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Wear comparison between a dual mobility total hip prosthesis and a typical modular design using a hip joint simulator

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Abstract

The wear behaviour of a new dual mobility total hip design was compared with that of a modular design using the 12-station anatomic hip joint simulator HUT-4. In addition, two positions of the acetabular shells were compared, at 45° and 60° abduction. The acetabular insert material was conventional ultra-high molecular weight polyethylene (UHMWPE) in both designs, and the femoral head material was stainless steel. The differences in the mean wear rates between the two designs in either position, and between the two positions in either design were not statistically significant. The wear rates were of the order of 20 mg per one million cycles.

Keywords: bio-tribology, joint prostheses; dual mobility insert; hip joint simulator; UHMWPE; abduction angle

1. Introduction

Patients with high risk of dislocation of the prosthetic hip joint may benefit from a dual mobility design having superior stability compared with typical modular total hip designs [1]. Philippot et al. [1] reported a retrospective series of 106 primary cementless Novae-1 dual mobility sockets with retentive polyethylene inserts. The cobalt-chromium (CoCr) femoral heads had a diameter of 22.2 mm. The overall survival rate was found to be 94.6 % at ten years, which was considered to be comparable to traditional total hip prostheses. There were no cases of instability in this series. The authors recommended the dual mobility system as a primary implant for patients with a high risk of post-operative instability.

In dual mobility polyethylene inserts, both the inner and the outer surfaces are spherical. The inner surface slides against the femoral head, and the outer surface against the concave bearing surface of the metallic acetabular shell. The femoral head is snapped into the insert. Therefore, the stability is increased due to the large outer diameter of the insert in the same way as an increase of femoral head diameter improves the stability in traditional total hip designs. However, the literature has very little in-vitro wear performance data from dual mobility designs. An in-vitro comparative study between a typical modular design and a dual mobility design will be useful in comparing the two design concepts in a controlled manner.

In the present study, the wear behaviour of a new dual mobility design was compared with that of a modular metal/polyethylene total hip design. The tests were carried out at Helsinki University of Technology using the 12-station anatomic hip joint simulator, HUT-4 (Fig. 1). The HUT-4 simulator and the test methods have been validated and described elsewhere [2].

2. Materials and methods

The dual mobility design employed in the current study was Stafit (Zimmer GmbH, Winterthur, Switzerland) paired with a 28 mm diameter femoral head (Fig. 2) and the modular metal-backed design was Allofit Alpha (Zimmer GmbH, Winterthur, Switzerland) paired with a 32 mm diameter femoral head. In both designs, the acetabular insert material was Sulene-PE, a compression molded GUR 1020 UHMWPE (ISO 5834-1/2), gamma sterilized at 25–40 kGy in a nitrogen package. The UHMWPE insert thickness was c. 6 mm in both designs, and the femoral head material was polished stainless steel (ISO 5832-9), Protasul-S30 (Zimmer GmbH, Winterthur, Switzerland). The insert thickness was minimized to represent the most severe contact conditions. The bearing surface of the Stafit shell was polished CoCr (ISO 5832-12), Protasul-20 (Zimmer GmbH, Winterthur, Switzerland).

The shell inclination angle was included in this study as a parameter to evaluate its influence on wear in both the dual mobility and the modular designs, since an acetabular shell inclination greater than 45º has been shown in some studies to correlate with increased wear [3,4]. Two positions of the shells in the simulator were included: one was at 45° abduction with 20° anteversion (flexion) and the other was at 60° abduction without anteversion (Fig. 3). With 60° abduction, an additional 20° anteversion could have compromised the stability. The acetabular shells were cemented in a special mould such that the hooded portions of the Stafit shell and of the Alpha insert were oriented superiorly and then rotated 30° posteriorly. The femoral heads were fixed to head holders, simulating a femoral neck at 45º abduction. For both designs, four sets of samples (femoral head, UHMWPE insert and acetabular shell) were employed in both shell positions (45º and 60º). The total number of couples tested was 16.

