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ANNEXURE A

Retrieval analysis of 20 acetabular cups

Patient 1

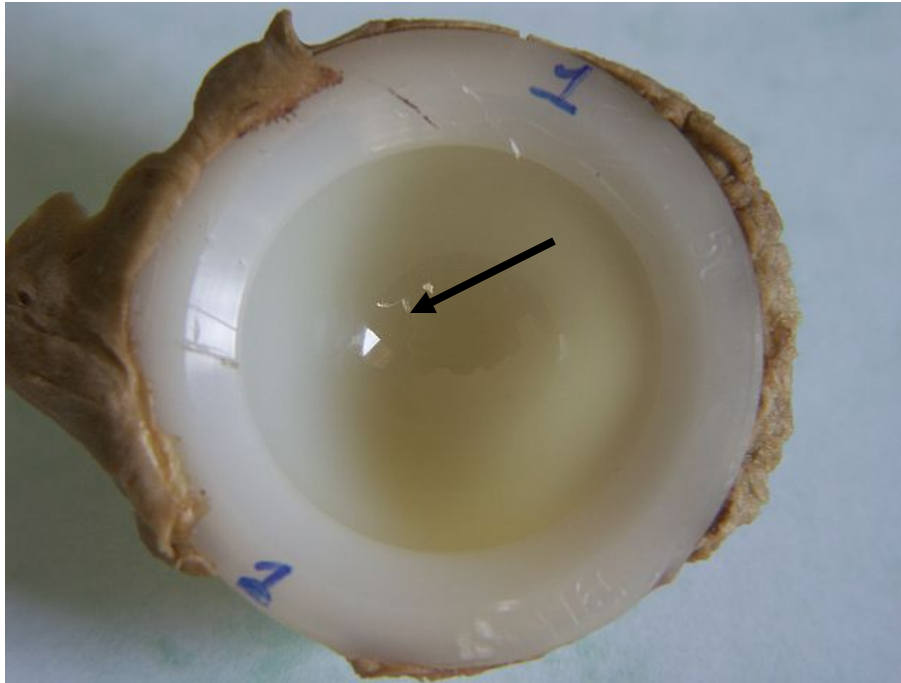


Figure A1



Figure A2

Cup analysis: Patient 1

1	Femoral head size	32 mm
2	Type of head	Alumina
3	Cup type	UHMWPE - Osteal
4	Crosslink	No
5	Amount of linear wear	± 1.1 mm
6	Duration in vivo	13 years and 7 months
7	Size of wear debris from pathologist	10 – 30 μ m
8	Visible discoloration	Yes (Figure 1)
9	Metal backing	No
10	Thickness of poly	9 mm
11	Mechanical damage	No
12	Cracks in material	No
13	Plastic flow	No
14	Scratches	No (visually)
15	Adhesion wear	Yes
16	Wear particles embedded in base material	No
17	Flaking	No

Patient 2

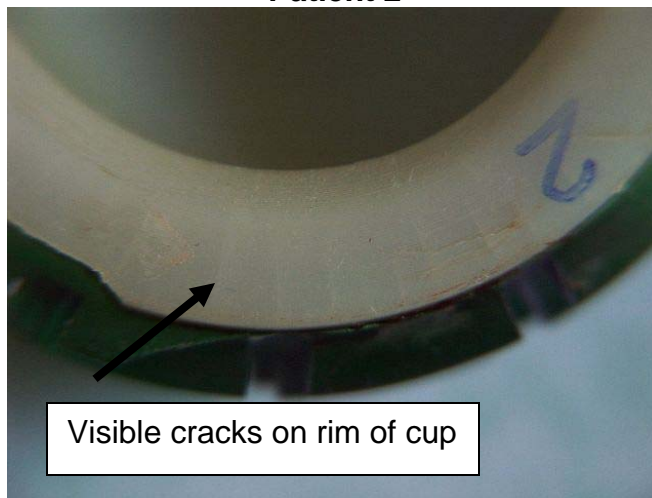


Figure A3

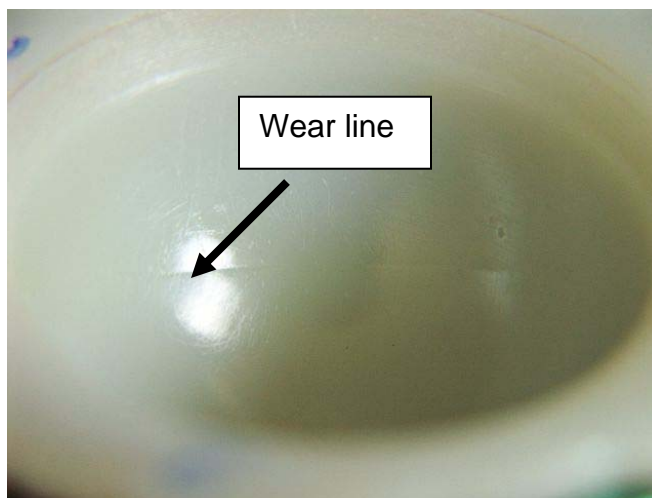


Figure A4

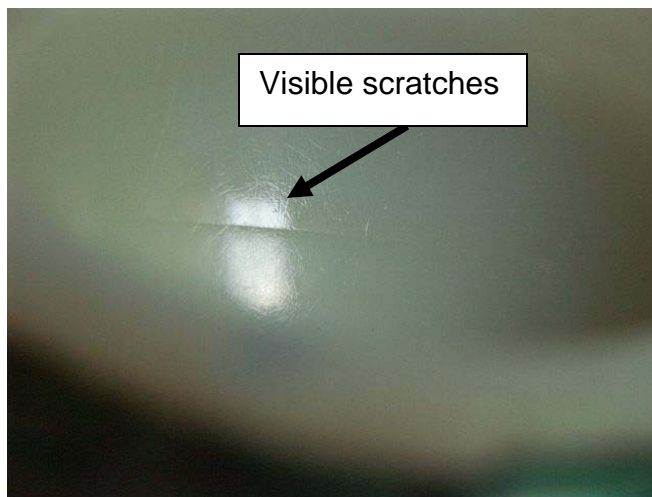


Figure A5

Cup analysis: Patient 2

1	Femoral head size	32 mm
2	Type of head	Alumina
3	Cup type	UHMWPE - Osteal
4	Crosslink	No
5	Amount of linear wear	± 0.8 mm
6	Duration in vivo	17 years
7	Size of wear debris from pathologist	20 – 110 μm , avg. 40 μm
8	Visible discoloration	Yes (Figure 1)
9	Metal backing	No
10	Thickness of poly	± 7 mm
11	Mechanical damage	Yes
12	Cracks in material	Yes
13	Plastic flow	No
14	Scratches	Yes
15	Adhesion wear	No
16	Wear particles embedded in base material	No
17	Flaking	No

Patient 3



Figure A6

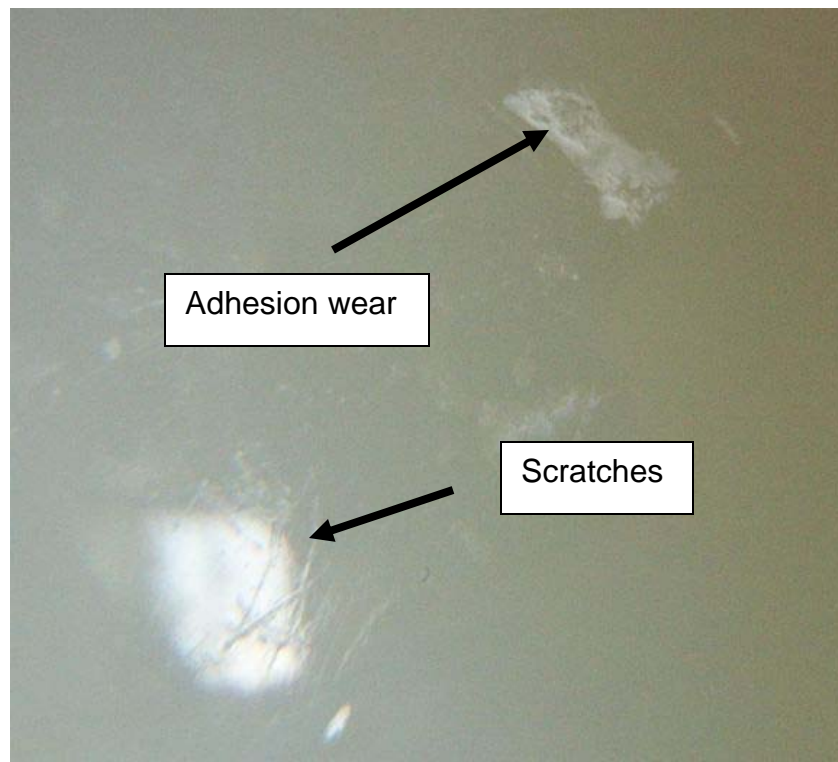


Figure A7

Cup analysis: Patient 3

1	Femoral head size	26 mm
2	Type of head	Alumina
3	Cup type	UHMWPE - Aesculab
4	Crosslink	No
5	Amount of linear wear	± 0.4 mm
6	Duration in vivo	6 years
7	Size of wear debris from pathologist	10 – 50 µm
8	Visible discoloration	Yes (Figure 6)
9	Metal backing	No
10	Thickness of poly	9 mm
11	Mechanical damage	No
12	Cracks in material	No
13	Plastic flow	No
14	Scratches	Yes
15	Adhesion wear	Yes
16	Wear particles embedded in base material	Yes
17	Flaking	No

Patient 4



Figure A8



Figure A9



Figure A10

Cup analysis: Patient 4

1	Femoral head size	32 mm
2	Type of head	Alumina
3	Cup type	UHMWPE – ARD
4	Crosslink	No
5	Amount of linear wear	± 4.5 mm
6	Duration in vivo	12 years
7	Size of wear debris from pathologist	10 – 90 µm
8	Visible discoloration	No
9	Metal backing	Yes
10	Thickness of poly	± 5 mm
11	Mechanical damage	Yes
12	Cracks in material	Yes
13	Plastic flow	No
14	Scratches	Yes
15	Adhesion wear	Yes
16	Wear particles embedded in base material	Yes
17	Flaking	No

Patient 5

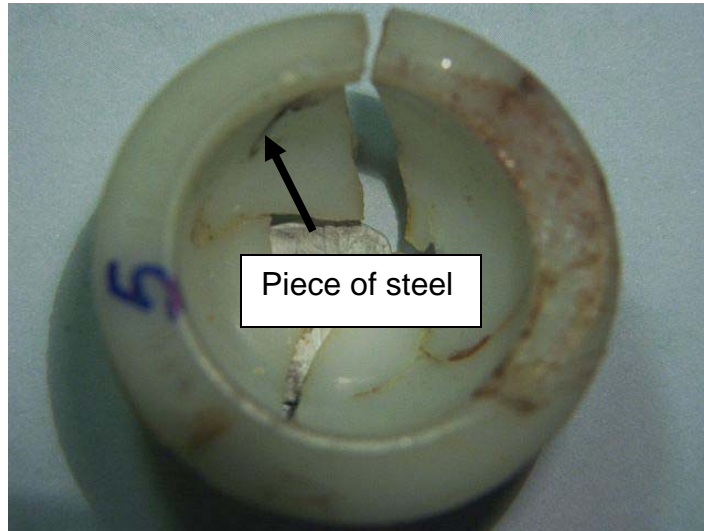


Figure A11

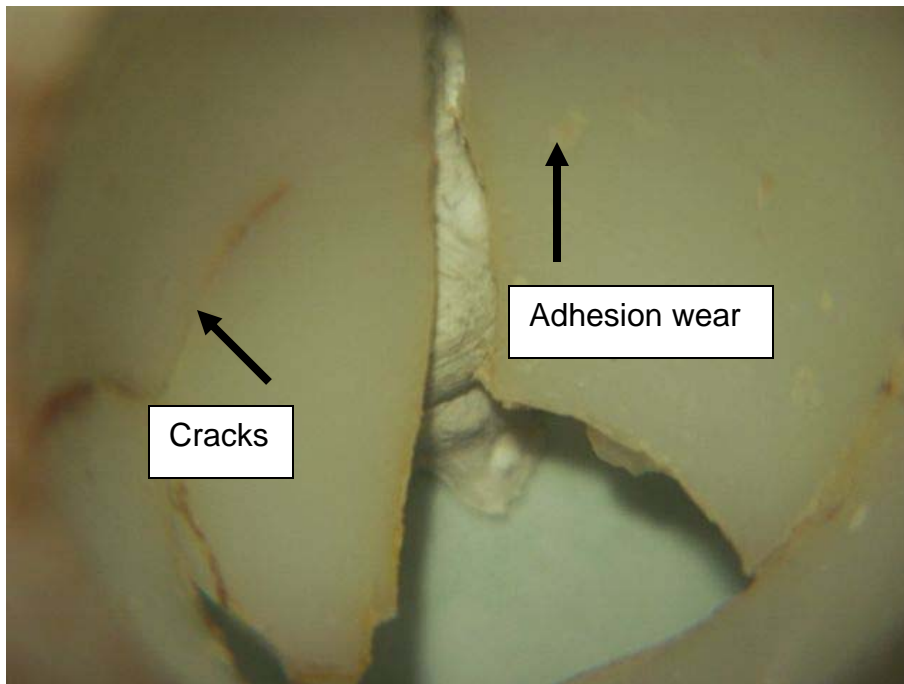


Figure A12

Cup analysis: Patient 5

1	Femoral head size	32 mm
2	Type of head	Stainless
3	Cup type	UHMWPE – ARD
4	Crosslink	No
5	Amount of linear wear	± 5 mm
6	Duration in vivo	9 years and 5 months
7	Size of wear debris from pathologist	100 – 800 µm, avg. 600 µm
8	Visible discoloration	No
9	Metal backing	No
10	Thickness of poly	7 mm
11	Mechanical damage	Yes
12	Cracks in material	Yes
13	Plastic flow	No
14	Scratches	Yes
15	Adhesion wear	Yes
16	Wear particles embedded in base material	Yes
17	Flaking	No

Patient 6



Figure A13

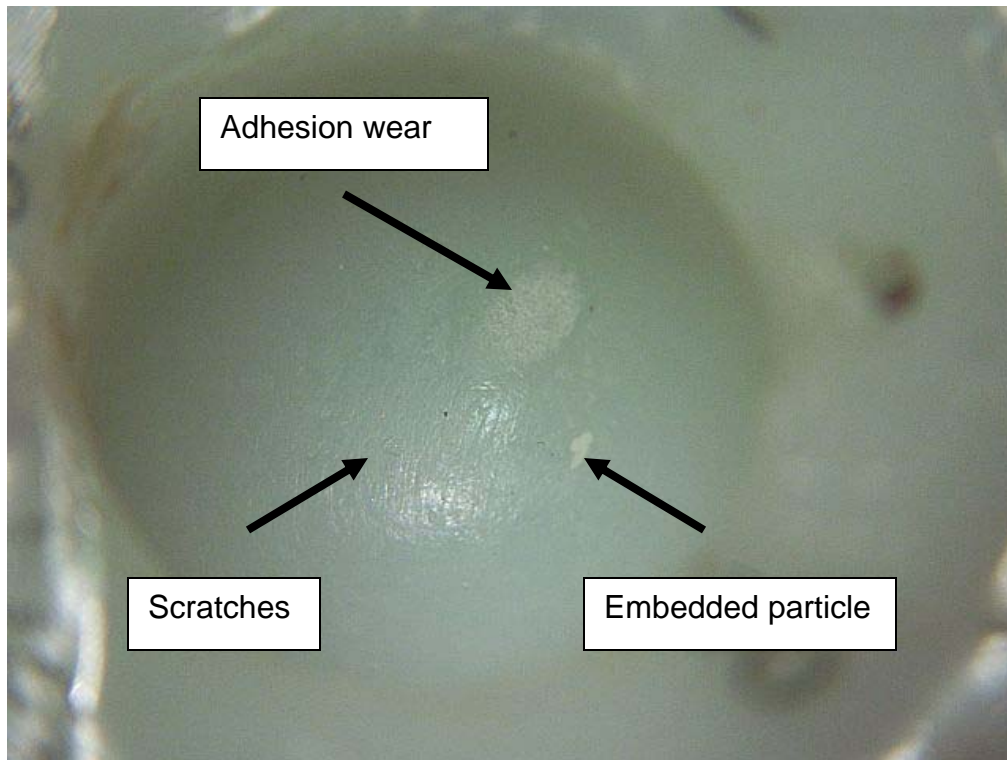


Figure A14

Cup analysis: Patent 6

1	Femoral head size	22 mm
2	Type of head	Stainless
3	Cup type	UHMWPE – Charnley
4	Crosslink	No
5	Amount of linear wear	± 3 mm
6	Duration in vivo	8 years
7	Size of wear debris from pathologist	60 – 140 µm
8	Visible discoloration	No
9	Metal backing	No
10	Thickness of poly	14 mm
11	Mechanical damage	No
12	Cracks in material	No
13	Plastic flow	No
14	Scratches	Yes (figure 14)
15	Adhesion wear	Yes (figure 14)
16	Wear particles embedded in base material	Yes (figure 14)
17	Flaking	No

