Increased Risk Of Revision After Anterior Cruciate Ligament Reconstruction With Bone-Patellar Tendon-Bone Allograft Compared To Bone-Patellar Tendon-Bone Autograft

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June 6, 2015
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- We have no potential conflicts with this presentation.
- IRB approval was obtained for this investigation.
Background

- Despite years of study, controversy still exists regarding the ideal graft for anterior cruciate ligament reconstruction (ACLR).
- Allograft use has become increasingly popular in the US having exceeded 40% in some large hospital and group settings.¹,²
- Some meta-analyses and systematic reviews have suggested that autografts have better stability or lower revision rates than allografts.³-⁶
- Yet others have suggested that there is no difference in outcome between autografts and allografts.⁷-¹¹
- Several large cohort studies have reported a 2-4 x higher risk of graft failure when allograft is used.¹²-¹⁵
Background

- The lack of clarity regarding graft performance is due to two primary problems:
  - Many studies are underpowered and therefore are unable to detect a difference in outcome
  - Allografts are often grouped together despite the fact that there are different graft types and different graft processing methods.

Purpose

1. To compare the risk of aseptic revision in patients with bone-patellar tendon-bone (BPTB) grafts.
2. Specifically to evaluate the risk of revision by tissue type (allograft and autograft) and tissue processing (irradiation, chemical processing, or non-processed)
Methods

- Design: Retrospective cohort study
- Setting: Kaiser Permanente, an Integrated Health Care System covering 9.5 million members in the United States
- Data source: Kaiser Permanente ACLR Registry
  - Prospective data collection
  - Outcomes validated via chart review
- Study sample:
  - Primary single ligament ACLR with BPTB autograft or BPTB allograft
  - 282 surgeons from 43 hospitals
  - 6 regions (Hawaii, Southern California, Northern California, Northwest, Mid-Atlantic, Colorado)
Methods

- Outcome of interest: Aseptic revision ACLR

- Exposures of interest:
  1. Graft type (BPTB autograft or BPTB allograft)
  2. Tissue processing:
     - Irradiation < 1.8 Mrad or ≥ 1.8 Mrad
     - Chemical processing
       - Allowash (LifeNet Virginia Beach, VA), AlloTrue (AlloSource Centennial, CO)
         » Ultrasonic bath with detergents, antibiotics, alcohol, and peroxide
       - BioCleanse (Regeneration Technologies Inc. Alachua, FLA)
         » Oscillating positive and negative pressure with alcohol and peroxide
     - Sterilely harvested non-processed tissue

- Effect modifiers: age (patients ≤ 21 vs. ≥ 22 years old)

- Analysis: survival analysis (Kaplan Meier curves and Cox regressions)
Results
Sample size 5586 BPTB grafts (81.6% Auto, 18.4% Allo)

<table>
<thead>
<tr>
<th></th>
<th># of Cases</th>
<th># of Revisions</th>
<th>Crude Revision Rate (%)</th>
<th>Cumulative Failure at 2 years with 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autograft</td>
<td>4557</td>
<td>85</td>
<td>1.9</td>
<td>1.7 (1.3, 2.2)</td>
</tr>
<tr>
<td>Allograft (Total)</td>
<td>1029</td>
<td>37</td>
<td>3.6</td>
<td>4.1 (2.9, 5.9)</td>
</tr>
<tr>
<td>No Processing</td>
<td>155</td>
<td>5</td>
<td>3.2</td>
<td>6.3 (2.6, 15.0)</td>
</tr>
<tr>
<td>&lt;1.8 Mrad w/o Chemical Processing</td>
<td>332</td>
<td>11</td>
<td>3.3</td>
<td>3.3 (1.7, 6.3)</td>
</tr>
<tr>
<td>&lt;1.8 Mrad with Chemical Processing</td>
<td>193</td>
<td>7</td>
<td>3.6</td>
<td>4.5 (2.0, 9.8)</td>
</tr>
<tr>
<td>≥1.8 Mrad w/o Chemical Processing</td>
<td>117</td>
<td>6</td>
<td>5.1</td>
<td>3.7 (1.4, 9.7)</td>
</tr>
<tr>
<td>≥1.8 Mrad with Chemical Processing</td>
<td>171</td>
<td>6</td>
<td>3.5</td>
<td>4.5 (1.8, 10.8)</td>
</tr>
<tr>
<td>BioCleanse</td>
<td>61</td>
<td>2</td>
<td>3.3</td>
<td>4.7 (1.2, 17.5)</td>
</tr>
</tbody>
</table>

### Graft (Allograft vs. Autograft)

<table>
<thead>
<tr>
<th>Graft (Allograft vs. Autograft)</th>
<th>Hazard Ratio (95%CI)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total (All ages)</td>
<td>4.54 (3.03-6.79)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Age &lt; 21 and younger</td>
<td>4.17 (2.49-6.97)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Age &gt; 22 and older</td>
<td>5.29 (2.70-10.36)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Results: Revision Risk Factors

Overall adjusted risk is 4.54 X higher with BPTB allografts
Discussion

- A recent systematic review of 8 different meta-analysis (n=15,819 patients) concluded that there was no difference in re-rupture rates between allografts and autografts, but differences due to graft type and graft processing were not assessed.\textsuperscript{10}

- Other review studies have suggested that using non-irradiated grafts may lead to better outcomes, but in those studies graft type was not accounted for.\textsuperscript{11,16,17}

- This study focused on BPTB grafts in order to eliminate the variation due to multiple graft types.

- BPTB allografts had a much higher risk of revision compared to BPTB autografts.

- The higher risk of revision was identified with all BPTB allografts irrespective of irradiation dose, chemical processing, or no processing.

- It appears that factors other than graft processing are responsible for the poorer results seen with BPTB allografts.
Discussion: Strengths & Limitations

- **Limitations**
  - Surgical technique and rehabilitation were not standardized
  - Return to sports and activity levels not evaluated
  - Strength, knee laxity and functional outcomes not available
  - Loss to f/u : 25.9%

- **Strengths**
  - Large racially diverse sample
  - Large sample size allowed for evaluation of multiple risk factors
  - Prospective standardized method of data collection and validation
  - Diverse patient and surgeon population make the results generalizable to the greater population of ACLR patients and providers/hospitals involved in their care
Conclusions

- BPTB allografts had a 4.54 X higher adjusted risk of revision than BPTB Autografts.
- Whether the allograft tissue was irradiated with either high or low dose irradiation, chemically processed, or not processed at all made little difference in the risk of revision.
- The differences in risk of revision were consistent in younger and older patients.
- Surgeons and patients need to be aware of the increased risk of revision when BPTB allograft tissue is used for ACLR.


