Long-term (20- to 25-year) Results of an Uncemented Tapered Titanium Femoral Component and Factors Affecting Survivorship

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Abstract

Background Uncemented femoral components in primary total hip arthroplasty (THA) are commonly used today, but few studies have evaluated their survival into the third decade.

Questions/purposes We evaluated (1) survivorship using femoral revision for any reason as the end point; (2) survivorship using femoral revision for aseptic loosening as the end point; and (3) patient-related and surgical risk factors for aseptic stem loosening at a minimum 20-year followup with an uncemented tapered titanium stem.

Methods We reviewed the clinical and radiographic results of 354 THAs in 326 patients performed between January 1985 and December 1989 using an uncemented grit-blasted, tapered titanium femoral stem. Mean age at surgery was 57 years (range, 13–81 years). Kaplan-Meier survivorship analysis was used to estimate long-term survival. Minimum followup evaluation was 20 years (mean, 22 years; range, 20–25 years); at that time, 120 patients (127 hips) had died, and four patients (five hips) were lost to followup. Multivariate survival analysis using a Cox regression model was performed.

Results Survivorship at 22 years with revision of the femoral component for any reason as the end point was 86% (95% confidence interval [CI], 81%–90%). Survivorship for femoral revision for aseptic loosening as the end point was 93% at 22 years (95% CI, 90%–96%). Undersized stems (canal fill index $\leq 80\%$) and stems in hips with cup revision were at higher risk for aseptic loosening (hazard ratio, 4.2 and 4.3, respectively). There was a high rate of acetabular revision in this series (38%), mostly related to smooth-threaded, cementless sockets.

Conclusions Uncemented femoral fixation was reliable into the third decade. Age, male sex, and diagnosis were not associated with a higher risk of aseptic loosening.

Level of Evidence Level IV, therapeutic study. See the Guidelines for Authors for a complete description of levels of evidence.

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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Introduction

Uncemented stems are widely used in THA all over the world. There are a variety of uncemented stems that have been associated with excellent mid-term clinical and radiographic outcomes, whereas others showed disappointing results [25, 30]. However, there are few reports on the survival of uncemented stems with a minimum followup of 20 years or more [1, 5, 36, 39]. Some uncemented stems with clinical followup into the third decade [1, 5, 13, 18, 35–37, 39, 40, 54] have undergone major design changes or are no longer available for clinical use [1, 18, 36, 37, 46]. In addition, there is little evidence on the factors influencing long-term survival of uncemented stems. Although other surveillance techniques are being proposed for the early assessment of new implant designs [26, 44], long-term clinical followup remains the gold standard.

The goals of this study were to evaluate (1) survivorship using femoral revision for any reason as the end point; (2) survivorship using femoral revision for aseptic loosening as the end point; and (3) patient-related and surgical risk factors for aseptic stem loosening at a minimum 20-year followup with an uncemented tapered titanium stem in a nondesigner series [2, 3].

Patients and Methods

We retrospectively evaluated the clinical and radiographic results of a series of 354 THAs using an uncemented grit-blasted, tapered titanium femoral stem (CLS[®] Spotorno[®] stem; Zimmer Inc, Warsaw, IN, USA [Fig. 1]) in 326 patients performed between January 1985 and December 1989. The FDA has cleared this femoral component for use in the United States. Indications for this device were the absence of severe femoral canal deformity and adequate bone stock for uncemented fixation using the Singh index as described by Spotorno et al. [49]. The mean age at surgery was 57 years (range, 13–81 years). During the study period, this group of patients represented 34% of the THAs performed at this center. The patient demographics showed a typical distribution of diagnoses leading to hip arthroplasty (Table 1). Informed consent for inclusion in our centers research database was obtained from all patients. The institutional review board of the University of Heidelberg approved all procedures and the study was conducted in accordance with the Helsinki Declaration of 1975 as revised in 2008.

The stems had a neck-shaft angle of 145° and were implanted using the press-fit technique described by Spotorno et al. [49]. The rectangular stem is collarless, wedge-shaped, and tapered in all three planes with proximal, anterior, and posterior located ribs/flutes (Fig. 1). The implant is made of TiAl6Nb7 alloy with a microporous

Fig. 1 The photograph shows the uncemented straight titanium CLS[®] Spotorno[®] femoral component with proximal fins and a grit-blasted surface finish.

