Validation Study for a Quantitative Method to Measure the Volumetric Material Loss from Taper Surfaces

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Introduction: Material loss from taper junctions in orthopedic devices is a clinical concern [1-3]. Previous studies of explanted orthopedic devices have relied on visual scoring methods to evaluate the severity of fretting-corrosion damage on the component interfaces [4]. Visual fretting-corrosion evaluation is correlated with the volume of material loss; but, scoring is semi-qualitative and does not provide a quantitative measure of the amount of material lost from the surface [5]. The purpose of this study was to develop and validate a quantitative method for measuring the volume of material lost from the surfaces of explanted devices at the taper-trunnion junction.

Methods: We used 10 new exemplar taper adapter sleeves (Ceramtec, Plochingen, Germany) and 3 exemplar femoral heads (Stryker, NJ, USA). Clinically representative taper damage is produced in exemplars using machining tools, confirmed using Talymap software (Taylor Hobson, UK) (Figure 1). Taper surfaces were measured before and after in vitro material removal using a roundness machine (Talyrond 585, Taylor Hobson, UK). The mass of artificially removed material was also measured gravimetrically using a microgram balance (Sartorius, CPA225D, accuracy = ± 0.00003g). The surface profiles were analyzed using a custom MatLab script. The calculated volume of material loss was compared to the gravimetric value.

Results: Damage created on exemplar taper surfaces in vitro was representative of those seen in explants (Figure 1). Our calculations of material loss predicted over 99% of the variation in gravimetric material loss (Figure 1b, r2 = 0.9962) (Figure 2). Sensitivity analysis showed that a minimum of 24 axial profiles are required for measurements to stay within 2% of the volume calculated with 144 traces for cases with an axisymmetric wear pattern.

Discussion: We have developed and validated a quantitative method for the material loss from taper junctions in orthopedic devices. Our sensitivity analysis showed that a minimum of 24 profiles are required to calculate volumetric material loss accurately, however a further sensitivity analysis is required to establish the minimum number of profiles required to accurately characterize “asymmetric”
wear patterns. The measurement of 24 profiles takes approximately 20 minutes. The validation thus far has comprised material loss in an axisymmetric pattern. Work is underway to validate the evaluation of tapers with an asymmetric wear pattern. The axisymmetric and asymmetric patterns are realistic representations of wear patterns seen in explanted taper surfaces. This validated method of estimating material loss from taper junctions will be used in our ongoing research program to understand the mechanisms of fretting-corrosion in retrieved orthopaedic tapers.

**Significance:** This study presents a quantitative method to measure the release of metallic products from taper surfaces that may lead to systemic and periprosthetic adverse reactions.

Figure 1: Example of material loss on an explanted femoral head (a) and exemplar taper adapter sleeve (b). Calculated volumetric material loss is 7.93mm$^3$ and 9.12mm$^3$ in a and b respectively.
Figure 2: Plot of volume of calculated material loss using quantification method vs. material loss from reference gravimetric measurement.

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