Patient 7

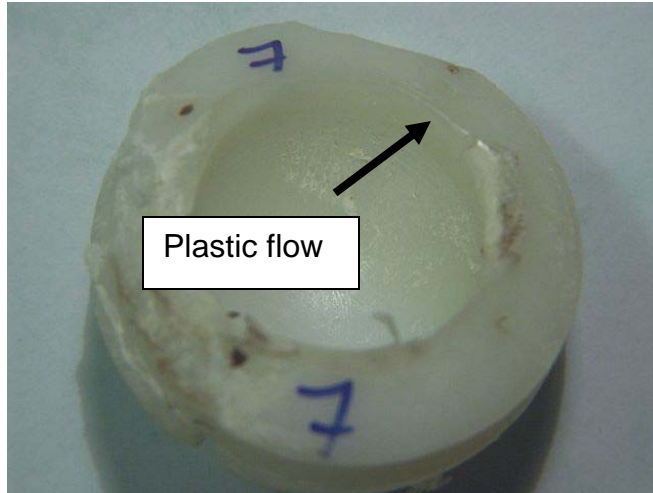


Figure A15

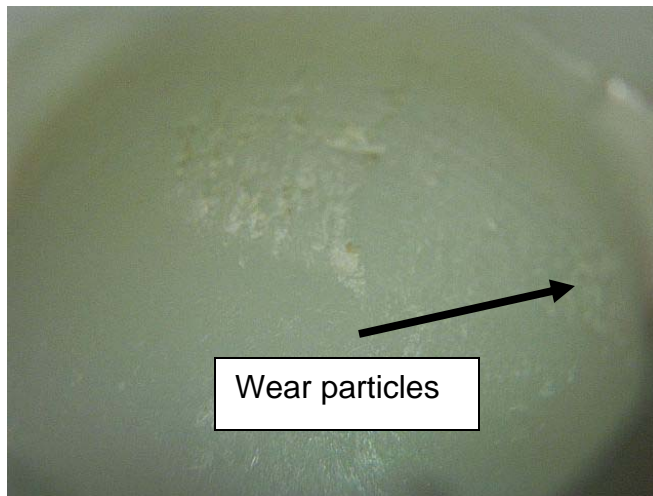


Figure A16



Figure A17

Cup analysis: Patient 7

1	Femoral head size	30 mm
2	Type of head	Stainless steel
3	Cup type	UHMWPE – ARD
4	Crosslink	No
5	Amount of linear wear	± 5 mm
6	Duration in vivo	23 years and 5 months
7	Size of wear debris from pathologist	20 – 180 µm
8	Visible discoloration	No
9	Metal backing	No
10	Thickness of poly	9 mm
11	Mechanical damage	Yes
12	Cracks in material	No
13	Plastic flow	Yes (figure 15)
14	Scratches	Yes (figure 16 & 17)
15	Adhesion wear	Yes (figure 16 & 17)
16	Wear particles embedded in base material	Yes (figure 16)
17	Flaking	No

Patient 8



Figure A18

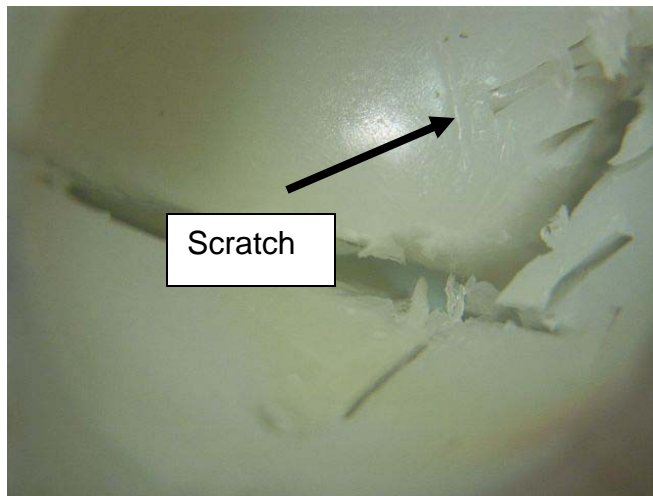


Figure A19

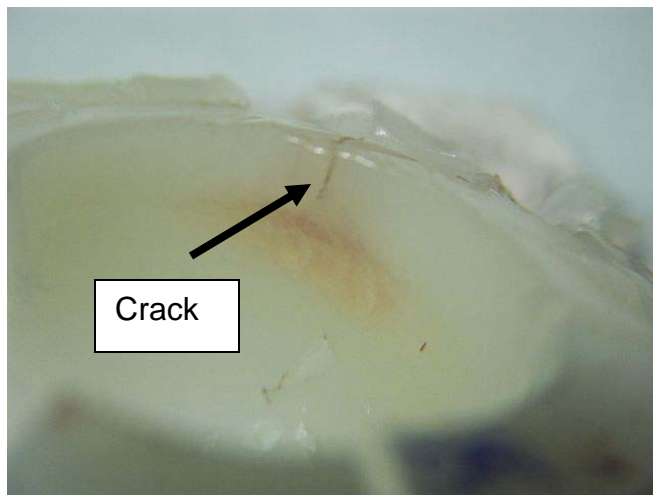


Figure A20

Cup analysis: Patient 8

1	Femoral head size	30 mm
2	Type of head	Stainless steel
3	Cup type	UHMWPE – ARD
4	Crosslink	No
5	Amount of linear wear	± 5 mm
6	Duration in vivo	16 years and 4 months
7	Size of wear debris from pathologist	Not known
8	Visible discoloration	Yes (Figure 18)
9	Metal backing	No
10	Thickness of poly	9 mm
11	Mechanical damage	Yes
12	Cracks in material	Yes
13	Plastic flow	Yes
14	Scratches	Yes
15	Adhesion wear	Yes
16	Wear particles embedded in base material	Yes
17	Flaking	No

Patient 9



Figure A21

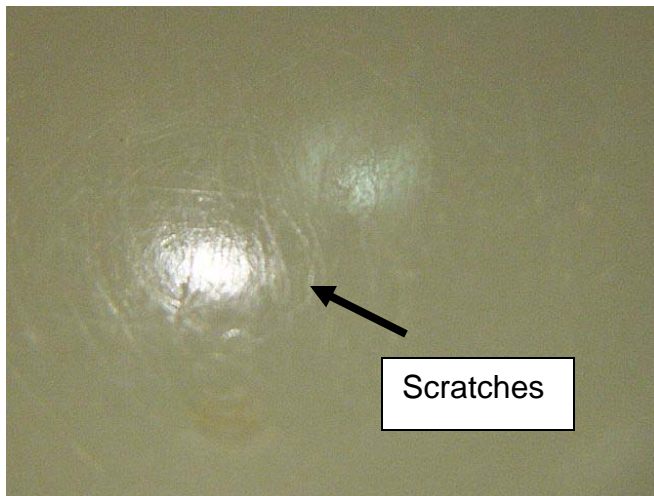


Figure A22

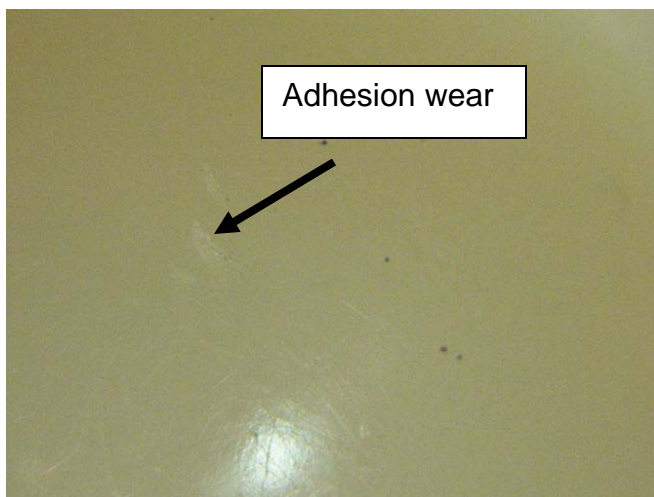


Figure A23

Cup analysis: Patient 9

1	Femoral head size	32 mm
2	Type of head	Zirconium
3	Cup type	UHMWPE – Aesculab
4	Crosslink	Yes
5	Amount of linear wear	\pm 0 mm
6	Duration in vivo	3 years and 9 months
7	Size of wear debris from pathologist	Not available
8	Visible discoloration	No
9	Metal backing	Yes
10	Thickness of poly	19 mm
11	Mechanical damage	No
12	Cracks in material	No
13	Plastic flow	No
14	Scratches	Yes (figure 22)
15	Adhesion wear	Yes
16	Wear particles embedded in base material	No
17	Flaking	No

Patient 10



Figure A24



Figure A25

Cup analysis: Patient 10

1	Femoral head size	28 mm
2	Type of head	Alumina
3	Cup type	UHMWPE – Aesculab
4	Crosslink	Yes
5	Amount of linear wear	\pm 0 mm
6	Duration in vivo	7 Months
7	Size of wear debris from pathologist	Not available
8	Visible discoloration	No
9	Metal backing	Yes
10	Thickness of poly	23 mm
11	Mechanical damage	No
12	Cracks in material	No
13	Plastic flow	No
14	Scratches	No
15	Adhesion wear	No
16	Wear particles embedded in base material	No
17	Flaking	No

Patient 11



Figure A26

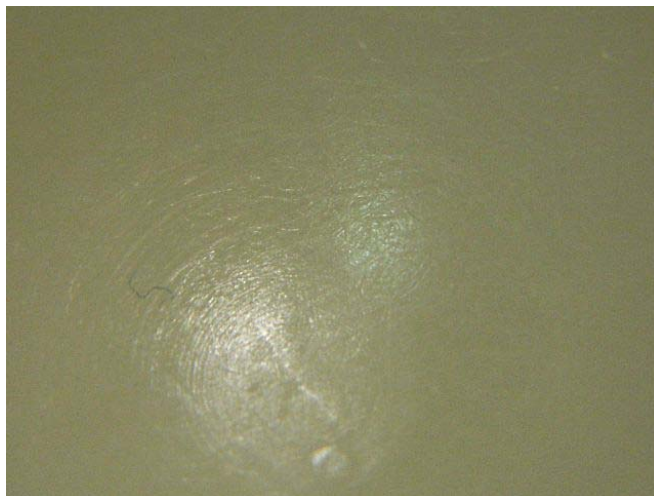


Figure A27

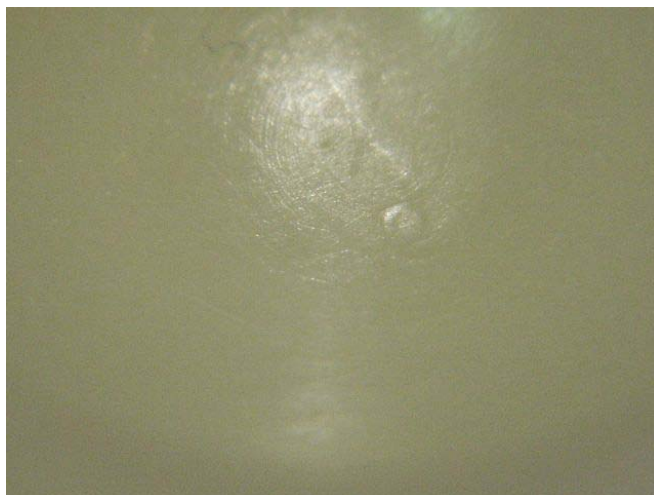


Figure A28

Cup analysis: Patient 11

1	Femoral head size	28 mm
2	Type of head	Zirconium
3	Cup type	UHMWPE – Aesculab
4	Crosslink	Yes
5	Amount of linear wear	± 0 mm
6	Duration in vivo	14 months
7	Size of wear debris from pathologist	10 – 40 µm
8	Visible discoloration	No
9	Metal backing	Yes
10	Thickness of poly	9 mm
11	Mechanical damage	No
12	Cracks in material	No
13	Plastic flow	No
14	Scratches	Yes
15	Adhesion wear	No
16	Wear particles embedded in base material	Yes
17	Flaking	No

Patient 12



Figure A29



Figure A30



Figure A31

Cup analysis: Patient 12

1	Femoral head size	28 mm
2	Type of head	Zirconium
3	Cup type	UHMWPE – de puy
4	Crosslink	No
5	Amount of linear wear	± 3.5 mm
6	Duration in vivo	10 years
7	Size of wear debris from pathologist	20 – 80 µm
8	Visible discoloration	Yes
9	Metal backing	No
10	Thickness of poly	9 mm
11	Mechanical damage	Yes
12	Cracks in material	Yes
13	Plastic flow	Yes
14	Scratches	Yes
15	Adhesion wear	Yes
16	Wear particles embedded in base material	No
17	Flaking	No

Patient 13



Figure A32

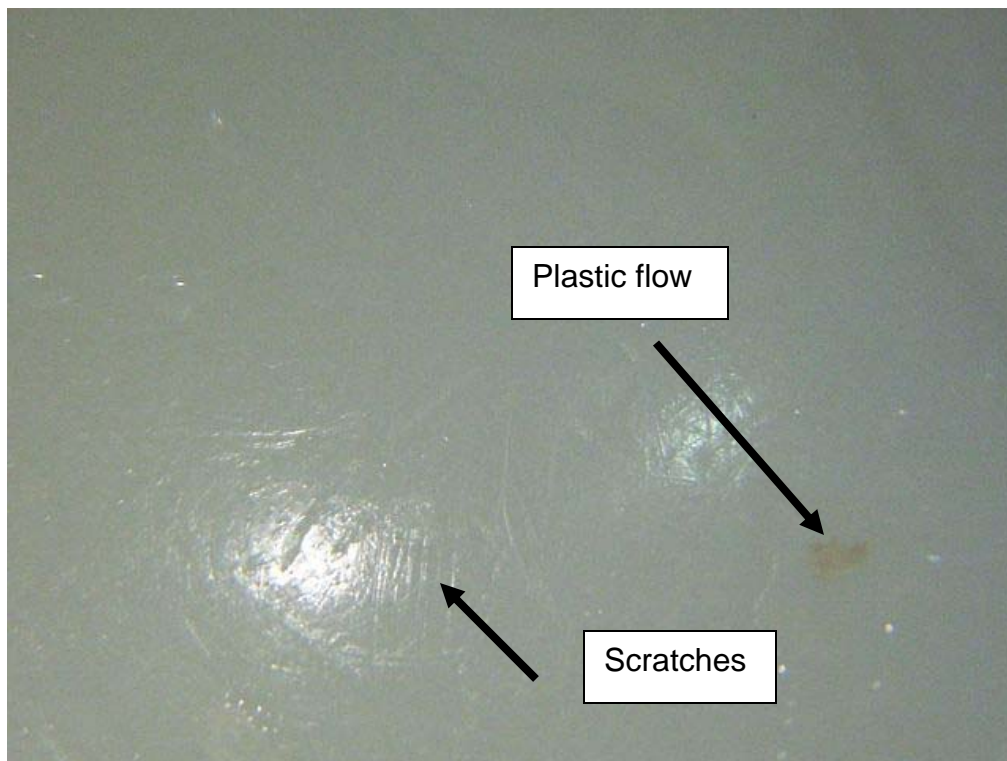


Figure A33

Cup analysis: Patient 13

1	Femoral head size	32 mm
2	Type of head	Zirconium
3	Cup type	UHMWPE – Aesculab
4	Crosslink	No
5	Amount of linear wear	± 3.5 mm
6	Duration in vivo	9 years and 3 months
7	Size of wear debris from pathologist	20 – 100 µm, avg. 60 µm
8	Visible discoloration	No
9	Metal backing	No
10	Thickness of poly	12 mm
11	Mechanical damage	No
12	Cracks in material	No
13	Plastic flow	Yes
14	Scratches	Yes
15	Adhesion wear	Yes
16	Wear particles embedded in base material	Yes
17	Flaking	No

