Five-year prospective subsidence analysis of 100 cemented polished straight stems: A concise clinical and radiological follow-up observation

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Abstract

Early subsidence (>1.5mm) has been shown to be an indicator for later aseptic loosening of cemented hip stems. For the cemented twinSys® stem we published excellent short-term results at 2 years. Mid-term data for this stem are available from national registers (NZL, NL), however in all of these sources, clinical and radiological results are missing. Aim of our study was to analyse mid-term survival and radiological changes around the cemented twinSys® stem with special emphasis on subsidence using EBRA-FCA. We conducted a prospective clinical and radiological 5-year follow-up study of 100 consecutive hybrid total hip arthroplasties (THA) using a polished, cemented collarless straight stem (twinSys®, Mathys AG® Bettlach, Switzerland) with a cementless monobloc pressfit cup (RM pressfit®, Mathys AG® Bettlach, Switzerland). Median age at surgery was 79 (69 to 93) years. No patient was lost to follow-up. Survival rates were calculated using the Kaplan-Meier method. Clinical (Harris Hip Score [HHS]) and radiological (cementing quality, alignment, osteolysis, debonding and cortical atrophy) outcomes and an in-depth subsidence analysis using EBRA-FCA were performed. 22 patients died in the course of follow-up unrelated to surgery, 21 stems had an incomplete radiological follow-up. 2 stems were revised, both due to an infection. The survival rate for the stem at 5 years was 98.0% (95% CI 95.3-100%). The survival rate of the stem for revision due to aseptic loosening at 5 years was 100%. The HHS improved from 53 (14-86) points preoperatively to 90 (49-100) points 5 years after surgery. Osteolysis was found in 2 stems without clinical symptoms. In 49 out of 55 patients with a complete radiological follow-up, the EBRA-FCA analysis was possible and showed an average subsidence of 0.66 (95% CI 0.46 to 0.86) mm 5 years after surgery. 10 patients showed a subsidence >1 mm, 5 of which bigger than 1.5 mm. Subsidence was independent from radiological changes and cementing quality.

The cemented twinSys® stem showed excellent clinical and radiological mid-term results at five years' follow-up and seems to be a reliable implant.

Introduction

Despite a growing popularity of cementless stems, cemented stem fixation can still be seen as the benchmark for stem fixation with negligible revision rates in the first decade after THA.[1-4] Early subsidence of cemented stems is highly predictive for later aseptic failure. Different cut-off values, depending on the means of measurement, are described.[5-8] These different measurements can be performed with plain radiographs, EBRA-FCA (Femoral Component Analysis using Einzel-Bild-Röntgen-Analyse) or RSA (Roentgen Stereophotogrammetric Analysis). Plain radiographs have the lowest accuracy and RSA offers the highest accuracy with EBRA-FCA being in the middle.[9]

Two different design concepts, namely "composite-beam" (shape-closed) and "load-tapered" (force-closed), are described for the fixation of a cemented stem,[10] with excellent long-term results for both design concepts.[11-17] The cemented twinSys stem analysed in the present study was designed according to the load-tapered concept, but as compared to the Exeter stem as one of the most successful load-tapered stems,[12-17] missing a distal centraliser. The Exeter design allows lodging as a wedge in the cement when axially loaded, reducing peak forces.[5] Some initial subsidence is frequently observed until an equilibrium between the axial loading forces and the radial compressive forces is reached and the implant is stable.[5]

We recently published excellent clinical and radiological 2- and 5-years follow-up data for the cemented and cementless version of the twinSys stem.[18,19] Excellent data for the TwinSys stem system is available from national registers (NZL, NL), however in these sources, clinical and radiological results are missing. Therefore, close monitoring of this new implant is still mandatory until long-term data with high case numbers exist which can confirm the longevity of the implant with clinical long-term results.

Aim of this study was to present a follow-up report after 5 years of the recently published 2-year data, focusing on mid-term survival, subsidence and radiological changes during follow-up of the cemented twinSys straight stem.

