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Cementless total hip arthroplasty in patients with rheumatoid arthritis using a tapered designed titanium hip stem minimum: 10-year results

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1 **Cementless Total Hip Arthroplasty in Patients with Rheumatoid**
2 **Arthritis using a Tapered Designed Titanium Hip Stem**
3 Minimum 10-Year Results
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51 **Abstract**

52 The results of a cementless tapered designed femoral stem was studied at a minimum 10
53 year follow-up in a non-selected, consecutive group of 27 patients (39 hips) with
54 rheumatoid arthritis. Clinical and radiological analyses were performed in 27 hips, 17
55 patients (mean age at surgery 45 years) after a mean of 12 years. Using the Harris Hip
56 Score, 14 hips were rated as excellent; 9, good; 2, fair; and 2, poor. No stem had to be
57 revised for aseptic loosening. Proximal stress shielding was observed in 26 hips (96%),
58 heterotopic ossification was present in 11 hips (41%). 6 hips required revision of the
59 acetabular component. With uncemented tapered femoral fixation excellent 12 year
60 results are achieved in patients with rheumatoid arthritis.

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74 **Introduction**

75 The total number of rheumatoid arthritis (RA) patients in total hip arthroplasty (THA)
76 databases ranges from 3% (61,568 THA patients) in a United States cohort to 6%
77 (93,852 THA patients) in the Swedish National Registry [1,2]. A multidisciplinary
78 approach is required for the management of these patients, with surgical procedures
79 preferably undertaken by orthopaedic surgeons who are familiar with the specific
80 problems of RA patients. While THA in patients with RA is known to greatly improve
81 functional ability and thus self-support of the patient [3], controversy remains among
82 orthopaedic surgeons concerning the optimal fixation of the implant [4-19].

83 Cemented THA has traditionally been considered the gold standard for the treatment of
84 patients with RA as poor bone stock caused by generalized disease activity, immobility
85 and steroid therapy was thought to undermine primary stability and bony ingrowth of
86 cementless implants [4,6].

87 Several studies have shown higher rates of loosening of cemented femoral components
88 in patients with RA compared with cemented THA in patients with osteoarthritis (OA)
89 [5,15]. The Finish arthroplasty register found that the risk of stem revision due to
90 aseptic loosening for patients with RA under the age of 55 (2557 primary THA) was
91 higher with cemented stems than with proximally porous coated uncemented stems [7].
92 Femoral failure rates of 5.3% and 8% after an average follow-up of 7.4 to 4.3 years
93 have been reported with cemented THA for patients with RA [16,17].

94 3 long-term follow-up series with a single uncemented contemporary femoral
95 component in patients with RA have been published. The results have been promising
96 with revision rates between 0% and 1% after a mean follow-up of 8 to 10 years
97 [9,10,14].

98 We have retrospectively assessed the long-term clinical and radiological results (mean
99 time of follow-up: 12,2 years; minimum 10 years) of a non-selected, consecutive series
100 for patients with RA who all underwent cementless THA with the femoral component
101 cementless system (CLS, Sulzer Medica, CH; now: Zimmer, Warsaw, Indiana, USA), in
102 combination with one of five different acetabular components.

103

104 **Patients and Methods**

105 We performed 39 consecutive, unselected primary THA in patients with adult-onset RA
106 using the CLS stem on 27 patients. All patients fulfilled the diagnostic criteria of the
107 American College of Rheumatology. For the follow-up analysis after a mean time of
108 12,2 years (minimum 10 years) there were 11 women (18 hips) and 6 men (9 hips) with
109 an average age of 45,3 years (26 to 56) at time of surgery. 5 patients (5 hips) were lost
110 to follow-up and 5 patients (7 hips) had died prior to follow-up investigation. Prior to
111 surgery 5 patients (8 hips) had been taking oral corticosteroids only, 3 patients (6 hips)
112 took oral steroids and at least one disease modifying rheumatic drug such as
113 methotrexate, 9 patients (12 hips) had no medication at time of the index operation. No
114 patient had received bone modulating drugs during the entire period of follow-up. There
115 were 4 patients (4 hips) rated as Charnely A, 1 patient (2 hips) as Charnely B and 12
116 patients (21 hips) as Charnely C [20].