Patient 14

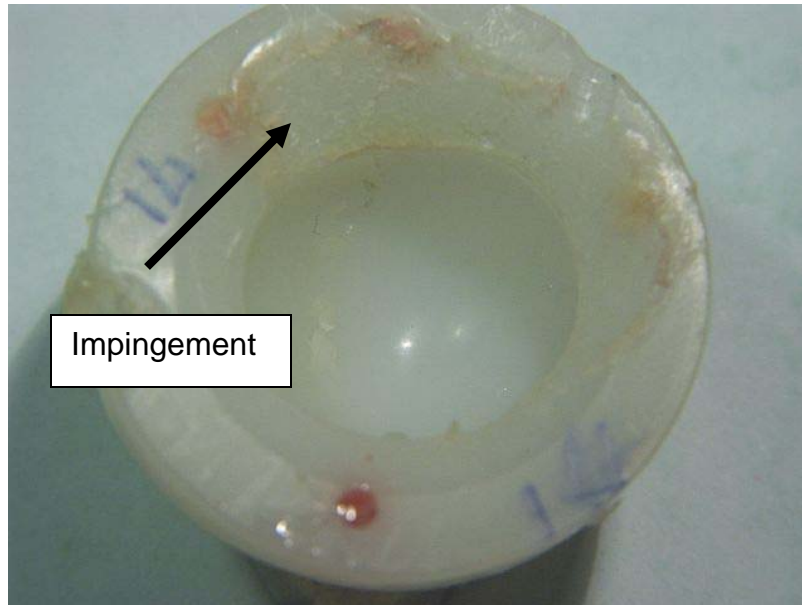


Figure A34

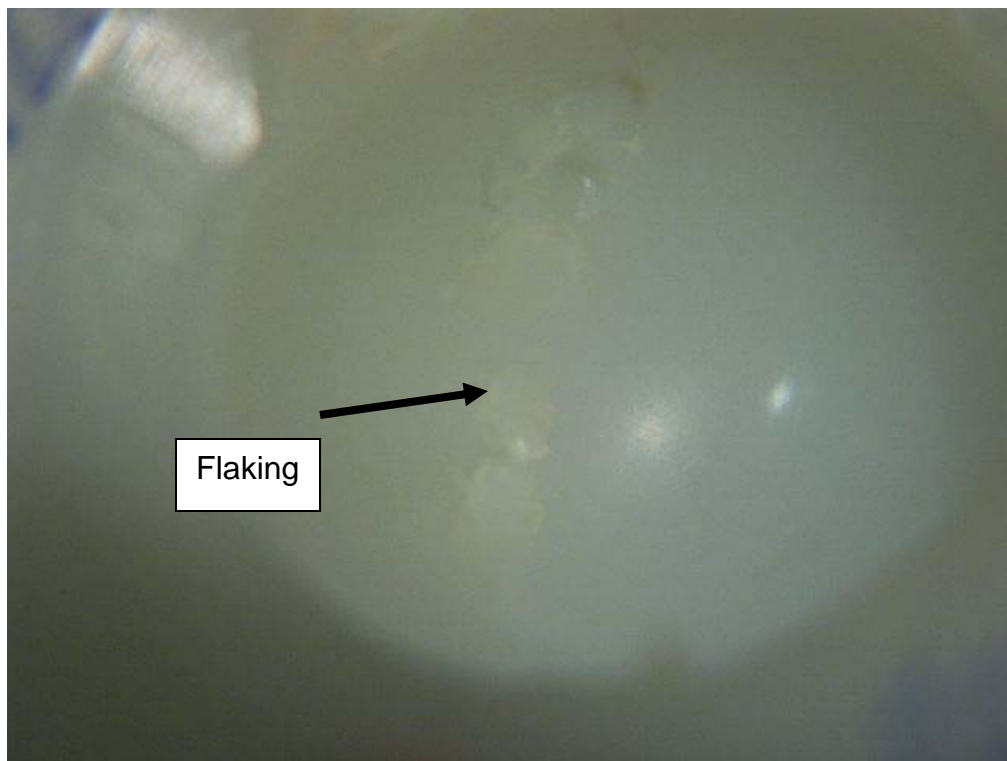


Figure A35

Cup analysis: Patient 14

1	Femoral head size	22 mm
2	Type of head	Zirconium
3	Cup type	UHMWPE – Aesculab
4	Crosslink	No
5	Amount of linear wear	\pm 5 mm
6	Duration in vivo	7 years
7	Size of wear debris from pathologist	Not available
8	Visible discoloration	Yes (Figure 34)
9	Metal backing	Yes
10	Thickness of poly	11 mm
11	Mechanical damage	Yes (serious impingement – see figure 34)
12	Cracks in material	Yes
13	Plastic flow	No
14	Scratches	Yes
15	Adhesion wear	Yes
16	Wear particles embedded in base material	Yes
17	Flaking	Yes

Patient 15

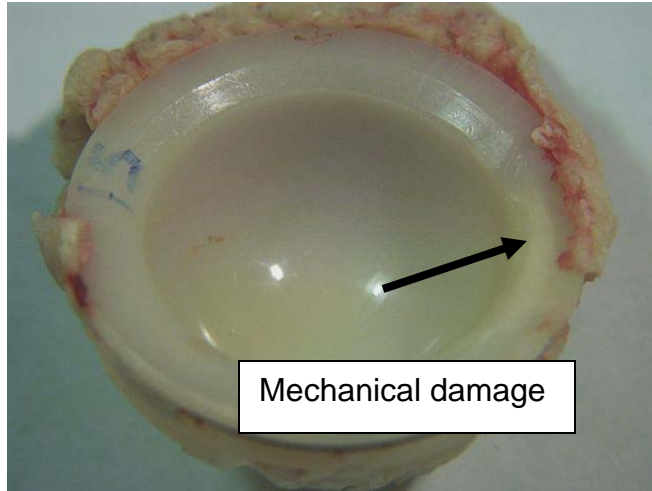


Figure A36

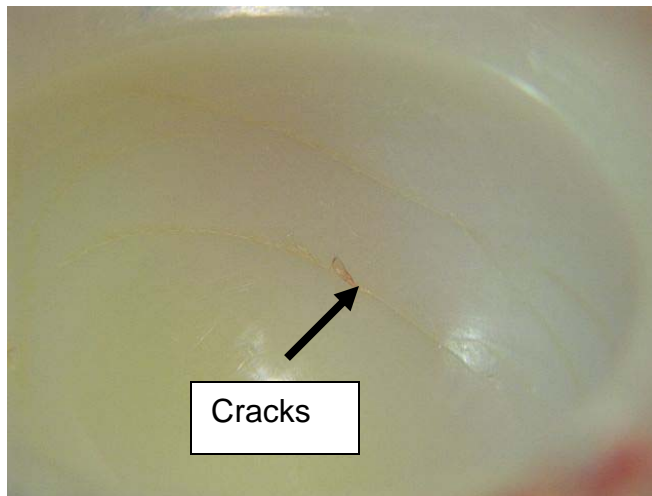


Figure A37

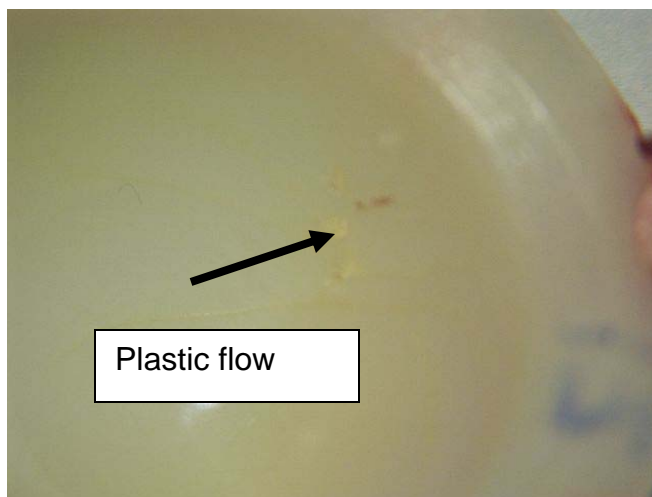


Figure A38

Cup analysis: Patient 15

1	Femoral head size	32 mm
2	Type of head	Alumina
3	Cup type	UHMWPE – Aesculab
4	Crosslink	No
5	Amount of linear wear	± 0.2 mm
6	Duration in vivo	15 years
7	Size of wear debris from pathologist	20 – 140 µm, avg. 80 µm
8	Visible discoloration	Yes (Figure 36)
9	Metal backing	No
10	Thickness of poly	7 mm
11	Mechanical damage	Yes (figure 36)
12	Cracks in material	Yes
13	Plastic flow	No
14	Scratches	Yes
15	Adhesion wear	Yes
16	Wear particles embedded in base material	Yes
17	Flaking	No

Patient 16



Figure A39

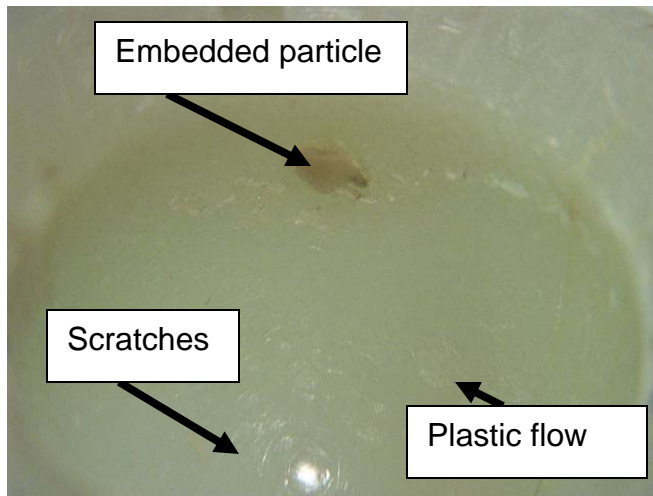


Figure A40



Figure A41

Cup analysis: Patient 16

1	Femoral head size	28 mm
2	Type of head	Zirconium
3	Cup type	UHMWPE – Aesculab
4	Crosslink	No
5	Amount of linear wear	± 3.5 mm
6	Duration in vivo	10 years
7	Size of wear debris from pathologist	20 – 350 µm
8	Visible discoloration	Yes (Figure 39)
9	Metal backing	No
10	Thickness of poly	11 mm
11	Mechanical damage	Yes (figure 39)
12	Cracks in material	No
13	Plastic flow	Yes
14	Scratches	Yes
15	Adhesion wear	Yes
16	Wear particles embedded in base material	Yes
17	Flaking	No

Patient 17



Figure A42



Figure A43

Cup analysis: Patient 17

1	Femoral head size	22 mm
2	Type of head	Stainless Steel
3	Cup type	UHMWPE – Charnley, de Puy
4	Crosslink	No
5	Amount of linear wear	± 6 mm
6	Duration in vivo	10 years and 6 months
7	Size of wear debris from pathologist	Not available
8	Visible discoloration	Yes (Figure 42)
9	Metal backing	No
10	Thickness of poly	13 mm
11	Mechanical damage	No
12	Cracks in material	No
13	Plastic flow	No
14	Scratches	Yes
15	Adhesion wear	No
16	Wear particles embedded in base material	No
17	Flaking	No

Patient 18

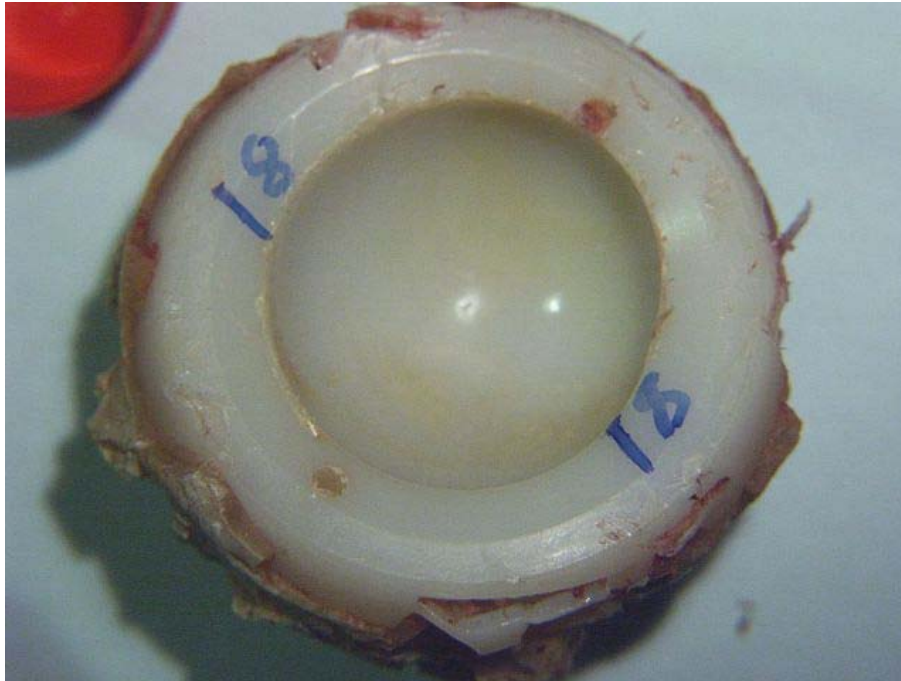


Figure A44



Figure A45

Cup analysis: Patient 18

1	Femoral head size	32 mm
2	Type of head	Alumina
3	Cup type	UHMWPE - Aesculab
4	Crosslink	No
5	Amount of linear wear	± 5 mm
6	Duration in vivo	6 years and 6 months
7	Size of wear debris from pathologist	Not available
8	Visible discoloration	Yes
9	Metal backing	No
10	Thickness of poly	12 mm
11	Mechanical damage	Yes
12	Cracks in material	No
13	Plastic flow	No
14	Scratches	Yes
15	Adhesion wear	Yes
16	Wear particles embedded in base material	Yes
17	Flaking	No

Patient 19

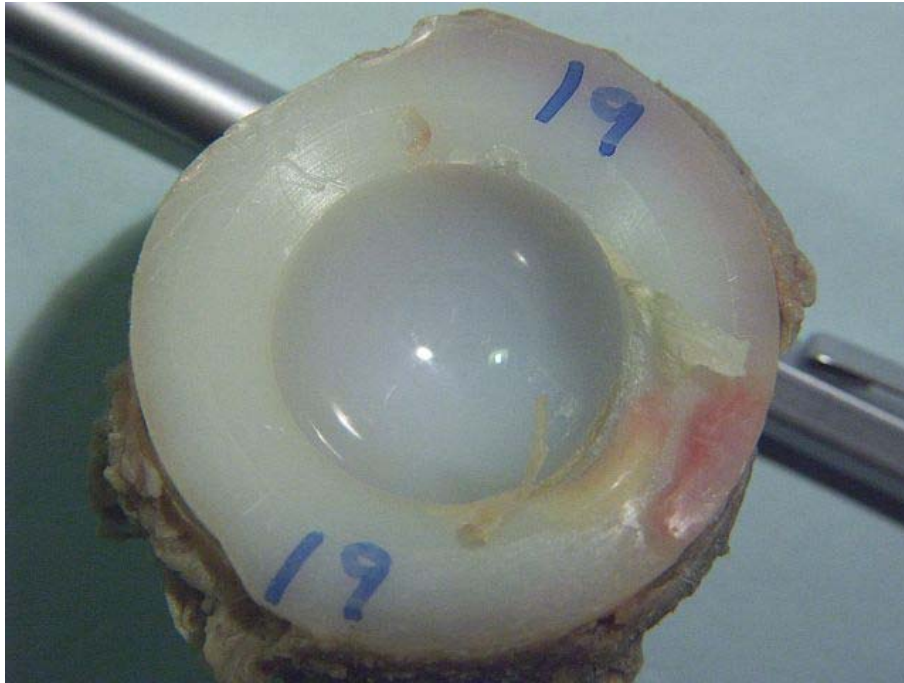


Figure A46



Figure A47

Cup analysis: Patient 19

1	Femoral head size	28 mm
2	Type of head	Alumina
3	Cup type	UHMWPE - BARC
4	Crosslink	No
5	Amount of linear wear	± 2 mm
6	Duration in vivo	15 years and 6 months
7	Size of wear debris from pathologist	Not available
8	Visible discoloration	Yes
9	Metal backing	No
10	Thickness of poly	10 mm
11	Mechanical damage	Yes
12	Cracks in material	Yes
13	Plastic flow	Yes
14	Scratches	Yes
15	Adhesion wear	Yes
16	Wear particles embedded in base material	Yes
17	Flaking	Yes

Patient 20



Figure A48



Figure A49



Figure A50

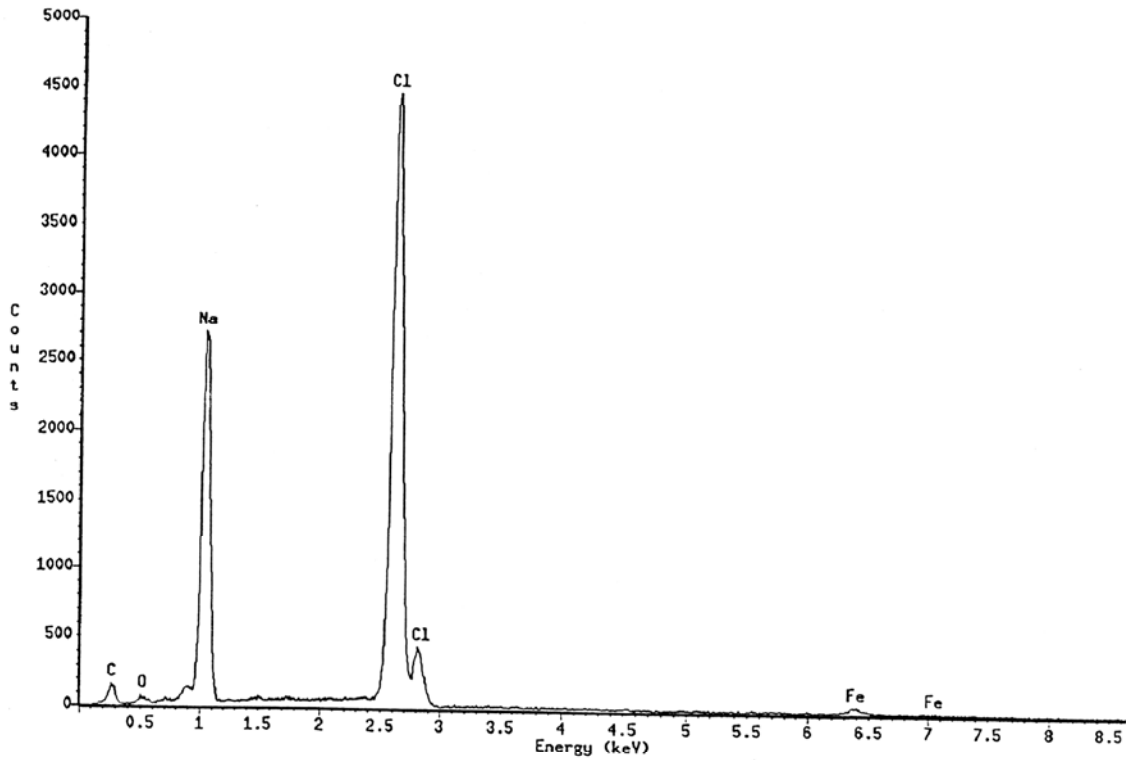
Cup analysis: Patient 20

1	Femoral head size	32 mm
2	Type of head	Zirconium
3	Cup type	UHMWPE - Aesculab
4	Crosslink	Yes
5	Amount of linear wear	± 0 mm
6	Duration in vivo	2 years and 4 months
7	Size of wear debris from pathologist	Not available
8	Visible discoloration	No
9	Metal backing	No
10	Thickness of poly	7 mm
11	Mechanical damage	No
12	Cracks in material	No
13	Plastic flow	No
14	Scratches	Yes
15	Adhesion wear	Yes
16	Wear particles embedded in base material	No
17	Flaking	No

