Original article

Cementless Corail™ femoral stems with laser neck etching: Long-term survival, rupture rate and risk factors in 295 stems

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\section*{Abstract}

\textbf{Introduction:} Implant neck fracture involving a non-modular femoral stem is rare in primary total hip arthroplasty (THA). Occasional cases have been reported following laser etching of the Corail\textsuperscript{TM} stem, but risk factors have not been precisely determined. We therefore performed a retrospective study on a series of Corail\textsuperscript{TM} stems with laser neck etching, in order to: (1) determine the exact implant neck fracture rate at 10 years, and (2) identify associated risk factors.

\textbf{Hypothesis:} Laser etching increases the rate of implant neck fracture.

\textbf{Materials and methods:} Between October 2002 and December 2003, 295 THAs were consecutively performed using the Corail\textsuperscript{TM} stem with laser neck etching, in 286 patients: 151 male (53\%), 135 female (47\%); mean age, 63 years (range, 18–89 years); mean weight, 73 kg (range, 45–120 kg). Stems were standard in 240 cases (81\%) and lateralized in 55 (19\%). The main assessment criterion was stem replacement for implant neck fracture.

\textbf{Results:} At a mean 10 years' follow-up (range, 1–11 years), 11 patients were lost to follow-up (4\%) and 35 had died (12\%) (with stem in situ). Overall 10-year stem survival was 91\% (95\% CI: [87–94\%]). Sixteen patients (5.4\%) underwent revision surgery for implant neck fracture, 6 (2\%) bone and joint infection and in 4 cases (1.3\%) the stem was replaced preventively for fracture risk suspected during a revision procedure on the cup. All fractures were of the fatigue type, implicating implant neck laser etching. Mean time to fracture was 4.5 years (range, 1.4–9.8 years). Risk factors comprised: weight > 80 kg (P = 0.002) (OR = 5.7; 95\% CI: 1.9–17), age < 60 years (P = 0.02) (OR = 3.4; 95\% CI: 1.2–9.6), male gender (P = 0.01) (OR = 14.8; 95\% CI: 1.9–113) and lateralized stem (P < 0.001) (OR = 6.5; 95\% CI: 2.3–18).

\textbf{Conclusion:} The present 5.4\% fracture rate was higher than in registry data (< 1\%). Fracture mechanisms involved excessive stress in an area under tension, leading to fatigue fracture. Male gender, high weight and young age were risk factors, as in the literature for fatigue fracture. Location and depth of laser etching induced fatigue fracture. The study demonstrated that laser etching creates an area of weakness in the implant neck and should therefore be eschewed in this part of the femoral stem.

\textit{Level of evidence:} IV, retrospective study.

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1. Introduction

Data for femoral stem fracture are sparse. Between 1979 and 2007, the Norwegian registry\textsuperscript{[1]} recorded 475 hip implant fractures (0.17\%), which represented the 8th most common cause of revision of total hip arthroplasty (THA). The 2014 Australian report found a fracture rate of 0.8\% in monoblock stems and 2.1\% in modular neck stems\textsuperscript{[2]}. A French study conducted by the SFHG (French Society of Hip and Knee) reported a 3\% rate of revision for implant fracture around the hip\textsuperscript{[3]}. Charnley was the first to report fractures of his cemented monoblock stem, with a rate of 0.23\% at 12 years\textsuperscript{[4]}. The Corail\textsuperscript{TM} femoral stem (DePuy J&J, Warsaw, IN), designed in France in 1986, was redesigned in February 2002 (batches ≤ 1,391,546), with a trapezoid cylindrical instead of circular neck. The manufacturer’s name and device references were laser-etched on the anterior and posterior sides of the neck, as previously but now on a thinner neck, thereby creating a zone

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of weakness implicated in implant neck fracture. In February 2004, following several cases of fracture, all such laser-etched batches were recalled and replaced by the present 3rd-generation model, where etching is on the superior part of the Morse taper. The rate of fracture with this “2002 design”, however, and the associated risk factors are not exactly known. We therefore conducted a retrospective study on a series of Corail™ stem with neck etching, in order:

- to determine the exact implant neck fracture rate at 10 years;
- to identify risk factors for implant neck fracture.

The study hypothesis was that laser etching results in a high rate of fracture.

