In-vivo assessment of the ingrowth potential of engineered surface topographies produced by E-beam technology

Introduction:
Five to ten percent of cementless prostheses fail within 10 years due to mechanical loosening. RSA studies showed that the loosening starts early in the postoperative period.[1] Therefore, it can be suggested that long-term success of a cementless prosthesis depends on adequate fixation by bone ingrowth in the early postoperative period. To stimulate early bone ingrowth new technologies such as electron beam melting (E-beam) can be utilized to engineer optimal ingrowth surfaces.

E-beam has the further advantage that it can produce a prosthetic component and a surface structure in one manufacturing step, which reduces cost price and delivery times.

The goal of this study was to analyse bone ingrowth characteristics of new surface structures produced by E-beam and compare these to those obtained with more conventionally made surfaces.

Materials and Methods:
Implants: The implants (10 mm, Ø 8 mm) were made of Ti6Al4V and produced with E-beam technology. Two different topographic surfaces were developed, each with a unique structure (either ‘wave’ or ‘cubic’, Figure 1). The wave structure had a pore size of 0.9 mm and a porosity of 49%, the cubic structure had a pore size of 1.2 mm and a porosity of 77%. Two control specimens were also tested, one with a Titanium plasma spray coating and one obtained by sandblasting the samples as they come out of the E-beam process. (Figure 1)

Experimental design: Surgery was performed on six goats. The four different specimens were implanted in the femoral condyles of each goat. Sharp cannulated drills with an increasing diameter (Ø 6.0, 8.0 and 8.5 mm) were used to drill the hole while cooling with saline. The implants were inserted into the holes and the facia and skin were closed separately with resorbable sutures. Weight bearing was unrestricted after surgery. Goats were sacrificed six weeks after surgery. This study was approved by the animal ethics committee of the Radboud University Nijmegen.

Histological analysis: The retrieved bone samples were fixed and embedded in methylmethacrylate (MMA) and cut into slices of ca. 40 µm. Light microscopy at Haematoxylin/Eosin (HE) stained slices was used to quantify bone ingrowth. Bone ingrowth depth at 4 and 6 weeks after surgery, bone area percentage (bone area / porous area) and percentage of direct bone implant contact (BIC) was measured.

Statistical: Statistical analysis was performed using a Mann-Whitney U test for both ingrowth depth and bone area %. An univariate analysis of variance of the ranked results was performed for direct bone-implant contact.

Results:
Clinical evaluation: No intraoperative complications occurred. Swelling of the knee was seen in three goats, tissue cultures next to the implantation location showed no infection.

Histology: The HE stained slices showed bone ingrowth into the pores of the new surface structures. (Figure 2) After both four and six weeks greater bone ingrowth depth was seen in the cubic structure compared to the wave structure (p = 0.009).

Contrastingly, the wave structure showed better results for bone area percentage than the cubic (p = 0.009). (Table 1) The bone-implant contact of the new topographic surface structures was comparable to the titanium plasma sprayed control. No significant differences in bone-implant contact were observed throughout the four tested surfaces (p = 0.400), due to a large variation for the wave structure and the control surfaces. (Table 1)

Discussion:
The results of this study are encouraging; both new surface structures showed good bone ingrowth. Although the results showed a high variability, the amount of direct bone implant contact of the E-beam produced surface structures is similar to a clinical in use titanium plasma spray coating.

The difference in outcome for ingrowth depth and bone area percentage can be explained by differences in the structure of the coating. The cubic specimen has a high porosity and large pores deep inside the core material, which were too deep for the bone to reach in the limited post-operative time (six weeks) of the study. Consequently bone area percentage of the cubic specimen was less than the wave specimen.

Thus, one set back of a larger pore size and a higher porosity (as seen in the new E-beam structures) is the length of time it takes for full integration of bone into the implant. Although bone-ongrowth is generally finalized at six weeks for non-porous ingrowth surfaces (as this study also shows), ingrowth in porous surfaces still takes place after this amount of time. Hence, the maximum bone ingrowth is not accomplished for the new E-beam structures in the six weeks study period. Based on the current results bone ingrowth is likely to continue after the six weeks study period and will further anchor the implant to the bone.

Unlike studies with non-porous surface structures, longer-term follow up studies are needed to assess whether the porous E-beam structures lead to a better long term performance than surfaces currently in use, such as titanium plasma spray coating.

References:

Acknowledgement:
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Table 1. Results and SD. a: p=0.009 b: p=0.009 c: p=0.047 d=NS

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Ingrowth depth (mm)</th>
<th>Bone area (%)</th>
<th>BIC (%)</th>
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<tbody>
<tr>
<td></td>
<td>4 weeks</td>
<td>6 weeks</td>
<td></td>
</tr>
<tr>
<td>Wave</td>
<td>0.78 (0.19)</td>
<td>0.98 (0.29)</td>
<td>18.1 (3.6)</td>
</tr>
<tr>
<td>Cubic</td>
<td>1.18 (0.10)</td>
<td>1.47 (0.20)</td>
<td>13.9 (4.7)</td>
</tr>
<tr>
<td>Ti-coated</td>
<td>NA</td>
<td>NA</td>
<td>25.5 (13.3)</td>
</tr>
<tr>
<td>Sandblasted</td>
<td>NA</td>
<td>NA</td>
<td>18.2 (16.0)</td>
</tr>
</tbody>
</table>

Figure 1. From left to right: specimens with wave, cubic, Titanium plasma spray coating and sandblasted

Figure 2. Cubic structure with extensive bone ingrowth. (bar = 1mm)