

Surface structure of retrieved ICLH femoral cups

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We characterized the surface structure of 21 retrieved femoral ICLH cups, as an indirect measure of surface damage, with an optical scanner specially developed for surface roughness measurements. 3 unused cups were measured and served as controls.

The mean insertion time was 10 (5–15) years. 5 areas on each cup were measured, 1 on the top and

4 at the edge. The mean value of 3 different, commonly used, surface roughness parameters was calculated for the edge measurements. We found no correlation between the surface topography and clinical patient data such as age, body-weight, head-shaft angle, implantation time and wear of the polyethylene socket.

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Submitted 97-03-09. Accepted 98-02-17

Wear products constitute a threat to the artificial joint. In an *in vitro* study, McKellop et al. (1981) reported increasing wear of polyethylene cups with increasing surface roughness of ceramic femoral heads. Dowson et al. (1985) likewise found, in another *in vitro* study, an increased wear rate of the polyethylene cup due to greater surface roughness of femoral stainless steel heads, which, with time, could result in penetration of the head into the acetabular socket. Isaac et al. (1987) suggested that barium sulfate and zirconium dioxide in the cement were responsible for the increased sur-

face roughness of the femoral stainless steel head which resulted in greater wear of the acetabular cup. Metal debris from hip prostheses into the periprosthetic tissue is one factor that is thought to cause bone resorption (Haynes et al. 1993, Maloney et al. 1993) and subsequent implant loosening.

Wear rates and surface roughness can be studied with weight-loss measurements, interference microscopy, surface spectroscopy and 2-dimensional profilometry. Since all surfaces interact 3-dimensionally, it is preferable to use methods for 3D characterization. Today, several commercially available systems exist, contact as well as noncontact ones, for such surface roughness characterization. We characterized the surface roughness of retrieved femoral cups in 3 dimensions with a confocal laser scanner for measuring surface damage and correlated the surface topography to clinical patient data.

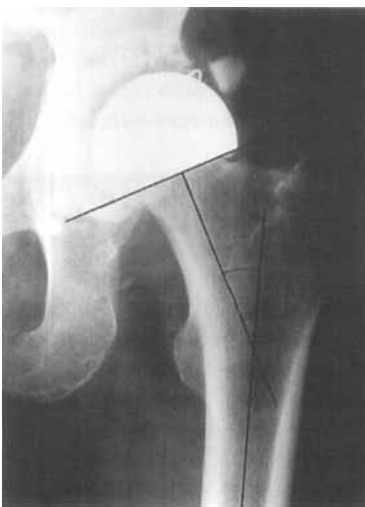


Figure 1. A cemented ICLH double cup. The acetabular component is loose, but the femoral cup is still well-fixedated 14 years after insertion. The head shaft angle was determined by a line perpendicular to the opening plane of the cup and a line through the midshaft of the femur.

Material and methods

Implants

We evaluated the surface roughness of 21 retrieved ICLH (Protek Ltd, Berne, Switzerland) femoral cups. The ICLH cups were manufactured from cobalt chromium molybdenum alloy (Protasul[®]), and the acetabular sockets were manufactured from polyethylene.

All 21 patients (16 women) had their femoral cups removed between June 1989 and November 1994, due to aseptic loosening of the acetabular component, while the femoral cups were in all cases well fixed (Figure 1). 2 of the patients had a uncemented acetab-

Table 1. 6 background factors

Implant	Sex	Age year	Mean weight kg	Head–shaft angle (°)	Insertion time months	Polyethylene wear mm
1	F	71	68 (68–69)	26	128	0.7
2	F	64	60 (60–61)	33	119	not measurable
3	F	70	59 (60–58)	26	126	1.6
4	F	61	92 (92–92)	42	102	1.5
5	M	53	84 (82–85)	10	67	0.6
6	F	59	56 (59–53)	35	69	0.8
7	F	57	64 (64–65)	42	101	1.0
8	M	58	80 (81–80)	18	63	uncemented
9	F	52	69 (66–73)	25	81	uncemented
10	F	70	66 (68–65)	26	136	2.0
11	F	61	76 (68–85)	19	145	1.3
12	F	53	79 (73–85)	24	169	0.7
13	F	72	68 (70–65)	28	170	1.3
14	M	61	86 (86–86)	14	108	1.4
15	F	66	73 (72–74)	17	178	1.0
16	M	80	81 (84–78)	31	136	1.5
17	F	58	63 (59–67)	25	129	1.7
18	F	68	74 (76–73)	42	177	1.2
19	F	77	56 (55–58)	26	132	1.5
20	M	71	85 (85–85)	29	130	2.7
21	F	63	70 (70–70)	27	125	1.1