ANNEXURE B

Electron microscope analysis of white deposits in acetabular cups

Annexure B



```

Column          : JEOL5800.Pioneer
Take-off angle  : 35
Acquisition type : eds
Creation time   : 10/05/17 15:05
Livetime        : 100
Deadtime        : 28.089
Channels        : 2048
Channel width   : 10
Detector type   : Silicon/Lithium
Window type     : norvar
Window thickness : 0.3
Coating material : Al
Coating thickness : 0.04
Contact material : Au
Contact thickness : 0.02
Crystal thickness : 3

Accelerating voltage : 20
Magnification        : 3500
Charge               : 100
Beam current         : 1
Beam spot size       : 0
Beam location        : 0.0
Working distance     : 10
Stage X              : 1.306
Stage Y              : -19.637
Stage Z              : 11.369
Stage tilt           : 0
Stage rotation       : 0
Contamination material : none
Contamination thickness : 0
    
```

File name :

Notes:

Wed May 17 15:04:01 2000

Livetime : 15.2 Sec.
Technique: Least Squares Fit

Elements Present:
C(6), Zn(30), Cl(17)

Energy (keV)	Intensity (counts)	Elements Present
0.273	127	C Ka
1.044	5019	Zn La1
2.626	8560	Cl Ka

ANNEXURE C

Electron microscope investigation into Brown discolouring in acetabular cups

C1

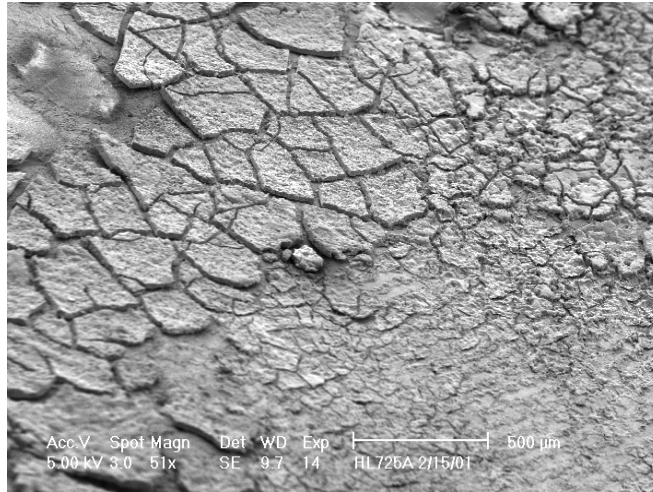


Figure C1

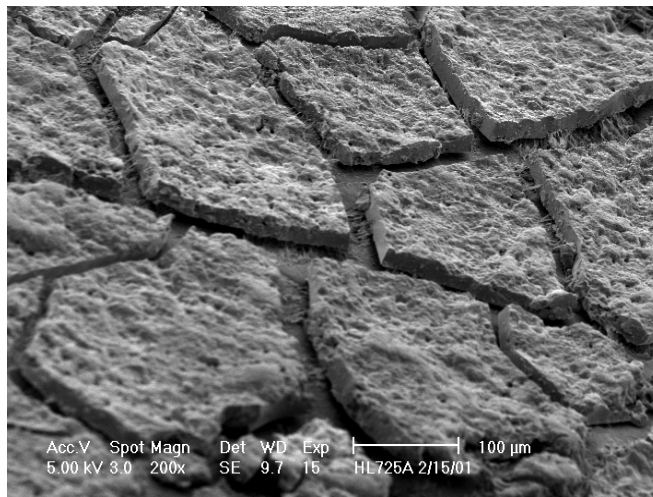


Figure C2

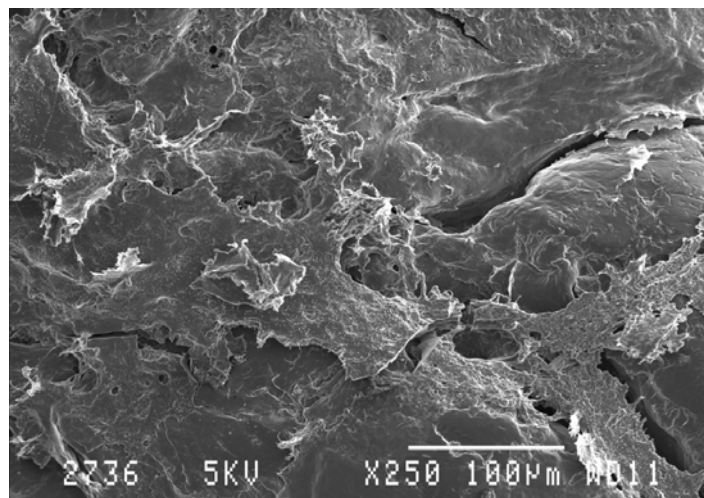


Figure C3

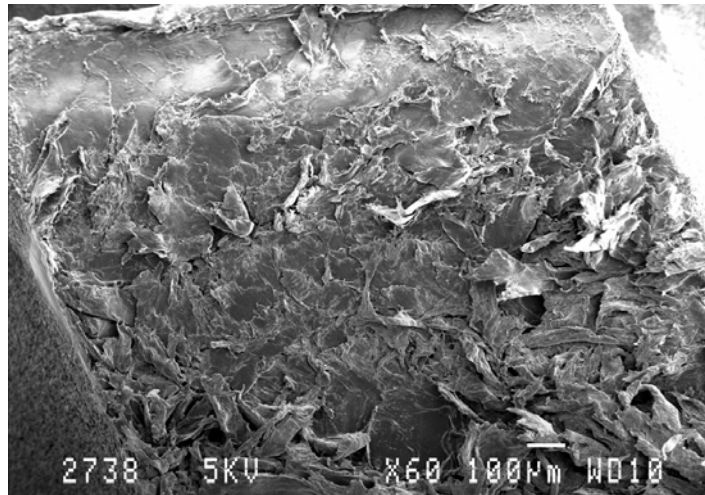


Figure C4

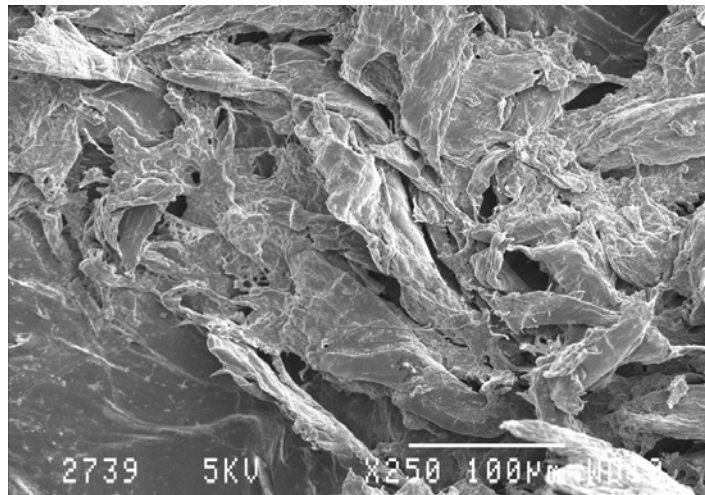


Figure C5

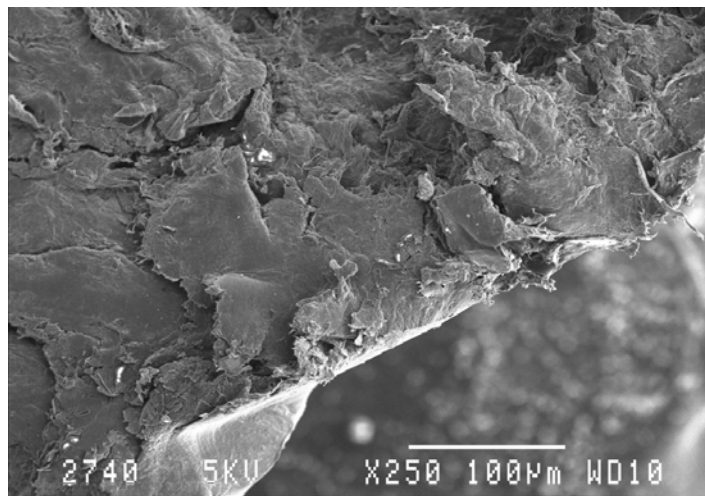


Figure C6

ANNEXURE D

Electron microscope investigation into structure of UHMWPE