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Materials and Methods

Between Jan 2009 and Oct 2010, a total of 285 primary total hip arthroplasties (THA) were performed at our institution. In 100 (97 patients) hips, a cemented twinSys stem was implanted. Patients had a prospective follow-up including radiographs (pelvis with the patient in supine position centred on the symphysis and a false profile view) after 1 week, 3, 12, 24 and 60 months. Mean age at surgery was 79 (SD 6) years; mean BMI was 25.4 (SD 4.8) kg/m^2. Mean duration of surgery was 124 (SD 23) min. THA were implanted as a primary procedure for osteoarthritis (n=79), osteonecrosis (n=6) and femoral neck fractures (n=15). In the remaining 185 hips operated on during the study period, the cementless twinSys stem was implanted. All operations were performed or supervised by two senior physicians (TI, MC). Data analysis and EBRA-FCA was performed by two independent observers (KM, WS) not involved in the operations or follow-ups. If there were disagreements between the observers, results were discussed with the senior author (MC) and decisions taken as a consensus. All patients agreed to participate in the study with written informed consent and approval of the local ethics committee (Ethikkommission Nordwestschweiz; EKNZ 2015-125) was obtained. No patient was lost to follow-up.

The cemented twinSys is a polished (mean surface roughness Ra 0.4 μm) triple taper stem. 97 stems were combined with a cementless RM pressfit cup (Mathys AG Bettlach, Switzerland) the remaining 3 stems with a Muller acetabular reinforcement ring (ARR) and a cemented PE cup.[18]

All patients were operated in the routine setup of a teaching hospital with either a direct lateral Hardinge approach on a fracture table (n=22, STD), or with an anterior MIS approach on a traction table (n=78, MIS), both in a supine position as recently published.[18] Stems were cemented with a third-generation cementing technique using a distal cement restrictor (Synplug®, Mathys AG Bettlach, Switzerland) using Palacos® R+G bone cement (Hereaus Medical, Dübendorf, Switzerland). Patients were mobilised either on the day of surgery or the day after with full weight bearing. Crutches were advised for comfort as needed for 6 weeks.

Clinical evaluation

Clinical follow-up included a standardised examination, using the Harris Hip Score (HHS)[20] at all time points.

Radiological evaluation

Cement mantle quality was rated according to Barrack.[21] Varus/valgus alignment of the stem was measured on the postoperative ap radiograph, a deviation of more than 3° was defined as malalignment.[22] Debonding was defined as a radiolucent line at the prosthesis-cement-interface not visible on the first postoperative radiograph.[22] Osteolysis was defined as a progressive, newly developed endosteal bone loss with a diameter greater than 3 mm at the cement-bone-interface.[7] Debonding and osteolysis were manually measured on the plain radiographs and reported according to their location in the Gruen zones.[23] Subsidence of the stem was measured using the software based EBRA-FCA method.[18] Additionally all radiographs were analysed for cortical atrophy.[24]

Osteolysis around the cup was rated according to the zones described by DeLee and Charnley.[25]

Statistics

A Shapiro-wilk test was used to test for normal distribution of the data. As data were not normally distributed, median and range were used to describe the data.

For comparison of the data we used either a Mann-Whitney (continuous data) or Chi-square test (categorical data). Paired data were tested using a Wilcoxon signed rank test. Implant survival was calculated using Kaplan-Meier survival analysis for the endpoints aseptic loosening of the stem and reoperation for any reason. A P-value<0.05 was considered significant. IBM SPSS Statistics 24 was used for statistical analysis.

Results

Survival analysis

Twenty-two patients died during the first five years unrelated to surgery. During the first 2 years, 4 hips sustained a prosthetic joint infection (PJI), all of them were treated successfully (2 debridement and implant retention (DAIR), 2 one-stage exchange), no further infection occurred