117 The CLS femoral component is a collarless, three-dimensional tapered wedged made of
118 titanium alloy (Ti₆Al₇Nb). Ribs in the proximal part of the prosthesis are designed to
119 minimize rotational migration. The distal part is intentionally made small to avoid
120 filling of the intramedullary canal in the diaphysis in order to encourage proximal load
121 transfer to the femur. The surface was rough blasted and had no porous coating [21]. All
122 procedures were performed in staged settings by three different senior surgeon in a

123 closed air enclosure with laminar air flow. All patients were placed in supine position
124 and operated on with a direct transgluteal lateral Bauer approach [22]. The largest stem
125 that provided a stable press-fit was inserted after preparation of the femoral canal with
126 chipped-tooth broaches.

127 Depending on availability and the surgeons preference one of four different cementless
128 press-fit acetabular components were used. There were 7 Fitek cups with a metasul
129 polyethylen (PE) liner (Zimmer, Warsaw, USA; before: Sulzer Medica, Wintherthur,
130 Switzerland) 6 of which were fitted with screws; 9 hydroxylapatit-coated and 4
131 zirconium-coated Phönix cups (Brehm, Weisendorf, Germany) fitted with PE-liners
132 (Brehm, Weisendorf, Germany) in 11 cases and alumina inlays in 2 cases (BioloX,
133 CermaTec, Plochingen, Germany) ; 1 Plasmacup (PE-inlay) fixed with screws
134 (Aesculap, Tuttlingen, Germany) and 1 Wagner cup (PE-inlay) (Zimmer, Warsaw,
135 USA; before: Sulzer Medica, Wintherthur, Switzerland). 5 acetabular components were
136 cemented: in 3 cases acetabular reconstruction was required and a Ganz reinforcement
137 ring (Zimmer, Warsaw, USA; before: Sulzer Medica, Wintherthur, Switzerland) was
138 implanted in addition to the cemented metasul PE-cup (Zimmer, Warsaw, USA; before:
139 Sulzer Medica, Wintherthur, Switzerland) and in 2 cases cemented PE-cups (Brehm,
140 Wesiendorf, Germany) were used without acetabular reconstruction.

141 The femoral head size was 28 mm in 20 hips and 32 mm in 7 hips, there were 16
142 alumina ceramic (BioloX, CermaTec, Plochingen, Germany) and 11 CoCrMo-alloy
143 (Metasul, Protek GmbH, Munich, Germany) heads. Due to the wide variety of
144 acetabular implants used their performance was not the major target of this
145 investigation.

146 All patients received prophylaxis for heterotopic ossification by oral administration of 3
147 doses of 50mg diclofenac for 2 weeks postoperatively. Routinely patients were given

148 perioperative antibiotics (single shot of 2g Cefazolin i.v.) and thromboembolism
149 prophylaxis with subcutaneous heparin. Postoperatively, touch weight-bearing up to 15
150 kg was allowed for the first 6 weeks, then progressively increased loading to full
151 weight-bearing within the next 2 weeks. At the final follow-up all patients were assessed
152 clinically using the Harris hip score [23]. Preoperative pain, range of motion and
153 function were reconstructed retrospectively by interview and patients charts.

154 Radiographs were evaluated by an independent observer (LAM) who was unaware of
155 the clinical outcome of the surgical procedure. Evaluation of the femoral and acetabular
156 components was performed using published criteria [24]. Radiological “stability” of the
157 femoral component was additionally assessed according to the criteria of Engh et al.
158 [25]. Location of radiolucent lines, osteolysis and cortical hypertrophy were rated
159 according to the Gruen criteria [26]. For evaluation of heterotopic ossification, the
160 Brooker classification was used [27]. Stress shielding was classified as grade I when
161 only resorption of the medial edge of the resection line appeared, grade II meant
162 additional proximal medial bone resorption, while grade III findings extended more
163 distally [28,29].

164

165 **Results**

166 Of the 27 patients (39 hips) in this study, 5 patients (7 hips) had deceased at the time of
167 the follow-up. Intermediate clinical and radiological follow up of 3 patients (5 hips)
168 ranging from 5 to 8 years of the deceased patients showed radiological signs of stable
169 ingrowth of all stems without impending failures. There were 2 patients (2 hips) who
170 had died with their hips intact but no clinical or radiological data beyond the 1-year
171 follow-up at which time the implant was functioning well. 5 patients (5 hips) were lost

172 to follow-up, only a 2 month postoperative clinical and radiological follow-up was
173 available with a well functioning hip (fig.1).

