Primary Stability of Cemented Tibial Implants

Katrin Nagel, Dipl.-Ing.¹, Ulf Schlegel, MD², Nicholas E. Bishop, Dr.-Ing.¹, Klaus Pueschel, MD³, Michael M. Morlock, PhD¹.
¹Institute of Biomechanics, TUHH - Hamburg University of Technology, Hamburg, Germany, ²Department of Orthopaedic and Trauma Surgery, University of Heidelberg, Heidelberg, Germany, ³Department of Legal Medicine, University Medical Centre Hamburg-Eppendorf, Hamburg, Germany.

Disclosures:

Introduction: The number of total knee replacement implantations is continuously increasing, both for primary and revision procedures. Registry data indicate that loosening of the tibial tray is a frequent reason for revision. Component loosening might be related to the initial strength of both the bone-cement and cement-implant interfaces. Use of jet lavage has been shown to increase the initial interface strength, which has been related to a greater penetration depth of the cement into the bone [1,2]. A similar association with bone mineral density (BMD) was assumed, but could not be demonstrated. This might be due to a confounding interaction between penetration depth and BMD. The aim of this study was to determine the influence of BMD and cement penetration depth on the pull-out strength of the bone-cement interface after jet lavage.

Methods: 56 human tibiae (34 male, 22 female) were implanted with P.F.C. Sigma® tibial trays (MBT Keeled and Ti Fixed Bearing, DePuy). The implants were modified to enable pull-out. Cementation was performed using high viscosity SmartSet® (40 g, DePuy). 36 specimens underwent jet lavage prior to implantation (JET group). The remaining 20 specimens underwent syringe lavage (SYRINGE group). After insertion the implants were axially loaded with 50 N for 12 minutes. In an attempt to prevent failure of the implant-cement interface, implants were covered by a release agent before implantation to enable temporary manual removal after cement polymerisation, followed by re-bonding using acrylic glue. The bone-cement interface strength was tested by measuring the axial pull-out force. Bone mineral density (BMD) was determined from CT scans prior to implantation. The specimens were also CT-scanned after implant removal (before re-gluing the implants to the bone cement) to reconstruct 3D models of the cement layer for morphology analysis (penetration depth). For this study only specimens with failure at the bone interface were evaluated. Data were analysed using linear regression and one-way ANOVA or Mann-Whitney U. BMD and penetration depth were evaluated as separate predictors of pull-out force (α = 0.05, PASW 18, SPSS Inc./IBM Corporation).

Results: 26 of the 56 specimens failed at the bone interface or by bulk bone fracture and were included in the analysis: JET group N = 14, SYRINGE group N = 12 (Tab. 1). One JET specimen was excluded from strength analysis due to mixed-mode failure. BMD was not significantly different between JET and SYRINGE (p = 0.621). The median pull-out strength and the mean penetration depth were significantly larger for the JET group (p < 0.001 for both parameters). The ranges of penetration depth of the JET and SYRINGE groups overlapped but the JET specimens showed significantly larger pull-out strength at the same penetration depth (p = 0.041, Fig. 1). Pull-out force was significantly and positively related to BMD in the JET group (p = 0.013, adjusted R² = 0.39, Fig. 2), but not in the SYRINGE group (p = 0.364, adjusted R² = -0.009, Fig. 2). Pull-out strength did not correlate with penetration depth for either group (p = 0.974, adjusted R² < 0.001, Fig. 1). There was a slight decrease in cement penetration depth with increasing BMD in the JET group (p = 0.281, adjusted R² = 0.021) and in the SYRINGE group (p = 0.18, adjusted R² = 0.092, Fig. 3).

Discussion: Using pulsed jet lavage to prepare the bone for cementation was shown to provide significantly larger pull-out forces than preparation using manual syringe lavage, increasing the median by a factor of almost 10. The explanation for greater strength after jet lavage was expected to be related to larger cement penetration into the bone, which was indeed more than twice greater on average (Tab 1). However, pull-out strength and cement penetration depth did not correlate, either overall or within the two cementing technique groups. Furthermore, there was a broad overlap in penetration depths for the JET and SYRINGE lavage groups, resulting in clearly higher pull-out strength for jet lavage (Fig 1). BMD was also expected to influence pull-out strength but with two opposing effects: On the one hand lower BMD was expected to lead to greater penetration and thus increased strength, but on the other hand to result in weaker bone. The former effect was not confirmed, with no clear relationship observed between penetration depth and BMD (Fig 3). The latter effect was confirmed, but only for jet lavage and not for syringe preparation (Fig 2). Thus, against expectations, neither cement penetration nor BMD nor their interaction explain the pull-out strength being larger for jet lavage than syringe bone preparation. Another explanation might be that the cement bonds with greater strength to bone prepared by jet lavage, which may be attributed to the more efficient removal of fat in contrast to syringe lavage. This improved contact between bone and cement after jet lavage preparation may explain the positive correlation of pull-out strength with BMD determined for jet lavage but not for syringe lavage, as it allows the BMD-dependent bone strength to come into effect.

Significance: These findings suggest that the use of jet lavage or any other technique that allows direct contact between bone
and cement, has an overriding importance in improving primary stability, without necessarily increasing cement penetration depth. Contrary to expectation, increased penetration seems to be less important.

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2. Gebert de Uhlenbrock et al., Influence of time in-situ and implant type on fixation strength of cemented tibial trays - A post mortem retrieval analysis, Clinical Biomechanics 27 (2012)

Tab. 1: Measured BMD, strength, penetration depth and corresponding p values for JET and SYRINGE groups.

<table>
<thead>
<tr>
<th></th>
<th>JET</th>
<th>SYRINGE</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td>N</td>
<td>14</td>
<td>12</td>
<td>-</td>
</tr>
<tr>
<td>Mean BMD [HA/cm³]</td>
<td>74</td>
<td>81</td>
<td>0.621</td>
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<tr>
<td>Median bone interface strength [N]</td>
<td>5707</td>
<td>591</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Range</td>
<td>3073 – 10550</td>
<td>242 – 1268</td>
<td>-</td>
</tr>
<tr>
<td>Mean penetration depth [mm]</td>
<td>1.64</td>
<td>0.71</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Range</td>
<td>0.79 – 3.23</td>
<td>0.20 – 1.66</td>
<td>-</td>
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Fig. 1: Measured pull-out force over penetration depth. No relation was found.
Fig. 2: Measured pull-out force over BMD. A significant relation was found for the JET specimens.

Fig. 3: Measured penetration depth over BMD. Correlations were not significant (slight negative trend).

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