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Introduction

Calcium sulfate bone void fillers (BVF) are increasingly being used in periprosthetic joint surgery. In this study the implications for the surface topography of the articulating surfaces and the wear of UHMWPE if pellets of BVF were to become trapped between the articulating surfaces of knee replacements was assessed.

Materials and Methods

Materials: 18 PS U2 total knee replacements (United Orthopedic Corp, Taiwan); Stimulan® calcium sulfate BVF prepared in 3mm beads (Biocomposites, Ltd.).

Methods: The study was split into 2 phases.

Phase 1: Damage simulation

- 5cc of BVF beads added to each tibial to represent a 'worst case' scenario with respect to BVF migration into the joint space (N=6) (Figure 1a)
- Simulator run for 60 cycles without lubricant (Figure 1b)
- 25% bovine serum added as a lubricant and run for 115,000 cycles under Leeds Intermediate kinematics (Figure 2 [1]) to represent the maximum duration the BVF may be present in the joint space based on the material dissolution profile and clinical observations.
- Surfaces analysed by contacting profilometry, determining the Ra, Rp and Rv

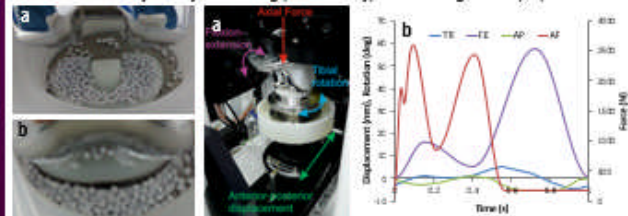


Figure 1: a: pellets of BVF loaded on tibial, b: damage simulation

Figure 2: a: the controlled axes of motion in a knee simulator, b: Input kinematic conditions

Phase 2: Wear simulation

- Wear simulation performed in 25% serum under Leeds intermediate kinematics (Figure 2b) with gravimetric analysis of tibials after 1 and 3 million cycles (MC)
- Wear of implants damaged with BVFs compared to negative controls (no damage) and positive controls damaged with a diamond stylus (mean lip height >3µm) to simulate severe third body damage to femorals, n=6 for each group.
- Post test surface topography of femorals measured

The mean wear rate, Ra, Rv and Rp with 95% confidence limits were determined. Statistical analysis was carried out using ANOVA with significance taken at p<0.05.

Results

Phase 1: Damage simulation

Following damage simulation with BVF, there were scratches on the surface of the cobalt chrome femorals in the principal direction of sliding (A-P). There was no significant difference in surface roughness between negative controls and implants damaged with BVF for any of the parameters measured (Table 1).

Phase 2: Wear simulation

There was no significant difference in wear rate of UHMWPE tibials against negative controls (2.8±1.5mm³/MC) and implants damaged with bone void fillers (3.3±1.5mm³/MC). The wear rate of the UHMWPE tibials was significantly (p<0.05) increased against positive controls (20.6±5.1mm³/MC), (Figure 3). Table 2 and Figure 4 show the surface of the femorals at the conclusion of the study.

Figure 4: Images representative of the surface of the cobalt chrome femorals after damage simulation and 3MC wear simulation taken with an Alicona G5 IF microscope, 10x lens. Scale bar represents 200µm.

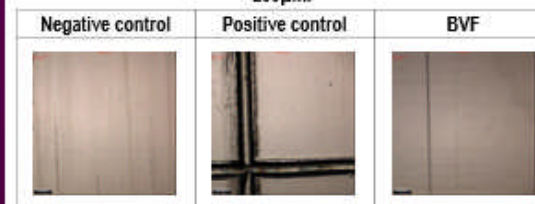


Table 1: Surface topography of cobalt chrome femorals following Phase 1: Damage simulation

Parameters	Phase 1: Damage simulation and 115,000 cycles of wear simulation		
	Negative controls	Positive controls	Stimulan BVF
Ra (µm)	0.020 ± 0.006	0.430 ± 0.039	0.023 ± 0.005
Rp (µm)	0.041 ± 0.014	1.327 ± 0.103	0.035 ± 0.010
Rv (µm)	0.046 ± 0.022	0.838 ± 0.095	0.042 ± 0.010

Table 2: Surface topography of cobalt chrome femorals following Phase 2: 3MC wear simulation

Parameters	Phase 2: 3MC wear simulation		
	Negative controls	Positive controls	Stimulan BVF
Ra (µm)	0.057 ± 0.035	0.450 ± 0.039	0.092 ± 0.047
Rp (µm)	0.125 ± 0.078	1.361 ± 0.153	0.143 ± 0.059
Rv (µm)	0.150 ± 0.080	0.878 ± 0.081	0.240 ± 0.108

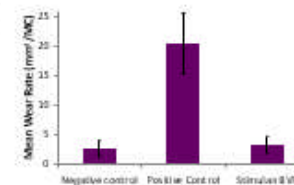


Figure 3: Mean wear rate/MC of UHMWPE tibials (n=6)

Discussion

- This study demonstrated a methodology for simulating third body damage obtaining both surface topography and wear data.
- This study showed that when calcium sulfate BVFs were trapped between the articulating surfaces of a total knee replacement, there was no significant change in the surface roughness of the cobalt chrome femorals and therefore no influence on the wear of UHMWPE tibials.
- To increase UHMWPE wear, damage to cobalt chrome femorals had to be over a threshold; this threshold was clearly exceeded in the positive controls where lip height Rp>3µm.

Significance

This study suggests that when used close to articulating surfaces, calcium sulfate bone void fillers may not influence the wear of UHMWPE and may not therefore be detrimental to knee implant longevity.

References

[1] McEwen, H. M. J Biomechanics, 2005, 38(2):357-65

Financial Disclosure

Biocomposites Limited supplied the knee system, the bone void filler and funding for this study.

