Failure of the Uncoated Titanium ProxiLock Femoral Hip Prosthesis

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New prostheses should be evaluated for stability and clinical performance. In a prospective randomized clinical trial, we implanted 22 titanium (Ti) and 20 hydroxyapatite-coated (HA) ProxiLock femoral hip prostheses during total hip arthroplasty in 42 patients. The patients were followed for 24 months with clinical, radiographic and radiostereometric analysis. Full weightbearing was allowed immediately postoperatively. One patient with a titanium stem was lost to followup. During the first two months, 34 of the 41 stems subsided and/or rotated towards retroversion, regardless of stem type. At the 24-month followup 35 of the 41 prostheses were either fully stabilized (16 HA and 11 Ti stems) or had clinical irrelevant migration (four HA and four Ti stems). Six Ti prostheses showed continuous migrations with maximums of 4.7 mm translation and 12.2° retroversion; four of these were revised, the other two had no clinical complaints. Clinical relevance: The migration pattern we found indicates insufficient primary fixation of the ProxiLock stem in an immediate full weightbearing protocol. The HA coating improves the secondary stability of the prosthesis compared to the uncoated stem. Early migration is associated with an increased risk of possible future loosening and revision, and therefore we discontinued the use of this prosthesis.

Level of Evidence: Therapeutic Level I. See Guidelines for Authors for a complete description of levels of evidence.

The Swedish National Hip Arthroplasty Register noticed an improved 10-year survival of un cemented total hip arthroplasty (THA) in 2000 of 87.7% against 56.9% over the first period from 1979–1989. Still, un cemented prostheses have worse results compared to cemented prostheses despite modern techniques (94.8%), with aseptic loosening of the femoral component as one of the main reasons for revision. New stem designs ostensibly improve the clinical outcome. To prevent disappointing results, short term analysis of new designs is necessary.

With radiostereometric analysis (RSA) the three-dimensional migration of prostheses can be assessed accurately. As early migration predicts future aseptic loosening, RSA is an ideal method to predict long term clinical behavior and future loosening of new implants within a short followup period.

The ProxiLock (STRATEC Medical, Oberdorf, Switzerland) femoral component is designed to achieve better proximal fixation through a double wedge design and retention of a large medial segment of the femoral neck. Special coatings contribute to enhanced fixation of the prosthesis. The ProxiLock stem is a grid-blasted titanium (Ti) alloy that is also available with HA coating. Generally, HA seems to have a positive effect on stability of uncemented femoral components, although other studies reported no benefits.

The questions addressed in this study are: (1) What is the migration pattern of the uncoated Ti and HA-coated ProxiLock stem during the first 24 months? (2) Has the HA-coating a positive effect on the fixation process? (3) Is the design sufficient to guarantee stability and good clinical performance? We hypothesized that the ProxiLock stem will be stable at 12 months, with less migration for the HA-coated prostheses compared to the uncoated titanium prostheses.

MATERIALS AND METHODS

After approval by the institutional medical ethics committee, this study was started in December 2000. We prospectively recruited
patients scheduled for a primary THA for a randomized clinical trial with 50 uncoated titanium and 50 HA-coated ProxiLock hip prostheses. Inclusion criteria were primary hip osteoarthritis and secondary hip osteoarthritis, due to developmental dysplasia or osteonecrosis of the femoral head. Only patients between 30 and 80 years and with a hip prosthesis size between 8 and 13.75 were included. Patients with a Body Mass Index over 30 were excluded. Randomization was done prior to the start of the trial, through a computer-generated random allocation to uncoated or HA-coated prostheses, in blocks of 4, per participating surgeon (Block Stratified Randomization version 4.4, 1997, S. Piantadosi, Baltimore, Maryland). The patients were not informed about the allocation. In November 2002 the inclusion was stopped, due to unsatisfactory results. At that moment we had included a total of 42 patients who gave informed consent. Thirty-six patients were diagnosed with primary osteoarthritis and 6 patients with secondary arthritis, of which five had developmental dysplasia (CHD) and one had osteonecrosis of the femoral head. The mean age at the time of surgery of the 15 men and 27 women was 58 years (range, 35–77 years). Twenty-two patients received an uncoated titanium ProxiLock femoral component and 20 patients received the HA-coated design. One patient received a titanium prosthesis with only one titanium bead, which is insufficient for RSA measurements. Therefore, this patient was excluded from the study. Inquiry by telephone at four years postoperatively revealed that the patient was satisfied.