Table 1. Diagnoses of patients undergoing THA in this series

Diagnoses	Number of hips
Osteoarthritis	188 (53%)
Congenital dislocation of the hip	85 (24%)
Avascular necrosis	39 (11%)
Posttraumatic osteoarthritis	21 (6%)
Rheumatoid arthritis	6 (2%)
Neck fracture	6 (2%)
Others	9 (3%)
Total	354 (100%)
Previous osteotomies	57 (16%)

surface treatment ($R_a = 4.4 \mu\text{m}$). Secondary osseointegration is achieved by osseous ongrowth to the grit-blasted implant surface. This component has remained relatively unchanged since its first implantation in 1984 except for a minor modification to the shape of the ribs in 1992 (proximally sharpened edges to enhance stem penetration and reduce the risk of fissures) and two offset options added in 1997 (135°) and 2004 (125°).

Of the 354 hips, 348 (99%) underwent acetabular reconstruction using smooth and uncemented threaded cups: 222 hips (63%) received threaded, spherical, and uncemented Mecron cups (Mecron GmbH, Berlin, Germany) and 126 hips (36%) received a threaded, conical, uncemented Weill ring (Zimmer Inc, Warsaw, IN, USA). Six hips (1%) received cemented cups (B. Braun Aesculap, Tuttlingen, Germany). In all hips, UHMWPE bearing surfaces and 32-mm Al₂O₃ ceramic heads (BioloX; CeramTec, Plochingen, Germany) were used.

Fig. 2 This flowchart demonstrates the distribution of hips at final followup.

The procedures were performed at our center by 23 surgeons. We used either a modified Watson-Jones or the transgluteal lateral approach of Bauer et al. [4] with the patient in the supine position. The femoral canal was prepared using a series of chip-toothed broaches of increasing size. No attempt was made to achieve cortical fixation; the surgeons did not consider that cortical contact would be necessary to achieve stability with this implant and relied on the feel of rotational and axial stability to determine fit. Fixation was regarded as satisfactory when a series of moderate hammer blows did not change the final position of the femoral implant.

Postoperative partial weightbearing was encouraged for 6 weeks and thereafter as tolerated. No regular prophylaxis (irradiation or NSAIDs) for prevention of heterotopic ossification was given.

Patients were followed in regular intervals at 3 months, 6 months, 1 year, and every 5 years thereafter. The Harris hip score [27] was used to determine the functional level at the most recent followup. Patient activity level was graded according to Devane et al. [15]. For radiographic evaluation, standard pelvis AP and lateral radiographs of the hip were taken. Radiolucent lines or osteolysis at the femoral bone-prosthesis interface were evaluated using the zones described by Gruen et al. [21]. Femoral osteopenia resulting from stress shielding and femoral component fixation were graded according to the criteria described by Engh et al. [17] and heterotopic ossification according to Brooker et al. [9]. The canal fill index (CFI) was defined as the ratio between implant to canal width in the AP plane at 3 cm below the level of the lesser trochanter as described previously [33] and measured on the intraoperative or first postoperative radiograph. Our criterion for defining an undersized stem was a CFI of $\leq 80\%$.

At minimum 20 years postoperative, 120 patients (127 hips) had died, and four (five hips) were lost to followup (Fig. 2). The mortality rate in this study cohort was comparable to the native population in Germany. In the patients who died, the femoral prosthesis was in situ at the time of death. Mean time between last clinical review and death was 1.2 (SD 2.3) years. We excluded revision surgery

between the last clinical review and death in deceased patients using information from relatives, health insurance, general practitioners, or review of clinical notes. Three hips that were lost at the minimum 15-year followup have been found again at the last followup. Forty-two hips (12%) underwent femoral revision and the remaining 180 hips (163 patients) were available for review at a minimum followup of 20 years (mean, 22 years; range, 20–25 years).

Kaplan-Meier survivorship analysis was used to determine long-term survival rates for different end points. Multivariate survivorship analysis using a Cox regression model was performed with an end point of aseptic loosening of the femoral component for the risk factors age at surgery, male sex, diagnosis, CFI $\leq 80\%$, type of acetabular component, and cup revision. We considered p values of < 0.05 to be significant. SPSS® Version 17.0 (SPSS Inc, Chicago, IL, USA) and Graphpad Prism® Version 5.0 (Graphpad Software, La Jolla, CA, USA) were used to record and analyze the data.