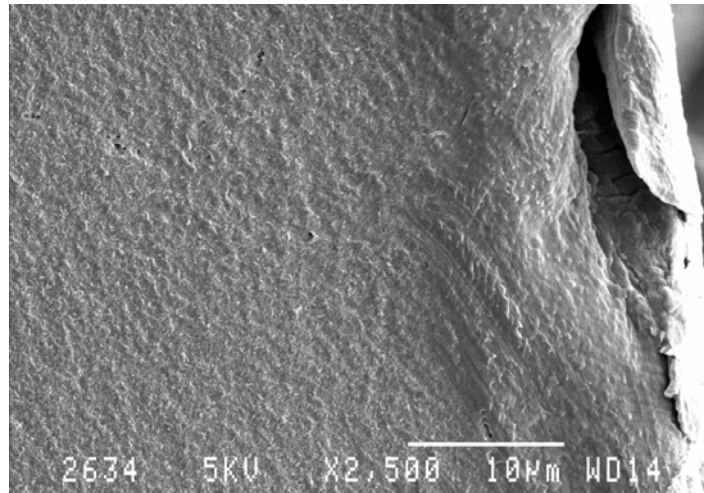


Figure D1: Test piece undeformed

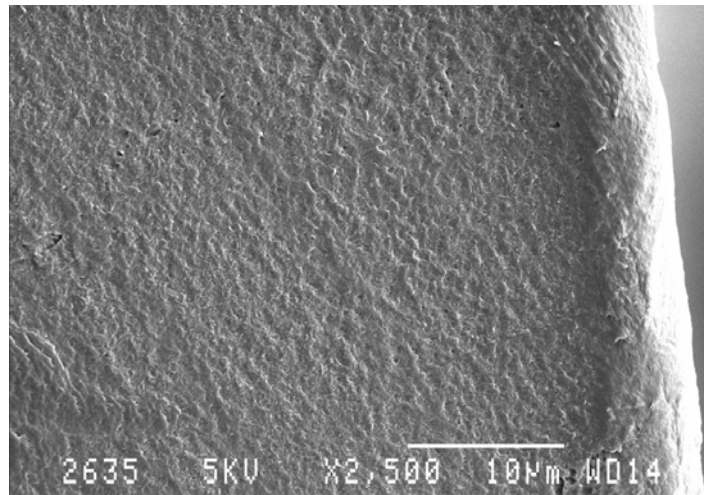


Figure D2: Test piece undeformed

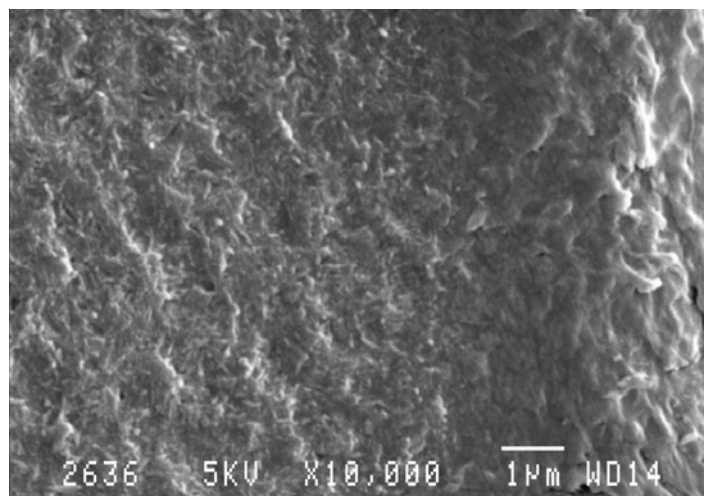


Figure D3: Test piece undeformed

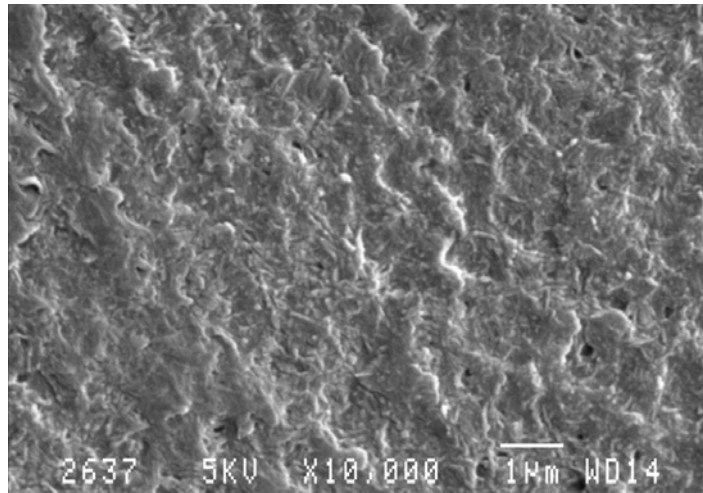


Figure D4: Test piece undeformed

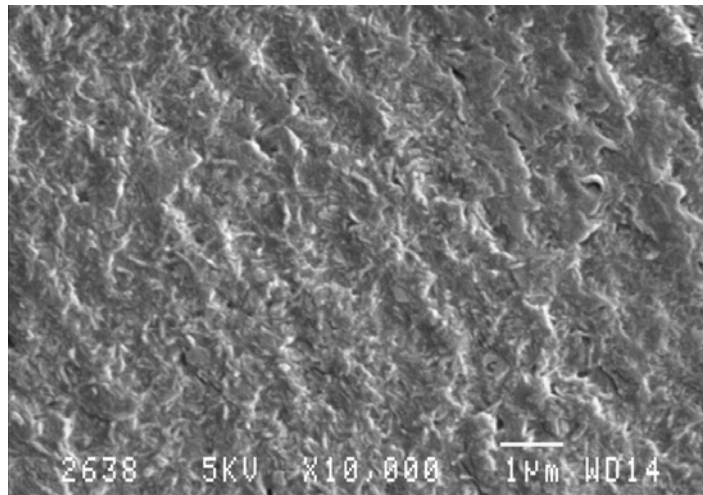


Figure D5: Test piece deformed

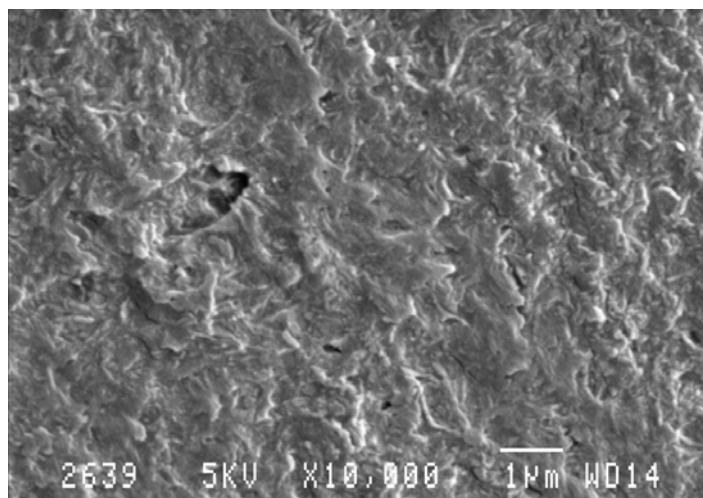


Figure D6: Test piece deformed

ANNEXURE E

Electron microscope investigation into micro wear

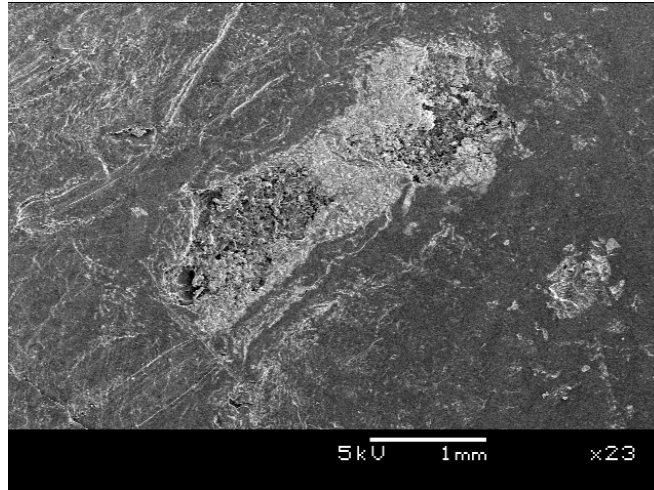


Figure E1: Adhesion wear

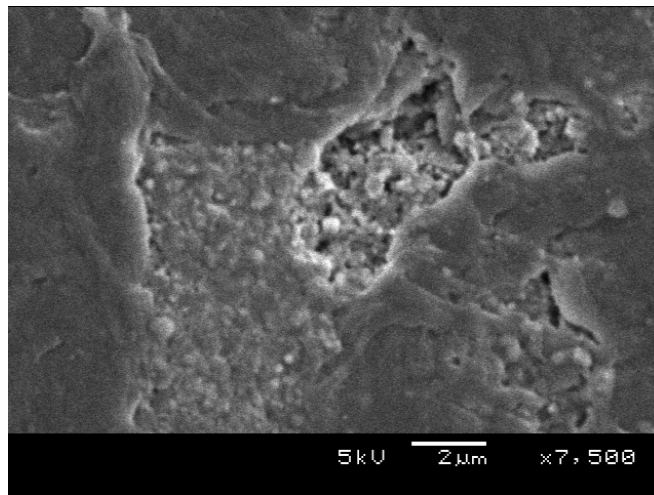


Figure E2: Adhesion wear

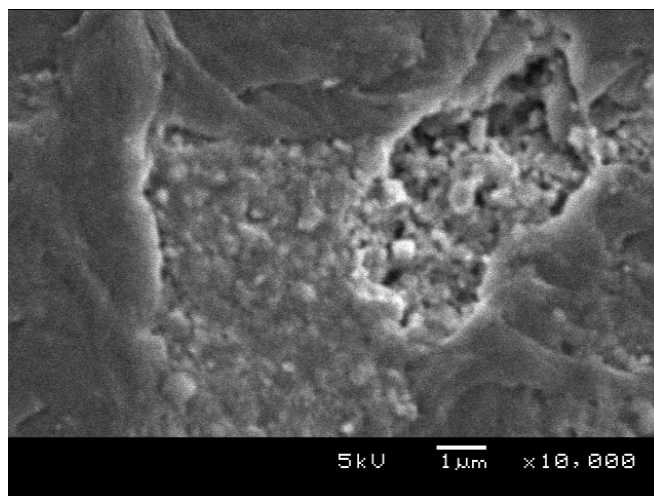


Figure E3: Adhesion wear

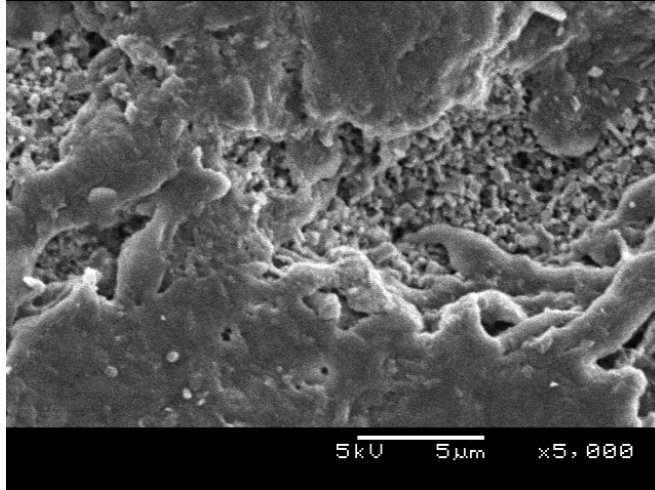


Figure E4: Adhesion wear

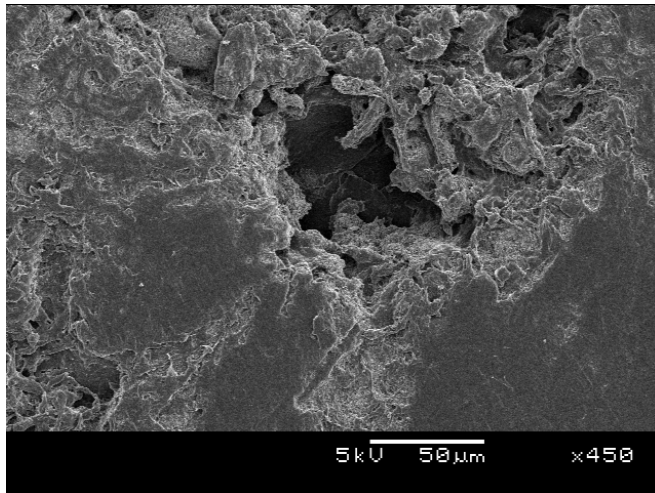


Figure E5: Crater after adhesion wear

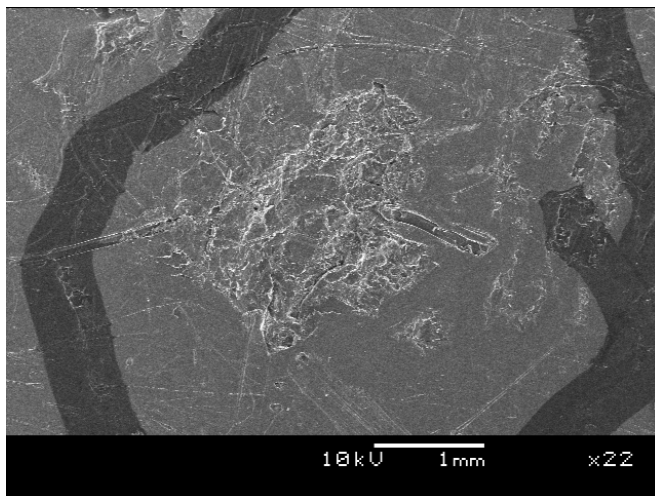


Figure E6: Patch with adhesion wear

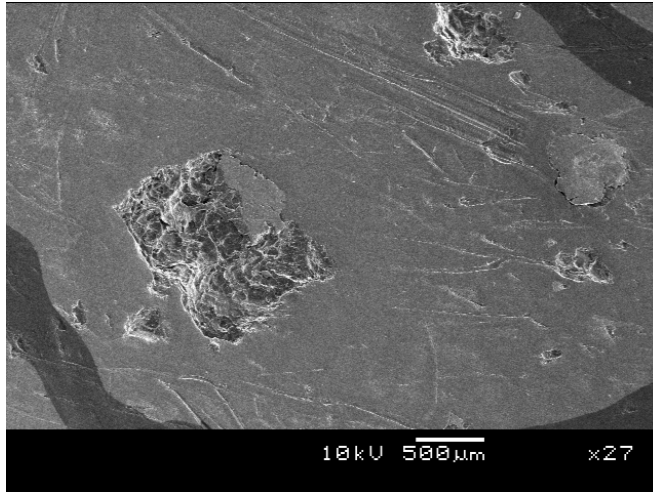


Figure E7: Patch with adhesion wear

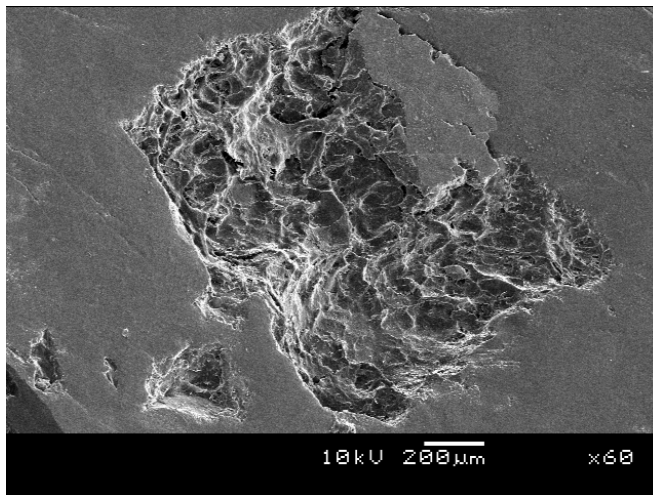


Figure E8: Patch with adhesion wear

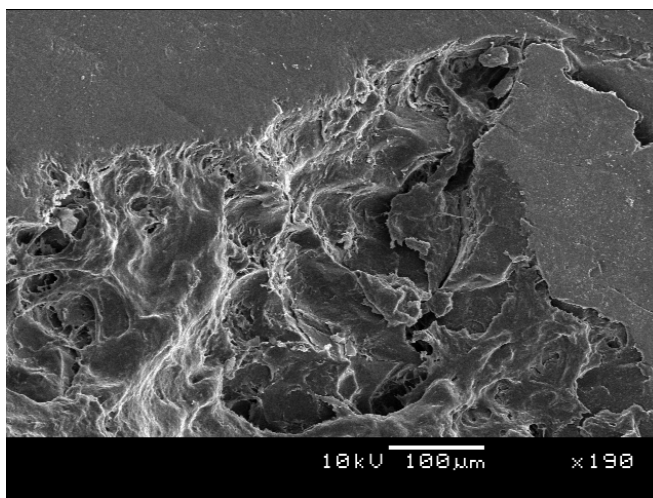


Figure E9: Patch with adhesion wear

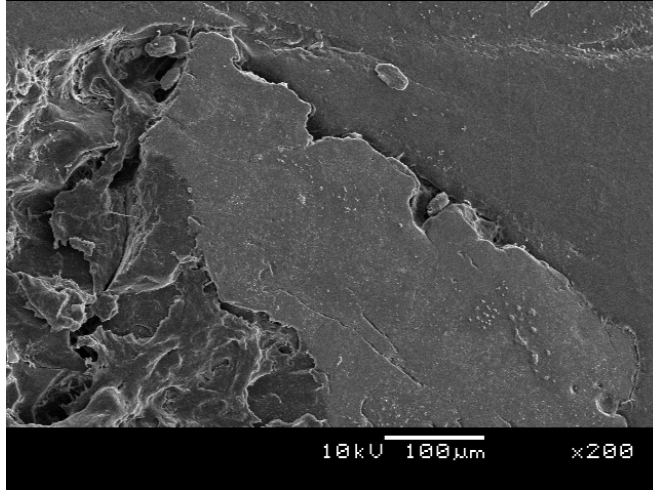


Figure E10: Remaining flake after adhesion wear

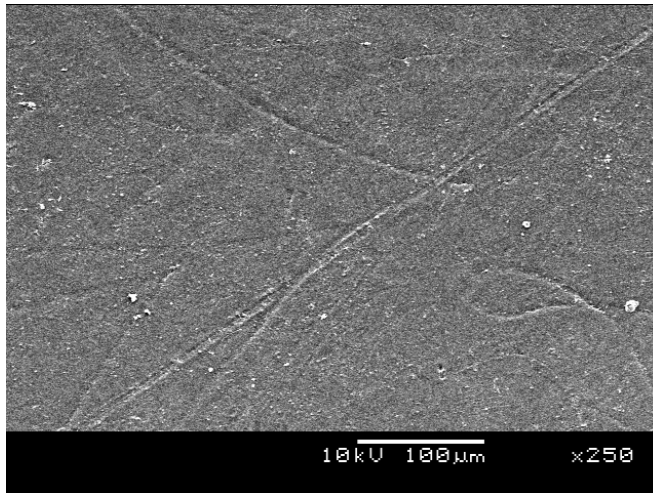


Figure E11: Scratches on bearing surfaces

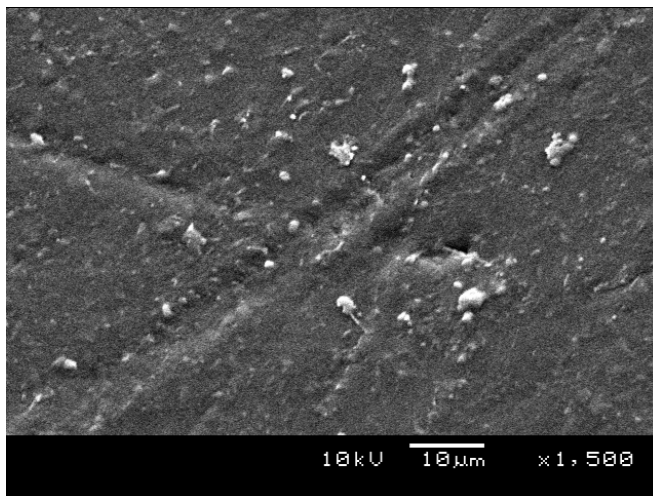


Figure E12: Scratches on bearing surfaces

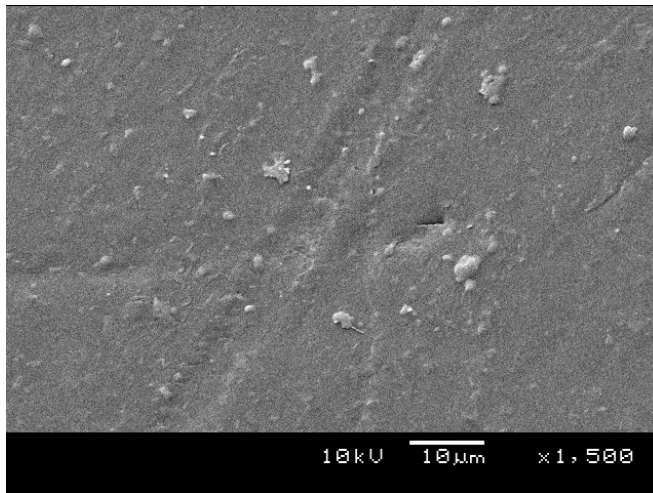


Figure E13: Back scatter analysis

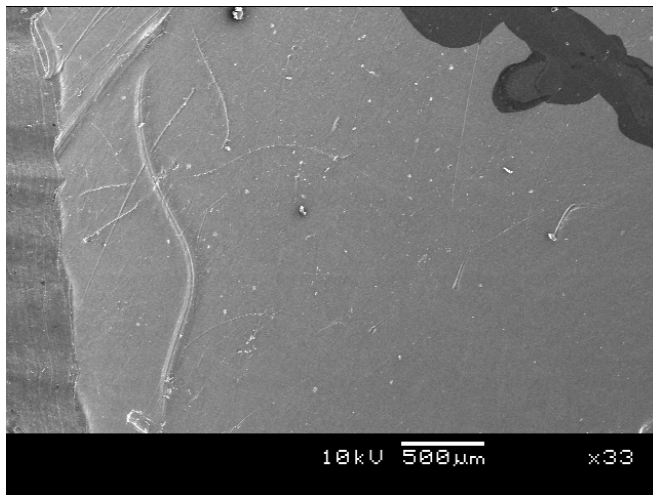


