Assessing the influence of third body damage to articulating surfaces with bone void fillers

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July 2019

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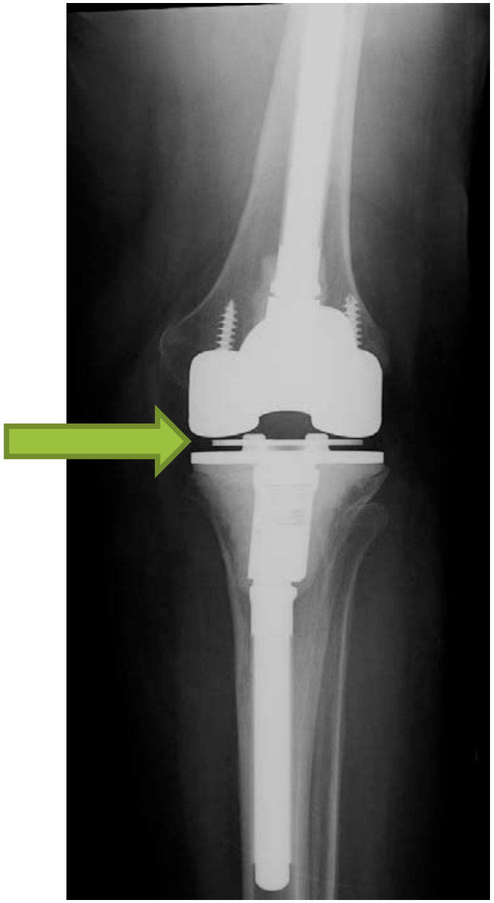
Assessing the influence of third body damage to articulating surfaces with bone void fillers.

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



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Study aim

To determine the effect of third body damage to cobalt chrome counterfaces by calcium sulfate bone void filler.

Phase 1
To simulate damage to a cobalt chrome (CoCr) plate by third body using pin on disk multi-axial reciprocating rigs*.

Phase 2
To determine damage to CoCr disk due to motion of pin on disk in the presence of particles of third body material.

Phase 3
To determine damage to total knee replacements mounted in simulators in the presence of particles of STIMULAN®.

*Industry standard test

Phase 1

Materials evaluated were:

- PMMA cement
- STIMULAN
- Positive control (scratched with diamond stylus)
- Negative control (no scratch)

Study determined:

- Damage / Scratches to the CoCr Plate
- Damage / Scratches / Wear to total knee replacements

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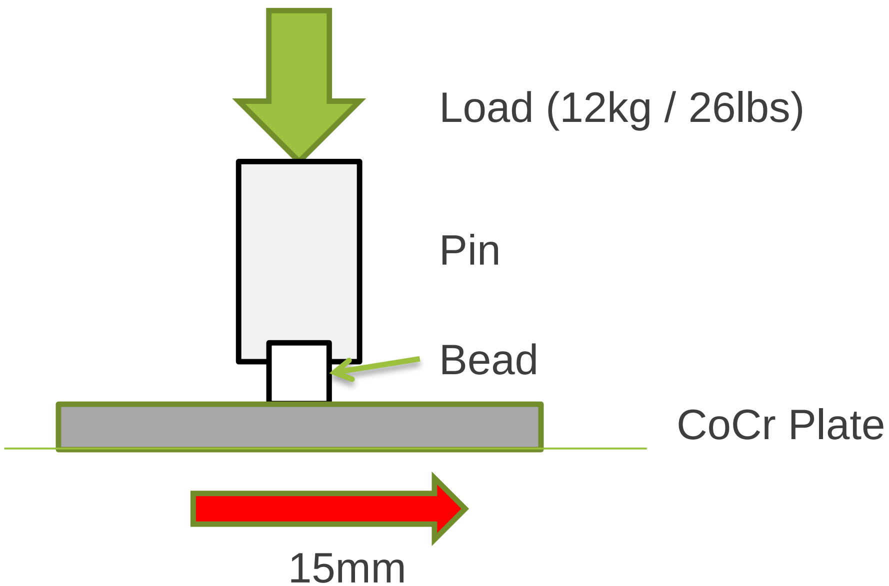
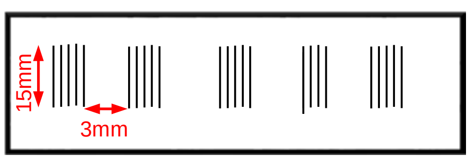
Method – Phase 1