174 Thus, clinical and radiological data were available of 17 patients (27 hips) after a mean
175 of 12,2 years follow-up (minimum 10 years). There were 10 women (18 hips) and 7
176 men (9 hips) with an average age at surgery of 45,3 years (26 to 55). Of the 27 implants
177 directly accounted for, no femoral component was revised and all stems had bony
178 ingrowth. 5 cups (19%) had to be revised due to aseptic loosening, for one additional
179 cup the liner had to be changed due to extensive wear (table 1).

180 The Harris Hip Score (HHS) was not taken preoperatively. Retrospective assessment of
181 patient charts showed marked pain in all patients. Range of hip motion was limited to
182 less than 110° in all cases, only 6 patients (35%) were able to walk without a cane or
183 crutches. At follow-up the average HHS was 86. 14 hips were rated as excellent (52%);
184 9, good (33%); and 4, fair (14%). 25 hips (93%) had total relief from pain in the thigh,
185 groin or buttocks. 2 hips (7%) presented with occasional pain of the buttocks and the
186 and the thigh. A Trendelenburg limp was found in 1 hip (4%) caused by a postoperative
187 partial paralysis of the sciatic nerve after acetabular revision surgery. 13 patients (76%)
188 could walk over 500 meters, 4 patients (24%) walked outdoors under 500 meters. 11
189 patients (65%) needed no assistive devices for walking while 2 patients (12%) used a
190 cane for outdoor walking only, 3 patients (18%) regularly used one cane.

191 No stem had to be revised for aseptic loosening and all stems presented complete bony
192 ingrowth with no signs of definite or probable loosening. No postoperative subsidence
193 was seen. 5 stems were undersized, 4 in slight varus and 2 in minimal valgus position.
194 Proximal stress shielding was observed in all hips. Bone resorption in the proximal
195 portion of the femur (Gruen zones 1 and 7), which was interpreted as grade II stress
196 shielding, was present in 26 hips (96%), in one cases stress-shielding extended to Gruen

197 zones 2 and 6 (grade III). A non progressive 4x5x5mm osteolysis was seen in 1 patient
198 (1 hip) located in Gruen zone 7, with 1-2mm wear of the cemented PE-cup. In another
199 case of suspected press-fit cup loosening both stem and cup were intraoperatively found
200 to be stable, a small proximal osteolysis in Gruen zone 7 was filled with autologous
201 bone graft.

202 Radiolucencies of the stem without progression were found in 3 cases, all of which were
203 located in the proximal Gruen zones I. Cortical hypertrophy was seen in 3 hips (11%) in
204 Gruen zone 3 and 5. 12 hips 45% developed a radiographic appearance of bone
205 apposition at the tip of the stem. Heterotopic ossification was present in 11 hips (41%):
206 8 hips (30%) grade I and 3 hips (11%) grade II.

207 With uncemented tapered femoral fixation excellent 12 year results are achieved in
208 patients with rheumatoid arthritis (figure 2).

209 **Acetabular component.** For 22 acetabular components (81%) fixation was good
210 without change in position. 5 cups (19%; 4 press-fit zirconium-coated Phoenix cups and
211 one cemented PE-cup; Brehm, Weisendorf, Germany) had to be revised due to aseptic
212 loosening, for one additional cup the liner had to be changed due to extensive wear
213 (table. 1). Of the 22 non-revised acetabular components none showed signs of osteolysis
214 and radiolucencies were seen in 1 hip (4%) in Zone II and III.

215 The amount of wear of the polyethylene liner or cup (n=20 of the 22 non-revised hips)
216 was analyzed in increments of 1 mm maximum accuracy: < 1 mm (1 hip, 4%), 1-2 mm
217 (7 hips, 26 %, 4 PE-liners, 3 metasul-PE-liners).

218 The 6 hips which required isolated revision of the cup had radiographically bone-
219 ingrown femoral components that were stable on examination during the operation. The
220 radiological follow-up showed that these stems remained radiologically bone-ingrown.