2. Patients and methods

2.1. Patients

Between October 2002 and December 2003, 295 THAs (286 patients) were performed consecutively (258 primary, 37 revision procedures), in 151 male (53%) and 135 female patients (47%), with a mean age of 63 ± 13 years (range, 18–89 years), and mean weight of 73 ± 12 kg (range, 45–120 kg). The surgical approach was systematically posterolateral. Etiologies in primary THA comprised osteoarthritis of the hip (n = 223, 86%), aseptic osteonecrosis (n = 13, 5%), dysplasia (n = 4, 2%), and other (n = 18, 7%) and, in revision procedures, osteolysis or loosening (n = 33, 89%), infection (n = 3, 8%) and instability (n = 1, 3%).

2.2. Material

The Corail™ femoral stem studied here was a 2nd-generation model, launched in 2002, featuring a thin trapezoid cylindrical neck. It was a straight, cementless stem, made of a titanium alloy (Ti6Al4V) coated by a plasma torch with 155 ± 35 μm calcium hydroxyapatite (HA), presanded with aluminum oxide granules. The 12/14 Morse taper had been shortened, from 15 to 10 mm, so as to be covered by the modular head whatever the chosen neck length. Laser etching was always applied at the same points on the neck in the first two Corail™ generations (Fig. 1). The Corail™ range comprised two types of stem: standard with collar (KA), or lateralized, either coxa vara with collar (KLA) or high-offset without collar (KHO) (Fig. 2); there were three neck lengths: short +1.5, medium +5, and long +8.5. Implant data are shown in Table 1.

2.3. Methods of assessment

Data were collected by telephone contact with patients and analysis of medical files (age, gender, weight, type of stem, reason for reoperation). The main assessment criterion was surgical revision for femoral stem fracture. The secondary criterion was stem revision for all causes.

2.4. Statistics

Demographic data were collected. Survival curves with 95% confidence intervals were plotted following Kaplan-Meier. Statistical analysis used XLStat software (Addinsoft, New York, NY, USA). Multivariate analysis was then performed using a Cox proportional risks model to identify risk factors for neck fracture. Qualitative variables were introduced in contingency tables and compared between groups on Chi². Normal distribution and equal variance of quantitative variables were checked following Breslow, and

Table 1

<table>
<thead>
<tr>
<th>Type of implant</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stems</strong></td>
<td></td>
</tr>
<tr>
<td>Corail™ standard</td>
<td>240 (81)</td>
</tr>
<tr>
<td>Corail™ lateralized</td>
<td>55 (19)</td>
</tr>
<tr>
<td>KLA (coxa vara)</td>
<td>52 (18)</td>
</tr>
<tr>
<td>KHO (high-offset)</td>
<td>3 (1)</td>
</tr>
<tr>
<td><strong>Cups-head diameter</strong></td>
<td></td>
</tr>
<tr>
<td>Allofit™ (Zimmer) – 28 mm</td>
<td>220 (75)</td>
</tr>
<tr>
<td>Lagoon™ (DePuy) – 32 mm</td>
<td>75 (25)</td>
</tr>
<tr>
<td><strong>Friction couple</strong></td>
<td></td>
</tr>
<tr>
<td>Hard-hard</td>
<td>295 (100)</td>
</tr>
</tbody>
</table>
regression coefficients were calculated with a significance threshold of 0.05. Odds ratios with 95% confidence intervals were calculated according to presence of risk factors.

3. Results

3.1. Overall results

This was a single-center retrospective study, with a mean 10 years' follow-up (range, 1–11 years). Eleven patients (4%) were lost to follow-up at a mean 2 years (range, 1–4 years); 35 (12%) died, at a mean 2 years (range, 1–7 years), but with known stem status. Overall 10-year survivorship was 91% (95% CI: 87–94%) (Fig. 3). Survivorship at last follow-up for the event “implant neck fracture” was 94.6% (95% CI: 91–97%) (Fig. 4). Twenty-six stem revision procedures were performed for all causes. Causes comprised: implant neck fracture (n = 16, 5.4%), infection (n = 6, 2%) and in 4 cases (1.3%) preventive replacement of a stem deemed at risk of fracture during acetabular cup revision motivated by ceramic cup fracture, instability, squeaking or cup loosening (n = 1, 0.3%, each). Thus, 20 stem revision procedures were related to laser etching (16 fractures and 4 preventive replacements): i.e., 92.6% 10-year survivorship related to laser etching (95% CI: 89.4–95.7%).

