

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 |
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| 2 | Arthritis using a Tapered Designed Titanium Hip Stem |
| 3 | Minimum 10-Year Results |
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Abstract

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

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], controvorsy remains among 82 orthropaedic surgeons concerning the optimal fixation of the implant [4-19].

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

Several studies have shown higher rates of loosening of cemented femoral components in patients with RA compared with cemented THA in patients with osteoarthritis (OA) [5,15]. The Finish arthroplasty register found that the risk of stem revision due to aseptic loosening for patients with RA under the age of 55 (2557 primary THA) was higher with cemented stems than with proximaly porous coated uncemented stems [7]. Femoral failure rates of 5.3% and 8% after an average follow-up of 7.4 to 4.3 years 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 promesing
96 with revision rates between 0% and 1% after a mean follow-up of 8 to 10 years
97 [9,10,14].

We have retrospectively assessed the long-term clinical and radiological results (mean time of follow-up: 12,2 years; minimum 10 years) of a non-selected, consecutive series for patients with RA who all underwent cementless THA with the femoral component <u>cementless system (CLS, Sulzer Medica, CH; now: Zimmer, Warsaw, Indiana, USA), in</u> combination with one of five different actabular 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 fullfilled 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 (Ti_6Al_7Nb). Ribs in the proximal part of the prothesis 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 hydroxlapatit-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.

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

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

perioperative antibiotics (single shot of 2g Cefazolin i.v.) and thromboembolism prophylaxis with subcutaneous heparin. Postoperatively, touch weight-bearing up to 15 kg was allowed for the first 6 weeks, then progressively increased loading to full weight-bearing within the next 2 weeks. At the final follow-up all patients were assesed clinically using the Harris hip score [23]. Preoperative pain, range of motion and 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 actabular 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**

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

Thus, clincal and radiological data were available of 17 patients (27 hips) after a mean of 12,2 years follow-up (minimum 10 years). There were 10 women (18 hips) and 7 men (9 hips) with an average age at surgery of 45,3 years (26 to 55). Of the 27 implants directly accounted for, no femoral component was revised and all stems had bony ingrowth. 5 cups (19%) had to be revised due to aseptic loosening, for one additional 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 tigh. 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 zones 2 and 6 (grade III). A non progressive 4x5x5mm osteolysis was seen in 1 patient
(1 hip) located in Gruen zone 7, with 1-2mm wear of the cemented PE-cup. In another
case of suspected press-fit cup loosening both stem and cup were intraoperatively found
to be stable, a small proximal osteolysis in Gruen zone 7 was filled with autologous
bone graft.

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

With uncemented tapered femoral fixation excellent 12 year results are achieved inpatients with rheumatoid arthritis (figure 2).

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

The amount of wear of the polyethylene liner or cup (n=20 of the 22 non-revised hips) 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).

The 6 hips which required isolated revision of the cup had radiographically boneingrown femoral components that were stable on examination during the operation. The

220 radiological follow-up showed that these stems remained radiologically bone-ingrown.

We observed no deep vein thrombosis, no luxation and no periprosthetic fracture in ourcohort.

223

224 Discussion

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

The greater incidence of actabular and femoral loosening after cemented THA for patients with RA compared to those with OA [5,12,15,17,18,30] has been attributed to periactabular and generalized osteoporosis related to disease activity, steroid therapy and immobility [6,31,32]. As for elderly patients with OA, the hypothised poorer bone stock of patients with RA has been the main arguement for cemented THA.

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

Three long-term follow-up series with a single uncemented contemporary femoral component in patients with RA have been published: Lyback et al. [4] reported an excellent 100% 10-year survival rate (with aseptic loosening as an endpoint) for a group 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).

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

radiological ingrowth with the same implant show equally excellent results for bothgroups in our hospital [35].

All published short- and longterm data with a single contemporary uncemented femoral component for patients with juvenile and adult-onset RA confirm the encouraring results of our series [4,8-11,13] underlined by the report of the Finnish Arthroplasty Register [7] who analysed 2,557 THA for RA in younger patients and found favourable 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 clincal 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 clincal results with an average HHS of 86 at follow-up. All patients 285 reported clinical improvement with reduced pain and increased walking distance.

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

tapered geometry that is believed to distribute stress over a larger area remainsspeculative [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 coritcosteroids 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 to small to make any 306 conclusion on the observed rate of infection and the influence of discontinuing MTX 307 therapie perioperatively.

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

315 Despite polyethylen 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.

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

The results of cementless THA for young patients with rheumatoid arthritis are very promising and comparable to patients with OA. Durable femoral and actabular fixation was achieved. Slight undersizing, varus and valgus positioning of the stem did not 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.
- Figure 2
 Stress-shielding in Gruen zones I and VII.
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484 Table 1. Reoperation summary of all analysed hips

485 486 487 488 After operation Components Revision revised diagnosis (years) 4.1 Zirconium coated Phoenix cup aseptic loosening Zirconium coated Phoenix cup aseptic loosening 89 7.10 490 Inlay (Aesculap plasmacup) 10.1 extensive inlay wear 491 8.8 Zirconium coated Phoenix cup aseptic loosening 492 493 9.3 cemented PE cup aseptic loosening Zirconium coated Phoenix cup 12.0 aseptic loosening 494

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)

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

^aHarris-Galante porous (Zimmer)

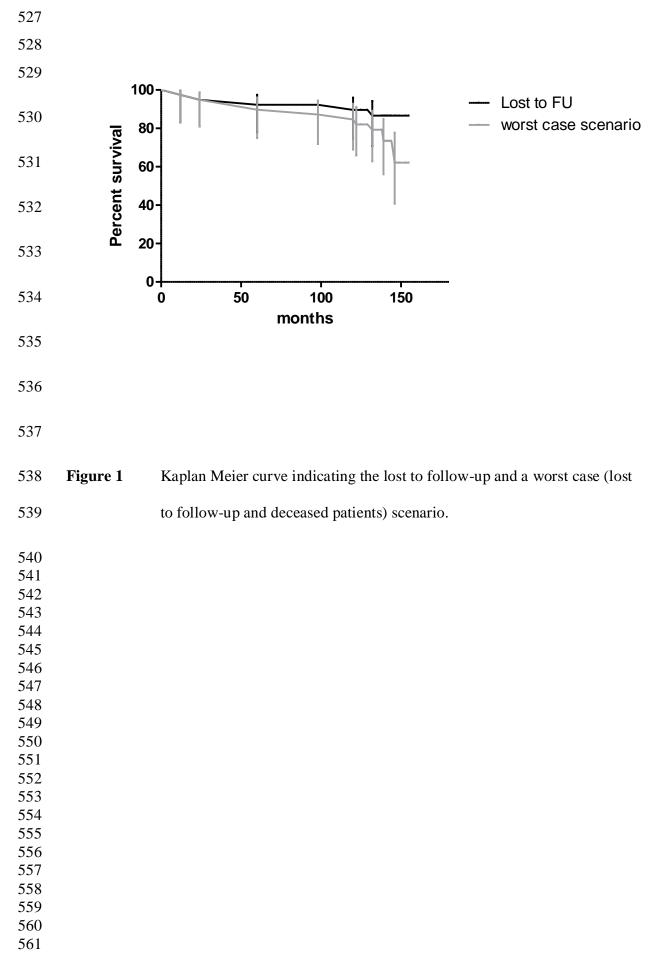
^bAGB hip prosthesis (Howmedica)

^cCLS-stem (Zimmer)

^dTaperloc femoral stem (Biomet)

eAnatomic Medullary Locking stem (DePuy, Johnson & Johnson)

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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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