The test conditions were the same as those in the validation study of the simulator [2]. The lubricant was Alpha Calf Fraction serum (HyClone, SH30212.03) diluted 1:1 with distilled water. The protein concentration of the lubricant was 21 mg/ml. The lubricant volume in each test chamber was 500 ml. The tests were run at room temperature to retard the serum degradation. The motions in the articulation consisted of 46° flexion-extension, and 12° abduction-adduction of the head. The Stafit UHMWPE insert was free to articulate either at its outer diameter surface against the shell or at its inner diameter surface against the femoral head. The load had a double-peak profile with 2000 N maximum and 400 N minimum. The direction of the load was vertical and fixed relative to the acetabular shell. The test frequency was 1 Hz. The test was interrupted for cleaning, gravimetric wear measurement, and serum change at intervals of approximately 0.5 million cycles (mc). The test duration was 5 mc.

Prior to testing, the Stafit inserts were assembled to the femoral heads. Because the inner diameter at the rim of the Stafit insert was smaller than the head diameter, a press was used to assemble the Stafit insert to the femoral head, while a custom-made lever tool (Fig. 4) was used to disassemble the Stafit insert from the femoral head at each pause of the test for cleaning and weighing of the insert. The assembly and disassembly did not cause permanent deformation of the insert. At every restart of the test, the position of Stafit insert was random, although to a certain degree restricted by the head holder. During the test, the insert position was not controlled in order to simulate the clinical conditions as closely as possible.

Pneumatic load frames for 12 soak control inserts were used in parallel to the HUT-4 simulator, with the same double-peak load command signal as in the HUT-4 simulator. For each test insert, there was a similar load soak control insert. The control inserts were immersed in the diluted serum as described above. Hence, a good estimate of the amount of fluid absorbed by the test inserts was obtained, as the method of wear measurement was gravimetric [2]. It was assumed that the amount of absorbed fluid in the test insert at weighing, after cleaning and 30 min vacuum desiccation, was equal to the measured weight gain of the corresponding soak control insert. The weight loss of the test insert was corrected by the weight gain of the soak control insert.

3. Results

The running of the HUT-4 simulator and the entire test sequence was uneventful. No luxations, fractures or other difficulties were encountered. Since the wear was mostly linear, the wear rate was determined using linear regression (Fig. 5 and Table 1). The correlation coefficient R^2 values ranged from 0.9803 to 0.9995. The differences in the mean wear rates between Stafit and Alpha, and between 45º and 60º abduction cases, were not statistically significant (Table 2).

The microscopic images of the bearing surfaces of the Alpha inserts at 45º and 60º showed adhesive polishing as the principal wear mode (Fig. 6). There was a distinct borderline between the worn superior region and the unworn inferior region. The Stafit inserts at 45º and 60º did not have distinguishable worn and unworn regions. On the entire outer bearing surface of Stafit inserts at both angles, the machining marks could still be seen after the tests (Fig. 7). The flat rim face was polished, and the heads and the bearing surfaces of the Stafit shells were undamaged after the tests (Figs. 8 and 9).

On the average, the weight gain of the Alpha and Stafit soak control inserts was 6.4% and 8.7%, respectively, of the weight loss of the corresponding wear test inserts. There was no distinct increasing or decreasing trend in these figures with increasing number of cycles.

