Assessing the Influence of Third Body Damage to Articulating Surfaces with Bone Void Fillers

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Abstract

Third body particles such as those from bone cements and bone void fillers when trapped between articulating surfaces can accelerate wear of arthroplasty materials leading to premature failure. In this three phase study the damage to cobalt chrome (CoCr) by PMMA bone cement, STIMULAN® and a competitor calcium sulfate material were investigated. Damage simulation was evaluated using pin on disk testing and total knee replacements, and compared to that of control samples.

Phase one damage simulation showed that STIMULAN resulted in no third body damage - causing no significant damage to CoCr plates.

Phase two results showed no additional damage to CoCr disks as a result of the STIMULAN, with results comparable to negative controls, where no third body material was present.

Phase three results showed STIMULAN had no significant change in surface roughness of CoCr femoral components of total knee replacements, and therefore no influence on wear of UHMWPE tibials.

Introduction and Aim

Third body particles originating from bone cements and bone void fillers have the potential to become trapped between articulating surfaces of joint replacements, potentially damaging components, accelerating wear and leading to premature failure.

In phase one of the study, third body damage to CoCr counterfaces by STIMULAN and PMMA bone cement were assessed.

In phase two of the study, damage to CoCr disks due to motion of the pin on disk in the presence of particles of third body materials from STIMULAN and a competitor calcium sulfate material were assessed and compared against control disks.

In phase three of the study, total knee replacements were mounted in a motion simulator rig. The effect on the CoCr surfaces and wear of UHMWPE, if beads of STIMULAN were to become trapped between the articulating surfaces was assessed.

Methodology

Phase One

In phase one, the damage to CoCr plates by STIMULAN and PMMA bone cement was simulated using a six station pin on disk multi-axial reciprocating rig (figure 1). Third body particles were trapped between an UHMWPE pin and a polished CoCr rectangular plate. A load of 120N was applied to the pin and the plate was pulled for 5 adjacent strokes of a length of 15mm, at a speed of 8mm/min to simulate third body damage. A positive control (scratched with diamond stylus) and a negative control (no scratches) were also included. Changes in surface topography were analyzed using white light interferometry.

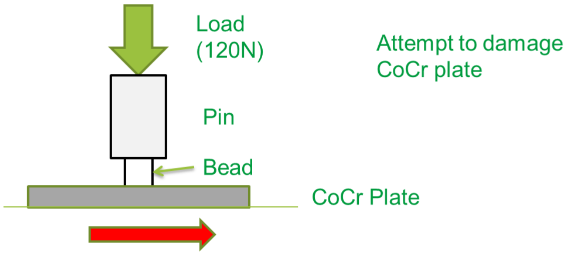


Figure 1

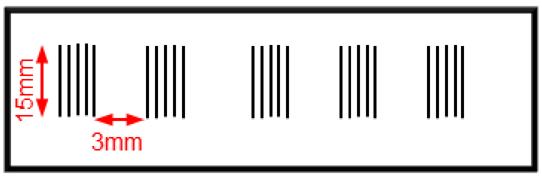


Figure 3

Figure 2

Figures 1 and 2. Phase one test rig. To simulate damage to CoCr plate by third body.
Figure 3. Demonstrates the position of damage created on the plates during the test.

Phase Two

In phase two, damage by STIMULAN and a competitor calcium sulfate material was assessed by a pin on disk frame rig (figures 4 to 6). The STIMULAN and competitor calcium sulfate materials were crushed and 1.5g of material was added to each of the stations, each containing 150ml of bovine serum. No crushed material was added to stations containing the control disks. A load of 200N was applied to each pin, which were moved in a square pattern with 10mm sides at a linear speed of 40mm/s for up to 480,000 cycles (4 cycles of 120,000). Deionized water was added during the testing to maintain constant fluid volume. Serum temperature was maintained at 37°C. Disks were examined after intervals of 120,000 cycles to assess damage using contact profilometry and microscopy.