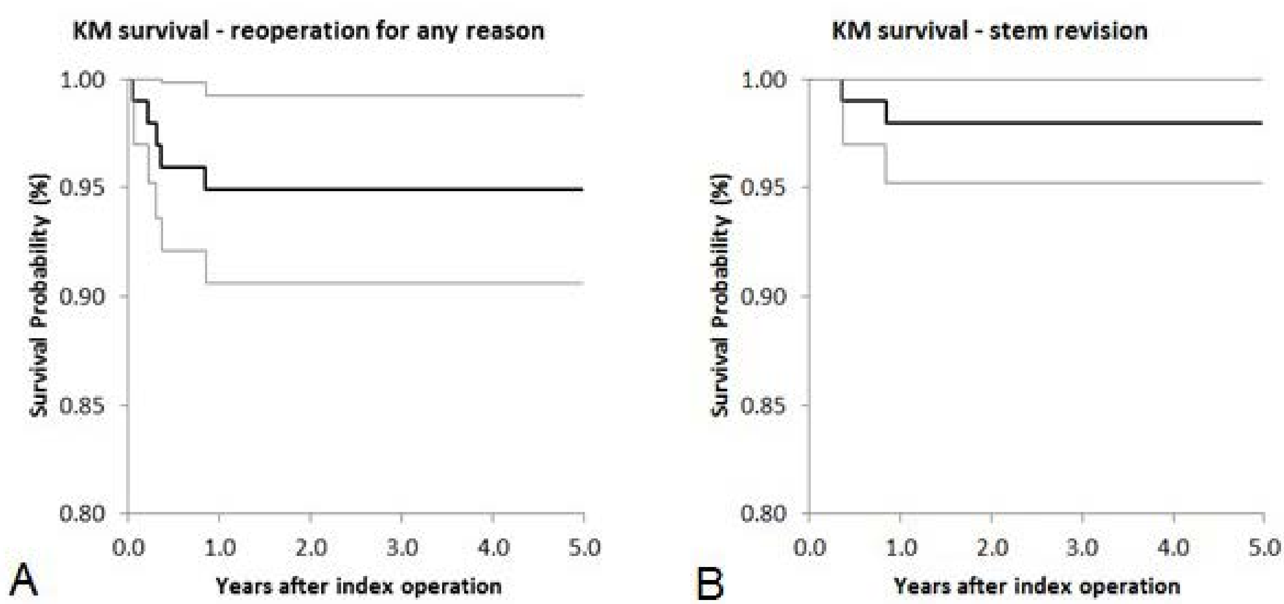

Figure 1. Kaplan Meier survival A) for the reoperation and B) for the stem revision for any reason.

during the further 3-year follow-up. One patient sustained a periprosthetic fracture (Vancouver type B1) 3 months after surgery due to a fall, and was treated with osteosynthesis, stem survival was uneventful thereafter. One patient had two early dislocations 4 and 5 weeks postoperative after an anterior approach. These were treated with closed reduction and healed uneventfully without further subluxations during the follow-up period. The KM survival remained unchanged between 2- and 5-year follow-up and was 98.0% (95% confidence interval 95.3-100%) for the stem revision, 94.9% (95% confidence interval 90.6-100%) for the reoperation for any reason (Figure 1) and 100% for the revision due to aseptic loosening.

Clinical outcome

The HHS (Harris Hip Score) improved from 56 (14-86) preoperatively [STD 57 (20-86) *vs* MIS 56 (14-85), P=0.64] to 95 (60-100) 2 years postoperatively (STD 95 (79-100) *vs* MIS 95 (60-100), P=0.91) and decreased again to 90 (49-100) 5 years [STD 91 (59-100) *vs* MIS 89 (49-100), P=0.90] after the operation. The only difference in HHS between the two approaches was found 6 weeks after surgery [STD 76 (49-94) *vs* MIS 84 (51-100), P=0.06].

Radiological outcome

At 5 years 52 stems had a complete radiological follow-up consisting of 5 radiographs and 3 stems had a radiological follow-up consisting of at least 4 radiographs (minimum number needed for EBRA measurement) including a 5-year radiograph. 21 patients had an incomplete radiological follow-up (<4 radiographs or no 5-year radiograph) and were thus not suitable for EBRA analysis. 2 patients were revised for the reasons mentioned above and 22 patients had deceased (Figure 2).

Cementing quality was rated grade A in 47%, B in 44%, C in 7 % and D in 1% of the stems. The overall alignment was neutral for 70%, varus in 15% and valgus in 14% of the stems and did not change during the follow-up. Alignment was independent of the approach (P=0.273).

Osteolysis around the stem was seldom and seen in only 2 stems in Gruen zone 7. Between the 2 and 5-year follow-up there were no newly detected osteolysis. No debonding was observed during the whole study period. During 2- and 5-years' follow-up 8 stems developed cortical atrophy. This phenomenon always started in Gruen zones 2 and 6. Extensive cortical atrophy involving Gruen zones 2, 3, 5, and 6 was found only once (Figure 3).