4. Discussion

The wear rate of the Stafit dual mobility design was close to that of the modular total hip prosthesis, which agreed well with clinical observations regarding an older dual mobility design [5]. The mean wear rates were close to that measured earlier for custom-made metal-backed Sulene-PE inserts against 28 mm diameter CoCr heads, 15.5 mg/mc [2]. Moreover, the present wear factors were in the range 0.63 to 0.79 × 10^{-6} mm^3/Nm, well below typical clinical wear factors measured for the classic Charnley design with a 22.2 mm diameter stainless steel head, which were of the order of 2.1 × 10^{-6} mm^3/Nm [6]. The distinct borderline between the worn and unworn region and the polishing in the Alpha inserts were in excellent agreement with clinical retrieval studies [7]. The borderline was attributable to the fact that the position of the acetabular shell in the HUT-4 simulator was anatomical and the load vector was fixed relative to the insert. The initial position of the Stafit inserts was deliberately quite random, because this was likely to resemble the clinical situation. Hence, the Stafit inserts had several wear directions and no borderline, whereas in Alpha inserts, there was one wear direction only.

The wear rate was not sensitive to the abduction angle of the shell. Regarding this question, conflicting results can be found in clinical literature. Some researchers did not find a correlation between the wear rate and abduction angle [8–13], whereas others found a positive correlation [3,4]. The correlation is likely to be design-dependent. Especially inserts that are thin and weak at the rim are prone to be worn through and fractured [14,15]. Apparently, this was not the case with the present designs.

As the machining marks could still be seen on the entire outer bearing surface of Stafit inserts after the tests, the motion between the insert and the shell must have been minimal (Fig. 7). However, the flat rim face of the inserts was polished and this could only be explained by rubbing against the head holder (Fig. 3). This rubbing would not be possible without some relative motion between the insert and the shell.

5. Conclusions

The mean wear rate of the new Stafit dual mobility design was close to that of the modular total hip prosthesis that has a long, successful clinical history. The principal articulating interface in the Stafit was that between the head and the inner surface of the insert where most of the wear consequently took place. The increase of the acetabular shell abduction angle from 45º to 60º did not result in any luxations, or in a significant change of the wear rate.

Acknowledgements

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Table 1. Summary of wear.

Test	Mean wear rate ± SD ($mg/10^6$ cycles)	Mean wear factor (10^{-6} mm^3/N m)
Stafit 45º	21.49 ± 3.21	0.79
Alpha 45º	19.63 ± 1.59	0.63
Stafit 60º	17.81 ± 4.64	0.65
Alpha 60º	20.79 ± 1.29	0.67

Table 2. Comparison of mean wear rates (two-tail t-test assuming unequal variances).

Comparison	P-value
Stafit 45º, Alpha 45º	0.36
Stafit 60º, Alpha 60º	0.30
Stafit 45º, Stafit 60º	0.25
Alpha 45º, Alpha 60º	0.30

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Figure captions

Figure 1. HUT-4 anatomic hip joint simulator running with 12 stations and the test chambers filled with 500 ml of serum-based lubricant in each. The universal joints making acetabular inserts self-centering on femoral heads are clearly visible above the test chambers. On the top of the simulator are the pneumatic loading cylinders.

Figure 2. Representative components of the Stafit design employed in the current study.

Figure 3. One of the simulator's test chambers just after the stop and removal of lubricant showing a Stafit dual mobility specimen with 60º abduction of the shell that was surrounded by bone cement forming the loading surface. Note the deep profile of the retentive polyethylene insert. The head holder replaced femoral stem.

Figure 4. Lever tool used to disassemble the Stafit insert from the femoral head.

Figure 5. Variation of wear of (a) Stafit 45º, (b) Alpha 45º, (c) Stafit 60º and (d) Alpha 60º with number of cycles. The symbols ◇, □, ○, and △ represent the four bearings tested in each case.

Figure 6 (a). Optical micrograph from the borderline between the contact zone and the unworn inferior region with original machining grooves still clearly visible of Alpha 60º insert after 5 mc. Picture width corresponds to 2 mm.

Figure 6 (b). As above, but picture width corresponds to 1 mm.

Figure 7. Optical micrograph from outer surface contact zone of Stafit 60º insert after 5 mc with original maching grooves still clearly visible. Picture width corresponds to 2 mm.

Figure 8. Optical micrograph from contact zone of femoral head of Stafit 60º test after 5 mc. There are no wear marks. Picture width corresponds to 2 mm.