Figure E14: Scratches on bearing surfaces

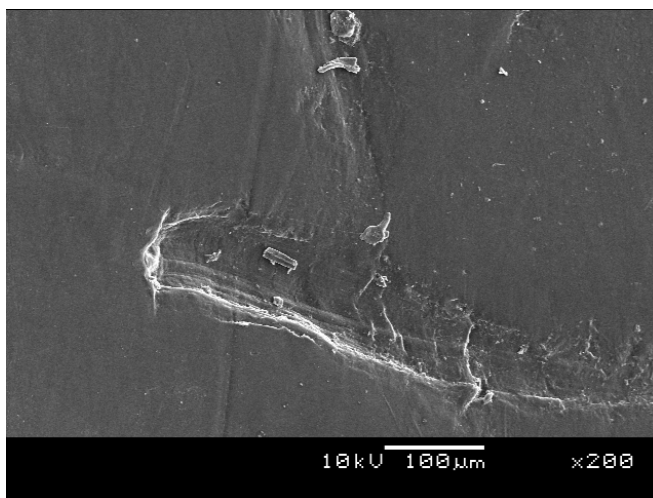


Figure E15: Scratches on bearing surfaces

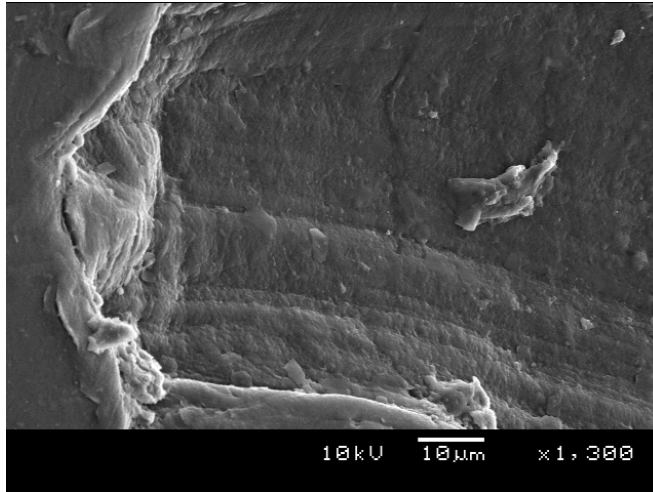


Figure E16: Ploughing mark

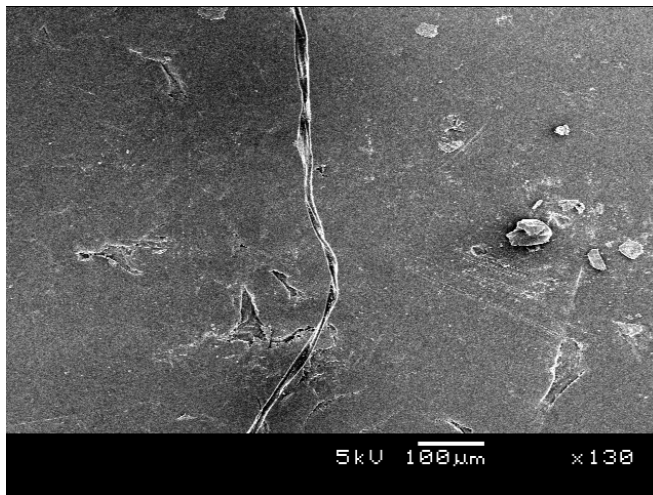


Figure E17: Scratch on bearing surface

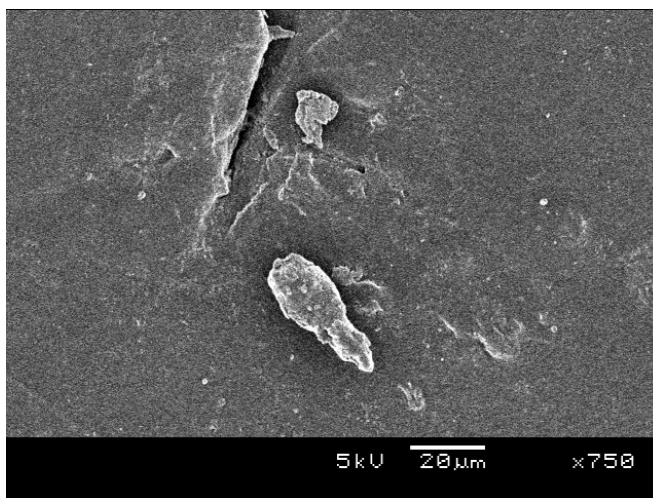


Figure E18: Wear particle

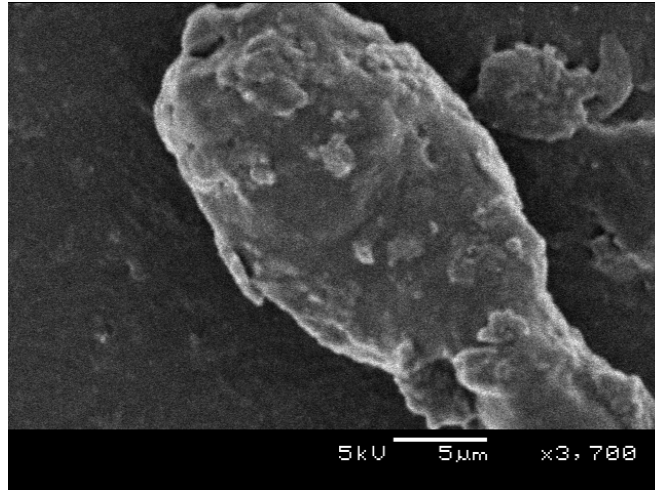


Figure E19: Wear particle

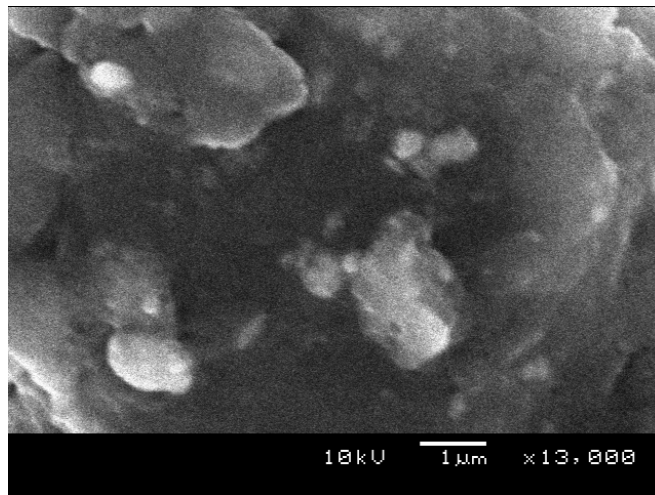


Figure E20: Wear particle

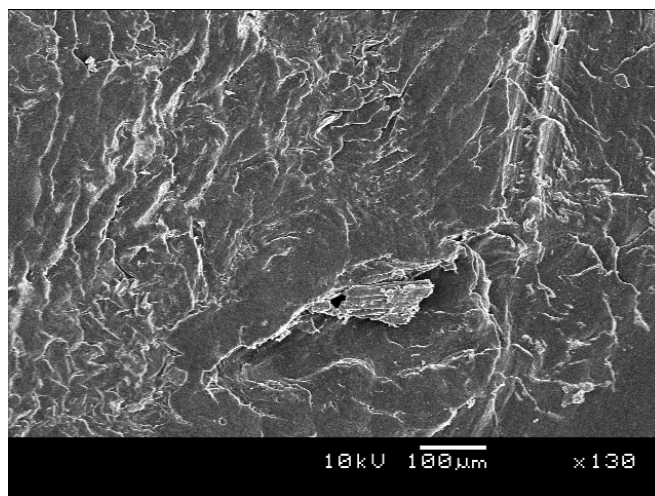


Figure E21: Plastic flow

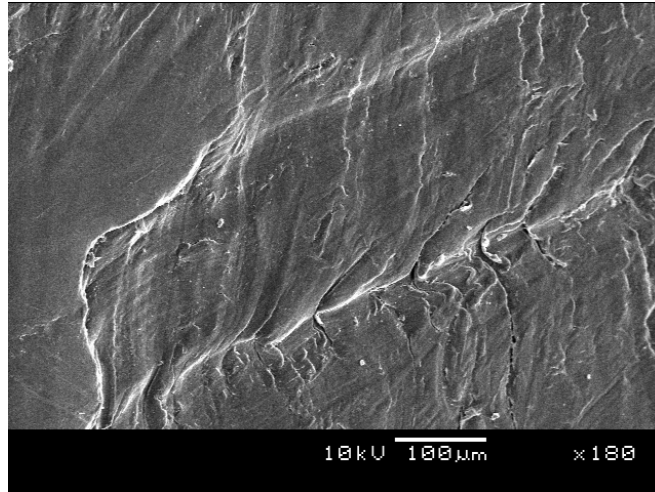


Figure E22: Plastic flow

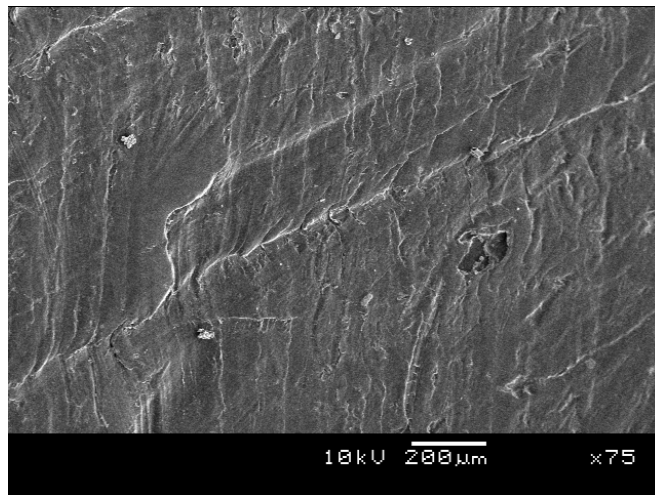


Figure E23: Plastic flow

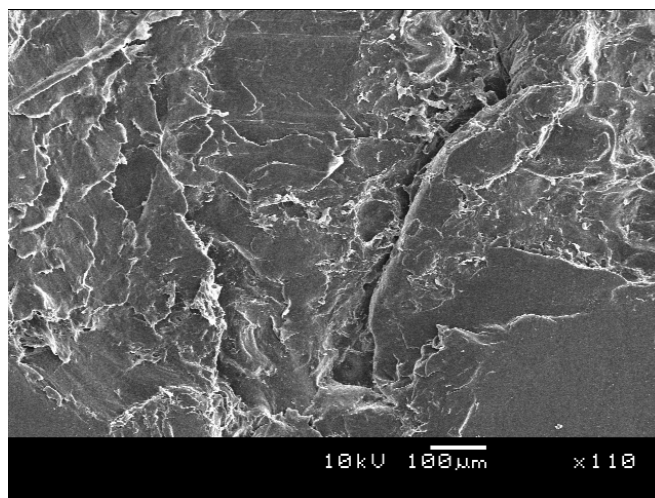


Figure E24: Crack after adhesion wear

ANNEXURE F

Electrophoresis analysis of particles retrieved from brown deposit in acetabular cups and synovial fluid

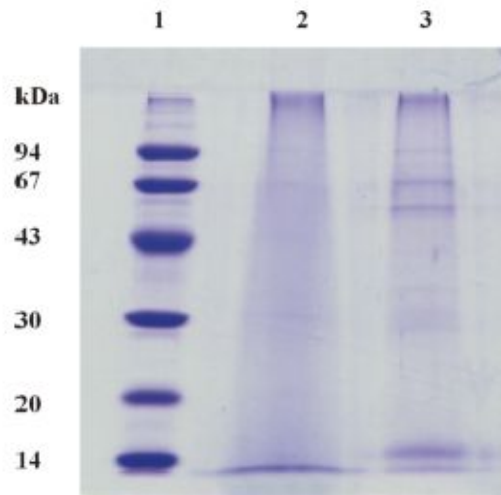


Figure F1: SDS-PAGE analysis of samples as trial study. Lane 1 is the molecular mass markers with mass indicated in kDa, on left hand side, line 2 and 3 is two different samples from different retrievals

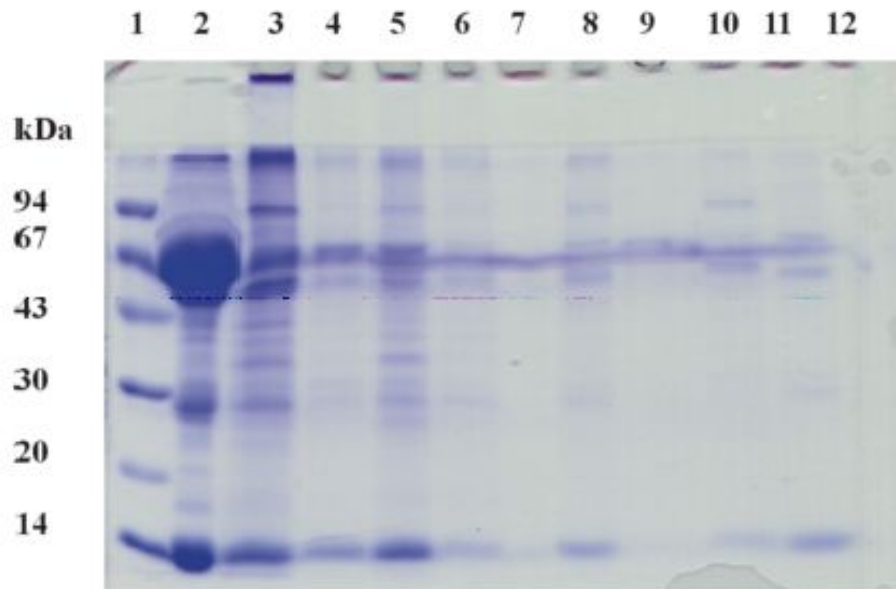
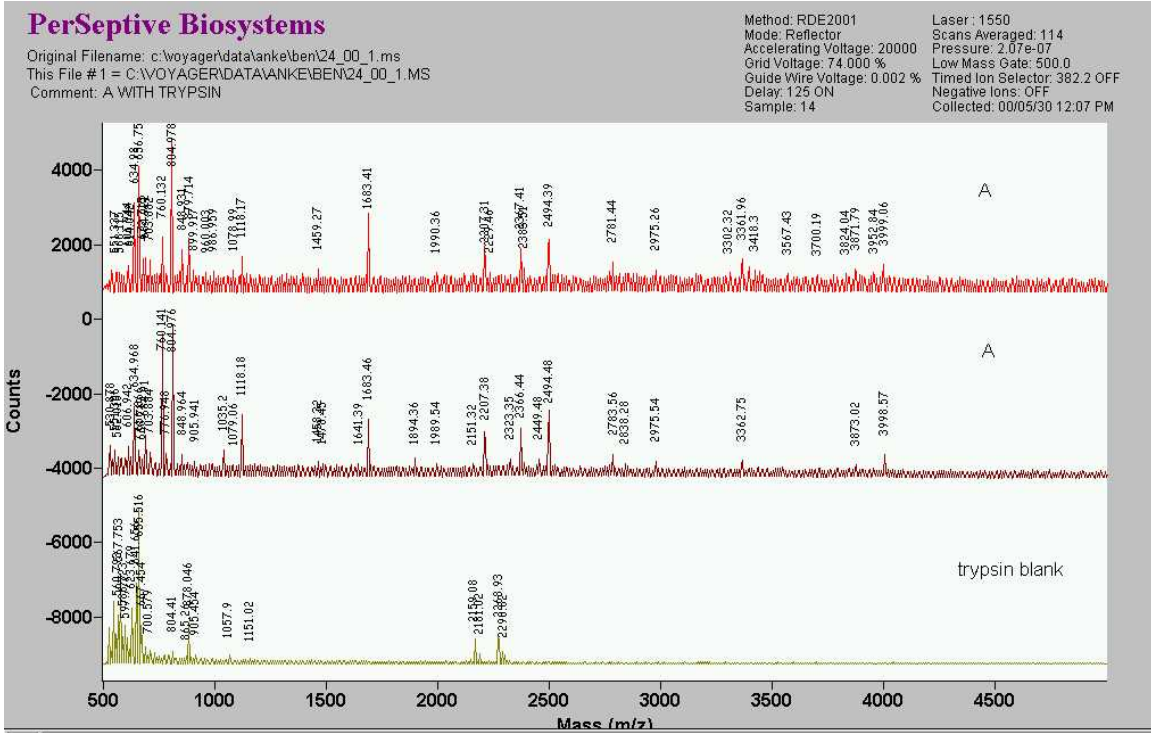


Figure F2: SDS-PAGE analysis of fresh retrievals. Lane 1 is the molecular mass indicated in kDa on left hand side. Lane 2 to 6 is a sample from a patient after 8 years in-vivo with lane 2 the synovial fluid. Lane 8 to 12 is a sample from patient after 4 years in-vivo

ANNEXURE G

Mass spectrometric analysis of particles retrieved from brown deposit in
acetabular cups and synovial fluid



