Quantification of material loss from the neck piece taper junctions of a bimodular primary hip prosthesis. A retrieval study from 27 failed Rejuvenate bimodular hip arthroplasties

The early failure and revision of bimodular primary total hip arthroplasty prostheses requires the identification of the risk factors for material loss and wear at the taper junctions through taper wear analysis. Deviations in taper geometries between revised and pristine modular neck tapers were determined using high resolution tactile measurements. A new algorithm was developed and validated to allow the quantitative analysis of material loss, complementing the standard visual inspection currently used.

The algorithm was applied to a sample of 27 retrievals (in situ from 2.9 to 38.1 months) of the withdrawn Rejuvenate modular prosthesis. The mean wear volumes on the flat distal neck piece taper was 3.35 mm³ (0.55 to 7.57), mainly occurring in a characteristic pattern in areas with high mechanical loading. Wear volume tended to increase with time to revision ($r^2 = 0.423$, $p = 0.001$). Implant and patient specific data (offset, stem size, patient’s mass, age and body mass index) did not correlate with the amount of material loss observed ($p > 0.078$). Bilaterally revised implants showed higher amounts of combined total material loss and similar wear patterns on both sides. The consistent wear pattern found in this study has not been reported previously, suggesting that the device design and materials are associated with the failure of this prosthesis.

The risk of early revision of primary bimodular total hip arthroplasty prostheses with modular necks has been identified as a significant clinical problem. High early failure rates have resulted in the withdrawal of certain designs from clinical use.1 Several studies have reported corrosion and wear at modular neck taper junctions, leading either to implant fracture (mostly in titanium alloy combinations)2 or elevation of serum cobalt (Co) and chromium (Cr) ion concentrations arising from implantation of prostheses with a combination of titanium and CoCr components.3-7 The systemic release of Co and Cr ions can be associated with adverse tissue reactions, causing symptoms such as severe pain, soft-tissue necrosis or pseudo-tumour formation.3,8,9 The explanation for differing concentrations of metal ions and the relationship with symptoms are unclear.10

Increased Co and Cr levels have been associated with early clinical failure and revision with this design. In the literature the time to revision has varied between 15.2 months and 32.4 months.4-6 Presently, the amount of taper corrosion from non-circular tapers is evaluated using the qualitative Goldberg or Cook scales, which are based on visual estimations and analyses.11 The amount of material loss is not reflected well by these scores.12 This method also does not quantify the risk to which patients might be exposed from released ionic CoCr.13 A method of quantifying the amount of material lost from the implant interfaces and the ability to correlate with clinical outcome is desirable.

The aim of this study was to develop a method to quantify wear of non-circular tapers, and to apply it to a cohort of retrievals from one specific bimodular primary hip arthroplasty design, the Rejuvenate prosthesis.

Materials and Methods

Measurement method. All prostheses were cleaned in an ultrasound bath (Elmasonic P, Elma, Singen, Germany) using soap (Edisonite 5%) and a tooth brush, for mechanical
cleaning, after dried organic material had been removed from the neck surfaces using an ethanol soaked cloth.

The surface geometry of the taper surfaces was then determined using a tactile co-ordinate measurement machine with an accuracy of 3 μm (Mitutoyo BHN 805, Tokyo, Japan).

A ruby sphere, with a diameter of 2 mm and a sampling resolution of 0.1 mm, was used for the measurements.

The original geometry of individual neck piece tapers and mechanical tolerances were unknown because of commercial confidentiality and had to be estimated for each implant. For circular taper geometries this was achieved by ‘excluding’ the worn areas from the original surface by estimation, using a ‘least square fitting’ to a circular reference circumference. This approach has shown to produce reliable estimates for changes to circular taper surfaces.14,15 For the distal flat taper of the neck piece, it was necessary to develop a new method to determine changes from an estimated original geometry owing to its non-circular shape. The computer code for estimating material loss was written in Matlab (MathWorks, Natick, Massachusetts). The algorithm is based on the reconstructed original geometry from the interpolation (shortest fitting lines or planes to point clouds) between measurement points on two circumferential unloaded, and thus unworn, taper surface areas, which the Rejuvenate taper design provides distally because of the chamfered aspect of the female taper, and proximally owing to the protruding taper geometry (Fig. 2). These two areas are not altered by wear or corrosion, since this is limited to surfaces in contact with each other. The individual, original geometry is estimated by interpolating between the closest distance measured points from these ‘non-contact’ areas.