The ProxiLock FT stem (Fig 1A) has a double wedge design. The stem has a conical shape in both anteroposterior (A-P) direction and mediolateral direction. In craniocaudal direction the stem consists of 3 tapered parts, each with a different cone angle. The proximal one-third of the prosthesis body has a large angle of 14°, aiming at proximal locking of the component in the metaphysis. At that part the HA coating is applied. In the middle part of the stem the angle is 6°. The distal part is small, with an angle of 2°, not aiming at filling the diaphyseal femoral canal (Fig 1B). The femur resection angle is 25°, retaining a large medial segment of the femur, resulting in a large bone-contacting area. The caput-collum-diaphysis angle is 131.5°.

Three experienced surgeons performed the THAs using a posterolateral approach. With an Osteotomy Guide the femoral neck was resected. The femoral canal was opened in a standard fashion. The metaphyseal and diaphyseal femoral canal were prepared using a Femoral Rasp, until the shaver filled the metaphysis at the neck resection level. We used an uncemented RM beveled cup, composed of a monobloc ultra-high molecular weight polyethylene with a titanium powder coating (Mathys Ltd, Bettlach, Switzerland). No intraoperative or early postoperative complications occurred. The patients were mobilized with two crutches immediately postoperative and were allowed full weightbearing.

For the RSA measurements, the ProxiLock femoral component was equipped with tantalum beads (0.8-mm diameter) at the shoulder and the distal tip of the stem (Fig 1A). The center of the femoral head served as the third prosthesis marker. During surgery 5 to 9 tantalum beads (1.6 mm) were distributed in the greater and lesser femoral trochanters with a special insertion instrument (Mathys Ltd, Bettlach, Switzerland). Baseline radiograms and Related Research
three time intervals. A prosthesis is defined as nonmigrating when translations and rotations values in all six directions were below the detection limit, ie, the precision of the RSA measurement procedure. A migrating prosthesis exhibited migration above the detection limit in one or more directions. The migrating prostheses were subdivided in prostheses with small migrations (less than 2 mm or degrees) and large migrations (more than 2 mm or degrees).

In 6 cases rotation could not be calculated due to missing or obscured markers. In one case the postoperative radiograph was missing, and migration from 0 to 2 months could not be calculated. In one case the 12-month radiograph was missing, and migration was calculated for the 2 to 8 month time interval in stead of the 2 to 12 month time interval. In 4 cases the 8-month (2x) and the 12-month (2x) followup examinations were the final evaluations, due to revision of the implant.

To assess the detection limit, double examinations were made in 40 patients at the 2-month followup evaluation. Two cases were deleted due to inadequate marker matching. In 4 cases rotation could not be calculated due to missing markers. We used the remaining radiographs, 38 for translational directions and 34 for rotational directions, to calculate the upper limits of the 99% confidence interval (CI). This resulted in a detection limit of 0.3 mm, 0.2 mm and 0.4 mm for the translations in x, y and z directions. The detection limit for the rotations was 0.8°, 0.9° and 0.3° about the x, y and z axes.

We evaluated the patients clinically preoperatively and postoperatively after 2, 12, and 24 months using the Harris hip score (HHS). Pain was scored on a visual analogue scale (VAS). Regular A-P radiographs were taken within 7 days postoperatively and after 12 and 24 months as part of the clinical routine.

Statistical analyses were performed using SPSS® (12.0.1 for Windows, SPSS Inc, Chicago, IL). Because the data were not normally distributed due to outliers, we used nonparametric methods. The Mann–Whitney U test was used to compare the Harris hip scores, pain, and migration at the three followup examinations between the coated or uncoated implants. We used the nonparametric Wilcoxon signed rank sum test to detect a substantial migration increase between two consecutive followup evaluations within each group. Besides statistical significance, migration increase should exceed the detection limit to be assigned as relevant. Tests were two sided and probability values less than 0.05 were considered significant.