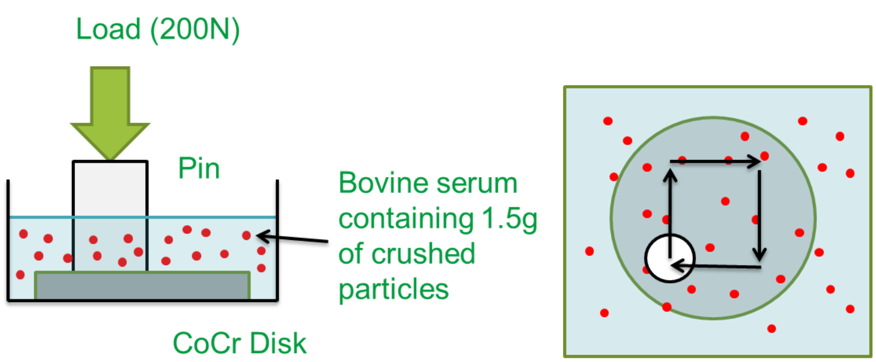


Figure 4

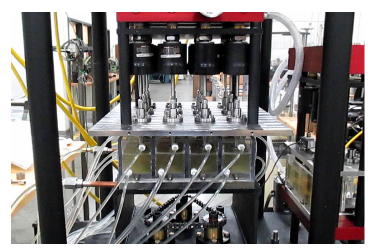


Figure 5

Figures 4, 5 and 6. Phase Two test rig. To determine damage to disk due to motion of pin on disk in the presence of particles of third body material.

Figure 6

Phase Three

The total knee replacements were mounted in a motion simulator rig and 5cc of STIMULAN beads were placed between the articulating surfaces (figures 7, 8a and 8b). To assess the effect of the beads on CoCr surfaces, the simulator was run for 60 cycles without lubricant. Bovine serum was then added to the STIMULAN debris and run in the simulator for 115,000 cycles. This first test mimics "worst case" damage simulation for the maximum 6 week duration the STIMULAN would be present based on its dissolution rate. The second test mimics UHMWPE wear as a result of any damage resulting from the first test. To do so, the simulator is run with lubricant alone for 3 million cycles to determine wear over a simulated 3 years. After each test, the UHMWPE tibials were examined for measurement of wear and CoCr femorals assessed for damage using contact profilometry and microscopy, all in comparison to prostheses as negative (no STIMULAN added) and positive (CoCr pre scratched with diamond stylus) controls.

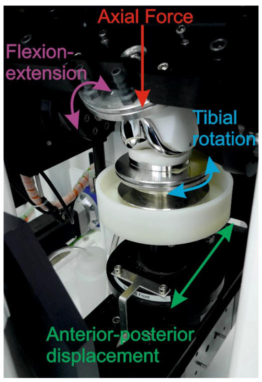


Figure 7

Figure 8a

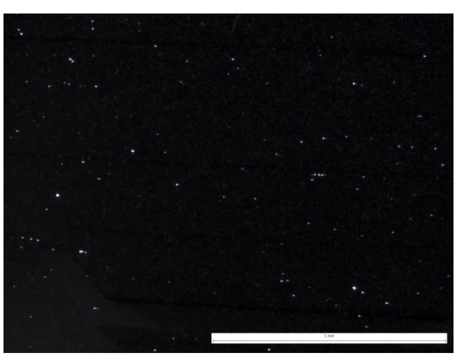
Figure 8b

Figure 7. Motion simulator rig
Figure 8a. Beads of STIMULAN loaded on the tibial of the total knee replacement. Figure 8b. Damage simulation.