Fig. 1
Photograph showing the condition of the prosthesis components as received: 36 mm option head (Biolox Delta, CeramTec GmbH, Plochingen, Germany), neck piece, stem, polyethylene-inlay. Areas of corrosion and contamination with blood are difficult to separate. Note the piece of grease found inside the head taper (indicated by the white arrows).

Fig. 2
Photograph showing how the proximal stem has been cut to make the female stem taper accessible (left). Areas of corrosion or contamination can be identified. The contact regions on the female and male neck piece tapers are indicated by the red arrows. The white arrows indicate the chamfered area on the female taper, allowing no-contact areas on the male taper when assembled (corresponding, protruding area is indicated by the black arrows). The stem-neck piece taper consists of curved, ‘conical’ regions (right) (red) connected by flat sides (green).
using triangular planes to the measured data (Delaunay Triangulation).\textsuperscript{16} This method generates an original taper surface by assuming ideally straight surface extension in the longitudinal taper axis all around the taper’s circumference. In a second step, changes in the measured taper surface to the assumed original taper surface were calculated. Shortest distances of any measurement point to the estimated original geometry is calculated for each point. Deviations between original and worn topography were mapped on the taper surface, and, for a better display, amplified 20-fold (Fig. 3). Material loss is calculated by integrating all deviations $> 3 \mu m$, as limited by the measurement accuracy.

The contact region of the taper surface was divided into its conical (medial, lateral) and flat (anterior, posterior) surfaces for the quantification of material loss around the taper circumference (Fig. 2). Point clouds of around 75 000 points were determined for the flat male taper of the neck piece. The circular regions take up three-quarters of the whole taper surface, which is reflected in the number of patches that represent the circular and flat regions. Material loss was calculated by patch-wise integration, and the mean wear depth (MWD) was determined for flat and circular regions (Fig. 4).

The method was validated topographically (using infinite focus optical microscopy; measurement resolution 100 nm; Alicona, Graz, Austria) and gravimetrically using a class I precision balance with a linearity 0.2 mg (BP110S, Sartorius AG, Göttingen, Germany). Infinite focus variation was performed on a highly worn region of a retrieved neck piece adjacent to regions of no-contact. Depths of material loss were determined locally by interpolating the unworn surface from the non-contacting regions (similar to the method used for the tactile measurements). The gravimetric approach was used to verify the material volume loss calculated from the tactile measurements to the weight loss. Artificial defects were introduced four consecutive times on a new flat taper of the specific design (Fig. 1) to simulate...
Retrieval study. Repeated measurements of a retrieved taper with medium a density of 8.3 g/cm³ for the CoCr neck piece alloy. Measured mass loss, which was converted to volume using removed material was determined with the new algorithm different amounts and spatial distribution of material loss. Removed material was determined with the new algorithm based on the tactile measurements and compared with the measured mass loss, which was converted to volume using a density of 8.3 g/cm³ for the CoCr neck piece alloy.

Repeatability of the method was assessed based on three repeated measurements of a retrieved taper with medium wear. Differences in determined material loss and wear depth between measurements were analysed.