221 We observed no deep vein thrombosis, no luxation and no periprosthetic fracture in our
222 cohort.

223

224 **Discussion**

225 In our non-selected, consecutive series of patients with RA who all underwent
226 cementless THA the survival of the tapered designed stem has been excellent. No stem
227 had to be revised and all showed signs of stable ingrowth after a mean follow-up of 12,2
228 years (minimum 10 years). Aseptic cup loosening was seen in four cases which had to
229 be revised, additionally one liner had to be replaced due to extensive wear. Durable
230 acetabular fixations remains to be the major problem compromising the longevity of
231 cementless THA for patients with RA.

232 The greater incidence of acetabular and femoral loosening after cemented THA for
233 patients with RA compared to those with OA [5,12,15,17,18,30] has been attributed to
234 periacetabular and generalized osteoporosis related to disease activity, steroid therapy
235 and immobility [6,31,32]. As for elderly patients with OA, the hypothesised poorer bone
236 stock of patients with RA has been the main argument for cemented THA.

237 The increasing number of investigations with promising results for cementless THA for
238 patients with RA [4,8-11,13] has recently been confirmed by a study of the Finnish
239 Arthroplasty Register for the femoral component, while for the acetabulum cemented
240 all-polyethylene cups were the implant of choice [7] (table 2).

241 Three long-term follow-up series with a single uncemented contemporary femoral
242 component in patients with RA have been published: Lyback et al. [4] reported an
243 excellent 100% 10-year survival rate (with aseptic loosening as an endpoint) for a group
244 of 55 patients (77 hips) with juvenile chronic arthritis (mean age at operation 28 years)

245 who had received the proximally circumferentially porous-coated Bi-metric stem. For
246 another proximally circumferentially porous-coated uncemented stem (Biomet
247 Taperloc) Keisu et al [10] reported no revision and no signs of radiological loosening
248 after a mean follow-up of 8 years in group of 39 patients (50 hips) with adult-onset RA
249 (mean age at operation 55 years). Jana et al [9] reported of 55 patients (71 hips) with
250 adult-onset RA (mean age at operation 55.1 years) after a mean follow-up of 11.2 years
251 with 1 stem revised and an additional 4 stems showing radiological signs of loosening
252 (porous-coated Anatomic Medullary Locking stem).

253 It is well published, that for patients with OA of the hip joint, tapered designed
254 uncemented stems achieve excellent clinical and radiological results at 10 years
255 postoperatively [33-35]. Specifically with the CLS stem used in the present patient
256 cohort, we have observed similar excellent results for 94 patients (107 hips) with OA
257 (mean age at operation 51 years) after a mean follow-up of 10.3 years, no stem had to
258 be revised and radiological stable ingrowth was observed in 95% of the radiographically
259 analysed cases [35].

260 Our single femoral implant, single surgeon series is the first with a mean 12,2 year
261 (minium 10 years) follow-up for tapered designed uncemented stems in patients with
262 RA and only the second publication thus far with an above mean 10-year-results for
263 uncemented stems of patients with adult-onset RA. We recognize that our study is
264 limited by the relatively small patient cohort and the retrospective nature of our
265 investigation. Furthermore our series is nonrandomised, thus no direct comparisons with
266 a cemented group is possible. Nevertheless, we managed to account for all but 5 of the
267 patients still alive of this series. Even though no match of the presented RA group was
268 possible with an osteoarthritic control group, the number of stem revisions and stable

269 radiological ingrowth with the same implant show equally excellent results for both
270 groups in our hospital [35].

271 All published short- and longterm data with a single contemporary uncemented femoral
272 component for patients with juvenile and adult-onset RA confirm the encouraging
273 results of our series [4,8-11,13] underlined by the report of the Finnish Arthroplasty
274 Register [7] who analysed 2,557 THA for RA in younger patients and found favourable
275 results for uncemented femoral implants.

276 The chronic course of RA with multiple affected joints of the lower limbs affected,
277 makes the clinical evaluation of a specific surgical procedure difficult to interpret.
278 While excellent clinical results after THA were reported by Keisu et al. [10] with a
279 relatively high HHS of 93 (follow-up mean: 8 years; mean age at operation: 55 years)
280 and 32% of their patients classified according to Charnley as grade C, Jana et al. [9]
281 found the Merle D'Aubigné and Postel walking score (follow-up mean: 10 years; mean
282 age at operation: 55.1 years) to improve in only 61% of their patients, 20% had lower
283 scores. Even though 12 patients (21 hips, 78%) of our patients were rated as Charnely C
284 we found satisfying clinical results with an average HHS of 86 at follow-up. All patients
285 reported clinical improvement with reduced pain and increased walking distance.

