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Buente, D, Bryant, M orcid.org/0000-0003-4442-5169, Ward, M et al. (3 more authors) (2017) The taper corrosion pattern observed for one bi-modular stem design is related to geometry-determined taper mechanics. *Medical Engineering & Physics*, 46. pp. 79-88. ISSN 1350-4533

<https://doi.org/10.1016/j.medengphy.2017.06.003>

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1 **The Taper Corrosion Pattern Observed for One Bi-Modular Stem Design**
2 **is Related to Geometry-Determined Taper Mechanics**

3 **AUTHORS, CONTACT DETAILS, AND AFFILIATIONS**

4 Dipl.-Ing Dennis Bunte^{1*}, dennis.buente@tuhh.de

5 Dr. Michael Bryant², m.g.bryant@leeds.ac.uk

6 Dr. Michael Ward², m.b.ward@leeds.ac.uk

7 Prof. Anne Neville², a.neville@leeds.ac.uk

8 Prof. Michael Morlock¹ morlock@tuhh.de

9 Dr. Gerd Huber¹, g.huber@tuhh.de

10 *corresponding author

11 ¹TUHH Hamburg University of Technology
12 Institute of Biomechanics, Denickestrasse 15
13 21073 Hamburg, Germany

14 ²University of Leeds,
15 Faculty of Engineering
16 Institute of Materials and Research/ Functional Surfaces,
17 Leeds LS2 9JT, UK

18 **KEYWORDS**

19 Taper Mechanics, Geometrical Mismatch, Design, Failure Mechanism, Wear Pattern,
20 Fretting Corrosion

21

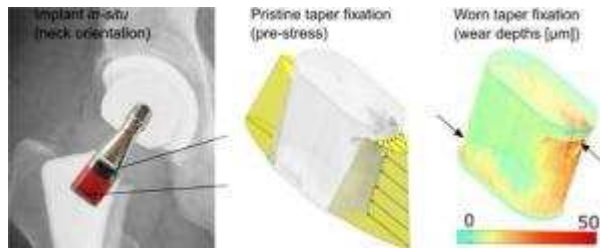
22 **ABSTRACT**

23 Bi-modular primary hip stems exhibit high revision rates owing to corrosion at the
24 stem-neck taper, and are associated with local adverse tissue reactions. The aim of
25 this study was to relate the wear patterns observed for one bi-modular design to its
26 design-specific stem-neck taper geometry.

27 Wear patterns and initial geometry of the taper junctions were determined for 27
28 retrieved bi-modular primary hip arthroplasty stems (Rejuvenate, Stryker
29 Orthopaedics) using a tactile coordinate-measuring device. Regions of high-gradient
30 wear patterns were additionally analyzed via optical and electron microscopy.

31 The determined geometry of the taper junction revealed design-related engagement
32 at its opening (angle mismatch), concentrated at the medial and lateral apexes (axes
33 mismatch). A patch of retained topography on the proximal medial neck-piece taper
34 apex was observed, surrounded by regions of high wear. On the patch, a deposit
35 from the opposing female stem taper —containing Ti, Mo, Zr, and O—was observed .

36 High stress concentrations were focused at the taper apexes owing to the specific
37 geometry. A medial canting of the components may have augmented the
38 inhomogeneous stress distributions *in vivo*. In the regions with high normal loads
39 interfacial slip and consequently fretting was inhibited, which explains the observed
40 pattern of wear.



41

42 **INTRODUCTION**

43 Total hip replacements with modular necks show an increased risk for early failure
44 [1]. Clinical failures range from neck fracture [2–6] to symptomatic adverse tissue
45 reactions [7–9]. Early failures of one specific design (Rejuvenate, Stryker
46 Orthopaedics, Mahwah, New Jersey) were linked to fretting-corrosion and
47 substantial wear from the bi-modular neck-piece taper (~~CoCrMo~~) [10–16]. The
48 system was consequently recalled [17]. A recent study demonstrated that sections
49 with high local *in vivo* loads exhibited distinct material loss from the CoCrMo neck
50 pieces [18]. An implant specific failure mechanism was suggested because a distinct
51 and evolving wear pattern was observed on the cohort of retrieved neck pieces
52 (CoCr₂₉Mo₆, hereafter referred to as CoCrMo; Figure 1), whereas the Titanium-alloy
53 counterparts (TiMo₁₂Zr₆Fe₂, hereafter referred to as TMZF) remained without a
54 notable wear pattern [19].

55 Mechanically assisted corrosion had been identified as the dominant mechanism for
56 material loss from conical metallic tapers *in vivo* [19,20], which may be a concern for
57 implant survivorship of modern hip implant designs [21–23]. The mechanical
58 damage of native oxide layers initiates the corrosive attack of otherwise inert
59 components [24–26]. Thus, local relative motions and insufficient normal stress at
60 the contact interface are considered mechanical prerequisites for taper wear [27].

61 The determining risk factors of the degradation processes *in vivo* are multifactorial
62 [14,28,29] and still largely debated. However, the initial mechanical condition at the
63 junction is thought to determine the initiation and progression of the degradation of
64 taper interfaces [30,31].

65 The mechanical contact situation within tapers can be seen as a superimposition of
66 1) the permanent normal pre-stress from the elastic strain that occurred from the
67 assembly of the taper, and 2) the temporally applied stresses caused by applied joint
68 loads. The taper geometry and its implant-specific orientation with respect to the
69 joint load predetermine the contact stress configuration. Relative motion will occur,
70 if the interfacial shear stress exceeds the available frictional shear stress provided by
71 the local normal pre-stress. This imbalance can be attributed to a variety of factors,
72 such as the design (taper geometry, clearances between male and female tapers,
73 taper orientation, and taper materials [32,33]), the assembly conditions (assembly
74 force and taper contamination [34]), or surgical and patient-specific factors (surgical
75 techniques and activity levels [35]).

76 Within circular tapers, the contact configuration between the male and female taper
77 can be mainly described by their angular mismatch (ASTM F3129-16). The angular
78 mismatch predicts the location of the ideally ring-shaped engagement, and is
79 consequently considered as an important parameter for the taper function [36–39].

80 Non-circular taper geometries, which are common in bi-modular implants,
81 incorporate additional shape parameters (Figure 2) and additional strategies for
82 adjusting the mismatches [40]. The geometry and clearances of the tapers could be
83 attuned to provide the required pre-stress to transmit the expected loading *in vivo*

84 [23]. However, this adaption might miss the real clinical situation, which could be the
85 reason why certain bi-modular tapers appeared to be less robust [12,13,23,41–43].

86 This study aims to explain the wear pattern of one specific taper design with
87 trigonometric considerations of male and female taper geometries.

88 **MATERIALS AND METHODS**

89 Cohorts of new and retrieved bi-modular hip replacements (2 new stems, 4 new neck
90 pieces, 27 explanted stems and corresponding neck pieces of the Rejuvenate
91 modular hip system) were available for analysis. The retrieved implants were revised
92 owing to adverse tissue reactions between 2.9 and 38.1 months after their
93 implantation (see Table 1; further patient and cohort details can be found in our
94 previous research work [18]). After obtaining informed consent of the patient, the
95 retrieved implants were manually cleaned with an ethanol-immersed cloth, and
96 were then exposed to an ultrasound bath (Elmasonic P, Elma Schmidbauer GmbH,
97 Singen, Germany) with soap (Edisonite 5%, Schülke & Mayr GmbH, Norderstedt,
98 Germany). Male neck-piece tapers and female stem tapers of the retrieved and the
99 new tapers were measured via a point-by-point method using a tactile coordinate-
100 measuring device (Mitutoyo BHN 805, Tokyo, Japan; 3 μm precision; scanning grid:
101 0.5 mm x 0.5 mm or 0.1 mm x 0.1 mm). The measurements were obtained using a
102 Ruby sphere with a diameter of 2 mm.