Table I. Patient and implant information, together with the results of the wear analysis

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age (yrs)</th>
<th>Weight (kg)</th>
<th>BMI (kg/m²)</th>
<th>Stem size (n)</th>
<th>Head size (mm)</th>
<th>Head material</th>
<th>Neck Version</th>
<th>Neck length (mm)</th>
<th>Total offset (mm)</th>
<th>Side</th>
<th>Surgeon (n)</th>
<th>Mass/Fluid Collection (MRI)</th>
<th>Time in situ (mths)</th>
<th>Max. wear depth (μm)</th>
<th>Material loss (mm³)</th>
<th>MWD flat side (μm)</th>
<th>MWD circular side (μm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>58</td>
<td>74.8</td>
<td>29.23</td>
<td>7</td>
<td>32</td>
<td>Ceramic</td>
<td>-</td>
<td>34</td>
<td>42.6</td>
<td>Left</td>
<td>1</td>
<td>Yes</td>
<td>9.1</td>
<td>45</td>
<td>2.15</td>
<td>2</td>
<td>12</td>
</tr>
<tr>
<td>2</td>
<td>44</td>
<td>131.5</td>
<td>36.24</td>
<td>10</td>
<td>36</td>
<td>Ceramic</td>
<td>+</td>
<td>38</td>
<td>44.1</td>
<td>Left</td>
<td>2</td>
<td>Yes</td>
<td>36.2</td>
<td>86</td>
<td>7.57</td>
<td>13</td>
<td>35</td>
</tr>
<tr>
<td>3</td>
<td>71</td>
<td>104.3</td>
<td>33.00</td>
<td>7</td>
<td>36</td>
<td>Metal</td>
<td>+</td>
<td>34</td>
<td>40.4</td>
<td>Right</td>
<td>3</td>
<td>NA</td>
<td>14.6</td>
<td>18</td>
<td>0.96</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>60</td>
<td>78.5</td>
<td>25.54</td>
<td>7</td>
<td>36</td>
<td>Ceramic</td>
<td>+</td>
<td>34</td>
<td>42.6</td>
<td>Left</td>
<td>4</td>
<td>NA</td>
<td>29.3</td>
<td>52</td>
<td>5.29</td>
<td>8</td>
<td>27</td>
</tr>
<tr>
<td>5</td>
<td>61</td>
<td>86.2</td>
<td>28.89</td>
<td>7</td>
<td>28</td>
<td>Metal</td>
<td>+</td>
<td>34</td>
<td>42.6</td>
<td>Left</td>
<td>5</td>
<td>Yes</td>
<td>10.1</td>
<td>48</td>
<td>2.13</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>6</td>
<td>81</td>
<td>102.1</td>
<td>30.51</td>
<td>9</td>
<td>40</td>
<td>Metal</td>
<td>+</td>
<td>34</td>
<td>42.8</td>
<td>Right</td>
<td>4</td>
<td>NA</td>
<td>5.6</td>
<td>55</td>
<td>3.15</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>7</td>
<td>47</td>
<td>117.5</td>
<td>35.10</td>
<td>8</td>
<td>36</td>
<td>Ceramic</td>
<td>-</td>
<td>34</td>
<td>41.3</td>
<td>Left</td>
<td>1</td>
<td>NA</td>
<td>NA</td>
<td>72</td>
<td>2.7</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>8</td>
<td>65</td>
<td>72.6</td>
<td>25.82</td>
<td>8</td>
<td>36</td>
<td>Ceramic</td>