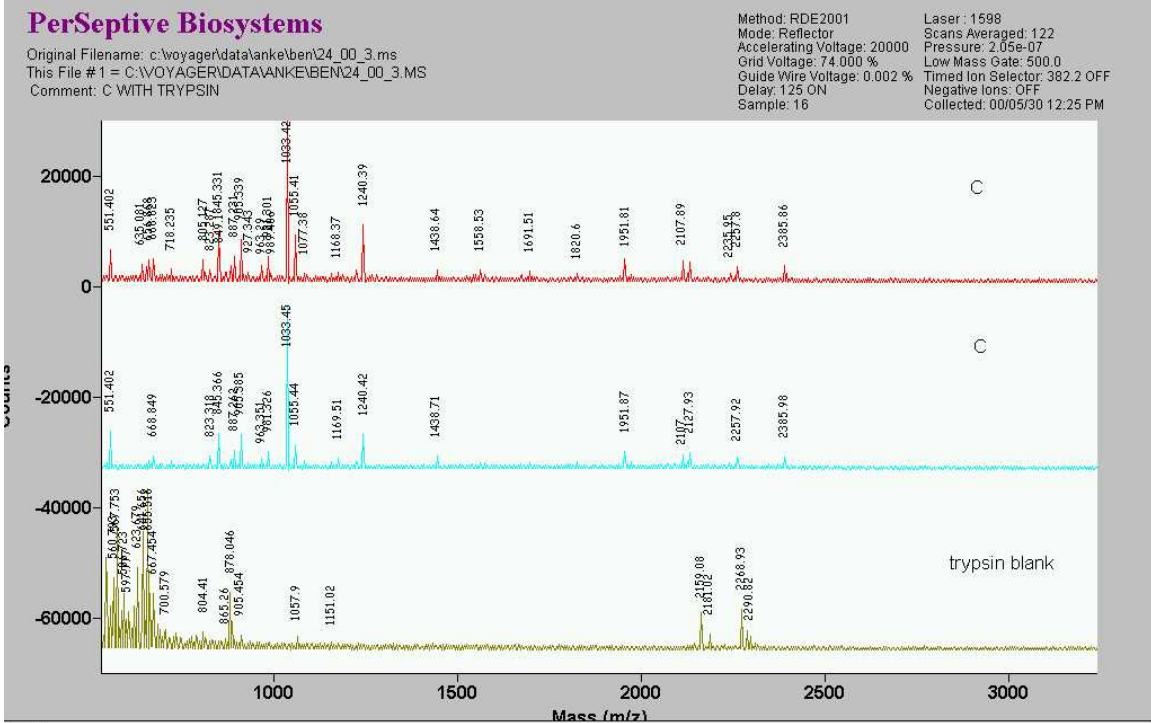


Figure G3

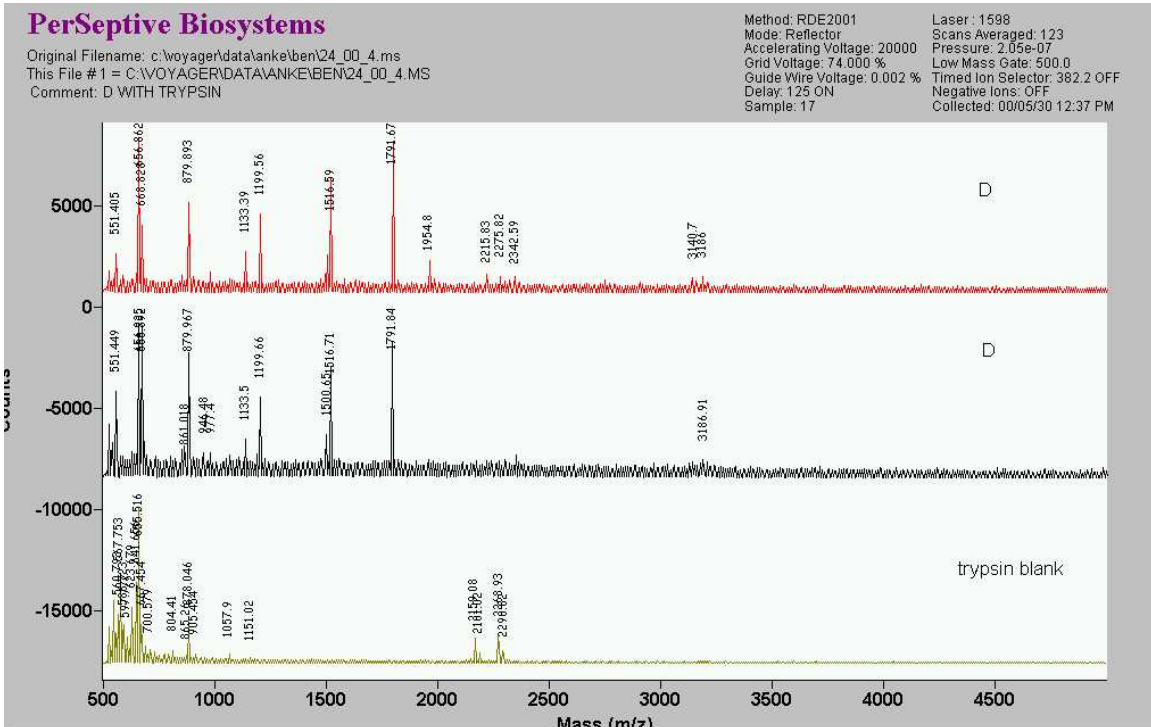


Figure G4

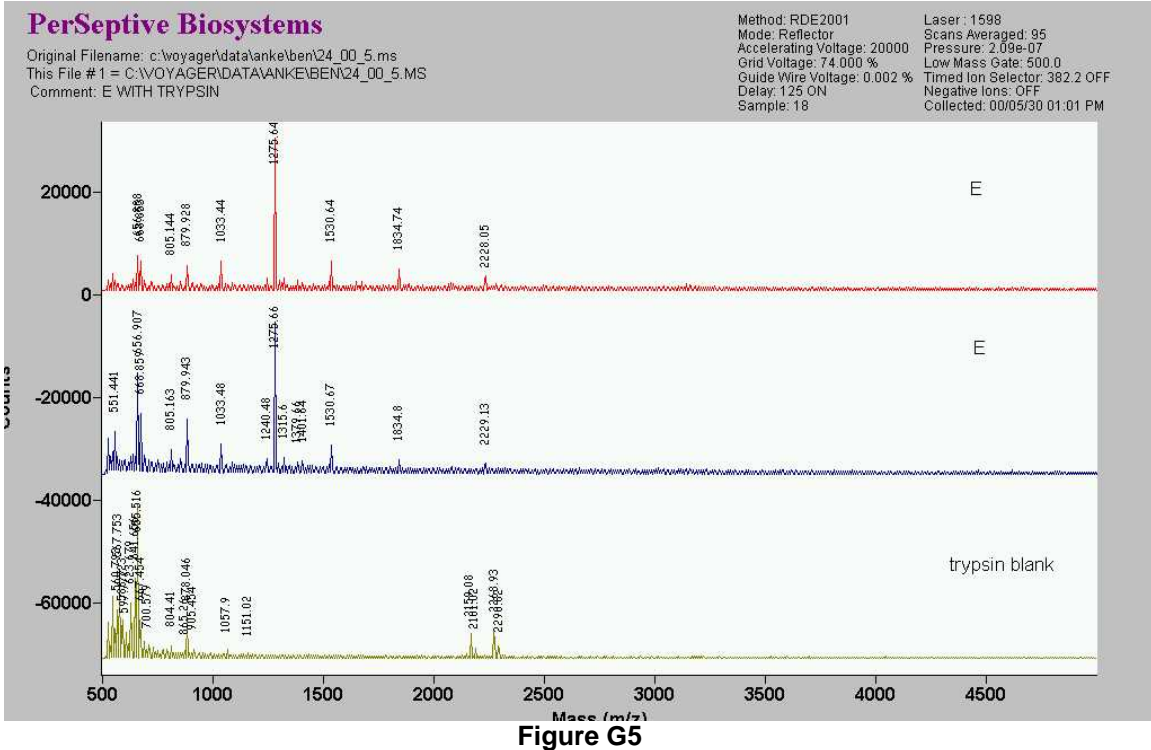


Figure G5

ANNEXURE H

Lubricity analysis of retrieved synovial fluid

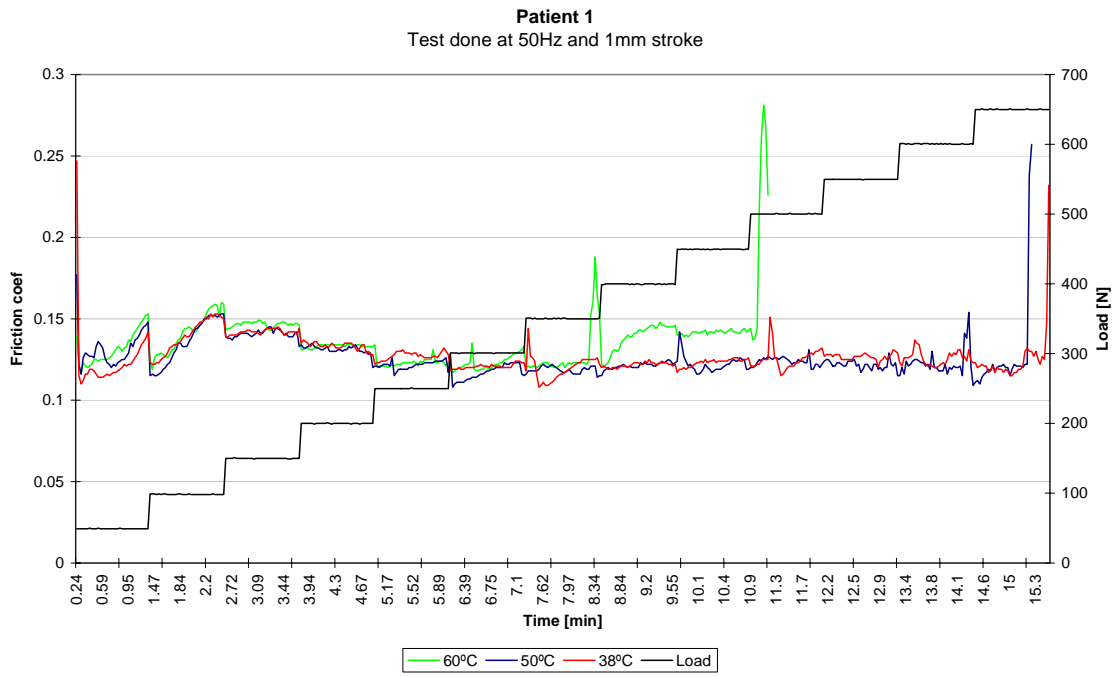


Figure H1

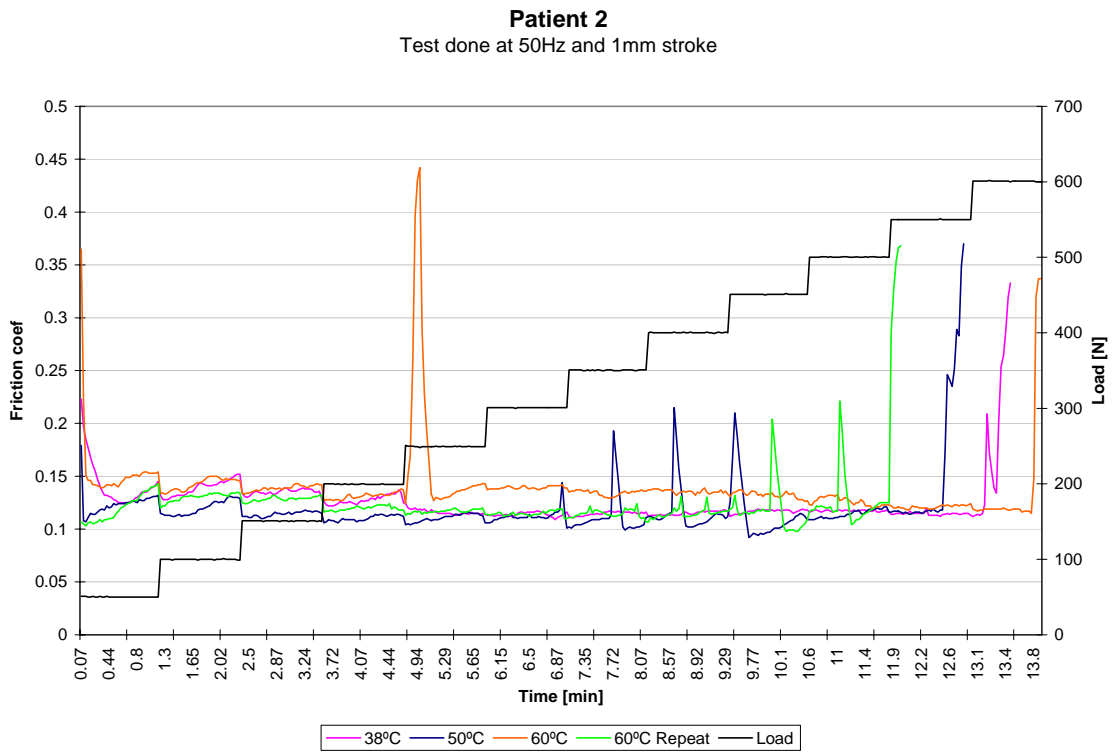


Figure H2

H2

Patient 3

Test done at 50Hz and 1mm stroke

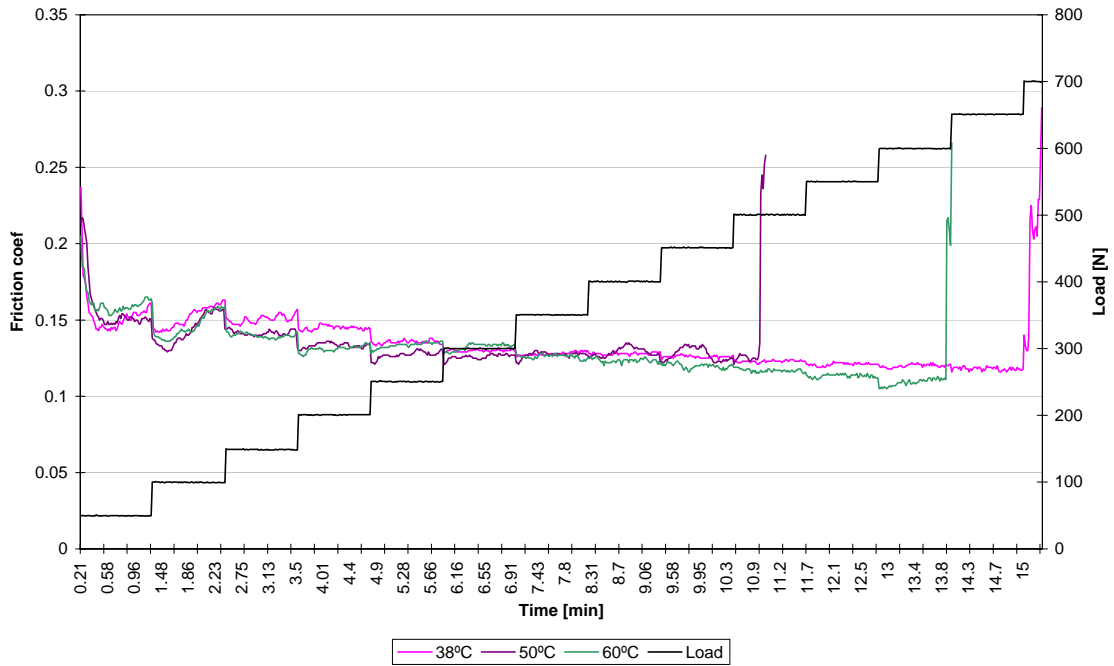


Figure H3

Patient 4

Test done at 50Hz and 1mm stroke

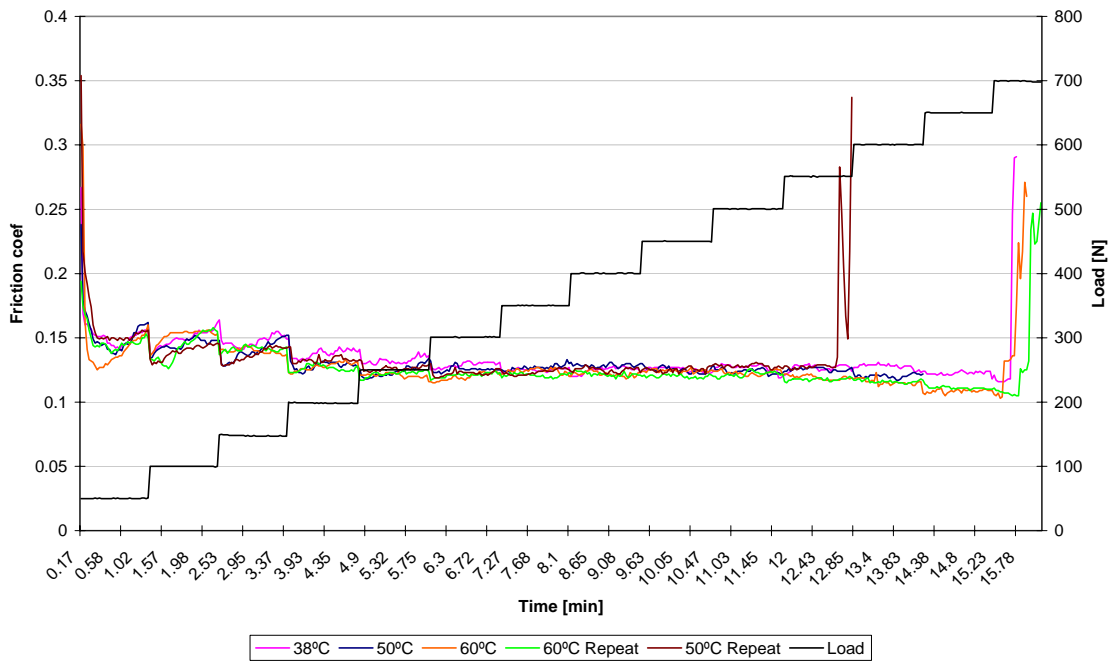


Figure H4

Patient 5
Test done at 50Hz and 1mm stroke

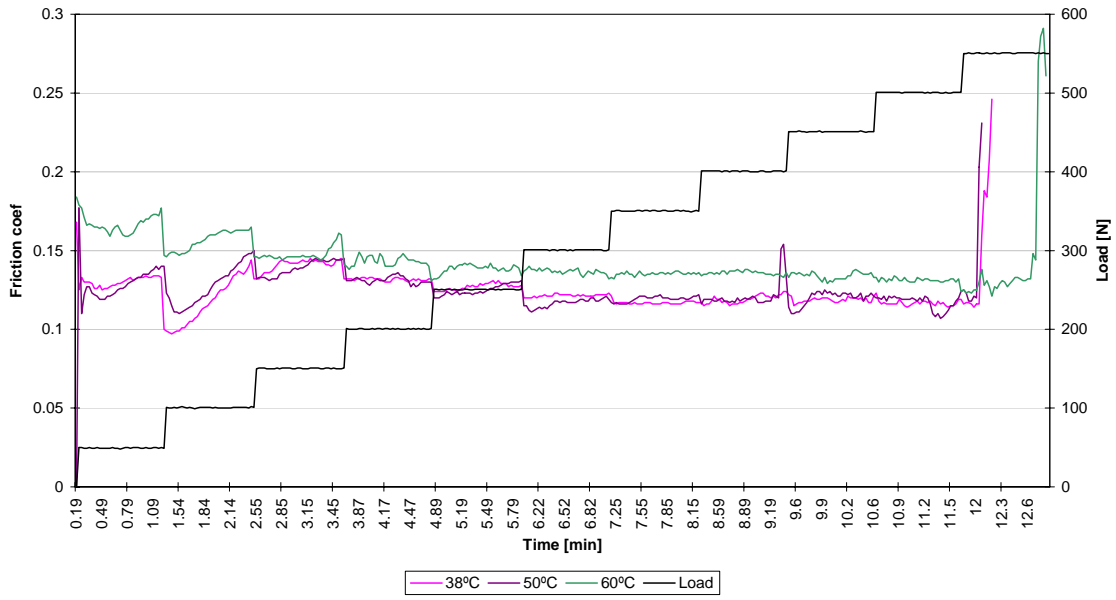


Figure H5

Patient 6
Test done at 50Hz and 1mm stroke