103 The female tapers were mostly damaged by longitudinal rupture marks at their
104 lateral apexes, which had been likely caused by revision tools. The male tapers were
105 worn (material loss of $3.35 \pm 1.83 \text{ mm}^3$, ranging from 0.55 to 7.57 mm^3); however,
106 distally and proximally they exhibited pristine, non-contact bands. These unworn

107 areas were exploited for the reconstruction of the initial, pristine tapers. For two
108 retrievals, the aforementioned areas were mechanically damaged during
109 explantation; therefore, the components were completely excluded from further
110 analysis.

111 **Estimated original taper geometry:** In order to understand the contact mechanics
112 of the taper interface and its relation to the observed wear patterns, the original
113 taper geometry must be determined. The male and female taper geometries of the
114 analyzed bi-modular taper design may be described as two separated parallel conical
115 sections (180° each) that are connected by planes (Figure 3). The distance between
116 the two cone axes, and a global taper angle averaged within the conical sections
117 were used for the parametrization of each taper.

118 Both conical sections were approximated by horizontal roundness and vertical
119 straightness profiles (ASTM F3129-16) fitted onto the 3D data cloud from the tactile
120 measurements. In the transverse direction, the roundness profiles were made
121 available by fitting circles to the left and right conical sections at every height level
122 (least squares fits; height resolution of 0.02 mm). By equalizing the radii between the
123 two conical sections, the location of the adjusted reference systems of left and right
124 conical section were iteratively computed. This computation yielded the distance of
125 the two conical axes (d). The global orientation was determined via slopes that were
126 fitted around the taper circumference of the two conical sections (500 equally
127 spaced slopes per side). By iteratively reducing the opposing angles, the reference
128 system was aligned. The pristine taper geometries were recovered from the results
129 of tactile measurements by the interpolation between the two non-contact bands

130 (male tapers only). The root mean-square errors indicated local deviations from one-
131 dimensional profile (e.g., by wear). Dependent on the wear extent, 50 to 70% of the
132 best slopes and semi-circles were used for the reconstruction of the taper axes. The
133 inclination of the local slopes from the conical sections yielded local taper angles,
134 hereafter denoted as α_i . The local variations from the connecting planes were not
135 further quantified. The spread of the local taper angles ($\Delta\alpha$) around the
136 circumference of the male and female tapers was recorded.

137 Apart from the distance between the axes of the conical sections, a global taper
138 angle $\bar{\alpha}$ was computed by averaging the available local taper angles of both conical
139 sections.

140 A pilot study of three randomly selected explants revealed the repeatability of the
141 method, for sampling distances of 0.1 and 0.5 mm. Within 10 iterations, the
142 alignment residuals fell below an accuracy threshold ($0^{\circ}0'18''$ for orientations;
143 $0.01 \mu\text{m}$ for offsets). Female taper geometries were reproduced for the coarser
144 $0.5 \text{ mm} \times 0.5 \text{ mm}$ grid (test–retest error of $\bar{\alpha} = 1'6'' \pm 0'18''$, $d = 2.5 \pm 1 \mu\text{m}$). The
145 male tapers exhibited higher wear; consequently, they required sufficient
146 measurement points within the non-contact bands. Thus, a narrow measurement
147 sampling distance of 0,1 mm was used (reproducible test–retest error $\bar{\alpha} = 0'6$
148 $'' \pm 0'12''$, $d = 0.7 \pm 1 \mu\text{m}$).

149 The angular mismatch (A) and the mismatch of the distances of the conical axes (D)
150 between male and female tapers were determined by calculating the difference of
151 their respective values (Equations 1 and 2).

$$A = \bar{\alpha}_{male} - \bar{\alpha}_{female} \quad (1)$$

$$D = d_{male} - d_{female} \quad (2)$$

154 To create the control group, new implants were randomly combined for all
155 permutations (n = 8) to obtain corresponding values.

156 **Taper engagement model:** Based on the estimation of the original taper geometry,
157 a trigonometric-taper engagement model was created. It was assumed that the
158 materials of the tapers elastically deformed within the contact interface, and that
159 the computed clearances dominated the contact stress at the taper interface. The
160 theoretical contact mechanics of the analyzed taper design can thus be categorized
161 according to the taper clearance parameters (Figure 4): The angular mismatch (A)
162 describes the pre-stress distribution in the longitudinal direction (throat contact vs.
163 mouth contact, as defined in the ASTM F3129-16). The axes mismatch (D) describes
164 its characteristics in the transverse direction (apex contact vs. flat contact). The initial
165 gap dimensions were estimated for different seating depths (S) through
166 trigonometric relationships of the determined taper geometries. Negligible
167 deformation of the components at the non-contact regions was assumed. However,
168 it has to be mentioned that incongruent taper surfaces subjected to high bending
169 loads may cause the male and female taper components to be vulnerable to canting.
170 This would result in a pre-stress distribution different from the one predicted via the
171 taper geometries alone (Figure 4). A large degree of tilting might even overcome
172 angular clearances and may lead to a diagonally pre-stress orientation with an even
173 higher stress concentration.

174 **Taper wear analysis:** Assuming that wear is related to the mechanical contact
175 situation, the taper clearances will be replicated in the typical wear pattern. In
176 addition to tactile taper wear analyses that were previously conducted for the cohort
177 [18], the wear patterns of the neck-piece tapers in proximity of the original surface
178 patches were analyzed via microscopic techniques (Figure 1).

179 Infinite focus microscopy (Alicona InfiniteFocus, Alicona, Austria) was employed for
180 the quantification of the topographies around the high-wear regions near the medial
181 apexes, proximally to the retrieved tapers (Figure 1; $\times 10$ magnification, lateral
182 resolution of $2\ \mu\text{m}$, and vertical resolution of $0.5\ \mu\text{m}$). The surface heights of the local
183 patches within the high-wear regions were quantified by leveling them to heights of
184 adjacent, proximal non-contact areas. The patch dimensions, texture quality, and
185 deposits were recorded and its positions were determined by mapping the optical
186 images to wear patterns from the global tactile method (Figure 1).

187 One neck piece with a highly developed wear pattern (Figure 1; Patient 4 (Table 1),
188 material loss of $5.29\ \text{mm}^3$; [18]) was available for destructive testing. It was selected
189 for advanced electron microscopy (scanning electron microscopy (SEM), Zeiss Supra
190 55 VP, Carl Zeiss AG, Germany; transmission electron microscopy (TEM), FEI Tecnai
191 F20 FEG-TEM/Oxford Instruments X-Max SDD–EDX detector).

192 A focused ion beam (FIB) system (FEI Nova 200 NanoLab dual beam SEM/FIB; the
193 method has been described in past research works [44]) was used for the
194 determination of the material characteristics from differently worn locations within
195 the taper contact regions (sites I–III, Figure 5). For the purposes of comparison, a

196 proximal non-contact location was additionally analyzed (site IV). At one site, the
197 element composition throughout an interfacial layer was recorded (site II).

198 The geometrical taper parameters were statistically analyzed; the analysis was
199 conducted using the one-way analysis of variances technique and the Mann–
200 Whitney U-test (IBM Corp., SPSS Statistics, Armonk, New York, USA). The probability
201 of a Type I error was set to 5%.