3.2. Fracture group (Table 2)

The 16 patients in the fracture group comprised 15 males and 1 female, with a mean age of 56 ± 8 years (range, 38–70 years) and mean body-weight of 84 ± 12 kg (range, 70–120 kg). Mean implant-to-fracture interval was 4.5 ± 2 years (range, 1.4–9.8 years), most fractures (n = 14, 88%) occurring before 6 years. Fig. 5 presents fractures interval data.

Fracture rate in the standard stem subgroup was 3% (n = 7), and 17% (n = 9) in the lateralized stem subgroup. Fractures occurred during walking (n = 14, 88%), hip flexion (n = 1, 6%) or jogging (n = 1, 6%).
Table 2

Characteristics of patients presenting with implant neck fracture.

<table>
<thead>
<tr>
<th>Patient number</th>
<th>Gender (M or F)</th>
<th>Age (years)</th>
<th>Weight (kg)</th>
<th>Type of stem</th>
<th>Size</th>
<th>Head length</th>
<th>Time to fracture (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>66</td>
<td>97</td>
<td>Standard</td>
<td>12</td>
<td>Long</td>
<td>1.4</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>53</td>
<td>90</td>
<td>Standard</td>
<td>13</td>
<td>Medium</td>
<td>6.4</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>49</td>
<td>75</td>
<td>Lateralized KLA</td>
<td>11</td>
<td>Short</td>
<td>4.3</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>48</td>
<td>73</td>
<td>Lateralized KLA</td>
<td>9</td>
<td>Long</td>
<td>3.6</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>61</td>
<td>95</td>
<td>Lateralized KLA</td>
<td>13</td>
<td>Medium</td>
<td>3.5</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>59</td>
<td>80</td>
<td>Lateralized KLA</td>
<td>11</td>
<td>Long</td>
<td>5.6</td>
</tr>
<tr>
<td>7</td>
<td>M</td>
<td>50</td>
<td>82</td>
<td>Lateralized KLA</td>
<td>12</td>
<td>Short</td>
<td>1.4</td>
</tr>
<tr>
<td>8</td>
<td>M</td>
<td>56</td>
<td>81</td>
<td>Standard</td>
<td>15</td>
<td>Medium</td>
<td>9.8</td>
</tr>
<tr>
<td>9</td>
<td>M</td>
<td>69</td>
<td>85</td>
<td>Lateralized KLA</td>
<td>12</td>
<td>Medium</td>
<td>8.3</td>
</tr>
<tr>
<td>10</td>
<td>M</td>
<td>51</td>
<td>85</td>
<td>Standard</td>
<td>12</td>
<td>Medium</td>
<td>3</td>
</tr>
<tr>
<td>11</td>
<td>F</td>
<td>60</td>
<td>75</td>
<td>Standard</td>
<td>9</td>
<td>Medium</td>
<td>5</td>
</tr>
<tr>
<td>12</td>
<td>M</td>
<td>56</td>
<td>120</td>
<td>Lateralized KLA</td>
<td>12</td>
<td>Medium</td>
<td>1.8</td>
</tr>
<tr>
<td>13</td>
<td>M</td>
<td>70</td>
<td>83</td>
<td>Lateralized KLA</td>
<td>12</td>
<td>Short</td>
<td>2.6</td>
</tr>
<tr>
<td>14</td>
<td>M</td>
<td>38</td>
<td>70</td>
<td>Standard</td>
<td>10</td>
<td>Medium</td>
<td>2.9</td>
</tr>
<tr>
<td>15</td>
<td>M</td>
<td>49</td>
<td>74</td>
<td>Lateralized KLA</td>
<td>12</td>
<td>Long</td>
<td>6.7</td>
</tr>
<tr>
<td>16</td>
<td>M</td>
<td>63</td>
<td>90</td>
<td>Standard</td>
<td>11</td>
<td>Medium</td>
<td>5.9</td>
</tr>
</tbody>
</table>

M: male; F: female.

The Arto Institute developed specific extraction equipment for these cases of Corail™ stem fracture, using supple blades, lanced blades, and a dedicated extractor that can be screwed onto the implant shoulder. Extraction could thus be performed using an intramedullary approach in 23 cases (88%), and via a lateral longitudinal slit with cerclage in 2 cases (8%) or by femorotomy in 1 case (4%).