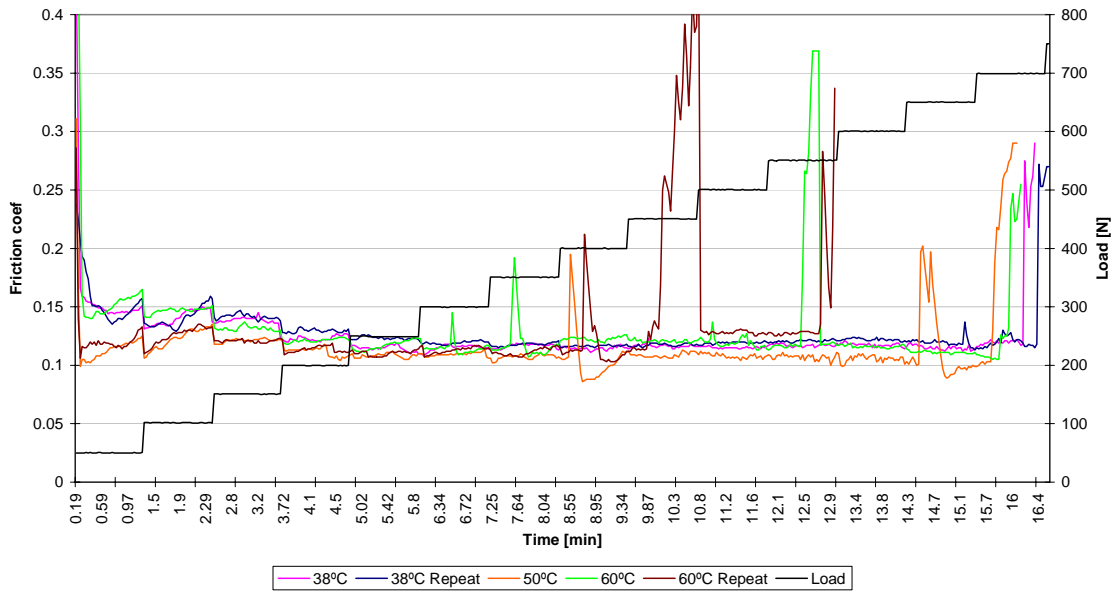


Figure H6

Patient 7
Test done at 50Hz and 1mm stroke

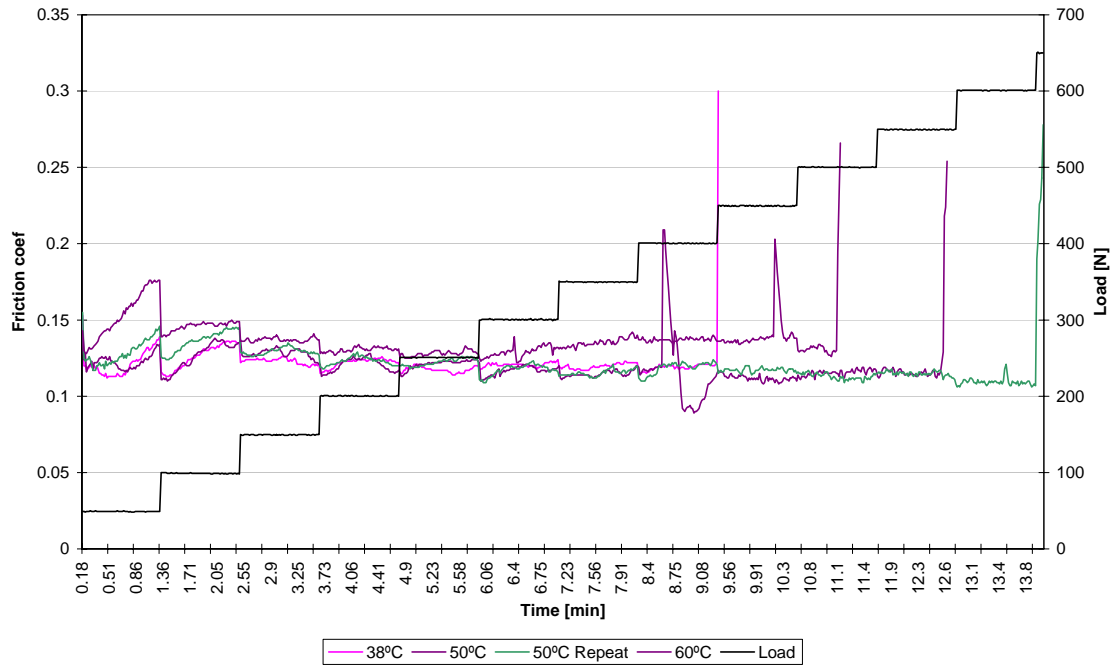


Figure H7

Patient 8
Test done at 50Hz and 1mm stroke

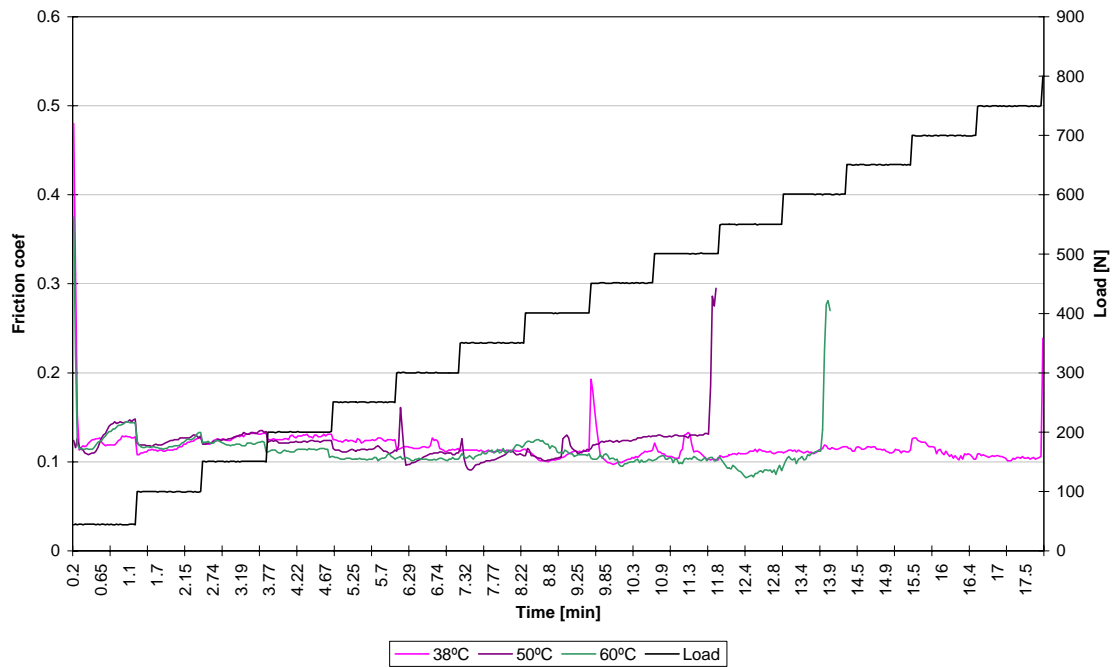


Figure H8

Patient 9
Test done at 50Hz and 1mm stroke

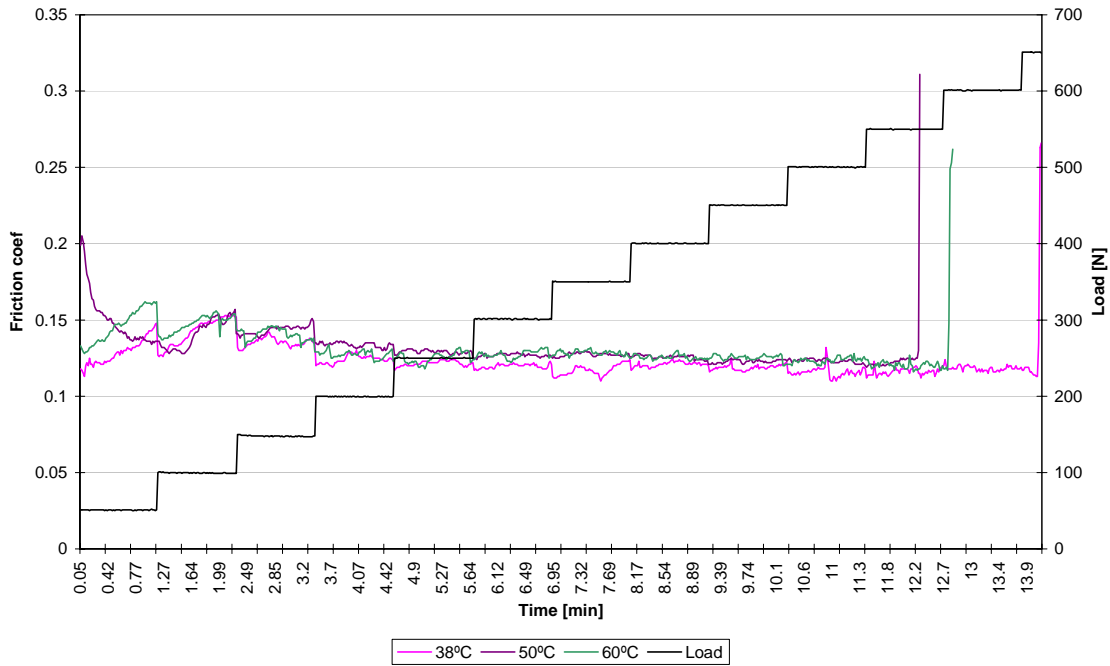


Figure H9

Patient 10
Test done at 50Hz and 1mm stroke

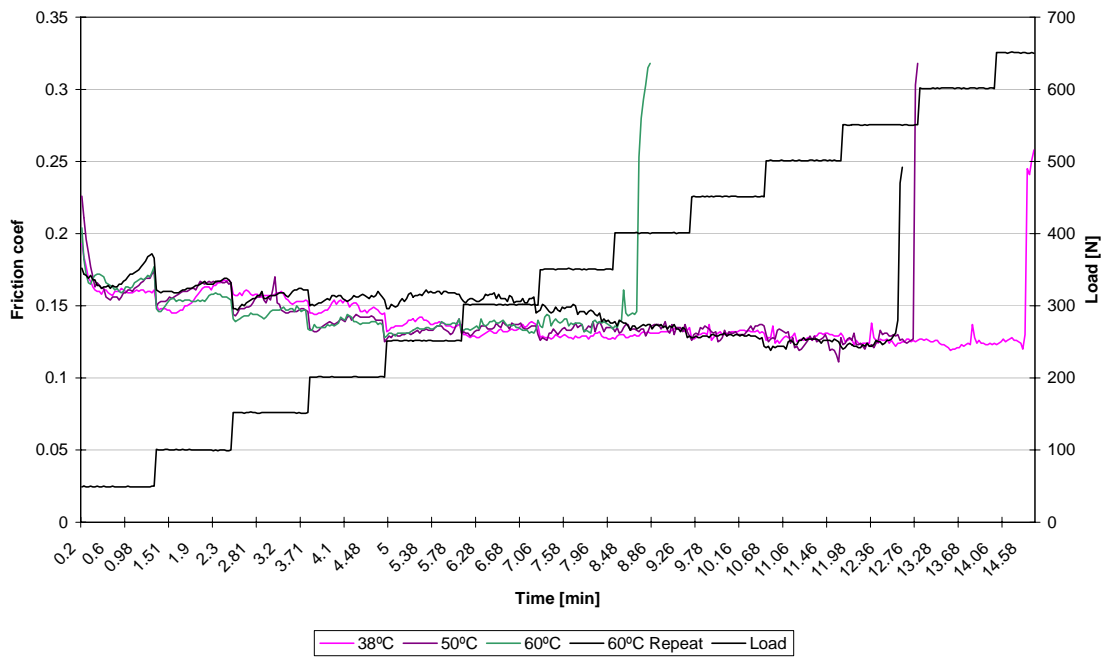


Figure H10

Patient 11

Test done at 50Hz and 1mm stroke

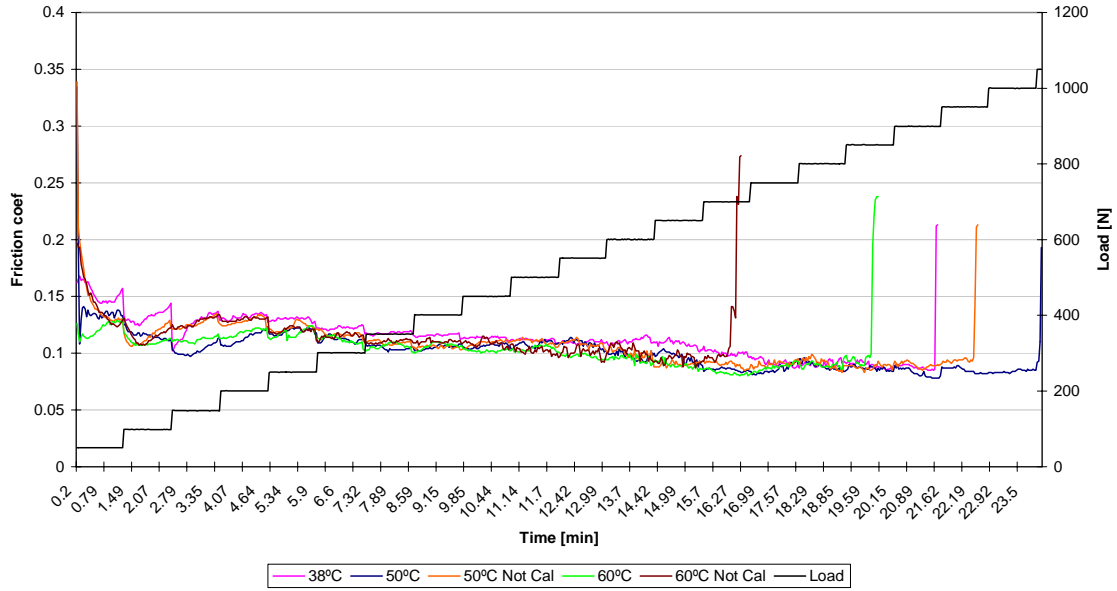


Figure H11

Patient 12

Test done at 50Hz and 1mm stroke

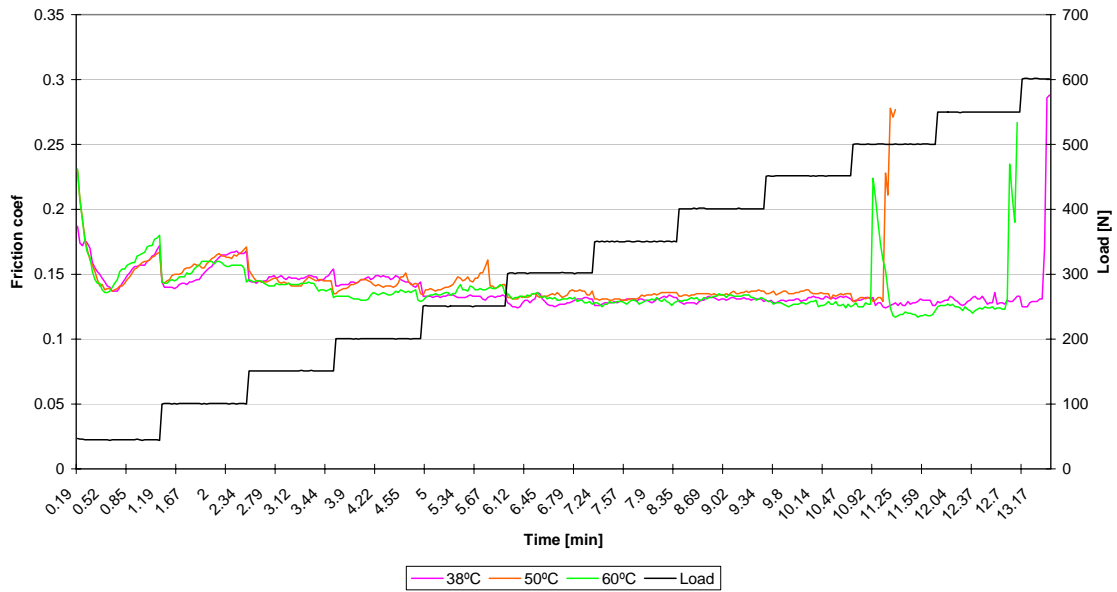


Figure H12