Simulating damage to CoCr plate





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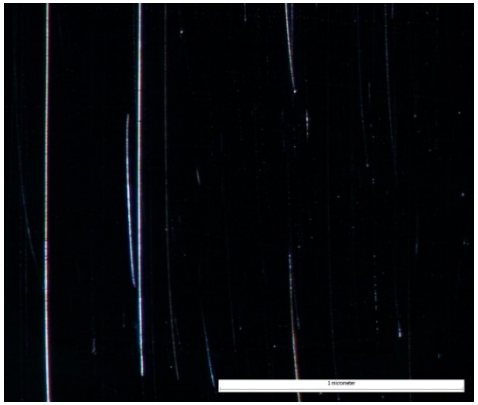
Results – Phase 1

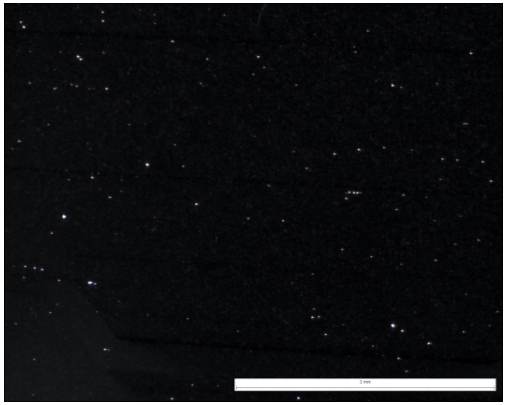
- Plates tested with STIMULAN had **no visible scratches** on any of the 5 traces on the plate.

- PMMA caused long and continuous scratches.

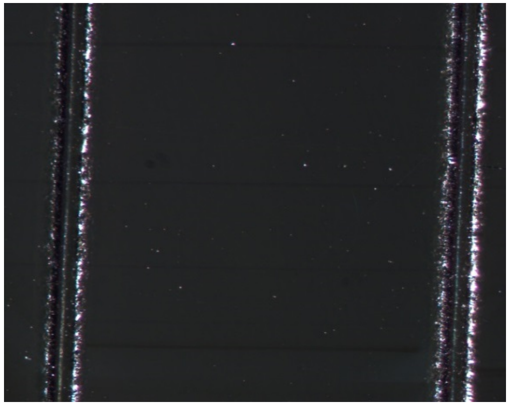
Stereomicroscope images, 63x, Scale bar represents 1mm



PMMA



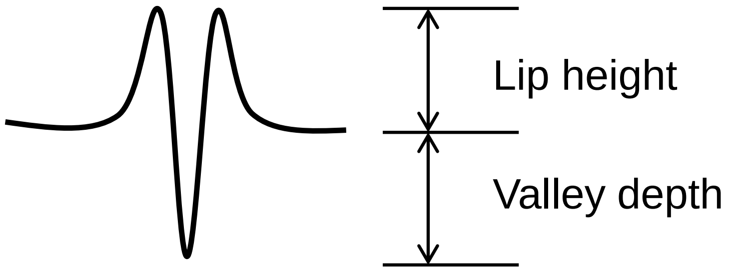
STIMULAN



Positive Control

Results – Phase 1

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



Phase 2

Aim

To determine damage to CoCr disk due to motion of pin on disk in the presence of particles of third body material.

- CoCr disks first polished to mirror finish
- Pins moved over the surface of the CoCr disks in the presence of bovine serum containing 1.5g of particles of crushed third body material
- Pin moved for up to 480,000 cycles (4 cycles of 120,000)

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Phase 2

Study compared:

- STIMULAN
- Competitor calcium sulfate
- Negative control (no crushed material)

Disks were examined after intervals of 120,000 cycles to assess damage using contact profilometry and microscopy.