3.3. Risk factors

As risk factors for implant neck fracture, there emerged: bodyweight > 80 kg (P=0.002; OR = 5.7, 95% CI 1.9–17), age < 60 years (P=0.02; OR = 3.4, 95% CI 1.2–9.6), male gender (P=0.01; OR = 14.8, 95% CI 1.9–11.3) and use of a lateralized stem (P<0.001; OR = 6.5, 95% CI, 2.3–18).

Neither stem size or neck length correlated with occurrence of fracture; nor did type of acetabular cup or friction couple.

4. Discussion

According to DePuy, 204 claims (7%) were lodged for the 2970 Corail™ stems implanted with laser etching on a thin neck. Patients implanted with the model had received a letter informing them of the risk of fracture; compensation was offered only in case of actual fracture, and thus of surgical revision. The present 10-year fracture rate was slightly lower (5.4%). Lateralized stems were at greater risk of fracture. To our knowledge, this is the first report of long-term implant neck fracture implicating laser etching.

The study involved several limitations:

- 4% of patients were lost to follow-up at a median 10 years, although this was less than the 10% usually found in retrospective studies;
- no control group could be applied, as follow-up in our institution for the same model without etching was less exhaustive;
- finally, follow-up was by telephone, but the assessment criterion was well-adapted to this method, and follow-up was fairly long, with a good number of patients.

The mechanisms underlying femoral implant fracture were studied by Galante [5], and implicate excessive stress in an area under tension, inducing fatigue fracture. The fatigue region comprises 3 zones [6]: starting point, propagation region (parallel striae seen on microscopy), and final “fast fracture” zone.

Lee and Kim [7] reported 2 cases of fatigue fracture at a laser-etching site at the junction between the neck and shoulder. Fracture

![Ruptures](image)

**Fig. 5.** Number of implant neck fractures according to time (years).
has largely been reported in modular necks. It begins with corrosion [8–13], and chromium-cobalt has therefore come to be used rather than titanium, although even this does not eliminate risk of fracture [14]. Corrosion is mainly due to fretting, set off by micromotion at the stem/neck junction, which is greater with titanium than with chromium-cobalt [15,16].

Male gender, high weight and strong physical activity are reported as risk factors [4,7,17,18]. Charmley reported a fracture rate of 6% in males weighing > 88 kg, versus 0.23% in the series as a whole [4]. Varus stem positioning appears to be a risk factor [5,19]; increased lever arm increases stress by 25 to 33%, depending on neck length [8,10,12].

Implant metallurgy may also be a factor: stainless steel and chromium-cobalt alloy shows poor fatigue resistance (0.2% to 0.7% fracture rate) [4,20]. Cast chromium-cobalt is highly porous, increasing fatigue fracture risk [5,18,21]. Large-size alloy grains reduce stem strength and resistance [5]. Cementing technique is largely implicated in fractures of cemented stems [4].

Various causes have been found for fracture in cementless stems: weakness between madreporic striae and smooth part (in Lord implants [22]), metal casting technique, excess stem tension [23], mesh recess depth in titanium stems [24], implant neck corrosion [25–27] and proximal stem fixation defect [21,28].

Laser etching, situated in a region of very high loading (anterior and lateral parts of the stem [29]), constitutes a starting point for fatigue fracture [7,18,30]. Etching depth is a factor: as of 50 μm, fatigue resistance is reduced by 20%, and by 50% at 70 μm [6]. The etching process may alter the microstructure of the neck, the temperature exceeding the alloy fusion threshold [28].

In our opinion, revision for any other cause is an opportunity to remove any lateralized stem with laser-etched neck, given the very high frequency of fracture. Standard stems should be removed if the patient has any risk factor for fracture. Fig. 6 presents our strategy in acetabular revision.

5. Conclusion

The main cause of implant neck fracture in standard stems is laser etching, which is to be proscribed in implant regions subject to strong loading, such as the neck. Each case of material fracture must be reported to the national health-products safety materials vigilance agency (in France, the ANSM).

Disclosure of interest

M.-H. F. receives royalties from DePuy and Serf, without relation with the present study. The other authors declare that they have no competing interest.

References