202

203 **RESULTS**

204 **Estimated original taper geometry and location of taper engagement:** The global
205 taper angles were similar among retrievals and new implants (differences < 1°; Table
206 2). The retrieved female tapers presented the highest variation in global taper
207 angles. The spread of the local taper angles around the taper circumference was
208 higher for female than for male tapers ($\Delta\alpha_{\text{female}} = 03'50'' \pm 01'00''$, $\Delta\alpha_{\text{male}} =$
209 $02'10'' \pm 01'10''$). Within the cohort of the new implants, the fluctuations of the local
210 taper angle of the male tapers exhibited small spreads ($\Delta\alpha_{\text{male}} = 01'00''$), whereas the
211 new female tapers were the least uniform ($\Delta\alpha_{\text{female}} = 05'00''$).

212 The angular mismatches (A) were always negative ($A_{\text{retrieved}} = -03'20'' \pm 02'20''$,
213 $n = 25$; $A_{\text{new}} = -03'00'' \pm 00'10''$; randomly combined, $n = 8$), thus resulting in first
214 contact in the throat (Figure 4, right). The mismatch of the distance between the
215 conical axes was always negative ($D_{\text{retrieved}} = -21.5 \pm 10.3 \mu\text{m}$; $D_{\text{new}} = 16.1 \pm 5.0 \mu\text{m}$),
216 thus resulting in taper engagement at their apices (Figure 4, left). Between the new
217 and the retrieved components, no significant differences were found in the taper
218 angle mismatch ($p = 0.27$) or the axes mismatch ($p = 0.07$). Assuming elastic
219 deformation only, the trigonometric model showed that increasing seating depth
220 will result in a growth of the contact areas from the throat to the mouth of the
221 tapers, beginning at the apices of the conical sections (first contact). The proximal
222 gaps at the flat sides close only when the apices are fully in contact (Table 3).

223 **Taper wear:** The infinite focus microscopy from the medial apices of the male tapers
224 revealed a high-gradient wear pattern at the proximal taper opening (Figure 1).
225 Surrounded by worn areas, characteristic patches with preserved original texture

226 were discovered (Figure 5). These patches appeared to have remained unchanged
227 from the wear process. Their maximal surface heights deviated less than $\pm 5 \mu\text{m}$ from
228 those of the proximal non-contact regions. Although a few patches were only
229 partially exposed to the worn surrounding ($n = 5$; material loss $< 2.3 \text{ mm}^3$) or multiple
230 patches appeared ($n = 3$), most explants ($n = 18$) presented singular patches that
231 were completely surrounded by deep wear and shiny texture (site III, wear depth
232 $> 40 \mu\text{m}$). These patches all covered the medial apexes of the tapers, and their
233 centers had slightly shifted toward the taper anterior (patch width: $700 \pm 400 \mu\text{m}$;
234 the patches on the left implants shifted clockwise, whereas the right implants shifted
235 anti-clockwise by $140 \pm 90 \mu\text{m}$). Pristine surface texture with horizontal
236 manufacturing lines was identified on proximal regions on the patches (Figure 5,
237 insert; Figure 6). Furthermore, singular deposits were observed in this region. More
238 distally, patches were densely covered by bulk deposit. In these regions, vertical
239 scratches and other marks that were probably caused during disassembly were
240 observed .

241 Subsurface measurements from a location of high-wear depths (site III) and from two
242 locations on the proximal patch (preserved surface or deposit; corresponding sites I
243 or II, respectively) were compared to a non-contact location on the same taper (site
244 IV; Figure 5). For the non-contact location, crystalline layers were observed that
245 transitioned to larger grains as the depths become greater (Figure 7). Deep wear had
246 left behind large undistorted grains at the surface. On the patch, crystalline layers
247 were found of comparable thickness to the non-contact location. Collective grain
248 orientation was observed at the $500 \mu\text{m}$ subsurface zone (Figure 8). The element
249 analysis across the interface between the CoCrMo patch and the deposit revealed

250 attached responsive elements in the ratios of the TMZF alloy [45] onto the CoCrMo
251 bulk neck-piece material [46]. The line scan (100 μm wide) shows how Co and Cr
252 abruptly decline when TMZF elements (Titanium, Molybdenum, Zirconium, iron)
253 become responsive. Cobalt does not fully fade out within the deposit. At the
254 interface, Oxygen was only responsive in 100 nm widths (Figure 9).

255 **DISCUSSION**

256 This paper presents a mechanical model to describe the implant-specific failure
257 modes of bi-modular hip prostheses. The determined *in vivo* contact mechanics,
258 based on the taper angles and axes, could explain the distinct pattern of extensive
259 wear and corrosion that were observed consistently on retrieved implants.

260 **Taper design:** For the analyzed design, geometrical mismatches predict taper
261 engagement at the taper throat (distal) at the apexes of the conical sections (medial-
262 lateral). Gaps on the flat sides persist on the μm -scale, if the taper is not seated to
263 full contact (Table 3). The designed axes mismatch (D) predicts considerable
264 engagement of the conical apexes. If the local straining of the taper directly
265 translates into contact stress, the taper assembly will generate permanent
266 concentrations of normal contact stress at the apexes of the conical taper sections
267 (Figure 10a). The normal contact stress diminishes quickly to the anterior and
268 posterior flat sides.

269 The distances of the axes among analyzed male and female tapers (d) varied in the
270 order of magnitude of axes mismatches of their corresponding taper junctions (D;
271 μm scale). Local taper angles (α_i) spread in the order of magnitude of angular
272 mismatches (A) of their corresponding taper junctions. Thus, variations in taper

273 geometry between pristine implants could largely influence the distribution of
274 contact stress, hence adding up to the individual risk for local taper corrosion.

275 *In vivo* loads applied within the longitudinal plane containing both taper apices are
276 transmitted effectively, as the loading coincides with the designed high pre-stress at
277 the apices of the conical sections (Figure 10b). Loads with an offset to this symmetry
278 plane create oblique bending, which is not as efficiently transmitted (Figure 10c). If
279 the taper had not been seated to full contact, it is possible that the elastic
280 deformation of the implant components under cyclic loading would have caused the
281 continuous closing and opening of the gaps and cavities; this could have fostered
282 fluid ingress. In contrast to a circular taper, which does not have a preferred
283 directionality, the taper orientation (e.g., owing to stem anteversion or retroversion)
284 could thus have influenced the extent of micromotions and the development of wear
285 at a distance to the apices (Figure 5).

286 **Explant analyses:** At the time of explantation, the retrieved neck pieces indicated
287 dominant wear from the conical sections, which was arranged diagonally across the
288 taper contact region [18]. Subsurface microscopy offered valuable insight to the
289 dominant degradation mechanisms that were responsible for the local wear depths
290 (Figure 5). The non-contact site revealed a nano-crystalline layer (Figure 7), which is
291 typical for mechanically machined CoCrMo surfaces [46,47]. In proximity to the patch
292 (site III), the microstructure near to the surface coincided with the bulk
293 microstructure, with large grains reaching the surface. This region of high wear
294 appeared as electro-polished, which suggested a corrosion-dominated degradation

295 process; mechanical wear components would have triggered the reformation of an
296 outermost nano-crystalline zone [46,47].