<td>-</td>
<td>34</td>
<td>45.8</td>
<td>Right</td>
<td>6</td>
<td>Yes</td>
<td>Yes</td>
<td>7.2</td>
<td>1.67</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>9</td>
<td>52</td>
<td>90.7</td>
<td>27.12</td>
<td>9</td>
<td>40</td>
<td>Ceramic</td>
<td>-</td>
<td>38</td>
<td>49.7</td>
<td>Left</td>
<td>1</td>
<td>Yes</td>
<td>Yes</td>
<td>38.1</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>10</td>
<td>52</td>
<td>90.7</td>
<td>27.12</td>
<td>9</td>
<td>36</td>
<td>Ceramic</td>
<td>-</td>
<td>42</td>
<td>53.7</td>
<td>Right</td>
<td>1</td>
<td>Yes</td>
<td>Yes</td>
<td>35.7</td>
<td>2.34</td>
<td>4</td>
<td>11</td>
</tr>
<tr>
<td>11</td>
<td>64</td>
<td>72.6</td>
<td>25.82</td>
<td>8</td>
<td>36</td>
<td>Ceramic</td>
<td>-</td>
<td>34</td>
<td>43.8</td>
<td>Left</td>
<td>1</td>
<td>No</td>
<td>Yes</td>
<td>18.3</td>
<td>2.04</td>
<td>3</td>
<td>11</td>
</tr>
<tr>
<td>12</td>
<td>38</td>
<td>86.2</td>
<td>25.06</td>
<td>8</td>
<td>36</td>
<td>Ceramic</td>
<td>-</td>
<td>30</td>
<td>40.1</td>
<td>Right</td>
<td>7</td>
<td>NA</td>
<td>6.2</td>
<td>37</td>
<td>1.66</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>13</td>
<td>66</td>
<td>68.0</td>
<td>24.21</td>
<td>7</td>
<td>36</td>
<td>Ceramic</td>
<td>-</td>
<td>34</td>
<td>42.3</td>
<td>Right</td>
<td>7</td>
<td>Yes</td>
<td>18.2</td>
<td>40</td>
<td>3.58</td>
<td>6</td>
<td>17</td>
</tr>
<tr>
<td>14</td>
<td>60</td>
<td>74.8</td>
<td>26.63</td>
<td>7</td>
<td>36</td>
<td>Ceramic</td>
<td>+</td>
<td>34</td>
<td>37.6</td>
<td>Left</td>
<td>3</td>
<td>Yes</td>
<td>15.2</td>
<td>60</td>
<td>4.64</td>
<td>6</td>
<td>25</td>
</tr>
<tr>
<td>15</td>
<td>74</td>
<td>99.8</td>
<td>31.56</td>
<td>7</td>
<td>36</td>
<td>Ceramic</td>
<td>-</td>
<td>34</td>
<td>45.1</td>
<td>Right</td>
<td>1</td>
<td>No</td>
<td>Yes</td>
<td>24.0</td>
<td>6.7</td>
<td>3</td>
<td>10</td>
</tr>
<tr>
<td>16</td>
<td>65</td>
<td>115.7</td>
<td>31.87</td>
<td>10</td>
<td>40</td>
<td>Ceramic</td>
<td>-</td>
<td>34</td>
<td>45.9</td>
<td>Right</td>
<td>1</td>
<td>No</td>
<td>Yes</td>
<td>32.6</td>
<td>6.64</td>
<td>10</td>
<td>33</td>
</tr>
<tr>
<td>17</td>
<td>71</td>
<td>69.9</td>
<td>24.85</td>
<td>8</td>
<td>36</td>
<td>Ceramic</td>
<td>-</td>
<td>34</td>
<td>40.8</td>
<td>Right</td>
<td>7</td>
<td>Yes</td>
<td>Yes</td>
<td>37.3</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>18</td>
<td>66</td>
<td>47.2</td>
<td>19.02</td>
