Randomized clinical trial of femoral and tibial fixation in hamstring ACL reconstruction

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ACL Study Group

Sardinia 2004
Outcome of ACL Reconstruction

- Tunnel Placement
- Graft Choice
- Graft Fixation
Evolution in Graft Choice

- Semi-t
- Pat Ten
- Others
Femoral Fixation
RCT – BioScrew versus Endobutton
Purpose

- Question – Is BioScrew/EndoPearl equal to Endobutton for femoral fixation in ACL hamstring reconstruction as measured by KT-1000 and IKDC outcome measurements?
Hypothesis

- That augmentation of interference screw fixation on the femoral side with an EndoPearl would improve the KT-1000 SSD results as compared to the Endobutton.
Surgical Technique

- Double-looped, four bundle semitendinosus-gracilis graft
- Trans-tibial drill technique
- Tunnels size = graft size
- Femoral screw same size as tunnel
- Tibial internal aperture screw one size larger with secondary button fixation
Follow-up

- Independent examiner
- History & Examination
- KT-1000
- IKDC subjective evaluation
Methods: ACL Reconstruction

- Sample size was derived to compare clinical outcome with a variable femoral fixation at two years. Outcome measures were set at 2mm of KT-1000 side-to-side difference and a 10% difference in IKDC scores between groups with a power of 80% and a significance of 0.05.

- Randomization of 51 patients using a computer generated table to determine the selection of femoral fixation using either a femoral interference screw/EndoPearl or a closed loop Endobutton.

- Clinical results, IKDC results and KT-1000 data were analyzed using the student-t test with significance set at 0.05.
Results

- The average follow-up time for the group was 2.3 years with a minimum 2-year follow-up.
- No significant differences were seen in the age and demographics of both groups.
- 26 patients BioScrew/EndoPearl group
- 23 in the Endobutton group.
- Two patients were excluded from the EB group due to contralateral ACL tear during the study period.
- No patients were lost to follow-up
## Results – Table 1

<table>
<thead>
<tr>
<th></th>
<th>KT-1000 side-to-side (2 yrs)</th>
<th>IKDC score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ENDOBUTTON</strong></td>
<td>1.8 +/- 2.4</td>
<td>85.9 +/- 9.8</td>
</tr>
<tr>
<td><strong>BIOSCREW + ENDOPEARL</strong></td>
<td>2.2 +/- 2.2</td>
<td>84.0 +/- 10.2</td>
</tr>
<tr>
<td><strong>Males</strong></td>
<td>2.1 +/- 2.4</td>
<td>86.4 +/- 9.6</td>
</tr>
<tr>
<td><strong>Females</strong></td>
<td>1.9 +/- 2.3</td>
<td>82.9 +/- 10.3</td>
</tr>
<tr>
<td><strong>Femoral Dilation</strong></td>
<td>2.0 +/- 2.3</td>
<td>84.3 +/- 10.7</td>
</tr>
<tr>
<td><strong>No Femoral Dilation</strong></td>
<td>1.9 +/- 2.4</td>
<td>85.8 +/- 9.0</td>
</tr>
<tr>
<td><strong>Tibial Dilation</strong></td>
<td>1.9 +/- 2.3</td>
<td>84.7 +/- 10.5</td>
</tr>
<tr>
<td><strong>No Tibial Dilation</strong></td>
<td>2.2 +/- 2.6</td>
<td>85.5 +/- 8.3</td>
</tr>
</tbody>
</table>
KT-1000 Side to side results

KT-1000: Side-to-Side Results
Discussions

- **Study Strengths:**
  - Randomized, Blinded
  - Two year follow-up

- **Two patient crossovers…**
  - One AF → EB for post wall deficiency
    » KT-1000 side to side 0-2mm, IKDC 80
  - One EB → AF for improper flipping
    » KT-1000 side to side 0-2mm, IKDC 85

- *In both cases alternate treatment represented a good back-up fixation option.*
In conclusion, this study supports the use of both the aperture fixation technique with a Bioscrew and Endopearl (Linvatec, Largo, FL) or an Endobutton (Smith and Nephew, Memphis, TN) reconstruction on the femoral side in a randomized and blinded model of hamstring ACL reconstruction where the only variable was femoral fixation.
Tibial Fixation
Purpose

- Question – Is ExtraLok BioScrew equal to Intrafix for tibial fixation in hamstring ACL reconstruction as measured by KT-1000 and IKDC outcome measurements?
Hypothesis

- The ExtrLok Bioscrew is equal to the Intrafix for tibial fixation of soft tissues.
- That the ExtraLok BioScrew tibial fixation would reduce the KT-1000 3-5 mm SSD results.
Methods

- Prospective randomized clinical trial
- Ottawa Hospital; 3 surgeons
- Standard ACL 4 bundle semi-tendinosus/gracilis trans-tibial arthroscopic reconstruction
Methods

- 105 sequential patients from the Ottawa Hospital undergoing ACL reconstruction were recruited.