EBRA-FCA analysis

49 of 55 hips (89.1%) with a radiological follow-up consisting of at least 4 radiographs at five years could be analysed with EBRA-FCA. The average subsidence was -0.4 mm (95% CI -0.2 mm to -0.6 mm) after 2 years and increased to an average of -0.7 mm (95% CI -0.5 mm to -0.9 mm) after 5

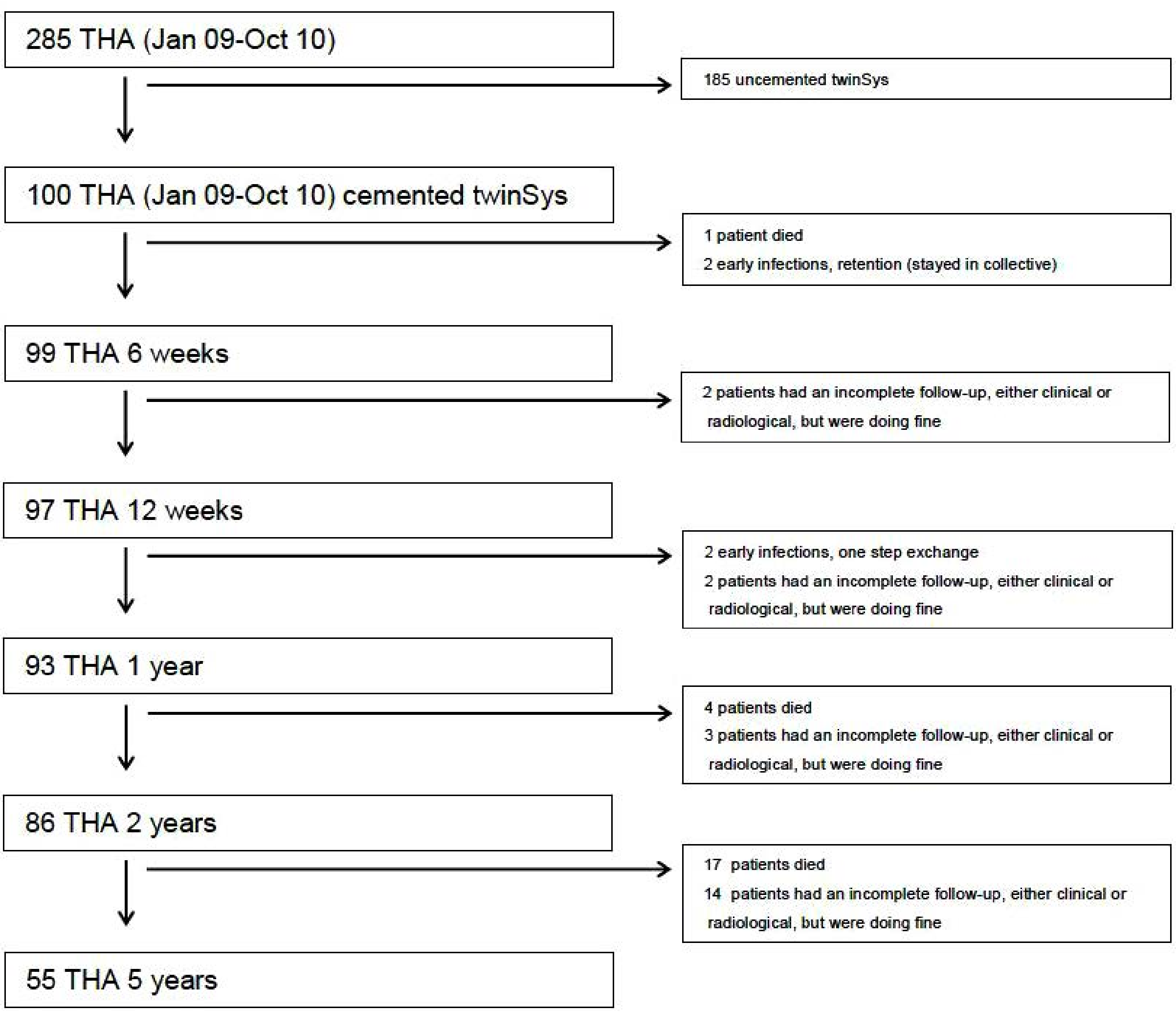

Figure 2. CONSORT flow chart of the included patients and the follow-ups.

years. 10 stems showed subsidence above 1 mm (Table 1). Only one stem (CRI414, Table 1) showed an accelerated subsidence between the 2- and 5-year follow-up visit, while all other stems showed a plateauing.