<td>8</td>
<td>36</td>
<td>Ceramic</td>
<td>+</td>
<td>34</td>
<td>43.3</td>
<td>Left</td>
<td>7</td>
<td>No</td>
<td>20.2</td>
<td>18</td>
<td>0.55</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>19</td>
<td>76</td>
<td>61.2</td>
<td>26.36</td>
<td>7</td>
<td>32</td>
<td>Ceramic</td>
<td>-</td>
<td>34</td>
<td>40.6</td>
<td>Left</td>
<td>1</td>
<td>Yes</td>
<td>Yes</td>
<td>20.3</td>
<td>7.38</td>
<td>3</td>
<td>23</td>
</tr>
<tr>
<td>20</td>
<td>77</td>
<td>61.2</td>
<td>26.36</td>
<td>7</td>
<td>36</td>
<td>Ceramic</td>
<td>-</td>
<td>30</td>
<td>41.7</td>
<td>Right</td>
<td>1</td>
<td>Yes</td>
<td>Yes</td>
<td>21.2</td>
<td>4.58</td>
<td>5</td>
<td>25</td>
</tr>
<tr>
<td>21</td>
<td>65</td>
<td>86.2</td>
<td>28.06</td>
<td>8</td>
<td>36</td>
<td>Ceramic</td>
<td>NA</td>
<td>34</td>
<td>43.5</td>
<td>NA</td>
<td>7</td>
<td>Yes</td>
<td>Yes</td>
<td>14.2</td>
<td>4.31</td>
<td>7</td>
<td>20</td>
</tr>
<tr>
<td>22</td>
<td>65</td>
<td>86.2</td>
<td>28.06</td>
<td>8</td>
<td>36</td>
<td>Ceramic</td>
<td>NA</td>
<td>34</td>
<td>41.7</td>
<td>NA</td>
<td>7</td>
<td>Yes</td>
<td>Yes</td>
<td>14.2</td>
<td>3.02</td>
<td>6</td>
<td>11</td>
</tr>
<tr>
<td>23</td>
<td>47</td>
<td>102.1</td>
<td>37.54</td>
<td>7</td>
<td>32</td>
<td>Ceramic</td>
<td>-</td>
<td>30</td>
<td>31.7</td>
<td>Left</td>
<td>1</td>
<td>No</td>
<td>Yes</td>
<td>14.8</td>
<td>2.16</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td>24</td>
<td>80</td>
<td>45.4</td>
<td>19.53</td>
<td>7</td>
<td>36</td>
<td>Ceramic</td>
<td>+</td>
<td>42</td>
<td>54.1</td>
<td>Right</td>
<td>4</td>
<td>NA</td>
<td>2.9</td>
<td>39</td>
<td>1.79</td>
<td>2</td>
<td>9</td>
</tr>
<tr>
<td>25</td>
<td>70</td>
<td>71.7</td>
<td>29.86</td>
<td>7</td>
<td>32</td>
<td>Ceramic</td>
<td>-</td>
<td>34</td>
<td>42.6</td>
<td>Right</td>
<td>6</td>
<td>No</td>
<td>NA</td>
<td>21.4</td>
<td>3.09</td>
<td>4</td>
<td>15</td>
</tr>
<tr>
<td>26</td>
<td>56</td>
<td>70.3</td>
<td>23.57</td>
<td>9</td>
<td>36</td>
<td>Ceramic</td>
<td>-</td>
<td>38</td>
<td>50.7</td>
<td>Left</td>
<td>5</td>
<td>Yes</td>
<td>Yes</td>
<td>22.0</td>
<td>4.28</td>
<td>6</td>
<td>21</td>
</tr>
<tr>
<td>27</td>
<td>56</td>
<td>70.3</td>
<td>23.57</td>
<td>9</td>
<td>28</td>
<td>Ceramic</td>
<td>+</td>
<td>34</td>
<td>42.8</td>
<td>Right</td>
<td>4</td>
<td>Yes</td>
<td>Yes</td>
<td>21.5</td>
<td>4.50</td>
<td>6</td>
<td>23</td>
</tr>
</tbody>
</table>