ular cup, the remaining 19 patients had cemented cups. All femoral cups were cemented with Palacos® containing gentamicin. Detailed information about the primary operative procedure has been published by Reigstad et al. (1986). The revision operations were performed through the direct lateral approach (Hardinge 1982), including extensive excision of the joint capsule. We tried to avoid scratching the femoral cup. After dislocating the joint and osteotomizing the femoral neck, we removed the femoral head with the cup and kept it in formalin, together with the enclosed tissue. Clinical data were collected from the hospital records. Polyethylene wear of the acetabular sockets was measured on the latest radiograph before loosening, using the technique of Livermore et al. (1990). The head–shaft angle of the femoral cup was measured from AP radiographs, in order to relate the main load to the top of the ICLH cup (Figure 1, Table 1).

Surface roughness measurement and evaluation

An optical profilometer, based on the principle of confocal laser scanning microscopy, was used for surface roughness characterization (TopScan 3D, Heidelberg Instruments, Heidelberg, Germany). This system, reported by Wennerberg et al. (1992) has been used in several experimental studies concerning fixation of implants manufactured with various degrees of surface roughnesses (Wennerberg et al. 1995a,b, 1996a,b). A comparison of the TopScan 3D system and contact stylus techniques has been published (Wennerberg et al. 1996c). The authors con-

cluded that the TopScan 3D system was well adapted for measurement of various biomaterials. Immediately before the topographical measurement, all ICLH cups were rinsed in ethanol and dried in air. To measure all 21 implants in the same way, 5 areas (0.5 mm²) were chosen in advance, 1 area at the top, 4 areas 5 mm from the edge, at an equal distance from one another. If scratches, most probably originating from the implant retrieval, were found in these areas, an area as close as possible was measured (Figure 2). Each measurement consisted of 167 scans, 3 µm apart. As controls, the surface roughness of three unused ICLH cups was measured in the same manner as the retrieved implants. Mean values for the different surface roughness parameters were calculated for the

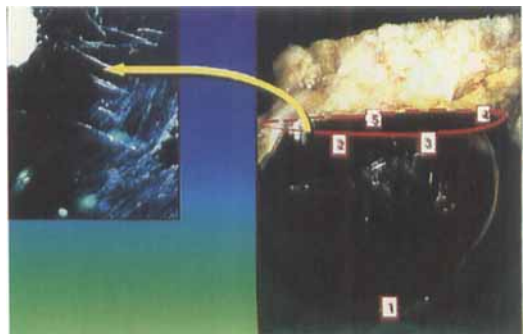


Figure 2. A ICLH femoral cup; the 5 squares indicate the areas measured on each sample. The close-up image demonstrates some deep scratches with sharp edges which should have been worn off if they were created while the implant was still functioning in the body.

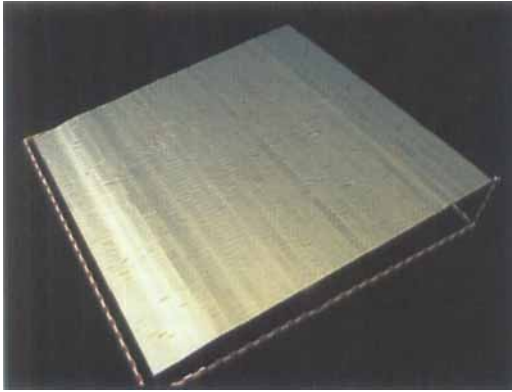


Figure 3. A computer-generated image from one of the measured areas. Some shallow scratches are visible. Each red and white bar section represents 10 μm .

edge measurements in each implant. To evaluate the surface roughness, 3 commonly used parameters were calculated, as proposed by Stout et al. (1993).