Results

Kaplan-Meier survivorship at 22 years, using revision of the femoral component for any reason as the end point (Fig. 3), was 86% (95% confidence interval [CI], 81%–90%; 67 hips at risk; Table 2). Of the 42 hips requiring femoral revision, 10 (3%) were revised for infection, 12 (3%) for late periprosthetic fracture and stem loosening resulting from trauma, and 20 (6%) for aseptic stem loosening. Of the acetabular components, 135 (38%) had been revised up to the latest followup. In the 135 hips with acetabular revision, a total of 30 stems have been revised either at the same time ($n = 21$) or subsequently ($n = 9$).

Survivorship at 22 years using femoral revision for aseptic loosening as the end point was 93% (95% CI, 90%–96%; 67 hips at risk) (Fig. 4). The survival rate with acetabular revision for any reason as the end point was 49% (95% CI, 43%–56%). Other than in those stems already revised for loosening, there was no radiographic evidence of

definite loosening of the femoral components. Osteolysis and radiolucent lines around the femoral component were limited to Gruen Zones 1 and 7 (Fig. 5). When comparing the minimum 10-year with the minimum 20-year followup, progressive osteolytic lesions were detected in three patients (2% of the hips evaluated radiographically). In one of these patients, a new osteolytic lesion developed between the 10- and 20-year minimum followup. Radiolucent lines were progressive in one patient (1% of the hips evaluated radiographically). Heterotopic ossification was found in 85 of 143 hips (59%) and graded according to Brooker as Grade I (55 hips), Grade II (11 hips), Grade III (17 hips), and Grade IV (two hips). Twenty-four percent of the stems had a CFI of $\leq 80\%$ and were graded as undersized.

All stems with late aseptic loosening were undersized (CFI $< 80\%$). In hips with CFI $> 80\%$, the 22-year survival rate of the femoral component with revision for aseptic loosening was estimated at 96% (95% CI, 92%–98%; 40 hips at risk); for those with CFI $\leq 80\%$, the survivorship was 84% (95% CI, 73%–91%; 19 hips at risk). Multivariate survivorship analysis using a Cox regression model revealed that undersized stems (CFI $\leq 80\%$) and

stems in hips with cup revision were at higher risk for revision for aseptic loosening. Age at the time of surgery, male sex, type of acetabular component, and diagnosis had no major influence on the risk of long-term aseptic loosening in this cohort (Table 3).

Discussion

Long-term implant-bone fixation and periprosthetic bone remodeling are critical issues related to the longevity of a THA, especially in young and active patients. Aseptic loosening remains the most important cause of long-term implant failure according to registry reports [19]. Uncemented implants were developed to achieve biological implant-bone fixation and reduce long-term failures resulting from aseptic loosening, which occurred with the first-generation cementing techniques [29] and in some later-generation cemented stem designs [34], a particular problem with young patients. The first generation of uncemented implants showed mixed survivorship with problems related to fixation failure, thigh pain, stress

Fig. 3 This graph shows the Kaplan-Meier survivorship curve and 95% CI with femoral revision for any reason as the end point. Twenty-two-year survival was estimated at 86% (95% CI, 81%–90%; 67 hips at risk).

Fig. 4 This graph shows the Kaplan-Meier survivorship curve and 95% CI with femoral revision for aseptic loosening as the end point. Twenty-two-year survival was estimated at 93% (95% CI, 90%–96%; 67 hips at risk).

Table 2. Estimated Kaplan-Meier survivorship of the femoral component using revision for any reason and aseptic loosening as the end point

End point	Time				
	5 years	10 years	15 years	20 years	22 years
Femoral revision for any reason (95% CI)	96% (93–98)	93% (90–96)	91% (87–94)	87% (82–90)	86% (81–90)
Femoral revision for aseptic loosening (95% CI)	98% (96–99)	97% (94–98)	95% (92–97)	93% (90–96)	93% (90–96)
Hips at risk	327	290	247	163	67

CI = confidence interval.

Fig. 5 This figure illustrates the findings of the radiographic evaluation at a minimum 20-year followup and distribution of radiological findings in Zones according to Gruen et al. (OL = osteolysis; RL = radiolucent line).

shielding, and osteolysis [11, 23, 31]. These issues have been addressed with the development of second-generation uncemented implants such as the tapered titanium stems. Consensus has not yet been found about the best method of femoral fixation in the long term [8, 13, 16, 24, 41, 43, 52]. Uncemented tapered titanium femoral components are widely used and have performed well in primary THA. Excellent long-term survivorship has been reported with minimum radiographic evidence of stress shielding and osteolysis [35, 38, 54]. However, despite their widespread use, there is only limited evidence on their survival and radiographic outcome beyond the 20-year followup [13, 35, 38, 39, 54]. Our study, therefore, sought to evaluate long-term results with one design of uncemented stem in the hands of a large group of surgeons at one center, focusing specifically on (1) survivorship using femoral revision as the end point; (2) survivorship using femoral revision for aseptic loosening as the end point; and (3) patient-related and surgical risk factors for aseptic stem loosening.