Cup

A single osteolysis was noted around the cup (Zone 2) on a radiograph taken 5 years after operative treatment, not visible on the two-year follow-up radiograph. No cup was revised for aseptic loosening or malpositioning.

Discussion

We present 5-year results of a prospective study with a clinical and radiological analysis of 100 consecutive cemented twinSys stems including an EBRA-FCA analysis of 49 stems. Survival for aseptic loosening at 5 years was 100%, 94.9% (95% confidence interval 90.6-100%) for all reasons of revision and 98% (95% CI: 95.3-100%) for the stem revision. This is comparable to survival rates of register data for the cemented twinSys stem and other well-known and successful cemented systems in larger multi-surgeon series (Table 2)[11,15,18,26,27] Furthermore it is comparable to the 5-year survival of the cementless TwinSys stem.[19]

Clinical outcome

Our clinical results are comparable to normal mid-term results of other successful THA implants. THA is known to be the operation of the 20thcentury. It has this reputation due to the high success rate and high patient satisfaction.[28] Our clinical data suggests that the cemented twinSys stem is on track to reach current standards of total hip implants. During the study period we changed our routine approach from a lateral transgluteal approach (STD) to a direct anterior minimal invasive approach (MIS).[29] While we found superior clinical results with the MIS approach up until 1 year after surgery analysing an non-selected cohort of patients receiving THA clinical results in this selected cohort of patients was the same already 12 weeks after surgery.[29] These differences might be explained due to institutional politics to implant cemented stems in elderly and/or rather frail patients (including femoral neck fractures), while the healthier and younger patients (n=185) during the observed time period were preferably treated with the cementless twinSys stem.

There might be some patient bias in our study. Prolonged operation time,[30] BMI and comorbidity[31] are well known risk factors for PJI. In our series the BMI was normal for patients receiving THA, but as our cohort is rather old comorbidities might have played a role in the development of PJI. Furthermore, a substantial number of operations have been performed by residents in training. This could have resulted in longer operation time, which, in part, might explain our higher rate of infec-