S_a (R_a for 2D measurements) is the arithmetic mean of the absolute values of the surface departures from a mean plane in the sampling area. S_a is measured in μm and is the most commonly used parameter for quality control. It gives a good general description of the surface features, but is insensitive to occasional high peaks or deep valleys.

S_{sk} (R_{sk} for 2D) skewness describes the symmetry of surface deviations about the mean plane. Profiles with peaks removed or with deep scratches have negative skewness. A Gaussian distribution has a skewness of 0.

S_{cx} (S_m for 2D) is the mean spacing between local irregularities crossing the mean plane.

A computer-generated image of a measured area is seen in Figure 3.

Statistics

Multiple regression and multivariate analysis were used to determine whether there was a correlation between the surface roughness parameters and one or several background factors, obtained from the patients' hospital records. To investigate whether any linear combination of mean weight and insertion time could explain the variation in polyethylene wear, a multiple regression model was used.

Results

Slightly higher height deviation was achieved in the retrieved implants than in unused control implants, the S_a values being 0.15 μm and 0.23 μm for top and edge measurements of the retrieved implants while

Table 2. Surface roughness parameters describing height, space variation for each of the 21 femoral cups. Top value and mean of four edge measurements

Implant	S_a (μm)	S_{sk}	S_{cx} (μm)
1 top	0.12	-1.55	40
1 edge	0.15	-1.52	45
2 top	0.13	0.25	35
2 edge	0.36	-1.05	24
3 top	0.20	-4.76	19
3 edge	0.33	-2.31	15
4 top	0.31	-0.83	19
4 edge	0.24	-0.73	28
5 top	0.11	-2.55	29
5 edge	0.17	-1.36	26
6 top	0.10	-2.33	28
6 edge	0.34	-1.05	27
7 top	0.23	-0.61	32
7 edge	0.16	-0.05	25
8 top	0.12	-1.54	24
8 edge	0.19	-0.59	26
9 top	0.06	4.29	31
9 edge	0.22	-2.16	35
10 top	0.26	-1.26	14
10 edge	0.18	-0.24	14
11 top	0.28	-1.87	30
11 edge	0.37	-0.68	13
12 top	0.28	-2.73	18
12 edge	0.15	-1.48	30
13 top	0.08	-2.95	28
13 edge	0.09	-1.87	24
14 top	0.12	-2.03	33
14 edge	0.28	-1.54	19
15 top	0.21	-3.47	32
15 edge	0.25	-1.47	19
16 top	0.05	-3.29	30
16 edge	0.30	-1.84	19
17 top	0.12	-1.88	24
17 edge	0.16	-1.37	26
18 top	0.09	-3.52	24
18 edge	0.34	-1.43	17
19 top	0.06	-5.24	22
19 edge	0.25	-1.71	23
20 top	0.11	-1.13	19
20 edge	0.19	-0.55	22
21 top	0.12	-3.54	26
21 edge	0.13	-2.09	26
Average	0.15	-2.02	27
all tops (SD)	(0.08)	(2)	(6.5)
Average	0.23	-1.29	24
all edges (SD)	(0.08)	(0.6)	(7.2)
Control 1			
top	0.08	-0.41	38
edge	0.10	-0.13	24
Control 2			
top	0.12	-2.40	24
edge	0.13	0.48	24
Control 3			
top	0.11	-0.61	23
edge	0.11	-0.62	21
Average			
all control	0.10	-1.14	29
tops (SD)	(0.02)	(1.1)	(8.5)
Average			
all control	0.11	-0.09	23
edges (SD)	(0.01)	(0.55)	(1.6)

the corresponding values of control implants were 0.10 μm and 0.11 μm (Table 2). The difference was