286 Keisu et al. [10] noted postoperative mild thigh pain in only 2,2% of his RA patients
287 after cementless THA with the titanium alloy, circumferential plasma spray coated,
288 Taperloc femoral stem. Accordingly, we observed 2 patients who presented with
289 occasional thigh pain. With the same implant in the same clinic and a comparable mean
290 follow-up time thigh pain was observed only for patients with OA in cases of
291 radiologically loose, but not yet revised acetabular components. Whether the low
292 incidence of thigh pain compared to other cementless implants [36,37] is due to the

293 tapered geometry that is believed to distribute stress over a larger area remains
294 speculative [10, 38].

295 No case of superficial or deep wound infection was seen in our series. While for all
296 patients who had taken oral corticosteroids preoperatively the dose was increased
297 perioperatively and administered intravenously to avoid an Addison-crisis, other
298 immunosuppressing drugs such as MTX were paused 2 weeks prior to surgery until
299 definite wound healing (2 weeks postoperatively) was reached. No clear consensus
300 exists on whether methotrexate (MTX) should be continued or whether this therapy
301 should be discontinued for a few weeks in patients with rheumatoid arthritis (RA)
302 undergoing surgery. Pieringer et al. [39] analysed the current literature according to
303 which continued MTX therapy appears to be safe perioperatively and seems also to be
304 associated with a reduced risk of flares, even though none of examined papers addressed
305 the issue of safety in connection with comorbidities. Our series is too small to make any
306 conclusion on the observed rate of infection and the influence of discontinuing MTX
307 therapy perioperatively.

308 Radiographic evidence of bone ingrowth of the stem in our series (100 %) is equal to
309 the radiographic results of Keisu et al. [10] (100% radiographic evidence of bone
310 ingrowth). Despite reported an increased polyethylene wear rate Keisu et al. [10]
311 observed no case of proximal or distal femoral osteolysis. They believed that the
312 circumferential plasma spray coating in combination with the 100% rate of proximal
313 bone ingrowth of the Taperloc titanium alloy femoral stem protected the femoral canal
314 from PE-debris and thus osteolysis [10].

315 Despite polyethylene particulate debris, osteolysis and radiolucencies were never of
316 clinical or radiological significance for the femoral component in our investigation.
317 Schramm et al [35] reported wear of the polyethylene liners of < 1 mm (56%), 1-2 mm

318 (29%), > 2 mm (5%), for patients with osteoarthritis of the hip joint (mean time of
319 follow-up 10.3 years, mean age at operation 51 years) who had received the same
320 prosthesis in the same clinic with an identical polyethylen liner. Even though our cohort
321 was slightly younger and our mean follow-up an average 2 years longer, we observed
322 less PE-wear (< 1 mm (1 hip, 4%), 1-2 mm (7 hips, 26 %, 4 PE-liners, 3 metasul-PE-
323 liners) which be contribute to the lower physical demand of RA patients.

324 Even though acetabular components were not the major target of this investigation due
325 to the wide variety of acetabular implants used, their performance was considered good.
326 The 4 revised press-fit cups were all zirconium coated and prone for asepting loosening
327 caused by debonding of the zirconium from the cup. None of the non-zirconium coated
328 press-fit cups had to be revised or showed radiological signs of loosening at follow-up.

329 The results of cementless THA for young patients with rheumatoid arthritis are very
330 promising and comparable to patients with OA. Durable femoral and acetabular fixation
331 was achieved. Slight undersizing, varus and valgus positioning of the stem did not
332 undermine good clinical results after a mean 12,2 year follow-up

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334

335 **Legends**

336 Figure 1 Kaplan Meier curve indicating the lost to follow-up and a worst case (lost
337 to follow-up and deceased patients) scenario.

338 Figure 2 45 year old male, 14 year follow-up. CLS-stem with Fitek press-fit cup.
339 Stress-shielding in Gruen zones I and VII.

