Debris Testing of VISIONAIRE® Patient Matched Cutting Blocks

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Summary
VISIONAIRE Patient Matched Instrumentation (Smith & Nephew, Inc., Memphis, TN, USA) consists of customized distal femoral and proximal tibial cutting blocks manufactured from pure medical grade Nylon 12 powder. While the design and function of these blocks have been fully validated, the potential for nylon debris generation during resection is unknown. The purpose of the current study was to assess debris generation following cadaveric and saw-bones testing. Seven (7) sets of custom cutting blocks were precision weighed before and after testing. Following cadaveric use, no evidence of debris generation was observed. Further, under the worst possible conditions of clinical use, non-lubricated saw-bone testing resulted in only minimal material loss. These results suggest that patient matched cutting blocks are durable and may be safely utilized during total knee arthroplasty.

Introduction
During total knee arthroplasty (TKA), contact between the oscillatory saw blade and metallic cutting blocks is thought to generate metal particle debris [1]. There is some concern that this debris can make its way into the knee articulation, potentially increasing polyethylene wear and subsequent osteolysis risk [2-4]. Therefore, it is appropriate to consider the potential for debris generation during the design of new cutting block instrumentation [4].

There is a recognized need to improve surgical accuracy and efficiency during TKA [5, 6]. VISIONAIRE Patient Matched Instrumentation (Smith & Nephew, Inc., Memphis, TN, USA) was developed to reduce surgical time, eliminate unnecessary instrumentation, and to achieve optimal postoperative mechanical alignment. This technology consists of customized distal femoral and proximal tibial cutting blocks manufactured from pure medical grade Nylon 12 powder [7] (Polyamide 2201, Figures 1 and 2). While the design and function of VISIONAIRE Patient Matched Instrumentation cutting blocks have been fully validated, the potential for operative debris generation has yet to be determined.
The purpose of the current cadaveric and saw-bones simulation study was to assess the potential for nylon debris generation during the use of VISIONAIRE™ Patient Matched Instrumentation cutting blocks. These results may be used to determine the durability and material safety of this technology.

**Materials and Methods**

All VISIONAIRE Patient Matched Instrumentation cutting blocks used in the current study were manufactured on a plastic laser-sintering system (EOS Laser Sentering System, D-82152 Krailling / Munchen, Germany) and then cleaned according to the standard in-house cleaning protocol. Prior to the study, all blocks were weighed using a precision balance (Mettler-Toledo, Inc., Columbus, OH, USA). A Stryker sagittal saw was used during all tests (Kalamazo, MI, USA).

Two (2) sets of VISIONAIRE Patient Matched Instrumentation cutting blocks exhibiting acceptable specimen fit were utilized for cadaveric bone resection. The femoral block was secured to the distal end of the femur and the distal cut was performed. After the distal femoral bone was cut, the tibial cutting block was secured to the proximal end of the tibia and the bone was resected. Following completion of resection, the used cutting blocks were cleaned and dried in a convection oven for 36 hours to drive out any possible absorbed moisture. The blocks were then weighed once again to assess material loss.

Five (5) additional cutting block sets were used for sawbone resection in the mechanical testing lab. Each block was secured in a vise while a saw blade was placed in the cutting slot and run for 30 seconds. This period of time was selected so that the mechanical testing would exceed the average observed cadaveric resection time of 15 seconds. During this test, the saw blade was intentionally pushed against the non-lubricated walls of the slots, creating the worst case scenario of clinical use. Once the test was completed, all blocks were again weighed to assess potential material loss.

**Results**

Cutting block weights before and after testing may be found in Tables 1 and 2.

During the cadaveric testing, all but one VISIONAIRE Patient Matched Instrumentation cutting block gained weight following use. The weight loss observed in Tibia 1 was attributed to drilling holes made in the block under the central anterior alignment hole. Intraoperatively, there were no visible signs of nylon debris on any of the specimen tissues. Further, the operating surgeons did not report any comments indicative of unacceptable block performance. A small amount of weight...
loss was observed following completion of saw-bone testing. The femoral and tibial cutting blocks lost an average of 0.0161 and 0.00626 grams of material, respectively.

**Discussion**

The results of the current study suggest that nylon debris generation during the use of VISIONAIRE® Patient Matched Instrumentation custom cutting blocks is minimal. The first cadaveric testing series was able to show an increase in weight for three cutting blocks. This result is easily explained by the fact that absorption occurs when the blocks come into contact with biological fluids. Some of this fluid appears to remain absorbed despite the convection oven drying that was performed. The saw bones testing results confirm the cadaveric observations. Under the worst possible scenario of clinical use, only minimal weight loss due to blade friction was observed. It must be noted that these extreme non-lubricated simulation conditions are unlikely to occur during surgery. Even so, this minimal amount of debris generation would likely be removed by standard pulsed lavage of the incision site, since their density is lower than the water.

Debris particles of medical grade Nylon 12 have been found to be biocompatible, based on internal testing and the manufacturer’s biocompatibility certificate [7, 8]. Considering the minimal risk of debris generation that was observed in the current study, in addition to the established biocompatibility of the manufacturing material, we have determined VISIONAIRE Patient Matched Instrumentation patient matched cutting blocks to be safe for utilization during TKA.

**References**


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**Table 1: Cadaveric Weight Loss/Gain Data**

<table>
<thead>
<tr>
<th>Block ID</th>
<th>Weight Before (g)</th>
<th>Weight After (g)</th>
<th>Weight Loss /Gain (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femur 1</td>
<td>41.1069</td>
<td>41.1602</td>
<td>Gain - 0.0533</td>
</tr>
<tr>
<td>Femur 2</td>
<td>43.1714</td>
<td>43.2397</td>
<td>Gain - 0.0683</td>
</tr>
<tr>
<td>Tibia 1</td>
<td>30.2069</td>
<td>30.1197</td>
<td>Loss - 0.0872</td>
</tr>
<tr>
<td>Tibia 2</td>
<td>30.6493</td>
<td>30.7082</td>
<td>Gain - 0.0589</td>
</tr>
</tbody>
</table>

**Table 2: Sawbone Weight Loss/Gain Data**

<table>
<thead>
<tr>
<th>Block ID</th>
<th>Weight Before (g)</th>
<th>Weight After (g)</th>
<th>Weight Loss (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femur 1</td>
<td>37.0304</td>
<td>37.0252</td>
<td>0.0052</td>
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<tr>
<td>Femur 2</td>
<td>35.5039</td>
<td>35.4934</td>
<td>0.0105</td>
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<tr>
<td>Femur 3</td>
<td>35.1111</td>
<td>35.1106</td>
<td>0.0005</td>
</tr>
<tr>
<td>Femur 4</td>
<td>35.1875</td>
<td>35.1525</td>
<td>0.0350</td>
</tr>
<tr>
<td>Femur 5</td>
<td>32.2955</td>
<td>32.2662</td>
<td>0.0293</td>
</tr>
</tbody>
</table>

Average Femur Block Weight Loss: 0.0161g

| Tibia 1  | 22.6534           | 22.6356          | 0.0178          |
| Tibia 2  | 22.7296           | 22.7236          | 0.0060          |
| Tibia 3  | 22.6508           | 22.6492          | 0.0016          |
| Tibia 4  | 22.5200           | 22.5199          | 0.0001          |
| Tibia 5  | 23.0502           | 23.0444          | 0.0058          |

Average Tibia Block Weight Loss: 0.00626g
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