not statistically significant, the p-value for the top measurement being 0.5 and 0.9 for the edge measurement. The surface structure of the retrieved implants had more valleys than control implants, as shown by the negative value of the parameter S_{sk} . The average S_{sk} value for the top measurement of the retrieved cups was -2 and -1 for control implants, corresponding values for edge measurements were -1 and 0. This showed that there were more scratches on the retrieved implants than on the controls. The average space between surface irregularities was similar for used and unused cups. Several measurements of the retrieved implants showed values similar to the measurements from the control cup, while others had a much rougher structure. The implants nos. 8 and 9 (Tables 1 and 2), which had uncemented cups, did not differ with respect to surface roughness from the implants with cemented cups.

There was no correlation between the 3 surface roughness parameters and the patients' weight, head-shaft angle, insertion time and polyethylene wear. No correlation was found between polyethylene wear and mean weight, or between polyethylene wear and insertion time. The multiple regression model showed no relationship between a combination of mean weight insertion time and polyethylene wear ($p = 0.8$).

Discussion

We found no correlation between surface roughness parameters, used as an indirect measure of surface damage, and clinical and radiographic data. Nor was there any statistical significant difference detected with respect to average height deviation between used and unused cups. Bauer et al. (1994) reported that an increased surface roughness (S_a value) of retrieved prostheses was relatively common compared with unused implants. Hall et al. (1996) found a statistical significant increase in height descriptive parameters for used Charnley prostheses, as compared to unused ones. We found some areas full of scratches on the retrieved cups, as a result of surface damage, and traces of the retrieval operation, while most areas could not be distinguished from unused implants. One possible explanation for the discrepancy between our study and those by Bauer et al. and Hall et al. may be the different ways of selecting areas for measurements. We chose 5 areas in advance. They were therefore easy to find and enabled us to perform similar measurements in all samples. The disadvantage of this method was that, except for the top area, the measured areas may not have included the areas most ex-

posed to surface damage. In the study by Bauer et al., 1 maximal, 1 minimal and 3 areas of typical roughness were chosen. However, the "typical roughness" must have been difficult to define before measurements.

In agreement with McKellop et al. (1990, 1995), no correlation was found between implantation time and the rate of surface damage of the prostheses. McKellop et al. (1990, 1995) appear with Betts et al. (1992), who found no correlation between implantation time and metal debris in the implant surrounding tissue. McKellop et al. (1990, 1995) suggest that the surface damage occurred primarily after significant loosening of the prosthesis.

In the study by McKellop et al. (1990), loosening refers to both the femoral head and the acetabular cup whereas, in our study, only the acetabular component was loose, which may have resulted in fewer cement particles being available to scratch the femoral head surface. If cement particles are to be blamed, the implants with uncemented cups ought to be the smoothest among the retrieved samples which, however, was not the case in our study. This may indicate that cement particles are not solely responsible for scratching the surface of the femoral head, even if one considers that we had only two uncemented cups for comparison.

According to the manufacturer of the alloy used, the quality of the metal remained unchanged during the years when the cups were inserted. Otherwise, this might have resulted in a difference in wear resistance with time.

Weight is used as a background factor potentially responsible for increased surface roughness. It could be argued whether this is an appropriate parameter, since it may vary after implantation. However, weight is a commonly used parameter and in our study only very small variations between the weight at days of insertion and reoperation were recorded.

Despite the lack of correlation between surface roughness and patient data in our study, we believe that 3D surface topography measurements can be an interesting method for quantifying surface damage, especially when a non-destructive method is needed, which allows measurements on the same implant before and after implantation. However, in future studies, the number of measurements ought to be increased, especially in areas known to be in contact with the polyethylene socket, i.e., top measurements.

In conclusion, we found extremely little surface damage with time in the metal femoral components.

Acknowledgments

This study has been supported by grants from Sylvans' foundation, NUTEK project no 9305121-2, the Greta and Einar Asker Foundation, the Loo and Hans Osterman Foundation, the Wilhelm and Martina Lundgren Science Foundation, the Swedish Medical Research Council (MFR), and the Hjalmar Svensson Research Foundation.

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