Max Load and Cyclic Load Physical Testing

Methods
All test specimens were assembled in the same manner. Five ToggleLoc™ devices were assembled with a #7 Polyethylene strand (ZipLoop™ Technology). Yield load testing was performed on Test Machine “Dorothy” (GPP-1257-3C, Serial # 128907A) and cyclic load testing was performed on Test Machine “Sandman” (GPP-1257-5, Serial # 184549A). In the yield load group, the implant construct was pulled at 1.18mm/sec until failure. The cyclic loading test was 2,000 cycles from 50N to 450N.

Results

<table>
<thead>
<tr>
<th>Implant</th>
<th>Avg. Peak Load (lbs)</th>
<th>Avg. Peak Load (N)</th>
<th>Cyclic Loading Slippage (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>#7 Adjustable Loop ToggleLoc™ Device</td>
<td>374.1</td>
<td>1664.1</td>
<td>0</td>
</tr>
</tbody>
</table>

This table shows the peak load and cyclic loading test data for the ToggleLoc™ Femoral Fixation Device with ZipLoop™ Technology.

Discussion or Analysis
In evaluating the failure modes of each test specimen, it was found that some samples failed because the #7 polyethylene strand broke and some failed because the ToggleLoc™ button broke. This indicates that the ToggleLoc™ Femoral Fixation Device with ZipLoop™ Technology assembly achieved maximum loads. The results obtained from the yield load testing show the ToggleLoc™ Femoral Fixation Device with ZipLoop™ Technology to be as strong/stronger than other devices indicated for ACL reconstructions tested under similar means.¹

Conclusions
The ToggleLoc™ Femoral Fixation Device with ZipLoop™ Technology provides significant fixation strength with virtually no slippage while also having the ability to change the length of its loop makes it an optimum device for ACL reconstructions. Due to the ZipLoop™ Technology a surgeon can maximize the amount of collagen in a femoral tunnel, tension the ACL graft from the femoral side (after tibial fixation is achieved), and eliminate the need for multiple sizes of implants.

¹ Data on file at Biomet Sports Medicine. Bench test results are not necessarily indicative of clinical results.

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