

# Design, Material, and Manufacturing Factors That Affect the Fixation of Metallic Implants to Bone: Evidence from Total Knee Replacements

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**Introduction:** Posterior stabilized total knee arthroplasty (TKA) is a common and successful operation to restore knee function. However, in recent years higher rates of failure have been associated with femoral component loosening, at the cement-implant interface, potentially related to the surface roughness of the backside of the components. This phenomenon has been prominent in a subset of TKAs retrieved at our institution, all by a single manufacturer (A). To better understand this issue, we sought to compare roughness values and surface finishes of femoral components across different manufacturers to determine if there is a correlation between degree of roughness and component failure. Our research question was divided into two parts; 1. Identify regions on retrieved femoral component surfaces interfacing with cement that showed burnishing and grade the severity, and 2. Compare roughness values and surface finish of pristine femoral components of manufacturer A against 2 competing manufacturers (B and C).

**Methods:** 32 retrieved posterior stabilized (PS) TKA from manufacturer A, revised for loosening, were graded for burnishing using a previously established burnishing protocol. The backside of the femoral component was split into 14 zones (Figure 1) which were each graded on a scale of 0 (no burnishing) to 2 (moderate burnishing) (Figure 2). Grading was performed under visual light microscopy at 20X magnification and any region which had >50% cement was excluded. A Keyence VK-X260 Laser-Scanning Profilometer was used to evaluate the surface roughness of 5 pristine components, including 3 components from Manufacturer A, and one each from Manufacturer B, and Manufacturer C. Components from Manufacturer B and C were chosen since revised femoral components from these manufacturers exhibited almost complete cement coverage in comparison to A. Surface roughness values across manufacturers were compared using one-way ANOVA.

**Results:** Burnishing grades from Manufacturer A showed that the most unworn regions of the femoral component occurred in zones 1 and 2 (anterior flange), and 9 and 10. Profilometry data revealed varying mean degrees of roughness among the 5 samples. Manufacturer C appeared to have the highest mean roughness value of  $12.9 (\pm 0.72) \mu\text{m}$ , and Manufacturer B had the lowest average Ra of  $3.7 (\pm 0.25) \mu\text{m}$ . The three components from Manufacturer A had roughness values of  $4.1 (\pm 0.46) \mu\text{m}$ ,  $7.6 (\pm 1.1) \mu\text{m}$  and  $5.4 (\pm 0.38) \mu\text{m}$ , with Manufacturer B having a significantly higher surface roughness in comparison to A and C ( $p < 0.05$ ). Line scans of each of the sampled surfaces illustrated differences in the texture and topography of the femoral components.

**Discussion:** We sought to better understand if factors such as surface roughness of components affect fixation at the bone-cement and cement-implant interfaces. Since surface roughness was significantly higher in Manufacturer B but did not significantly differ between Manufacturer A and C, we can speculate that surface roughness might not be a determining factor leading to high rates of loosening in Manufacturer A's components. Burnishing scores differing across zones indicate a difference in loading experienced at the flanges versus other regions. We plan to further investigate correlations between cementation, surface roughness, and burnishing grades for a larger sample set of retrieved femoral components, since the current analysis is limited by a small sample size, and roughness measurements have been done on pristine components alone.

**Clinical significance:** Femoral loosening, especially when observed at higher rates in a single manufacturer, might indicate a specific clinical concern associated with use of these components. Mechanisms leading to cement debonding at the implant-cement interface can inform clinical audiences of considerations they can make during surgical planning and can also assist in modifying implant design and surface finish to minimize implant failure.

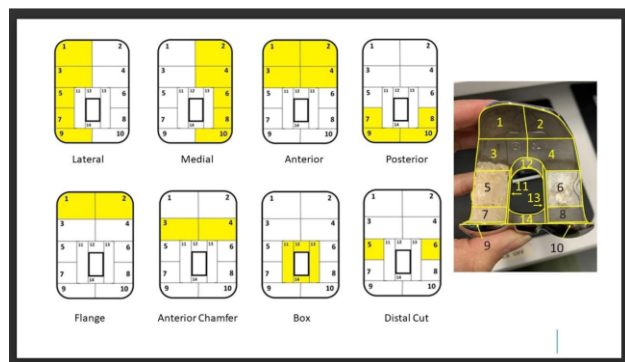


Figure 1 – Femoral components were divided into 14 regions of interest for burnishing grading. The highlighted areas represent combined regions of the implant.

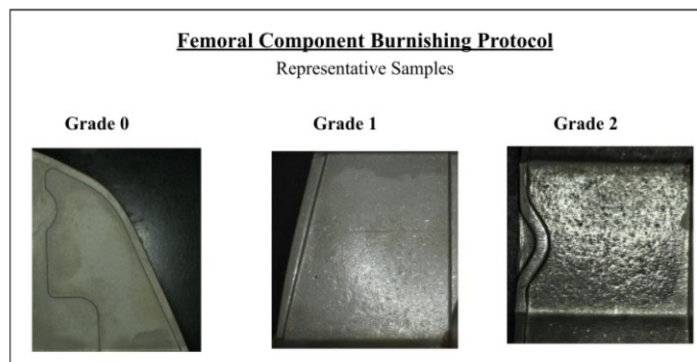


Figure 2 – Burnishing grades representative images indicating grade 0: no burnishing, grade 1: minor burnishing, grade 2: moderate burnishing