Limitations of the study are its retrospective cohort design, the lack of preoperative clinical data, the fact that in four hips the reason for stem revision is unknown because they were revised elsewhere, and the high rate of acetabular revisions, which may have biased the results. On the one hand, the high rate of cup revisions may turn high-activity

Table 3. Multivariate survivorship analysis using a Cox regression model (end point aseptic femoral loosening)

Variable	Hazard ratio	95% confidence interval	p value
Age at surgery (per year decrease)	1.00	0.93–1.07	0.91
Canal filling ≤ 80%	4.2	1.51–11.78	< 0.01
Cup revision	4.3	1.33–14.04	0.02
Cup type	0.94	0.40–2.19	0.88
Diagnosis	1.00	0.65–1.57	0.96
Male sex	1.54	0.54–4.42	0.42
Previous osteotomy	N/A		

N/A = not available.

patients into low-activity patients, and so may have reduced demand on the femoral stem leading to higher stem survival. On the other hand, stem survival might be influenced negatively as a result of complications associated with revision of the acetabular component. Furthermore, there is a possible selection bias at work here, because this implant was used in 34% of the THAs performed during the study period only, and, in general, these patients tended to be younger and more active than those who received the cemented stems during the period in question.

In this series, we found a high stem survival rate into the early third decade. The long-term stem survival with the end point revision for any reason was comparable to the best reported series in primary cemented THA [10]. High long-term survivorship consistently has been reported for the CLS Spotorno stem in independent cohort-based clinical studies and registry data (Table 4). When compared with other series and registry data that have been reported for this stem, the survival rates in this study are lower. One reason might be because of the high rate of cup revision in this series, which may result in complications such as infection and subsequent revision of a well-fixed stem. In a recently reported series, a considerably higher stem survival rate was found at 12 years when this stem was combined with a second-generation acetabular component [51]. As reported previously [50], late periprosthetic femoral fracture after minor trauma (eg, falls from ground level) was an important mode of failure in this series resulting in increasing rates of revision in the second and third decades after surgery. Periprosthetic femoral fractures have been reported as an important reason for failure in the long term with use of other uncemented [35] and cemented stem designs [12]. In the present study, we attribute the increasing failure rate for periprosthetic fracture to both a rising incidence of falls and age-related osteoporosis. Additionally, implant-related bone remodeling might also be a major factor.

An important finding in this series was the low rate of late aseptic stem loosening in the late second and early

Table 4. Results of the CLS Spotorno femoral component with a mean followup of at least 10 years

Study	Year	Number of hips	Mean followup (years)	Survivorship of all stem revisions (%)	Survivorship of aseptic stem loosening
Schramm et al. [47]	2000	107	10	100 at 10 years	100 at 10 years
Siebold et al. [48]	2001	298	12	94 at 12 years	–
Güther et al. [22]	2003	66	11	95 at 11 years	100 at 11 years
Aldinger et al. [2]	2003	354	12	92 at 12 years	95 at 12 years
Rozkydal et al. [45]	2009	122	16	98 at 15 years	–
Grappiolo et al.* [20]	2009	300	–	89 at 20 years	–
Aldinger et al. [3]	2009	354	17	88 at 17 years	94 at 17 years
Mueller et al. [42]	2010	107	17	99 at 17 years	100 at 17 years
Terre [53]	2010	171	18	97 at 21 years	–
Garellick et al. [19]	2011	1169	–	98 at 17 years	–
Streit et al. [51]	2012	89	12	96 at 12 years	99 at 12 years
de Witte et al. [14]	2011	102	12	–	99 at 15 years
Biernond [7]	2011	100	12	97 at 13 years	98 at 13 years
Hwang et al. [28]	2012	227	12	97 at 16 years	100 at 16 years
Current study	2012	354	22	86 at 22 years	93 at 22 years

* Results from the developer group.