297 The sample from the patch at the medial taper apex revealed microstructures with
298 high twinning densities and refined grains toward the surface. A nano-crystalline
299 layer directly beneath the surfaces is comparable in thickness with those observed
300 within the non-contact region (Figure 8). Furthermore, the preserved original
301 texture, including the machining marks, can be observed (Figure 5, Figure 6), and the
302 top of the patches are of the same height as the non-contact location. However, at
303 the locations of the preserved original texture on the patch (site I, Figure 6), the grain
304 directionality within the subsurface layers suggests plastic shearing below the
305 crystalline layers (Figure 8). The plasticity was probably induced by high shear
306 stresses [46], which required high normal stresses or adhesive forces at the taper
307 interface. These conditions could prevent fretting corrosion by inhibiting relative
308 motion and access of a medium.

309 Deposit was apparent on medial patch regions (site I). Subsurface measurements
310 identified TMZF bulk constituents that had attached onto male CoCrMo bulk (Figure
311 9). This may be explained by high adhesive forces between the CoCrMo and the
312 TMZF, which locally exceeded the disassembly shear and the ultimate strength of the
313 female taper TMZF material. Cobalt is expectedly soluble in this electrochemical
314 context [44]. It was responsive throughout the deposit, thus indicating microscopic
315 damages of the TMZF side, which are not further addressed here. The Oxygen
316 content was only responsive in a 100 nm band at the interface (Figure 9). This
317 suggests a frictional welding phenomenon between the CoCrMo and the TMZF. The

318 role of the oxide and the required permanent loading conditions are yet unclear. It
319 is suspected that this phenomenon is responsible for the local protection against
320 wear, and may depend on the specific material combination [48].

321 **Design performance *in vivo*:** The position of no-wear patches on the male taper
322 reflected the location of the engagement of tapers before the *in vivo* wear process
323 had begun. Their position at the taper apexes corresponded to regions of estimated
324 pre-stress concentrations, which had been determined from the negative axes
325 mismatch of the taper design (Figure 10a). The limited patch widths and the high-
326 wear gradients towards the anterior and posterior (Figure 5) reflect the
327 corresponding stress drops at the incongruent apexes. The posterior shifts of the
328 medial no-wear patches reflected the direction of the elastic deformation of the
329 male taper in the direction of the dominant *in vivo* load, which slightly shifted toward
330 the posterior. Interestingly, no-wear patches medially were consistently observed at
331 the proximal taper mouth, which indicates that the retrievals permanently overcame
332 their angular clearance. Instead of the engaging at the throat (Figure 10a), the tapers
333 had changed the permanent pre-stress to a diagonal engagement (Figure 10b). It was
334 thus suggested that the retrieved taper had seated into a canted position prior to
335 being worn. This indicated that the fixation had been insufficient for a stable transfer
336 of loads with the predicted engagement strategy (Figure 4). The permanent tilting of
337 the taper might impose additional incongruences to the taper contact surfaces that
338 potentially gave rise to local-wear phenomena and the observed wear transitions.
339 Once initiated, these “spacers” prevented a more homogenous contact
340 configuration with smaller crevices (Figure 10d). An increased fretting motion
341 toggling around these fulcrum points was suggested. This may explain the

342 harshening of the environment with excessive galvanic corrosion, which was
343 observed. The engagement features and their robustness against the canting of male
344 and female taper components may thus be considered an important design feature
345 for the prevention of mechanically assisted corrosion.

346 Reconstructing pristine taper geometries from the data acquired via tactile
347 measurements of worn implants had certain limitations. As female tapers may
348 exhibit contact over their entire surface, it was impossible to completely exclude *in*
349 *vivo* changes. Nonetheless, the determination of initial taper geometries appeared
350 successful, as the control group of new tapers did not show significantly different
351 taper angles and axes distances; the test–retest errors were comparable for male
352 and female components, despite the observed differences in damage [19]. It could
353 not be determined why new stem tapers presented the highest fluctuations in local
354 taper angles, owing to the limited group of new stems of this design. However,
355 regardless of whether tapers were new or explanted, consistent mismatches (A ,
356 $D < 0$) allowed the prediction of a global contact configuration for the analyzed
357 design.

358 Taper geometries were estimated through first-order approximation only, wherein
359 the surface roughness, the differences in elastic properties, and the textures were
360 not included. The qualitative stress estimates also neglected 3D effects of lateral
361 contraction and contact boundaries. The subsurface analysis was limited to singular
362 sites from one neck piece that was available for destructive testing, which only
363 served as proof of existence of different wear modes. Combined with surface
364 patterns recorded from all neck pieces, the findings were extrapolated to the cohort.

365 The occurrence of wear phenomena on the taper could be explained by the
366 mechanical conditions predicted at the taper interface; however, the initiation of
367 taper corrosion depended on more factors, which were mostly outside the
368 mechanistic scope of the analysis of the explants. Clinical factors, such as initially low
369 pH in the patient, might have triggered an onset of mechanically assisted corrosion.
370 Such data were unavailable in the explants-based analysis. Moreover, clinical and
371 ethical restrictions impede the availability of control groups with implants that differ
372 by selected design parameters. With regard to design improvements, it is thus
373 difficult to quantify the impact of each of the discussed parameters on the
374 development of tribocorrosion *in vivo*.

375 Consequently, not every implant of modular prosthesis should be considered as
376 being at a definite risk. Nevertheless, they cannot be considered to be definitely safe,
377 as the onset of the wear mechanism is unclear. However, the awareness of this
378 problem can be clinically useful; it justifies early diagnosis measures for taper wear
379 (magnetic resonance imaging (MRI) and screening of Co and Cr levels) in order to
380 prevent clinical disasters.

381 **CONCLUSIONS**

382 The analyzed taper design engages at the taper apexes, leaving low contact stresses
383 or gaps on the flat sides. The hereby-introduced permanent stress concentrations at
384 the taper apexes are additionally influenced by tolerated manufacturing variances.
385 These factors might contribute to the sensitivity of the design to canting. The
386 engagement strategy appears to be fundamental to local wear phenomena; it
387 facilitated the typical wear transitions in the taper contact zones that formed the

388 characteristic pattern. In regions of permanently high interfacial stress, the material
389 coupling (CoCrMo to TMZF) produced characteristic no-wear patches. The presented
390 taper mechanics may assist in the development of engagement strategies of future
391 taper designs in order to prevent excessive wear and subsequent clinical failure.

392

393 CONFLICT OF INTEREST

394 The corresponding author has no conflicting interests. The co-authors receive
395 research grants from DePuy Synthes, CeramTec, and Peter Brehm. The co-authors
396 are consultants for DePuy and Zimmer Inc. in projects not related to this study.

397 FUNDING

398 The research received funding from European Union's Seventh Framework Program
399 (FP7/2007-2013) grant agreement GA-310477.