BMI, body mass index; MWD, mean wear depth; Retro-, +; Ante, -; NA, not applicable

Results

Measurement method. The estimated material loss varied by ± 0.05 mm³ between the repeat measurements, the maximal wear depths were < 1 μm. Differences between repeated measurements were randomly scattered around the taper (test-retest root mean square error below 4 μm). The comparison between the tactile method and the optical measurements yielded an absolute accuracy of ± 5 μm. Weight loss corresponding to volume losses of 1.0, 1.9, 2.7
and 3.6 mm³ were underestimated by about 6% by the algorithm (mean 0.12 mm³, SD 0.09).

Retrieval study. The proximal, circular male head taper of the neck pieces showed no measurable material loss in any retrieval, whereas the distal neck piece tapers exhibited extended black discolouration and surface changes. The confined non-contact regions matching the female taper’s chamfers were found in all retrievals (Figs 2 and 3). The protruding male taper regions (required for the application of the algorithm for quantitative wear determination) showed an intact surface geometry in 25 of the 27 retrievals. Two tapers were damaged in this region during revision surgery and had to be excluded from analysis.

The largest amounts of material loss were found proximally at the medial, conical part of the taper (Fig. 3, top). MWDs between flat and circular sides were highly correlated ($r^2 = 0.77$, $p < 0.001$) with MWD circular exceeding MWD flat. The slope of this regression accounts to 2.76. The maximum wear depth ranged between 18 μm and 86 μm and is located on either side of a prominent patch of the original taper surface, which was found near the proximal-medial edge of the circular taper contact area (Fig. 3, top). Symmetrically across from this patch, at the distal-lateral edge of the conical part of the taper, a similar (but smaller) patch was observed, also surrounded by localised material loss. Lesser wear extended to the flat sides, with the same symmetry across the taper. Figure 5 shows the taper wear patterns of the explants arranged according to the amount of CoCr material lost for every second implant. All retrieved modular necks exhibited this typical material loss pattern, except for one case, which showed very minor material loss (Fig. 3). This neck piece originated from the patient with the undiagnosed peri-prosthetic fracture, probably sustained during surgery (patient 16, Table I).

Material deposits on the flat neck piece tapers were observed in very small quantities (mean 0.21 mm³, SD 0.02) and not further analysed. Volumes of material loss varied considerably between implants with a mean of 3.35 mm³ (SD 1.83; 0.55 to 7.57, Table I). Available clinical parameters that are suspected to affect the mechanical situation, such as stem size ($p = 0.078$), offset ($p = 0.905$), patient’s weight ($p = 0.092$), age ($p = 0.996$) or body mass index (BMI) ($p = 0.239$) did not predict material loss. Volumetric loss was found to increase with the time in situ ($r^2 = 0.423$, $p = 0.001$). Incorporating the available clinical parameters did not improve this correlation. No correlation was found between any soft-tissue reaction or fluid collection as seen on MRI examinations and quantities of lost material from the implant ($p = 0.991$, one-way ANOVA).

The modular neck components from bilateral implantations ($n = 13$) did not show individually a reduced loss of material compared with the unilateral ones ($p = 0.52$, one-way ANOVA). The sub-group with both implants of a single patient available for analysis (four patients and eight implants) showed similar intra-patient material loss patterns on either side (Figs 6 and 7).
Discussion

Measurement method. Our method of estimating material loss from non-circular tapers has shown good test-retest reliability with a variation in determined total material loss of ± 0.05 mm³ and maximal wear depths < 1 μm. The differences between repeated measurements were randomly scattered around the taper and thus did not alter the observed material loss patterns. The mass loss to volume was underestimated by 6%. This error, in part, was because of the rather large diameter ruby tip (2 mm) of the coordinate measurement machine and the lack of the exact manufacturer's density information of the CoCr implant material.

This method is only suitable if the non-contact regions on the retrieved implants are undamaged during revision. For this reason, two of the 27 implants were excluded from the analysis.

Retrieval study. The material loss from the taper was found to be distributed in a very characteristic pattern, with total wear volumes between 0.55 mm³ and 7.57 mm³ (Fig. 5). This indicates a unique failure mechanism for this specific prosthesis design.3-7,17 Greatest material loss was observed in those areas of the non-circular, distal neck piece taper which is subject to the highest contact stresses during oblique bending loading during activities in vivo.17,18 Implants from patients with assumed normal physiological loading showed an almost three-fold (2.76) greater MWD on the circular than on the flat taper sides (Fig. 3, top). The importance of mechanical implant loading on wear can be deduced from the small amount of wear observed in one retrieval, which was probably only exposed to very minor mechanical load because of an undiagnosed intra-operative peri-prosthetic fracture (patient 16, Table I; Fig. 3, bottom).

Despite a time in situ of 20.2 months, this neck piece did not show the typical pattern of material loss observed in the other explants (Fig. 5). It is most likely that the material loss at the taper junction is caused by mechanically induced corrosive processes.19

CoCr material loss occurred solely from the distal male stem taper of the modular neck piece, which articulates with the female titanium stem taper. The stem taper itself showed no material loss, indicating a corrosive mechanism between dissimilar materials that has been reported from previous retrieval studies.15

Time in vivo explains 42.3% of the variation in the amount of material loss observed. This correlation suggests the exposure to in vivo forces has, in general, a fundamental impact on volumetric loss rather than factors associated with implantation or patient characteristics. The observed pattern of wear results from major changes in the local contact conditions, and the worn surface area increases with increasing material loss (Fig. 5). However, the increase of wear volume with time was found to follow a linear trend for all retrievals (Fig. 7). This is surprising, since one might expect varying intervals for the onset of corrosion between each patient. However, this cannot be accessed in a retrieval study.