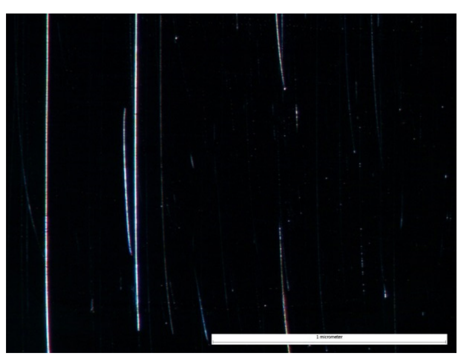
Results

Phase One

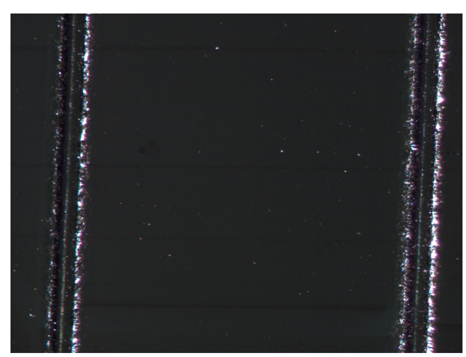
Following damage simulation, PMMA caused long and continuous scratches on the CoCr surface. No third body damage due to STIMULAN was observed. Plates tested with STIMULAN had no visible damage on any of the 5 traces on the plate - and any damage caused being outside the resolution of the measuring technique used (figures 9 and 10, table 1).



STIMULAN



PMMA



Positive Control

Figure 9. Stereomicroscope images, x63 magnification, Scale bar represents 1mm

SCRATCHING MATERIAL	SCRATCHES / MM	MEAN LIP HEIGHT (µm)	MEAN VELLEY DEPTH
STIMULAN	0	0	0
PMMA	0.185 ± 0.208	0.028 ± 0.051	0.0175 ± 0.031

Table 1. Analysis of scratches following third body damage simulation using the NPFLEX (mean±95%CL). Data was unfiltered.

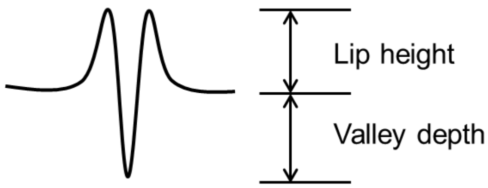
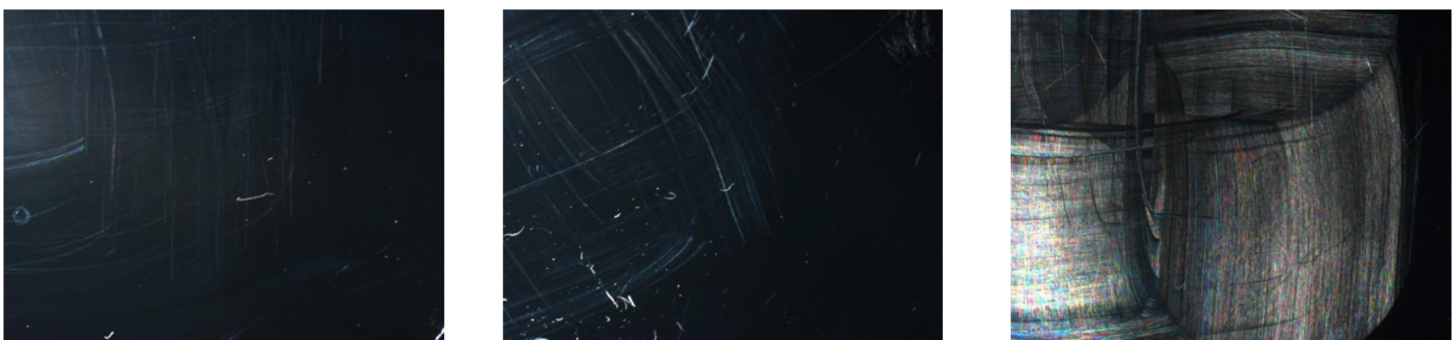


Figure 10. Image showing the profile of the lip height and valley depth of the scratch.