RESULTS

Four Ti stems had to be revised because of aseptic loosening, after an average of 16 months (range, 12–23 months). Three women and one man (between 51 and 61 years old), of whom 2 were diagnosed with CHD, returned to the clinic with complaints of increasing pain. All diagnostic methods (radiographs, technetium scan, and sonography) were negative. However, RSA showed continuous migrating prostheses. Three Ti stems most obviously showed retroversion (Ry), with 4.3° in 6 months, 3.2° in 9 months, and 7.8° in 16 months (Fig 3A–C). One Ti stem, where rotation could not be calculated due to an insufficient number of markers, translated in all directions with a maximum of 4.2 mm in posterior direction (Tz) in 6 months (Fig 4).

There were no differences in the mean migration results at the 2-month, 12-month, and 24-month postoperative followups between the two groups (Table 1).

During the first 2 months 34 out of 41 ProxiLock stems showed migration regardless of the coating. In both groups, we found mean migration (p < 0.05) in subsidence (Ty) and retroversion direction (Table 2). We found no differences between the two groups. Sixteen of 21 Ti stems migrated (Table 3). Five Ti stems had large migrations; two Ti stems subsided (3.5 mm and 3.9 mm) and three Ti stems retroverted (2.3°, 3.2° and 3.7°). Eighteen of 20 HA prostheses migrated, of which six HA stems showed large retroversion (2.4–9.2°), with additional large subsidence in two cases (2.5 mm and 3.3 mm).

From 2 to 12 months, we found mean migration (p < 0.05), subsidence and retroversion, in the Ti group. The subsidence increase of the Ti group was larger (p < 0.05)
than in the HA group. Eleven Ti stems migrated; six Ti stems had large migrations, of which five Ti stems retroverted (2.1°–5.5°) and one Ti stem translated more than 2 mm in all directions. The translating and one rotating Ti stem needed to be replaced within the first year. Three HA-coated prostheses migrated of which one HA stem had large migration (2.3° posterior tilt (Rx) and 2.1° anteverision).

In the second year of followup we did not find clinical significant migration for both groups. Eleven of the remaining 19 Ti prostheses stabilized. Eight of the 19 Ti stems migrated, of which four Ti stems continued migration started in the first year, with large retroversion (2.6°–7.1°). Two of the four rotating Ti stems had to be revised within the second year. The other two Ti stems, with retroversion of 12.2° and 4.8° from 2 to 24 months showed no clinical signs of loosening (Fig 3D–E). Sixteen of 20 HA prostheses stabilized. For four HA stems, we measured small migrations with a maximum of 0.4 mm for translation in posterior direction.

There were no differences in the mean Harris hip scores and visual analogue pain scores preoperatively and at the different postoperative followup evaluations between the two groups. The collective mean preoperative Harris hip score of the group was 60 (SD 14). There was an improvement (p < 0.05) after 24 months to 98 (SD 4). The collective visual analogue pain score improved (p < 0.05) from 58 (SD 24) preoperatively to 2 (SD 7) after 24 months. No striking results in the radiographs were noticed.

**DISCUSSION**

We measured the early migration pattern of the newly designed ProxiLock FT stem to get an impression of its

**TABLE 1. Migration* in the HA and Titanium Groups 2-Month Followup**

<table>
<thead>
<tr>
<th>Axis</th>
<th>HA-Coated Stems</th>
<th>Uncoated Titanium Stems</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Median</td>
</tr>
<tr>
<td>Tx</td>
<td>0.00 ± 0.23</td>
<td>0.03</td>
</tr>
<tr>
<td>Ty</td>
<td>−0.76 ± 0.92</td>
<td>−0.37</td>
</tr>
<tr>
<td>Tz</td>
<td>−0.23 ± 0.48</td>
<td>−0.14</td>
</tr>
<tr>
<td>Rx</td>
<td>−0.13 ± 0.32</td>
<td>−0.13</td>
</tr>
<tr>
<td>Ry</td>
<td>−2.22 ± 2.64</td>
<td>−1.06</td>
</tr>
<tr>
<td>Rz</td>
<td>0.12 ± 0.42</td>
<td>0.11</td>
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12-Month Followup