- Inclusion criteria:
  - Able to complete 2-year follow-up
  - No previous knee surgery
  - No evidence of multiple-ligament injury
  - Normal ACL contra-lateral knee
  - Closed proximal tibial physis
Methods

- Femoral fixation is same for both groups: EndoButton® (Smith & Nephew, Andover, MA).

- After drilling tunnels, a computer-generated randomization table used to allocate patients to a study arm.
Methods

- Assessment:
  - Clinical assessments at 6 weeks, and 3, 6, 12, and 24 months post-op.
  - KT-1000 arthrometer scores at each visit to compare side-to-side difference between knees (manual maximum)
  - IKDC scores pre-op, and at 12 and 24 months post-op
Results

- 105 patients
  - 74 (71%) available for follow-up at this time
    » 36 XtraLok
    » 38 Intrafix

- Preliminary data
  » 6 weeks: 42 patients
  » 3 months: 49 patients
  » 6 months: 51 patients
  » 12 months: 21 patients
Comparison of KT-1000 arthrometer side-to-side difference at 6 weeks

Number of patients

Side-to-side difference at 6 weeks

Comparison of KT-1000 arthrometer side-to-side difference

Number of patients

<1mm 0-2mm 3-5mm 6+mm

Intrafix XtraLok

Comparison of KT-1000 arthrometer side-to-side difference at 6 weeks
Comparison of KT-1000 arthrometer side-to-side difference

Number of patients

Side-to-side difference at 3 months

Comparison of KT-1000 arthrometer side-to-side difference
Comparison of KT-1000 arthrometer side-to-side difference

Number of patients

Side-to-side difference at 6 months

-1mm 0-2mm 3-5mm 6+mm

Intrafix

XtraLok
Comparison of KT-1000 arthrometer side-to-side difference

Number of patients

<table>
<thead>
<tr>
<th>Side-to-side difference</th>
<th>Intrafix n=27</th>
<th>XtraLok n=38</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;-3mm</td>
<td>3%</td>
<td>4%</td>
</tr>
<tr>
<td>-2 to 2mm</td>
<td>56%</td>
<td>40%</td>
</tr>
<tr>
<td>3 to 5mm</td>
<td>40%</td>
<td>13%</td>
</tr>
<tr>
<td>6+mm</td>
<td>4%</td>
<td>2%</td>
</tr>
</tbody>
</table>

Chi-square p=0.08
Comparison of KT-1000 arthrometer side-to-side difference

Number of patients

Side-to-side difference at 12 months
Comparison of KT-1000 arthrometer side-to-side difference

Intrafix
XtraLok

Number of patients

Side-to-side difference at latest follow-up

<1mm 0-2mm 3-5mm 6+mm
Preliminary Results

- KT-1000 arthrometer scores are early follow-up at 12 months or less.

- KT-1000 side-to-side difference between groups at 6 weeks, and 3, 6, and 12 months are not statistically significant (ANOVA).
KT change over time (SSD)

Minimal change

△ (delta) = 5.4mm
Discussion

- KT-1000 arthrometer literature:
  - Highly sensitive and predictive of stability of knee
  - Good objective measure
  - Validated
Discussion

- The Intrafix® tibial fastener has good clinical results and improved pullout strength in lab testing compared to eccentrically placed cancellous-type bioabsorbable screws.

  (Richmond JR, personal communication)
Discussion

Kousa P et al, AJSM 2003
Discussion

- Traditional interference BioScrews have been shown to be inferior to Intrafix® on lab testing (Kousa et al)
- No clinical studies available comparing cortico-cancellous interference BioScrew and Intrafix®
Conclusion

- Early mechanical results support the null hypothesis: BioScrew XtraLok® and Intrafix® provide equal graft fixation
- Both tibial fixation devices have a low clinical failure rate to one year
- EtraLok screws show a trend to reduce the KT 3-5 mm SSD
Thank You