Figure 9. Optical micrograph from contact zone of Stafit 60º shell after 5 mc. There are no wear marks. Picture width corresponds to 2 mm.

Figure 1.

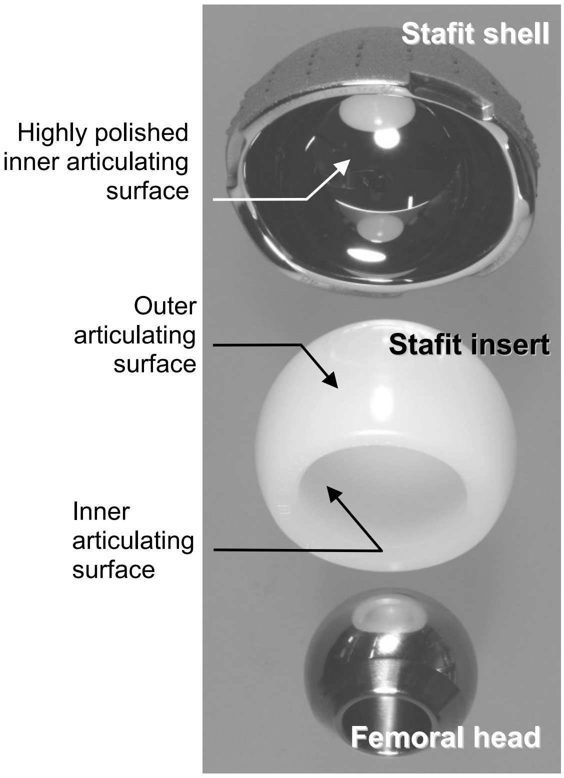


Figure 2.

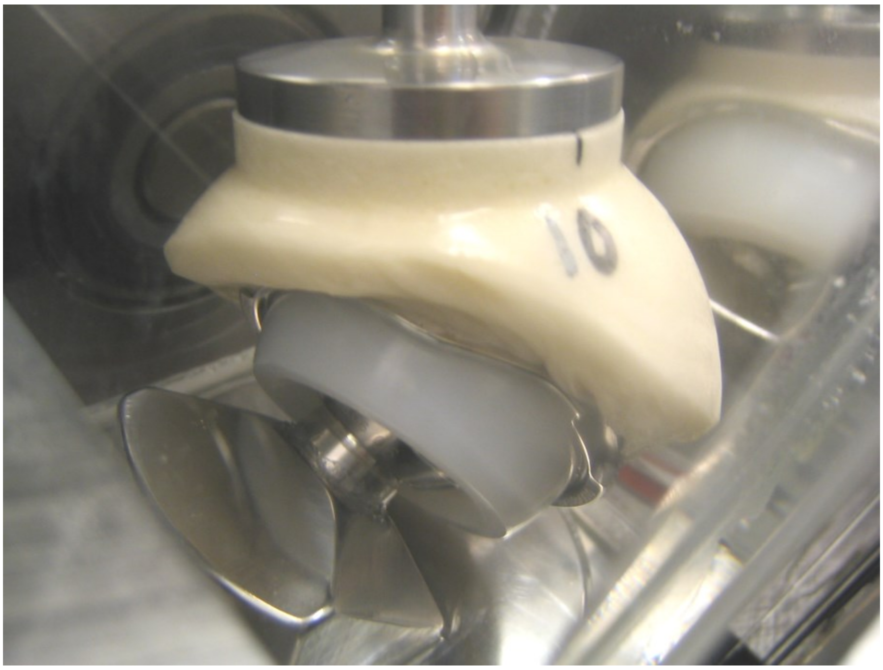


Figure 3.