A wide range of material loss from the modular neck pieces was observed. These large differences in released CoCr until revision, together with the finding that soft-tissue reactions or fluid collections as seen on MRI scans did not correlate to the amount of lost CoCr material, indicate highly idiosyncratic responses between patients.20

Despite the importance of the mechanical loading on the observed wear pattern in general (Fig. 5), patient and design related factors, associated with the mechanical contact condition, such as stem size, offset, patient mass, age or...
BMI did not show a correlation with the amount of material lost from the implant. Patient age and head offset have been shown to correlate with elevations in serum metal ion concentrations for the analysed design. For other implant designs, the occurrence of such correlation was shown to depend on the dominant wear mechanism, and material loss from tapers is hard to predict from data on metal ions. This highlights the impact of other factors on the relationship between clinical outcomes and the results of retro-respective retrieval studies, for example joint clinical constitution and joint fluid properties. These might affect fluid ingress into the taper and heavily influence the local wear dynamics at the taper interface, and also may play an important role in the distribution and elution of the metal ions into adjacent tissues or body fluids. Since these factors are largely unknown, a meaningful risk analysis for an individual patient is impractical.

The implants from bilateral implantations and especially the bilateral retrievals from four patients (Table I) revealed symmetrical intra-patient material loss and wear patterns (Fig. 6). The amount of material loss and time to revision for each side was similar for three of the four bilateral patients (Fig. 7), indicating double the amount of released ions compared with individuals with unilateral arthroplasties and similar time in vivo, which is in agreement with other studies. It is surprising that patients with bilateral arthroplasties did not require earlier revision. The similar material loss within the bilateral patients indicates that a predominant patient factor has a strong effect on the situation in vivo.

Missing individual factors, which might influence the amount of wear observed, such as taper assembly during implantation, clinical joint constitution, patient activity levels could not be analysed in this study. Measurements of Co and Cr concentrations in serum, blood or tissue would have helped greatly, as they would have provided a link between material loss and clinical symptoms. Although the progressive damage to implants with typical surface patterns of material loss and wear have been demonstrated in this study, the individual risk to any implant or patient cannot be estimated. The study only analysed clinically failed prostheses and the risk to the patients with well-functioning arthroplasties cannot be assessed, particularly since no prosthesis or patient specific factor correlated with material loss, in this small sample study.

This study has shown that time in vivo is a factor associated with material loss and wear in symptomatic patients. It remains unclear which specific conditions trigger the mechanisms which result in the patterns of wear observed. Based on the consistently observed patterns of wear, within the small heterogeneous patient cohort studied, we hypothesise that a common mode of failure dominates the frequently observed failure of the Rejuvenate design. This pattern of failure has not been reported in other retrieval studies and no individual patient characteristics have been correlated with our findings. We hypothesise a predominantly mechanically mediated in situ mechanism of CoCr material loss and mode of failure related to the specific design properties and material combination of this prosthesis. The quantitative analysis of material loss and wear presented in this study is an important step in the understanding of failure mechanisms of bimodular tapers, and will allow more detailed analyses during pre-clinical testing of new designs in the future.

Author Contributions:
D. Buente: Data collection, method development and data analysis, writing the paper.
G. Huber: Contributed to method development, data analysis and writing (co-ordination and supervision).
N. Bishop: Technical assistance.
M. Morlock: supervision, data collection, writing the paper.

The research has received funding from the European Union’s Seventh Framework Program (FP7/2007-2013) under grant agreement no. GA-310477 (Life-LongJoints).

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

This article was primary edited by D. Johnstone and first proof edited by G. Scott.
References