400 ETHICAL APPROVAL

401 Not required.

402 ACKNOWLEDGEMENTS

403 The authors thank Calvin Warriner for providing the explants.

404

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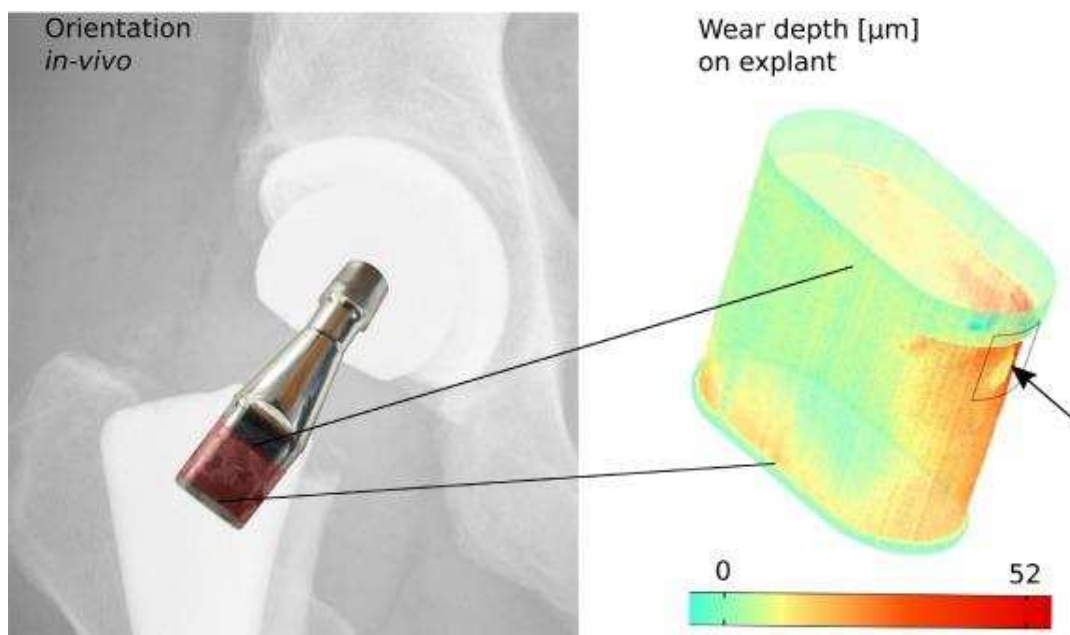
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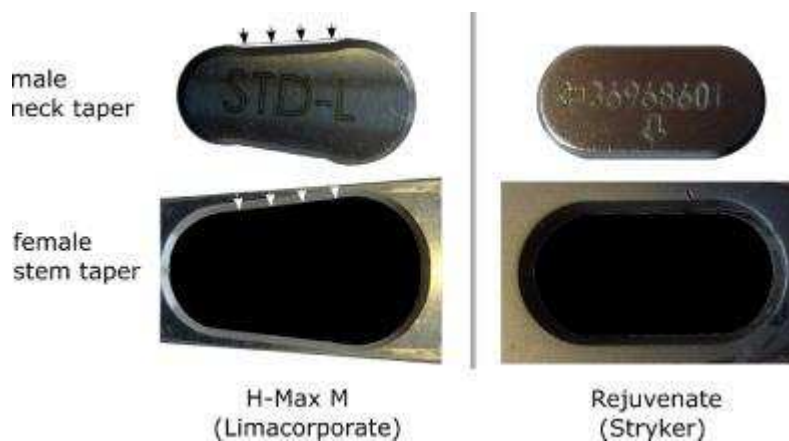
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559 LEGENDS



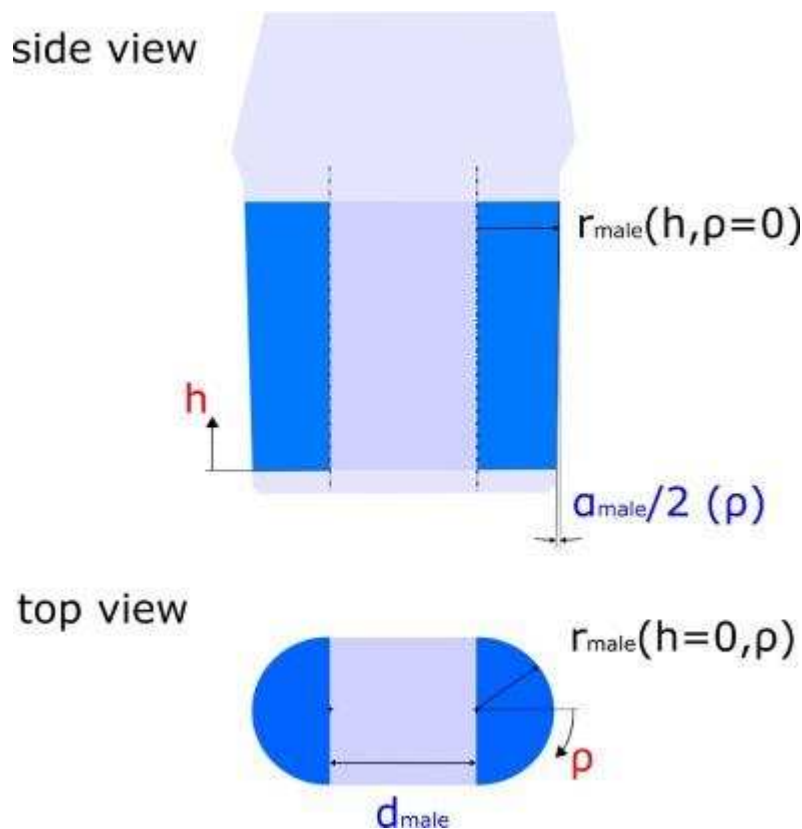
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561 *Figure 1: In vivo orientation of wear pattern for a male non-circular neck taper, 26*
 562 *months in situ. Surface deviations from the estimated pristine geometry*
 563 *are color-coded from green (no deviation) to red (wear). Wear in highly*
 564 *loaded regions exhibited a characteristic pattern, developing around the*
 565 *confined patches at the apex of the conical sections (most prominent*
 566 *medially at the proximal taper end (arrow), but and also diagonally*
 567 *across on the lateral apex).*



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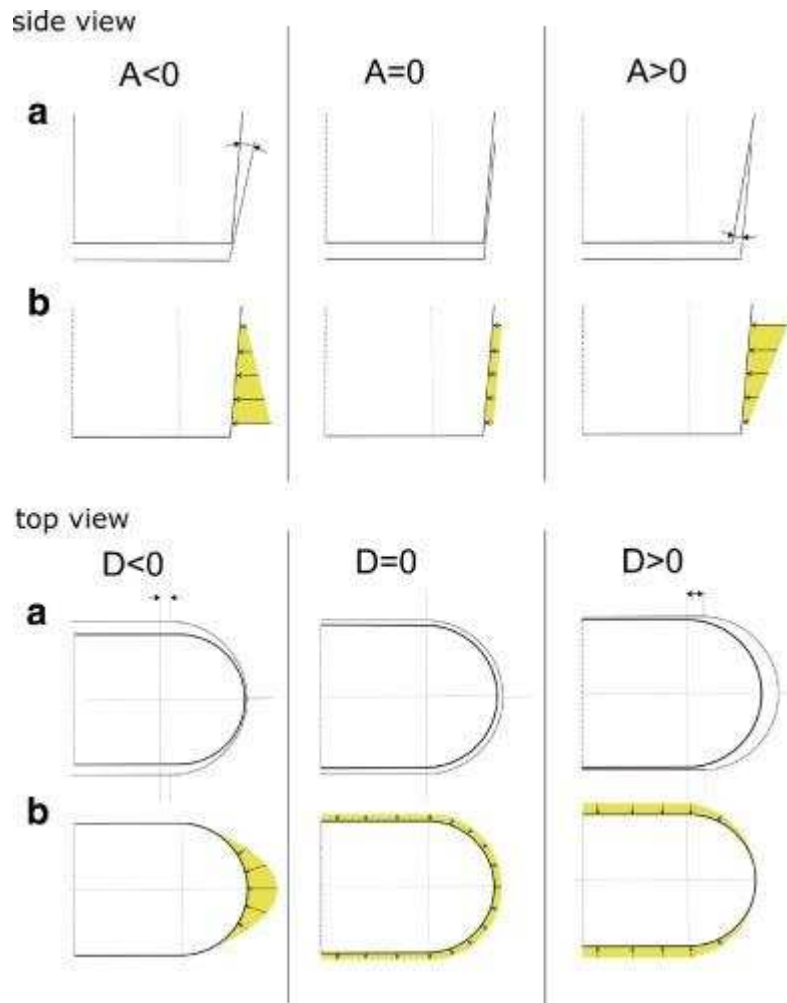
569 *Figure 2: Top view on two non-circular taper designs with different contact*
 570 *strategies. **Left:** Undercuts on the flat sides (arrows) macroscopically*
 571 *confines contact regions to conical taper sections (H-Max M,*
 572 *Limacorporate, Villanova di San Daniele (UD), Italy). **Right:** Specific*
 573 *contact regions cannot be identified on this scale, but will be determined*
 574 *by the taper congruency (Rejuvenate, Stryker Orthopedics, Mahwah,*
 575 *New Jersey).*