Phase Two

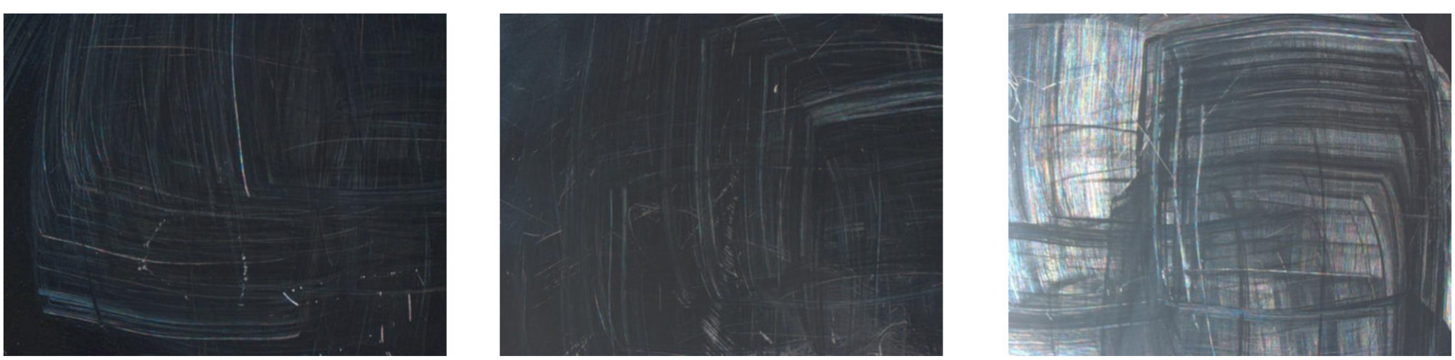
The damage to the CoCr disk was comparable between the STIMULAN group and the control group, where no third body material was present.

The competitor calcium sulfate material caused more scratching to the CoCr disk than both the control group and the STIMULAN group at each time point. This is evident from the microscope images (figures 11 to 13) and was confirmed by the surface roughness measurements, with competitor calcium sulfate material resulting in higher surface roughness values compared to STIMULAN and the control (table 2).



Control | STIMULAN | Competitor Calcium Sulfate

Figure 11. Microscope images, x6.5 magnification, 120,000 cycles.



Control | STIMULAN | Competitor Calcium Sulfate

Figure 12. Microscope images, x6.5 magnification, 360,000 cycles.

Control | STIMULAN | Competitor Calcium Sulfate

Figure 13. Microscope images, x6.5 magnification, 480,000 cycles.

		Control	STIMULAN	Competitor calcium sulfate
CONTROL	Ra(μm)	0.03	0.03	0.03
	Rz(μm)	0.38	0.50	0.53
	Rq(μm)	0.03	0.04	0.04
WORN	Ra(μm)	0.03	0.04	0.05
	Rz(μm)	0.60	0.68	0.83
	Rq(μm)	0.05	0.06	0.08

Ra values represent the arithmetic average of the roughness profile.
Rz values represent the maximum height profile (highest peak to the lowest valley).
Rq values represent the root mean square of the roughness profile.

Table 2. Average surface roughness comparison of test groups (n=4 per group) at 480,000 cycles.

Phase Three

The damage simulation results in step 1, showed there was no significant surface roughness in the negative controls and the CoCr femoral implants tested with STIMULAN between the articulating surfaces (table 3).

STEP 1: DAMAGE SIMULATION AND 115,000 CYCLES OF WEAR SIMULATION

PARAMETERS	Negative Control	STIMULAN	Positive Control
Ra(μm)	0.020 ± 0.006	0.023 ± 0.005	0.430 ± 0.039
Rz(μm)	0.041 ± 0.014	0.035 ± 0.010	1.327 ± 0.103
Rq(μm)	0.045 ± 0.022	0.042 ± 0.010	0.828 ± 0.095

Ra values represent the arithmetic average of the roughness profile.
Rp values represent the maximum height profile (highest peak to the lowest valley).
Rq values represent the root mean square of the roughness profile.

