**Risk factors for bacterial contamination of osteochondral allografts collected from cadaveric donors**

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**Introduction:** Osteochondral (OC) allografts are used for restoration of bone and joint defects with increasing frequency. Osteochondral allografts collected from cadaveric donors do not undergo terminal sterilization prior to implantation in order to preserve the viability and function of articular cartilage and chondrocytes. Implantation of OC allografts contaminated with Clostridium sp. has resulted in post-operative infections and death in some recipients.[1]

Contamination of OC allografts can be from bacteria of low or high pathogenicity.[2] Low pathogenicity bacteria are often skin commensals, either from the donor or exogenous sources such as the procurement team. Highly pathogenic (HP) bacteria commonly originate from an endogenous source, generally the gastrointestinal or respiratory systems. Contamination of donor tissues with HP bacteria is hypothesized to occur via bacterial translocation and hematogenous spread.[2]

Considerable resources are required to collect OC allografts. Identification of donor or procurement risk factors associated with an increased bioburden or the presence of HP bacteria may improve donor selection criteria, tissue procurement practices and utilization of resources and result in a significant gain in distributable OC tissues and a decreased risk to recipients.

**Materials and Methods:** Data were analyzed from 848 donors aged 15-45 years, from 7 tissue collection agencies for 2004 and 2005 that were processed at one tissue bank. Dependent variables examined were: age, gender, year, calendar quarter, cause of death, tissue collection agency, location of recovery, timing of tissue collection relative to autopsy, recovery technician experience, death to cool time and death to recovery time. Independent outcome variables were based on results of recovery and pre-processing swab cultures. Bacterial bioburden was defined as the number of positive cultures divided by the total number of cultures at the donor level. Final status of the donor tissues, for the purposes of this analysis, was determined using the following criteria: Donor tissue was considered unsuitable for JR use (JR Reject) if HP bacteria were cultured from any donor tissues or if donor bacterial bioburden was ≥50%. Donor tissues that did not meet these criteria were classified as acceptable for JR use (JR Accept).

Three logistic regression models identified potential risk factors:

- **Model 1:** JR accept / JR reject based on either HP bacteria positive culture or donor bioburden ≥ 50%.
- **Model 2:** JR accept / JR reject based on HP bacteria positive culture only.
- **Model 3:** JR accept / JR reject based on donor bioburden ≥ 50% and HP bacteria negative culture.

Univariate logistic regression for each of the independent variables was done for each of the three models. Independent variables with a p value of < 0.25 were entered into a backwards multivariate logistic regression model until all remaining variables had p values < 0.05.

**Results:** There were 580 males (68%) and 268 females (32%) with an equal distribution between years 2004 (n=414) and 2005 (n=434). Over eighty percent of donors came from 3 tissue collection agencies. The most frequent causes of death were motor vehicle accidents, trauma and cardiac-related events, accounting for 80% of all deaths.

Eighty-two percent of tissue recoveries occurred in a dedicated recovery environment (OR (n=278) or recovery suite (n=415)) compared to eighteen percent in other facilities (morgue (n=131) or funeral home (n=24)). The overall mean death to cool time was 2.3 ± 2.3 hours and the mean death to recovery time: was 11.6 ± 6.0 hours. No autopsy was performed in 46% (n=391) of donors. Recovery of JR tissues in donors that had an autopsy (n=457) occurred prior autopsy in 268 donors and after autopsy in 189 donors. The mean experience of the two recovery technicians for each donor was 67 ± 32 recoveries.

There was an increased incidence of donors rejected for JR tissue use in the third quarter (July to September) due to positive HP bacterial cultures. The calculated overall OC allograft tissue acceptance rate for JR use was 68.9%. (Table 1)

The significant risk factors identified in the three multivariate models were:

- **Model 1:** Agency, timing of tissue collection relative to autopsy (post autopsy OR 2.35), calendar quarter (Jul-Sept OR 1.80) and gender (Male OR 2.58).
- **Model 2:** Agency, calendar quarter (Jul-Sept OR 2.17), timing of tissue collection relative to autopsy (post autopsy OR 3.32) and death to recovery time (>16hr OR 2.58).
- **Model 3:** Gender (Male OR 3.43)

Factors that were not associated with JR tissue rejection in any multivariate model were: age, cause of death, combined technician experience, year, location of recovery and death to cool time.

**Discussion:** Collection of OC tissues after autopsy was associated with rejection for JR use due to contamination with highly pathogenic bacteria. Based on this finding we recommend that collection of JR tissues should be done prior to autopsy when possible.

Contamination with HP bacteria increased when tissue collection occurred greater than 16 hours after death. This finding confirms a similar report finding and time cut off examining Clostridial contamination of musculoskeletal allografts.

Factors that were not associated with JR tissue rejection in any multivariate model were: age, cause of death, combined technician experience, year, location of recovery and death to cool time.

The seasonal effect of increased contamination with HP bacteria in the summer months (July to September) has not been previously reported as a risk factor for OC allografts. This is potentially associated with increased ambient temperatures and bacterial sporulation.

Males had a higher bacterial bioburden than females. The subset of donors that were rejected for JR use due to high bioburden and had negative cultures for HP bacteria, represent a significant target population (13% of all donors) where tissue procurement factors may play a role increasing the release rate of allografts for JR use.

**References:**


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**Table 1:**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds Ratio (OR)</th>
<th>95% CI</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive HP bacteria</td>
<td>5.64</td>
<td>3.30-9.70</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Posterior HP bacteria + Hemorrhage</td>
<td>6.53</td>
<td>3.73-11.36</td>
<td>&lt;0.001</td>
</tr>
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<td>Positive HP bacteria, Hemorrhage ≤50%</td>
<td>3.07</td>
<td>1.70-5.64</td>
<td>0.001</td>
</tr>
<tr>
<td>Positive HP bacteria, Hemorrhage &gt;50%</td>
<td>4.6</td>
<td>2.6-8.0</td>
<td>&lt;0.001</td>
</tr>
</tbody>
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