<table>
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<th>Axis</th>
<th>HA-Coated Stems</th>
<th>Uncoated Titanium Stems</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Median</td>
</tr>
<tr>
<td>Tx</td>
<td>−0.05 ± 0.24</td>
<td>0.08</td>
</tr>
<tr>
<td>Ty</td>
<td>−0.84 ± 0.96</td>
<td>−0.46</td>
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<tr>
<td>Tz</td>
<td>−0.23 ± 0.50</td>
<td>−0.11</td>
</tr>
<tr>
<td>Rx</td>
<td>0.04 ± 0.55</td>
<td>−0.08</td>
</tr>
<tr>
<td>Ry</td>
<td>−2.10 ± 2.89</td>
<td>−1.12</td>
</tr>
<tr>
<td>Rz</td>
<td>0.23 ± 0.35</td>
<td>0.18</td>
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</table>

24-Month Followup

<table>
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<th>Axis</th>
<th>HA-Coated Stems</th>
<th>Uncoated Titanium Stems</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Median</td>
</tr>
<tr>
<td>Tx</td>
<td>−0.06 ± 0.27</td>
<td>−0.09</td>
</tr>
<tr>
<td>Ty</td>
<td>−0.89 ± 0.96</td>
<td>−0.53</td>
</tr>
<tr>
<td>Tz</td>
<td>−0.35 ± 0.53</td>
<td>−0.24</td>
</tr>
<tr>
<td>Rx</td>
<td>0.08 ± 0.48</td>
<td>0.08</td>
</tr>
<tr>
<td>Ry</td>
<td>−2.17 ± 2.80</td>
<td>−1.13</td>
</tr>
<tr>
<td>Rz</td>
<td>0.27 ± 0.36</td>
<td>0.23</td>
</tr>
</tbody>
</table>

*Translation along the x-axis, y-axis, and z-axis (Tx, Ty, and Tz) are in mm; rotations about the x-axis, y-axis, and z-axis (Rx, Ry, and Rz) are in degrees.

**One patient in the titanium group was excluded after surgery because of missing markers on the stem. The postoperative RSA radiograph of another patient with an uncoated stem was missing; for this patient, the 2-month result served as baseline. In other patients, evaluation of translation and/or rotation was not possible because fewer than three paired bone or prosthesis markers could be identified in the radiographs. At 12 months, two titanium stems were revised; at 24 month, four titanium stems were revised.
performance and to assess the risks of future aseptic loosening. We also wanted to detect any additional value of an HA-coating. The accuracy of the RSA method was sufficient to detect early micromotions. The radiographic examinations were limited to regular clinical observations. The migration pattern of the ProxiLock varied largely within the group and over time. Most prostheses (34/41) migrated in the first two months, mainly through subsidence and retroversion. In other studies, authors reported smaller mean ranges of subsidence at the first followup after 3 to 6 months (range, 0.1–0.4 mm) and smaller retroversion (0.6°), than we found. In contrast with our study, all authors used postoperative partial (15 kg) weightbearing protocols, over a period varying from 6 weeks to 6 months. During partial weightbearing loads, caused mainly by muscle tension, are small, and the aforementioned time period is generally sufficient to affect bony ingrowth and stabilization of the stem, resulting in small migrations. When the prosthesis is subjected to full weightbearing activities immediately postoperatively, the anterior load on the femoral head is the result of full body weight and accessory muscle tension. The higher forces can potentially result in larger migrations. In a study comparing 28 full weightbearing, bilateral THAs to 28 partial weightbearing, unilateral THAs using the Taperloc (Biomet, Warsaw, Indiana), the subsidence after 6 weeks was significant larger in the full weightbearing protocol. The HP-Garches prosthesis (Howmedica, Rutherford, New Jersey) showed large early subsidence, equal to the ProxiLock, in an immediate weightbearing protocol. In studies were migration is measured after increased weightbearing and activities, all authors reported increasing or continuous subsidence as well.