576

577 *Figure 3: The parametrization of the bi-modular taper (top: side view; bottom: top*
 578 *view). Two 180° conical sections (height h , radius r , circumferential angle*
 579 *ρ) connected by planes with length d , which corresponds to the distance*
 580 *between the two cone axes. The same parameters are used to describe*
 581 *the male and female tapers. Parameters are computed from averaging*

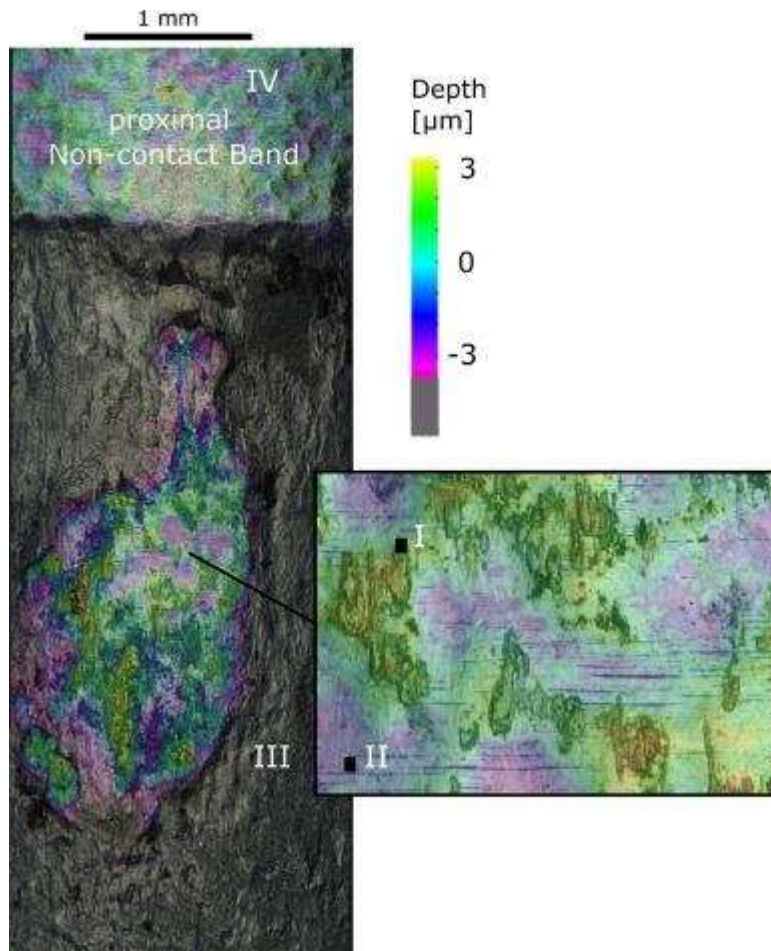
582 vertical straightness and horizontal roundness fits on both conical
 583 sections (blue; ASTM F3129-16). The connecting planes were not further
 584 quantified in geometry.



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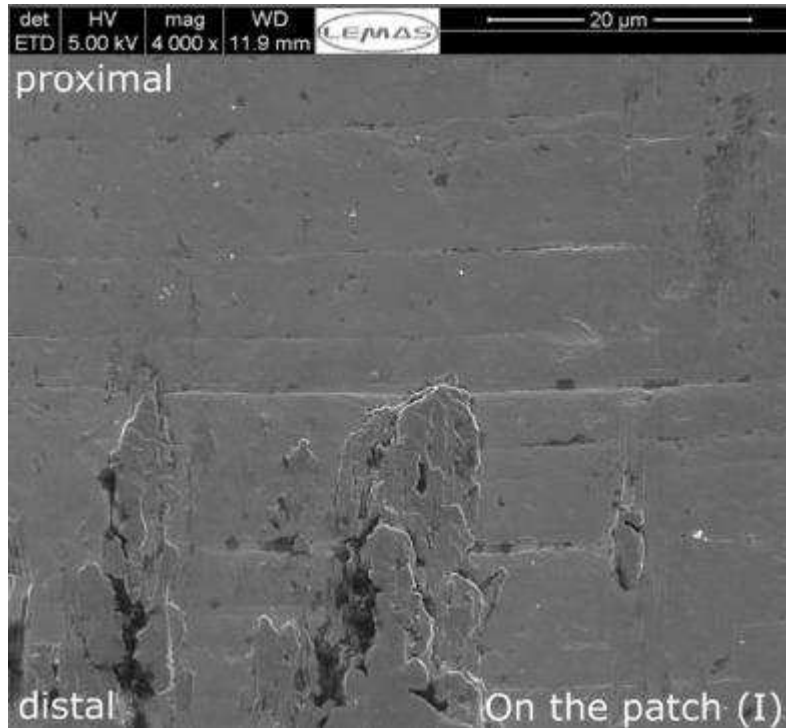
586 *Figure 4: Possible configurations of the engagement and the pre-stress resulting*
 587 *from incongruent non-circular taper geometries. Just one conical apex is*
 588 *shown, since the one on the opposite side behaves similarly. **Top:** The side*
 589 *view reveals the taper angle mismatch $A < 0$ (throat contact), $A = 0$ (line*
 590 *contact), and $A > 0$ (mouth contact). **Bottom:** The top view reveals the*
 591 *mismatch of conical axes distances $D < 0$ (apex contact), $D = 0$*
 592 *(circumferential contact) and $D > 0$ (flat contact). **a)** The engagement of*

593 *the idealized male and female geometry prior to the initial contact b)*
 594 *Simplistic estimates for the pre-stress acting on the male taper if pushed*
 595 *into the female taper.*



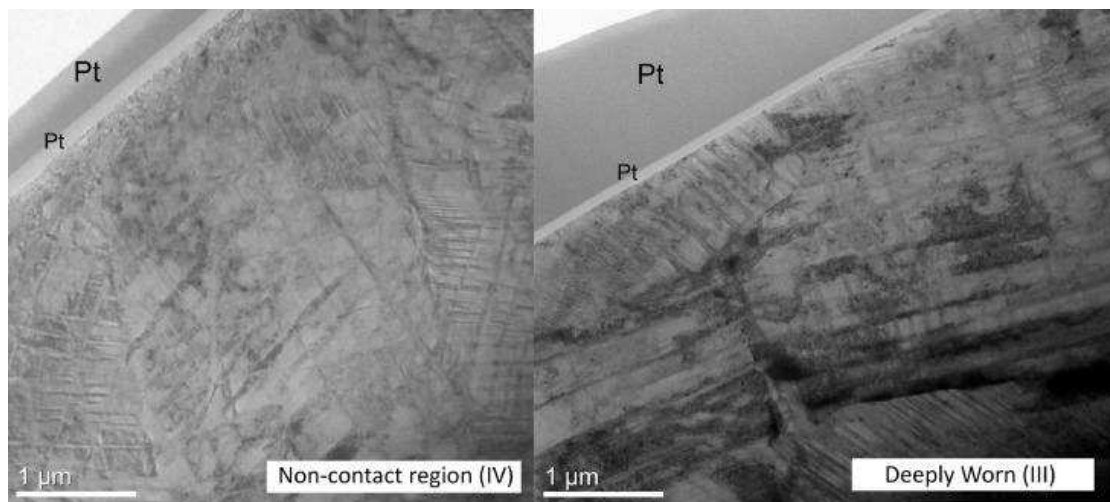
596

597 *Figure 5: Material loss around a characteristic patch produced high gradient wear*
 598 *patterns at the proximal tapers' opening. The patches at original surface*
 599 *height were identified at the medial apexes (reference: proximal non-*
 600 *contact band). Distinct locations on one taper were selected, in which*
 601 *site-specific subsurface measurements were performed (sites I & II on the*
 602 *patch, site III at high wear depths, site IV on the non-contact band).*