Table 3. Damage simulation and 115, 000 cycles of wear simulation.

The wear simulation results in step 2, showed there was no significant difference in wear rate of UHMWPE tibials between negative controls and implants tested with STIMULAN between the articulating surfaces (figure 14). The wear rate of the tibial was significantly increased with positive controls.

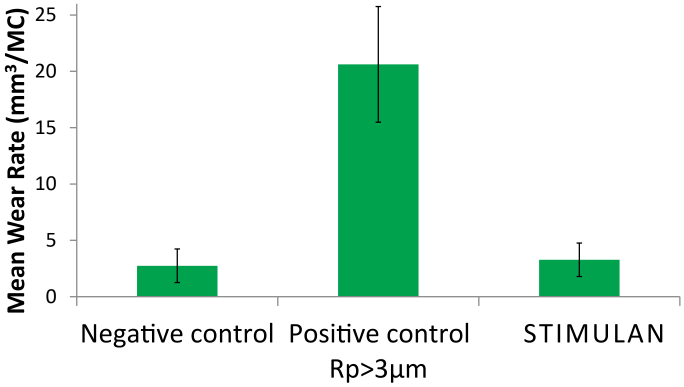


Figure 14. Mean wear rate/million cycles of UHMWPE tibials (n=6).

Conclusion

The pin on disk method is a routine test used to determine damage and wear of orthopaedic implant materials.

STIMULAN does not cause significant damage to CoCr, with results comparable to negative controls, where no third body material was present.

STIMULAN causes fewer scratches to CoCr than the PMMA and competitor calcium sulfate material chosen for this test.

The study showed that when STIMULAN was trapped between the articulating surfaces of a total knee replacement, there was no significant change in the surface roughness of the CoCr femorals and no influence on the wear of UHMWPE tibials.

Summary

Phase One

During phase one damage simulation, no third body damage due to STIMULAN was observed.

Phase Two

Testing demonstrated that scratches to CoCr were comparable between STIMULAN and the control. Competitor calcium sulfate material resulted in more scratches and increased surface roughness of the CoCr.

Phase Three

STIMULAN does not damage total knee replacements when trapped between the articulating surfaces of the implant.

References

Cowie, R.M., *et al.*, The Influence of Third Body Damage by a Calcium Sulfate Bone Void Filler on the Wear of Total Knee Replacements., in Orthopaedic Research Society Annual Meeting. 2016: Orlando, FL. p. 103.

Cowie, R.M., *et al.*, Influence of third-body particles originating from bone void fillers on the wear of ultra-high-molecular-weight polyethylene. Proc Inst Mech Eng H, 2016. 230(8): p. 775-83.

Cowie, R.M., *et al.*, The influence of a calcium sulphate bone void filler on the third-body damage and polyethylene wear of total knee arthroplasty. Bone Joint Res, 2019. 8(2): p. 65-72.

For indications, contraindications, warnings and precautions see Instructions for Use. The treating physician is responsible for deciding the type and quantity of antibiotic used. Concurrent use of locally administered antibiotics may affect setting time.

The mixing of antibiotics with the STIMULAN Kit / STIMULAN Rapid Cure device is considered off-label usage of the medicinal product. To do so is at the professional risk of the surgeon / healthcare professional.

This brochure may include the use of STIMULAN or techniques that go beyond the current clearance / approval granted by the relevant regulatory authority. Please contact your local representative for further information.

Patents granted: GB2367552, EP 1204599 B1, US 6780391, EP 2594231 B1, US 8883063, CN ZL201210466117.X, GB2496710, EP 3058899 B1

Patents pending: GB1502655.2, US 15/040075, CN 201610089710.5, US 15/288328, GB1704688.9, EP 18275044.8, US 15/933936, CN 108619579A

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