340

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342 **References**

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484 Table 1. Reoperation summary of all analysed hips

485	After operation	Components	Revision
486	(years)	revised	diagnosis
487			
488	4.1	Zirconium coated Phoenix cup	aseptic loosening
489	7.10	Zirconium coated Phoenix cup	aseptic loosening
490	10.1	Inlay (Aesculap plasmacup)	extensive inlay wear
491	8.8	Zirconium coated Phoenix cup	aseptic loosening
492	9.3	cemented PE cup	aseptic loosening
493	12.0	Zirconium coated Phoenix cup	aseptic loosening

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499 **Table 2. Results in Comparison to the literature of single femoral component series**
500 **(aRA: adult-onset rheumatoid arthritis; jRA: juvenile rheumatoid arthritis; OA:**
501 **Osteoarthritis; n.a.: not available)**

502	Author	No. of	Mean	Mean	Lost to	Excellent	Rate of	Rate of	Rate of	Rate of
503		THA/	age at	follow	follow	and good	stem	loosened	acetab.	loosened
504		no.of	operation	-up	-up	clinical	revision	stems:	revision	cups:
505			patients	(years)	(years)	or HHS	(%)	radiol.+	(%)	radiol.+
506								revised		revised
507								(%)		(%)
508	Lachiewicz (1994) ^a jRA	35/25	41	4.5	none	HHS 91	none	none	none	1 (3%)
509	Garcia (1998) ^b aRA	33/32	51	5	none	HHS 81	none	none	none	none
510	Loehr (1999) ^c aRA	21/15	53	3.3	none	n.a.	none	5 (24%)	none	none
511	Keisu (2001) ^d aRA	50/39	55	8	19%	HHS 93	none	none	7 (14%)	7 (14%)
512	Jana (2001) ^e aRA	71/55	55	11.4	13%	n.a.	1 (2%)	5 (7%)	14 (20%)	21 (30%)
513	Lybaeck (2004) ^d jRA	77/55	28	10	9%	n.a.	2 (3%)	n.a.	27 (39%)	n.a.
514	Schramm (2000) ^c OA	89/80	51	10.3	7%	84%	none	4 (5%)	3 (4%)	7 (9%)
515	Present study^c; aRA	39/27	45	12.2	13%	HHS 86	none	none	6 (22%)	6 (22%)

516 ^aHarris-Galante porous (Zimmer)

517 ^bAGB hip prosthesis (Howmedica)

518 ^cCLS-stem (Zimmer)

519 ^dTaperloc femoral stem (Biomet)

520 ^eAnatomic Medullary Locking stem (DePuy, Johnson & Johnson)

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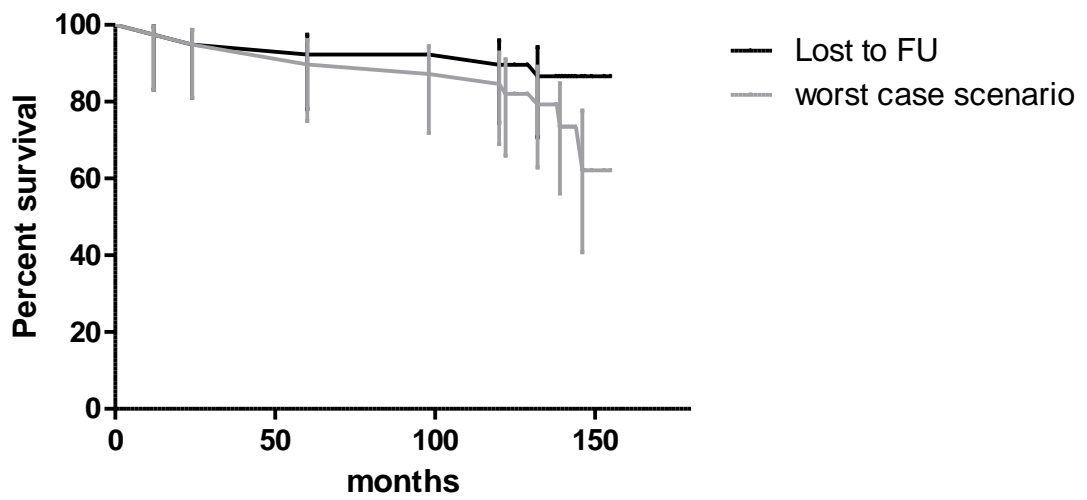


Figure 1 Kaplan Meier curve indicating the lost to follow-up and a worst case (lost to follow-up and deceased patients) scenario.

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569 **Figure 2** 45 year old male, 14 year follow-up. CLS-stem with Fitek press-fit cup.

570 Stress-shielding in Gruen zones I and VII.

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