Table 5. Results of uncemented femoral components with 20-year followup

Study	Stem	Year	Number of hips	Mean followup (years)	Survivorship of all stem revisions (%)	Survivorship of aseptic stem loosening (%)
Belmont et al. [5]	AML	2008	223	22	98 at 20 years	98 at 20 years
Current study	CLS Spotorno	2012	354	22	86 at 22 years	93 at 22 years
Vidalain [54]	Corail	2011	347	21	97 at 23 years	–
Martinez de Aragon and Keisu [37]	Lord*	2007	114	21	83 at 21 years	–
Lombardi et al. [35]	Mallory head	2009	2000	10 (196 hips at risk at 20 years)	95 at 20 years	99 at 20 years
Corten et al. [13]	Mallory head	2011	126	20	99 at 20 years	–
Ferrell et al. [18]	PCA*	2009	219	20	79–87 at 20 years	–
Loughead et al. [36]	PCA*	2012	311	23	95 at 23 years	–
Al Muderis et al. [1]	Spongiosa-I*	2011	209	22	86 at 20 years	–
McLaughlin and Lee [38]	Taperloc	2008	145	20	87 at 22 years	99 at 22 years
McLaughlin and Lee [39]	Taperloc	2010	145	24	–	99 at 26 years

Studies with < 100 hips were excluded [46]; * no longer available for clinical use.

third decades. Late aseptic loosening occurred mainly in undersized stems. Low rates of aseptic loosening were also reported for other uncemented stem designs at a minimum followup of 20 years (Table 5). Thus, the principle of biological fixation using a triple-tapered femoral component with a grit-blasted surface treatment allowing osseous integration of the titanium alloy seems to work into the early third decade.

Our radiographic analysis found that apart from the stems already revised, there were no other patients with radiographically evident loosening. We also observed a low overall incidence of osteolytic lesions around the

femoral component despite a high rate of osteolysis around the cups in these reconstructions. In most long-term reports (Table 4), the stem used in this series was associated with low rates of osteolysis, which was confirmed in our study into the early third decade. Osteolysis was progressive only in 2% of the hips evaluated radiographically, and remote osteolysis was not detected. Similar radiological findings were reported at a 20-year followup with use of other titanium stems such as the Corail stem [54], the Mallory-Head prosthesis [35], and the Taperloc femoral component [38]. This finding is in contrast to other mainly cobalt-chrome alloy cementless stems, ranging up to 37%

osteolysis of > 1.5 cm [5]. A possible explanation for this difference might be that the titanium alloy is more flexible and therefore prevents severe stress shielding of the proximal part of the femur; additionally, the more proximal metadiaphyseal loading of the CLS Spotorno stem may also prevent severe stress shielding.

There are relatively few other studies about factors influencing the long-term survival of uncemented femoral components. Undersizing the stem was found to be a risk factor for aseptic loosening in this series. Long-term aseptic stem loosening was rare (4% at 22 years) if the stem was adequately sized (CFI $> 80\%$). In the early years of use, many surgeons did not consider cortical contact of the stem to be necessary. We found that 24% of the stems had a CFI of $\leq 80\%$ and were graded as undersized according to the present standards. However, it has been reported by others that undersizing of the stem was not associated with aseptic loosening in the short term and midterm [28, 42]; our results suggest that it may be an issue when long-term stem survivorship is the end point being considered. Our data indicate that stems in hips requiring cup revision were at higher risk for stem revision. In some cases, the stem was extracted to facilitate access to the acetabular component or to restore hip offset and leg length at the time of revision surgery despite being well fixed. It is important to note that in our study using an uncemented stem, we found young age and male sex were not associated with a higher risk of aseptic stem loosening into the early third decade. Our results partially confirm the findings of Hallan et al., who found no influence of age at surgery on the survival of uncemented stems in a registry analysis [25]. In contrast to our findings, male sex had a moderate negative influence on long-term stem survival (relative risk 1.3) in their registry study. Berry et al. analyzed risk factors for aseptic loosening in a large series of cemented Charnley THAs at a followup of 25 years [6]. They found that young age and male sex were independent risk factors for long-term aseptic stem loosening. We believe the results from our study and others justify the use of cementless femoral fixation with contemporary implants, especially in young and active patients.

Long-term survival achieved with standard femoral components (Table 5) can serve as a benchmark for new implants. The excellent long-term results of uncemented standard femoral components leave little room for further improvement regarding longevity. Overall survivorship of the reconstructions in this series was principally limited by failures of smooth threaded, cementless acetabular components. However, more generally, there is a concern that the longevity of primary cementless THA may indeed be limited by failures related to the bearing surface and of the acetabular component [32].

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