Despite the above, the subsidence of the Biomet Taperloc prostheses in nine patients subjected to immediate postoperative weightbearing was only 0.1 mm after 6 months. This suggests there is another factor by which primary postoperative stability is influenced. Besides subjected loads, it depends on initial fixation during surgery as determined by prosthesis fit and implantation technique. The initial fixation of the Biomet Taperloc seems to be more sufficient in stabilizing the prosthesis and withstanding immediate postoperative loadings than the initial fixation of the ProxiLock femoral component. In view of the large postoperative migrations (only seven stems were stable), it seemed difficult to fixate the ProxiLock in a stable position during surgery. The design probably cannot achieve a tight fit at the isthmus, as was reported in an earlier study with a wedge-shaped prosthesis. This imperfect fit decreases the ability to counteract postoperative rotatory forces. The ProxiLock stems were positioned with 15° anteversion during surgery to prevent postoperative dislocation. However, in femurs with anatomic retroversion, a prosthesis with an inadequate fit might rotate back to its anatomical position under early postoperative load bearings. Rotational stress occurring during activities can initiate this process. When the settling period takes too long, no bony ingrowth and bonding can take place during the first months, increasing the risk of progressive migration and future loosening. If stems show continuous migration, especially rotation, it has been suggested that this may result in clinical loosening. The ProxiLock stem has a small tapered distal end that does not fill the

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**Fig 3A–E.** The retroversion (in degrees) at the different followup evaluations from 5 titanium prostheses with large migrations: (A) 4.3° retroversion from 2–8 months, revised at 12 months; (B) 3.2° retroversion from 2–11 months, revised at 18 months; (C) 7.8° retroversion from 2–18 months, revised at 23 months; (D) 4.8° retroversion from 2–24 months, no clinical signs of loosening; (E) 12.2° retroversion from 2–24 months, no clinical signs of loosening.

**Fig 4.** The translations in X-Y-Z direction (in mm) at the different followup evaluations from the titanium stem translating 4.2 mm in dorsal direction from 2–8 months. It was revised at 12 months. Rotation could not be calculated because of an insufficient number of markers.
medullary femoral canal completely, and will not contribute to bony ingrowth. This is in contrast with the Proxi-Lock stem used by O’Keefe et al (O’Keefe TJ, Arbor A, Lewis RJ, Unger AS, Gruen TA. Proxilock Femoral Hip Stem: Two to Five Year Results. Poster 046, the 70th AAOS 2003, New Orleans, LA). They reported positive clinical and radiographic results for HA-coated titanium and porous-coated Cobalt-Chromium ProxiLock femoral hip stems with a canal filling distal end.

Kärrholm et al reported that subsidence of cementless stems should be less than 1.2 mm within the first 2 years to prevent revision within 4 to 7 years. However, we showed that stabilization of the cementless ProxiLock prosthesis can take place even after large initial migrations of more than 1.2 mm in an early full weightbearing protocol. The migration after the settling time should be limited to prevent future loosening.

For most titanium stems and all HA-coated stems, a decrease in the rate of subsidence and rotation is seen and 35 of 41 prostheses were either fully stabilized (27) or had clinical irrelevant migration (8) one year postoperatively. Although other authors have reported no beneficial effect of HA coating, our data suggest HA coating on ProxiLock prostheses increased the chance for the stem to stabilize after the settling period. The results support the positive effect of HA coatings on bony ingrowth of the prosthesis as reported by other authors.

The effect of HA seems to be particularly beneficial when initial stem fixation is poor or when stem stability is influenced by heavy loads as in full weightbearing protocols. This was described previously in clinical situations in which there is a gap between the stem and the surrounding bone, such as in stems with an imperfect fit and even with unstable prostheses. RSA, in contrast to clinical outcomes and plain radiographs, can detect the subtle difference on migration of HA coating.