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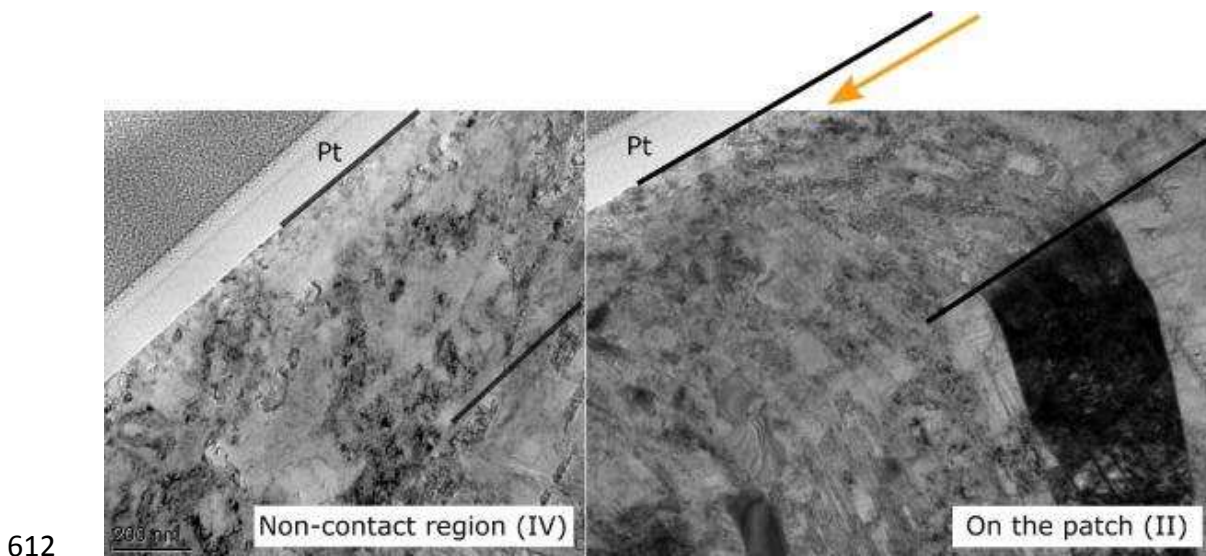
604 *Figure 6: SEM on site I (Figure 5) reveals the original surface texture with intact*
 605 *machining marks and singular deposit.*



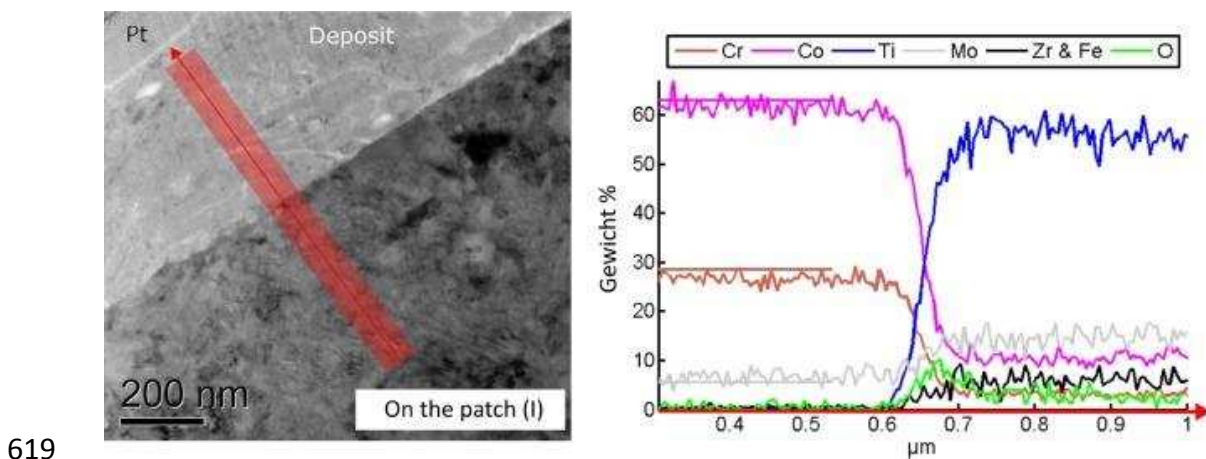
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607 *Figure 7: TEM bright field images showing the microstructure underneath the*
 608 *sputter layer of Platinum (Pt). Left: Non-contact site IV. Right: Site III of*
 609 *high wear depths in proximity to the medial taper apex. Large grains*

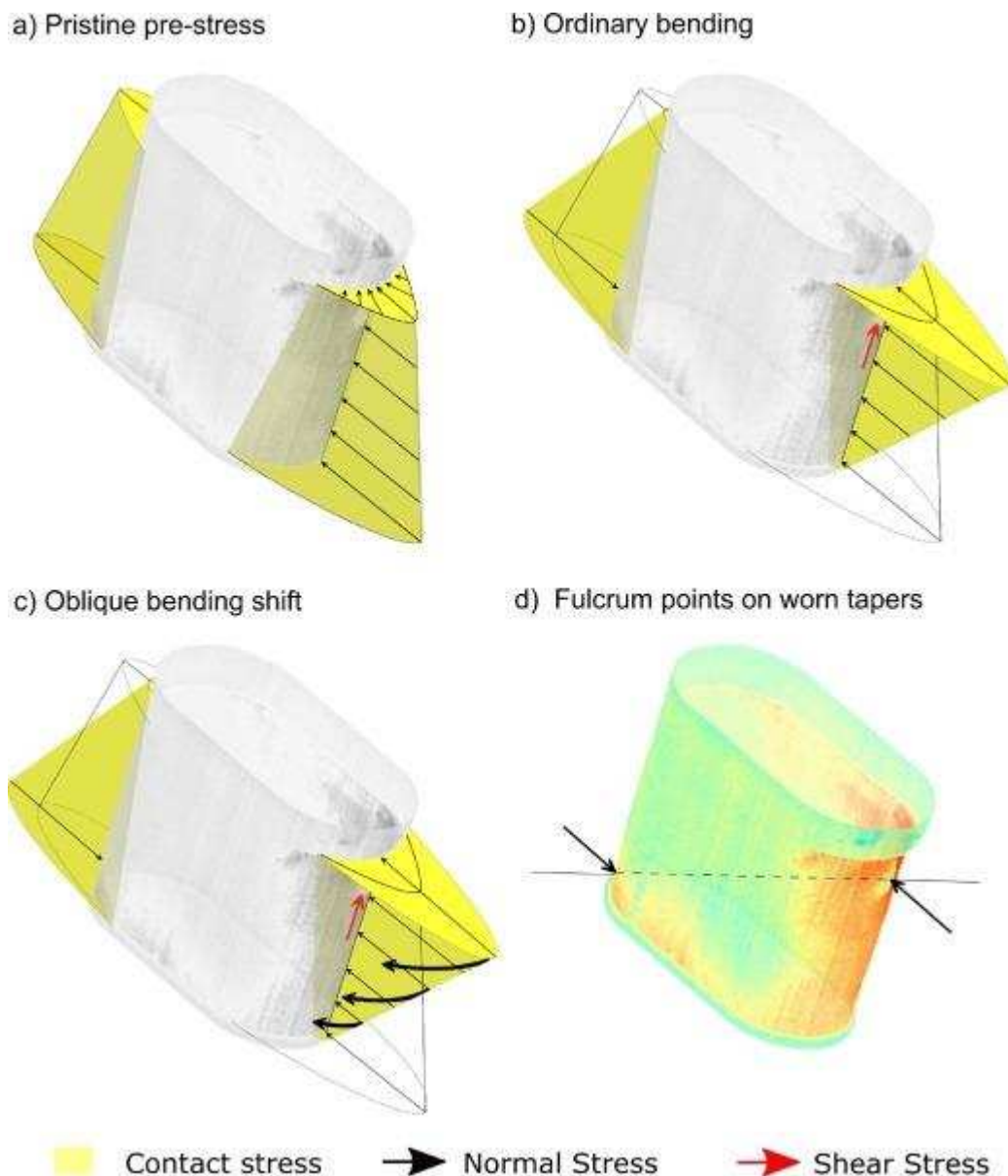
610 reaching the surface indicate the dominance of corrosive wear in this
 611 region.