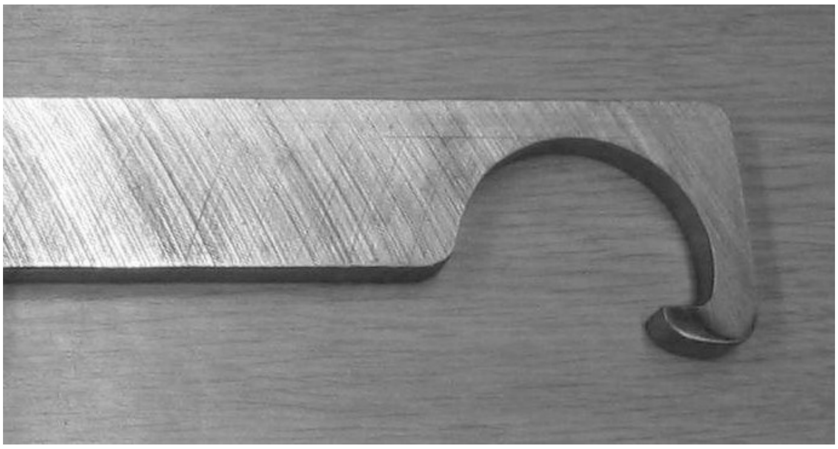


Figure 4.

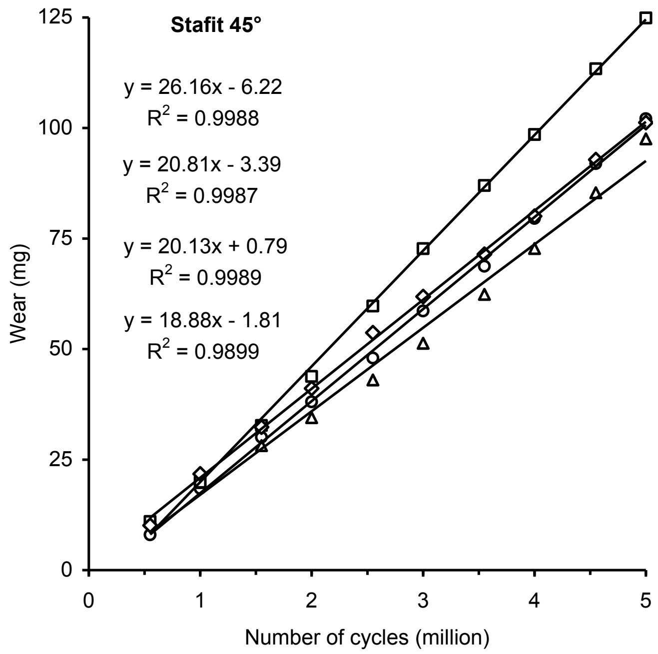


Figure 5(a).

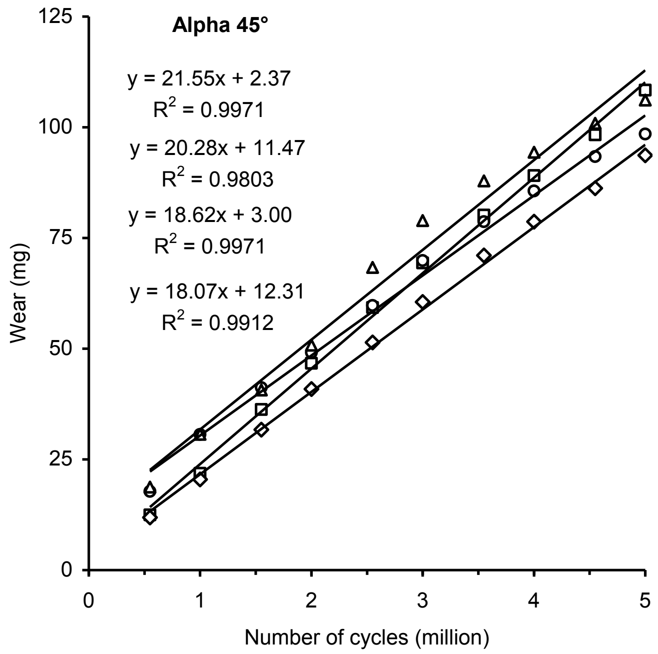


Figure 5(b).