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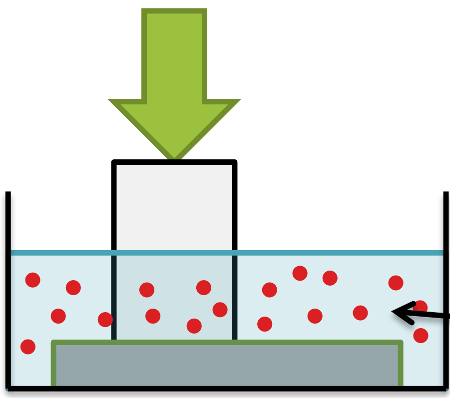
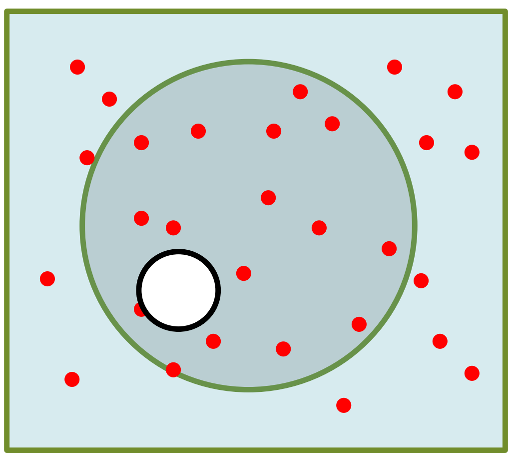
Method – Phase 2

Load (20kg / 44lbs)



Bovine serum containing 1.5g of crushed particles

Top view



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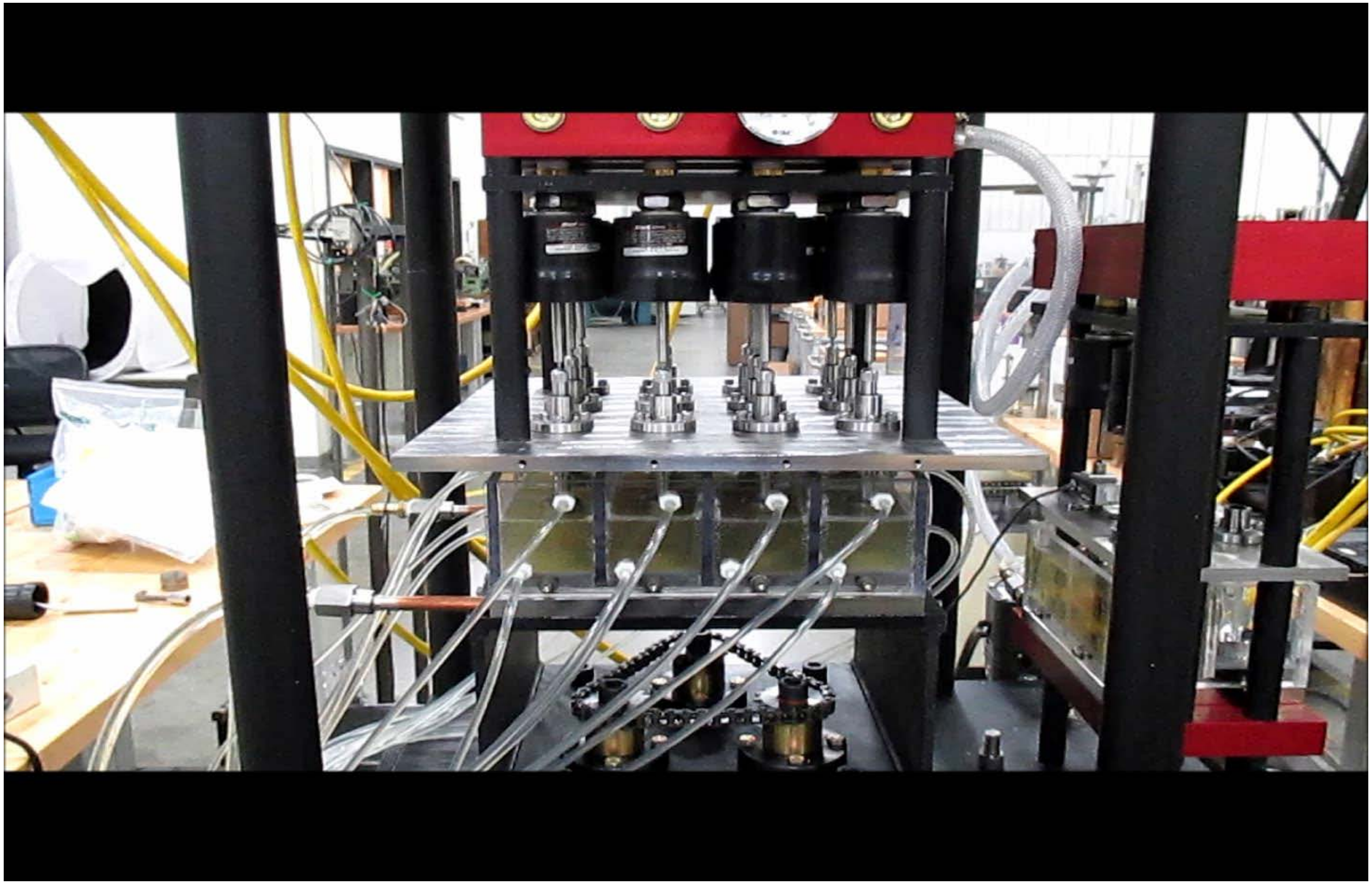
Method – Phase 2