### TABLE 2. The Migration* Increases** in the HA and Titanium Groups from 0 to 2 Months, 2 to 12 Months, and 12 to 24 Months Postoperatively

<table>
<thead>
<tr>
<th>Group</th>
<th>HA-coated Stems</th>
<th></th>
<th></th>
<th>Uncoated Titanium Stems</th>
<th></th>
<th></th>
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</thead>
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<tr>
<td></td>
<td>0–2</td>
<td>2–12</td>
<td>12–24</td>
<td>0–2</td>
<td>2–12</td>
<td>12–24</td>
</tr>
<tr>
<td>Tx</td>
<td>0.00 ± 0.23</td>
<td>−0.04 ± 0.19</td>
<td>−0.01 ± 0.14</td>
<td>−0.19 ± 0.77</td>
<td>0.07 ± 0.24</td>
<td>0.02 ± 0.15</td>
</tr>
<tr>
<td>Ty</td>
<td>−0.76 ± 0.92†</td>
<td>−0.07 ± 0.18£</td>
<td>−0.05 ± 0.11</td>
<td>−1.02 ± 1.07§</td>
<td>−0.31 ± 0.39§ £</td>
<td>−0.04 ± 0.20</td>
</tr>
<tr>
<td>Tz</td>
<td>−0.23 ± 0.48</td>
<td>−0.02 ± 0.20</td>
<td>−0.10 ± 0.17</td>
<td>−0.24 ± 0.24</td>
<td>−0.29 ± 0.69</td>
<td>−0.09 ± 0.26</td>
</tr>
<tr>
<td>Rx</td>
<td>−0.13 ± 0.32</td>
<td>0.20 ± 0.72</td>
<td>0.07 ± 0.16</td>
<td>−0.10 ± 0.25</td>
<td>0.01 ± 0.25</td>
<td>0.14 ± 0.44</td>
</tr>
<tr>
<td>Ry</td>
<td>−2.22 ± 2.64†</td>
<td>0.08 ± 0.69</td>
<td>−0.06 ± 0.37</td>
<td>−1.20 ± 1.16§</td>
<td>−0.92 ± 1.84§</td>
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</tr>
<tr>
<td>Rz</td>
<td>0.12 ± 0.42</td>
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<td>0.03 ± 0.09</td>
<td>0.00 ± 0.18</td>
<td>0.06 ± 0.16</td>
<td>0.12 ± 0.16</td>
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*Translation along the x-axis, y-axis, and z-axis (Tx, Ty, and Tz) are in mm; rotations about the x-axis, y-axis, and z-axis (Rx, Ry, and Rz) are in degrees.

**Migration increases are expressed as mean ± SD.

†, §Significant increase of migration (Wilcoxon test, 2-sided, p < 0.05) exceeding the detection limit, during the time intervals within †the HA group, and §the titanium group.

£Significant increase of migration (Mann–Whitney U test, 2-sided, p < 0.05) exceeding the detection limit, in the titanium group compared with the HA group.

### TABLE 3. Nonmigrating* and Migrating** Prostheses

<table>
<thead>
<tr>
<th>Period</th>
<th>0–2 Months</th>
<th>2–12 Months</th>
<th>12–24 Months</th>
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<tr>
<td>Group</td>
<td>HA</td>
<td>Titanium</td>
<td>HA</td>
</tr>
<tr>
<td>Nonmigrating*</td>
<td>2</td>
<td>4</td>
<td>17</td>
</tr>
<tr>
<td>Migrating**</td>
<td>18 (6)</td>
<td>16 (5)</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>20#©</td>
<td>20</td>
</tr>
</tbody>
</table>

*Number of prostheses with no migration of more than the detection limit.

**Number of prostheses with migration of more than the detection limit in one or more directions, between the brackets, the number of prostheses with large migration of more than 2 mm or degrees in one or more directions.

#For one patient with a titanium prosthesis no data are available because of missing prosthesis markers.

©For one patient with a titanium prosthesis no postoperative data are available because of a missing postoperative radiograph.

§Two titanium prosthesis were revised within 12 months.

$Two titanium prosthesis were revised within 24 months.
The positive effect of an HA coating can compensate for an inadequate fit or malplacement and turn the ProxiLock into a stable prosthesis with good clinical results 2 years postoperatively, even after large migration during the settling period. However, the design of the ProxiLock femoral component is not sufficient to guarantee stability and good clinical performance when applied as an uncoated titanium prosthesis used in a full weightbearing protocol. The uncoated stem lacks the potential to compensate for initial instability and therefore carries an unacceptable high risk of aseptic loosening and failure. We discontinued the use of this prosthesis.

Acknowledgments

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References