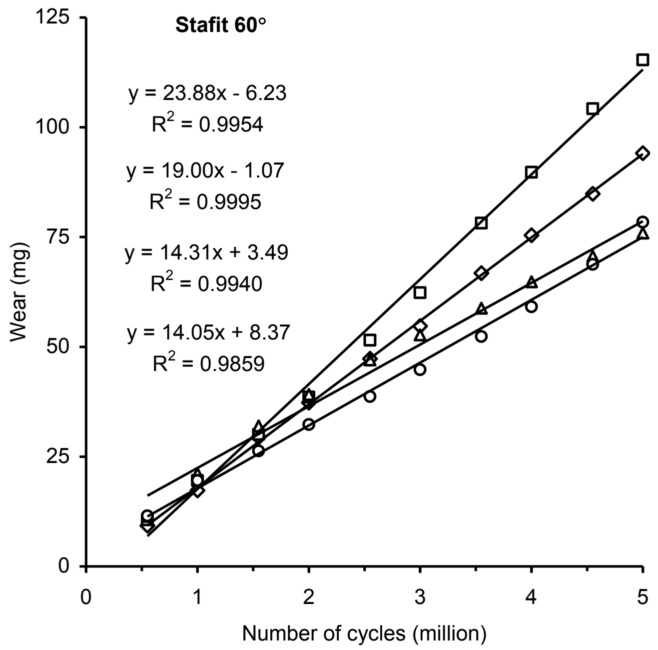
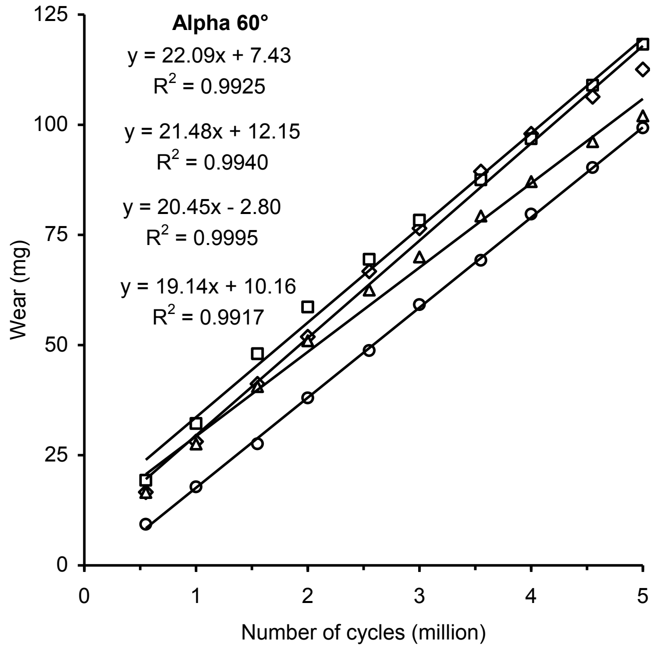


Figure 5(c).



