling through the bone tunnel, seen in 4 cases. In one instance the ToggleLoc implant fractured in half at the loop connection. Three Endobutton implants failed by pulling through the bone tunnel, with one showing permanent bending. One Endobutton fractured in half at the loop connection, and one additional tendon rupture at the loop tendon interface.

<table>
<thead>
<tr>
<th>Implant Device</th>
<th>Elongation</th>
<th>Failure Stiffness</th>
<th>First Failure</th>
<th>Load (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endobutton (n=5)</td>
<td>5.28 (0.62)</td>
<td>258.88 (20.36)</td>
<td>1190.93* (149.96)</td>
<td></td>
</tr>
<tr>
<td>ToggleLoc (n=5)</td>
<td>6.95* (0.99)</td>
<td>326.27* (9.68)</td>
<td>912.59 (82.39)</td>
<td></td>
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</table>

Table 1. Cyclic and tensile failure testing results for the anterior cortical fixation group. *Denotes a significant difference (P<0.05).

The Endobutton provided the strongest ACL cortical femoral fixation with the least graft/implant elongation of the implants tested. With double bundle ACL reconstruction or a lateralized single socket femoral tunnel, which places the exit of the tunnel on the lateral femoral cortex, the surgeon must appreciate that fixation strength is significantly less than a cortical fixation device that is placed on the anterior femoral cortex. The surgeon should consider this weakness when determining the postoperative rehabilitation protocol. Additionally, in single socket femoral ACL reconstruction, the surgeon should consider tunnel placement exit on the anterior femoral cortex if possible without compromising the anatomic ACL tunnel origin.