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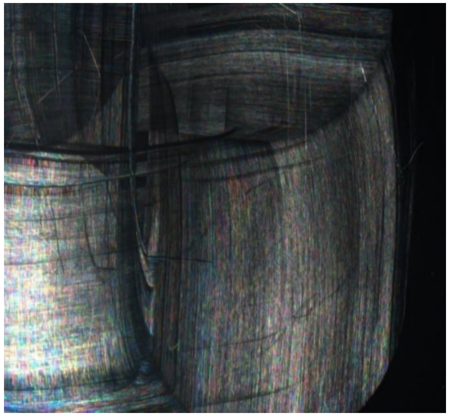
Results – Phase 2

120,000 cycles

Microscope images, 6.5x

Control

STIMULAN



Competitor calcium sulfate

Results – Phase 2

360,000 cycles

Microscope images, 6.5x

Control

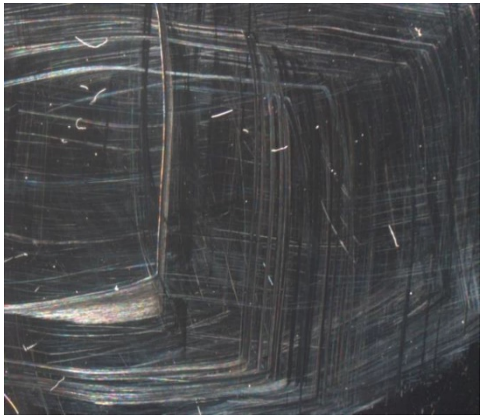
STIMULAN

Competitor calcium sulfate

Results – Phase 2

480,000 cycles

Microscope images, 6.5x



Control

STIMULAN

Competitor calcium sulfate

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Results – Phase 2

Average surface roughness comparison on completion of 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 squared of the roughness profile.

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Phase 3

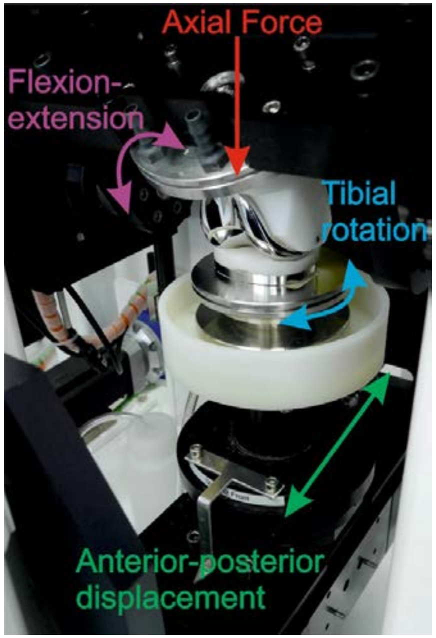
Aim

To determine damage to total knee replacements mounted in motion simulators in the presence of particles of STIMULAN.