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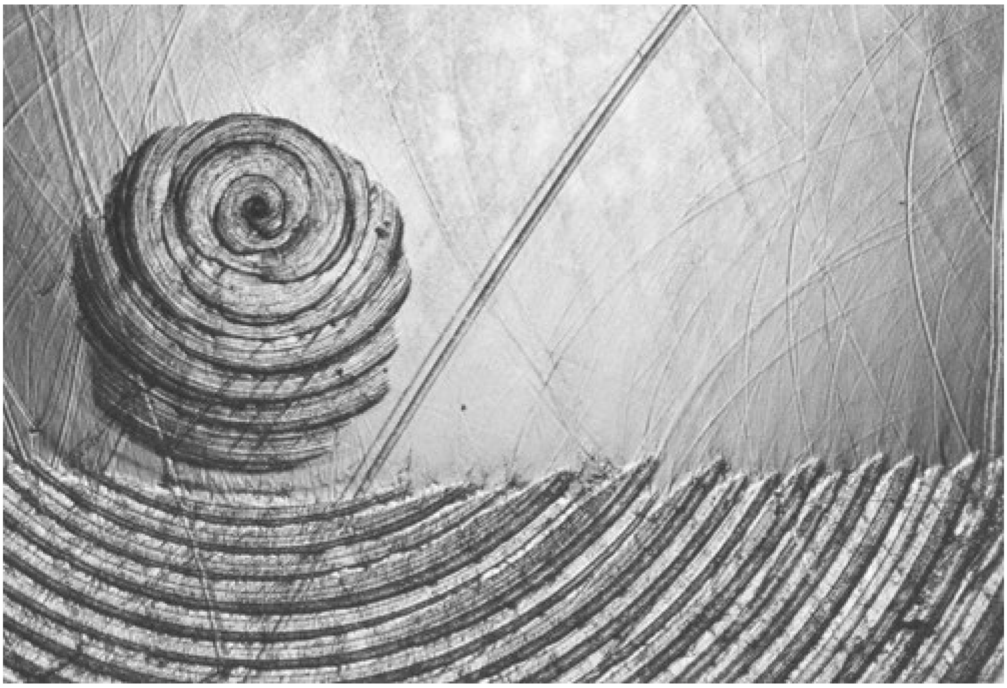

Figure 6(a).

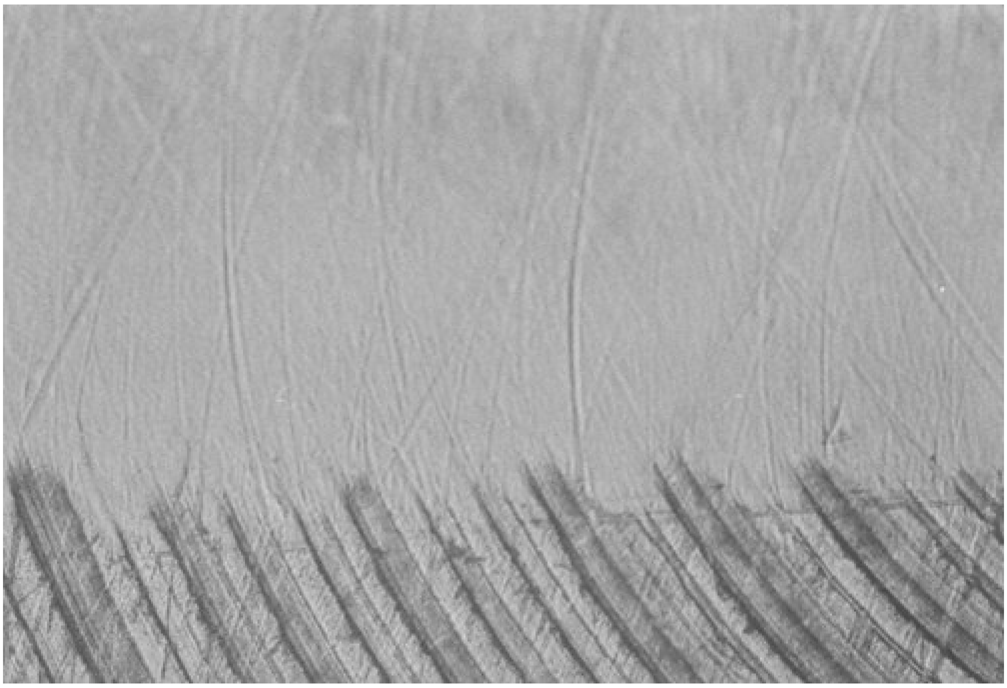

Figure 6(b).

Figure 7.

Figure 8.

Figure 9.