613 *Figure 8: TEM bright field images showing the microstructure underneath the*
 614 *sputter layer of Platinum (Pt). **Left:** Non-contact site IV. **Right:** Site II on*
 615 *the proximal patch. Black lines were added to indicate the crystalline*
 616 *surface layers. No signs of a corrosive attack to the neck piece material*
 617 *were observed. A collective grain shearing within the uppermost*
 618 *subsurface layers was observed (indicated by an arrow).*



620 *Figure 9: TEM bright field image at site I shows the deposit onto the neck piece*
 621 *material (left), and the element composition scanned across the deposit*
 622 *interface (100 nm wide; right): A transition from CoCr bulk neck alloy*
 623 *(reference lines according to [46]), separated by an oxygen responsive*
 624 *layer (~100 nm wide) to the deposit containing TMZF bulk alloy elements*
 625 *were recorded. While the Molybdenum content increases to above 10%*
 626 *according to the reported TMZF composition [45], the appearance of Co*
 627 *and Cr content within the deposit remains unclear.*



629 *Figure 10: Prediction of the configuration of normal contact stress (yellow) on a*
630 *male taper of the analyzed design, from pristine to worn. a) Initial taper*
631 *pre-stress in a potential, full apex seating position. Normal stresses*
632 *(yellow) are expected highest at the apexes, deep inside the taper*
633 *throat (Figure 3). b) An in vivo load within the longitudinal plane*
634 *connecting the taper's apexes produces bending in the direction of the*
635 *taper symmetry plane. In this case, the highest stress will remain at the*
636 *apexes. The elastic deformation of the components may result in a*
637 *temporary shift to diagonally distributed contact stresses. c) Loads with*
638 *an offset to the taper's symmetry plane create an oblique bending. In*
639 *this case, the highest stress at the taper interface may be tilted from the*
640 *location of maximal pre-stress available at the apexes. Anterior and*
641 *posterior flat taper sides may also experience contact loads. At a*
642 *distance from the apexes, lower pre-stress makes the tapers prone to*
643 *relative motion. d) Once wear has developed in a diagonal pattern,*
644 *engaging patches at the conical sections are suspected to act as fulcrum*
645 *points. Relative motion within the taper is then dominated by a single*
646 *axis toggling between them.*

647

Patient	Sex	Implatation side	Age at implantation	Weight	Implant geometry		Time in-situ	Material loss
[#]	M:male F:female	L:left, R:right	[years]	[kg]	Total offset to stem taper [mm]	R: Retroversion A: Anteversion	[months]	[mm ³]
1	F	L	58	74.8	42.6	R	9.1	2.15
2	M	L	44	131.5	44.1	A	36.2	7.57
3	M	R	71	104.3	40.4	A	14.6	0.96
4	M	L	60	78.5	42.6	A	29.3	5.29
5	M	L	61	86.2	42.6	A	10.1	2.13
6	M	R	81	102.1	42.8	A	5.6	3.15
7	M	L	47	117.5	41.3	R	7.2	1.49
8	F	R	65	72.6	45.8	R	7.2	1.67
9	M	L	64	72.6	43.8	R	18.3	2.04
		L	52	90.7	49.7	R	38.1	n.a.*
10	M	R	52	90.7	53.7	R	35.7	2.34
		R	38	86.2	40.1	R	6.2	1.66
11	F	R	66	68.0	42.3	R	18.2	3.58
12	F	L	60	74.8	37.6	A	15.2	4.64
13	F	R	74	99.8	45.1	R	24.0	6.31
14	M	R	65	115.7	45.9	R	32.6	6.64
15	M	R	71	69.9	40.8	R	37.3	n.a. ^a
16	F	L	66	47.2	43.3	A	20.2	0.55
17	F	L	76	61.2	40.6	R	20.3	3.86
		R	77	61.2	41.7	R	21.2	4.58
18	M	n.a.	65	86.2	43.5	n.a.	14.2	4.31
		n.a.	65	86.2	41.7	n.a.	14.2	3.02
19	F	L	47	102.1	37.7	R	14.8	2.16
20	F	R	84	45.4	54.1	A	2.9	1.79
21	F	R	75	71.7	42.6	R	21.4	3.09
22	M	L	56	70.3	50.7	R	22.0	4.28
		R	56	70.3	42.8	A	21.5	4.50

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Excluded from further analyses due to mechanical damage on non-contact reference bands.

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651

652

Table 1. Patient data and macroscopic implant information of the analyzed cohort. Details

653

on the wear status had been reported elsewhere [18].

654

Component	Condition	Sample size	Taper angle	Taper axis distance [μm]
Male taper (neck piece)	Retrieved	27	$02^{\circ}58'40'' \pm 00'50''$	8250 ± 10
	New	4	$02^{\circ}59'00'' \pm 00'40''$	8251 ± 5
Female taper (stem)	Retrieved	27	$03^{\circ}02'20'' \pm 02'20''$	8228 ± 10
	New	2	$03^{\circ}01'30'' \pm 00'10''$	8234 ± 3

655

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Table 2. Global taper angle and taper conical axes distance for cohorts of “new” and “retrieved” tapers (mean and standard deviations).

657

658

	<i>Seating depths</i>				
	0 μm	100 μm	200 μm	300 μm	400 μm
<i>Proximal gap at the apex of the conical sides</i>	5.2 μm	2.6 μm	0 μm	0 μm	0 μm
<i>Proximal gap at the flat sides</i>	10.2 μm	7.6 μm	4.9 μm	2.4 μm	0 μm

659

660

Table 3. Proximal gaps of the unloaded tapers are computed from trigonometrical relations for a mean, idealized taper geometry (α^- , d , Table 1). Gap sizes are given for a range of seating depths from first contact ($S = 0 \mu\text{m}$) to full taper contact (theoretical no gap situation, $S = 400 \mu\text{m}$).

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