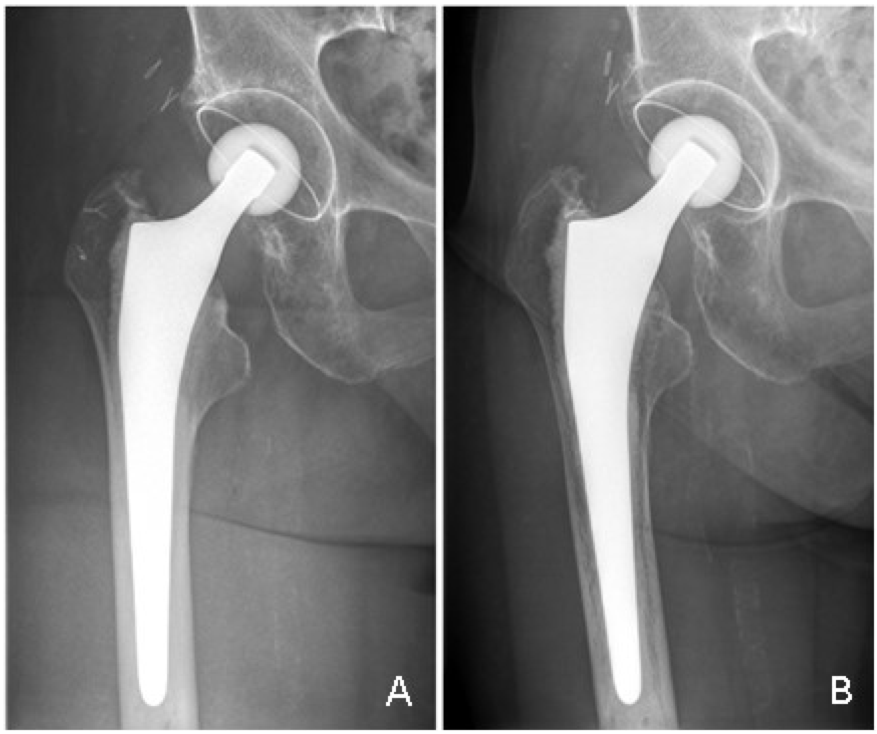

Figure 3. Development of cortical atrophy. Case description. A) Postoperative and B) 5 years after THA with cortical atrophy in Gruen zones 2, 3, 5 and 6 in a 91-year-old female patient treated with a cemented twinSys stem.

Table 1. Distribution of the subsidence measured by Femoral Component Analysis using Einzel-Bild-Röntgen-Analyse after 2 and 5 years (in mm) and the corresponding details on alignment, cementing quality (Barrack), offset, approach and diagnosis.

CRI	Subsidence at 2 years	Subsidence at 5 years	Alignment	Cementing Quality	Offset	Approach	Diagnosis
189	2.0	2.6	Neutral	D	Standard	STD	OA
276	0.9	1.2	Neutral	B	Lateralised	MIS	OA
315	1.2	1.9	Neutral	A	Lateralised	MIS	OA
332	0.7	1.4	Neutral	A	Lateralised	MIS	OA
338	1.3	1.6	Valgus	A	Standard	MIS	OA
351	1.6	1.6	Neutral	A	Lateralised	STD	OA
364	2.0	2.2	Valgus	B	Standard	STD	Fx
403	0.9	1.2	Neutral	A	Standard	MIS	OA
411	0.6	1.1	Valgus	B	Standard	STD	Fx
414	0.1	1.4	Neutral	B	Lateralised	MIS	OA

OA = Osteoarthritis, Fx = Fracture.

tion,[32,33] inferior cementing quality,[34] and due to the higher age group higher rate of death during the course of follow-up.[35,36]

A strength of the study is the complete follow-up of all patients, although some patients missed or declined to come to their follow-up appointments due to a lack of clinical complaints.

Radiological outcome

Radiological changes between the 2- and 5-years' follow-up were scarce concerning osteolysis and debonding. This is the expected course of a well cemented stem at mid-term follow-up. We found a substantial number of radiographs showing cortical atrophy. Some of these cases may have occurred due to the natural process, however cortical atrophy does not seem to be a risk factor for aseptic loosening.[11,24]

We did not analyse the false profile views as they were not done under fluoroscopy to standardise for rotational alignment.[34] Therefore we cannot exclude that we missed some osteolysis and debonding in the second plane.

EBRA-FCA analysis

A limitation of our radiological analysis is that at 5 years only 55 stems had a radiological follow-up suitable for EBRA-FCA (minimum 4 radiographs and 5-year radiograph). With a mean age of 79 years at the time of surgery the study group was rather old and an increasing number of patients, especially patients who were doing well, were not willing to come to all follow-up appointments. Nevertheless, 49 out of 55 stems were suitable for an EBRA-FCA analysis. This is much higher than reported in the literature.[7]

In the literature cut-off values between 1.2 mm and 1.5 mm for early subsidence being indicative for later aseptic loosening are described depending on the mode of measurement.[5-7,37] Krismer *et al.*[7] reported the highest cut-off value with a subsidence >1.5 mm in the first 2 years as the cut-off value for later aseptic loosening for cemented Müller straight stems. According to the "French Paradox",[38] the Müller straight stem is advocated as a shape closed stem,[24] which by design should not subside at all. In contrast to shape-closed stems, polished force-closed stems such as the twinSys, are intended to show some initial subsidence.[17,39] Aseptic loosening occurs as a consequence of cement mantle fatigue due to wear particles (PE and PMMA) created during walking (PE) and subsidence of the stem (PMMA). Interestingly De Vries *et al.*[37] using RSA analysis found an almost identical cut-off value (1.24 mm) using RSA investigating for 15 different stem designs representing both cementing philosophies (shape-closed and force-closed). It remains questionable whether a separation in cementing concepts is still meaningful or if factors like stem geometry and stem surface are more important for long-term survival of cemented stems.[40] We measured a mean subsidence of 0.66 mm at five years, which is clearly below all published cut-off values independent from the respective measuring method and philosophic considerations on stem design. All, except for one stem exceeding 1mm subsidence, showed an initial subsidence up until 2 years with a plateauing thereafter (Figure 4). Interestingly 5 year subsidence of the cemented TwinSys stem is rather the same as in a prospective series of cementless TwinSys stems which has recently been published.[19]