- 18 total knee replacements mounted in a motion simulator rig

- Study compared:
  - 6 test knees (determine damage resulting from presence of STIMULAN in the knee)
  - 6 negative controls (no third body material)
  - 6 positive control (CoCr pre scratched with diamond stylus)

- CoCr femorals assessed for damage using contact profilometry and microscopy and UHMWPE tibials were examined for measurement of wear



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Method - Phase 3

Damage simulation

Step 1
Place 5cc of STIMULAN beads between counterfaces - then attempt to damage surfaces by running **dry** in knee simulator for 60 cycles

Step 2
Run with lubricating serum AND debris present for 115k cycles
(equivalent to 6 weeks - maximum duration STIMULAN will be present)

5cc of beads (3mm diameter)

Wear simulation

Step 3
Run without debris present for 3 million cycles (equivalent to 3 years)

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Results - Phase 3

Following Damage Simulation:

- No significant surface roughness between the negative controls and the CoCr femoral implants tested with STIMULAN between the articulating surfaces.

	STEP 1: DAMAGE SIMULATION SND 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.
Rz values represent the maximum height profile (highest peak to the lowest valley).
Rq values represent the root mean squared of the roughness profile.

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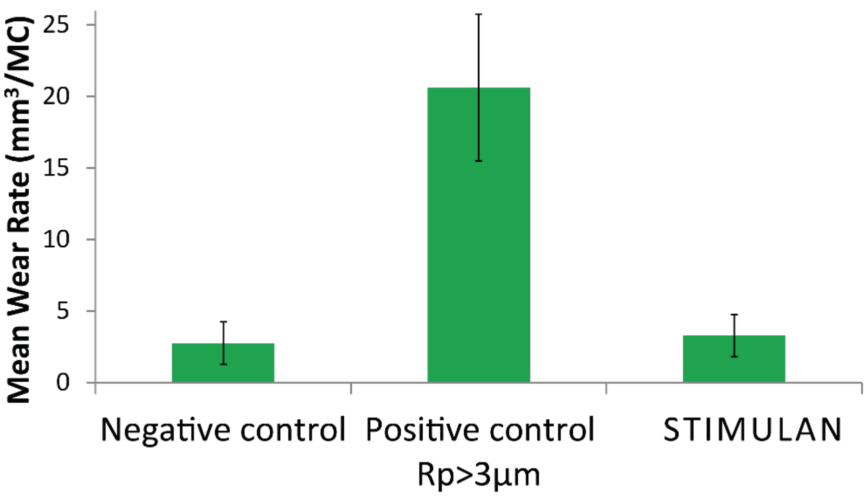
Results - Phase 3

Following Wear Simulation:

- No significant difference in wear rate of UHMWPE tibials between negative controls and implants tested with STIMULAN between the articulating surfaces.
- The wear rate of the tibial was significantly increased with positive controls.



Mean wear rate of the UHMWPE tibial inserts over 3 million cycles

Conclusion

Summary

- Phase 1 damage simulation showed that STIMULAN resulted in no third body damage - causing no significant damage to CoCr.
- Phase 2 results showed no additional damage to CoCr disks as a result of STIMULAN, with results comparable to negative controls, where no third body material is present.
- STIMULAN causes fewer scratches to CoCr than PMMA and competitor calcium sulfate.
- Phase 3 results show STIMULAN does not damage total knee replacements when trapped between the articulating surfaces of the implant.

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Find out more at biocomposites.com

References:
1. 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 EngH, 2016. 230(8): p. 775-83.
2. 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.
3. 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.

Company Confidential

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