Five stems in our series showed a subsidence >1.5 mm at 5 years' follow-up. These stems are by definition at risk for aseptic loosening at a later time point. 3 of the 5 exceeded the benchmark of 1.5 mm of subsidence at 2 years. These stems have to be closely monitored to assess whether they

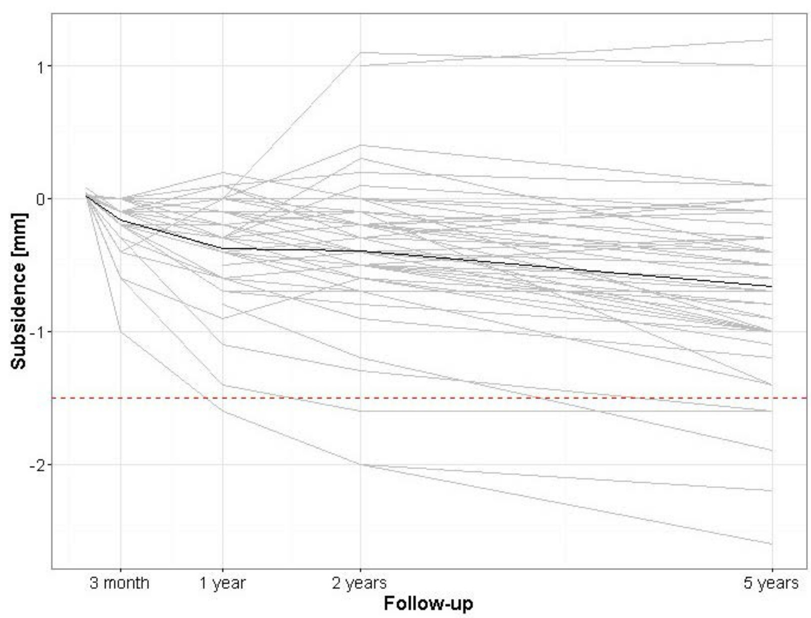

Figure 4. Subsidence of the 49 stems which could be analysed by EBRA-FCA at 3 months, 1, 2 and 5 years. The black line shows the average subsidence of all stems, while the red line shows the cut-off value for later aseptic looseni.

Table 2. Overview of the different implants and their long-term survival for aseptic loosening

Author	Year	Type	Implant	Fixation type	Survival rate and time
NZJR	2016	Register	TwinSys	Force-closed	0.52 revision per 100 component years
LROI	2016	Register	TwinSys	Force-closed	98.3 % survival 5 years
Siepen	2016	Follow-up	TwinSys	Force-closed	100 % survival 2 years
Ling	2009	Follow-up	Exeter	Force-closed	93,5 % survival 33 years
Makela	2008	Register	Exeter Müller straight	Force-closed Shape-closed	>90 % survival 15 years >90 % survival 15 years
Ogino	2008	Register	Exeter	Force-closed	95 % survival 15 years
Clauss	2014	Follow-up	TwinSys	Cementless	98,4% survival 5 years
This study	2018	Follow-up	TwinSys	Force-closed	98 % survival 5 years

have reached their final position or if further migration is occurring. 2 stems treated with DAIR early after the initial operation showed an uneventful course concerning the infection later on. However, one patient died (4 years after surgery) unrelated to surgery while the other showed a subsidence of -0.4 mm on radiographs taken at 5 years. The stem with the largest subsidence (CRI 189) was the only stem with an insufficient cementing quality (Barrack D). This highlights the importance of having a complete cement mantle in force-closed cemented stems.

Conclusions

The cemented twinSys stem showed excellent clinical and radiological short- and midterm results at 2- and 5-years' follow-up with only minimal subsidence of the stem. Our data supports the literature showing that poor quality of the cement mantle is a risk factor for later aseptic loosening. However, at 5 years' follow-up the cemented twinSys stem is a reliable implant.

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