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Mid-term results of an uncemented tapered femoral stem and various factors affecting survivorship

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ABSTRACT

Objective: CLS stem is commonly used today in primary hip arthroplasty, but only a few studies have evaluated their outcome in young high demanding patients. In Indian scenario, many patients require squatting and sitting cross-legged as part of their daily activities placing excessive load on the joint. We evaluated (I) Mid-long term functional and radiological results (II) Influence of age, gender, diagnosis, stem alignment, Canal fill index (CFI) on the outcome (III) Kaplan-Meier survivorship using revision for any reason or for aseptic loosening as an endpoint.

Methods: Retrospective evaluation of 64 THA in 54 patients operated between July 2000 to July 2011 using CLS stem was done. Mean follow-up was 10.3 years (5–14.9 years) with 5 patients lost to follow-up and 4 patients died. Mean age at surgery was 46.8 years (18–78 years).

Results: Mean Harris hip score was 89.4 (72–100). Thigh pain was present in 4 hips which were not associated with the sizing of the stem ($p = .489$). Stable fixation by bony ingrowth was seen in 53 hips (96.4%) and by fibrous ingrowth in 2 cases (3.6%) with no case of loosening seen. Stress shielding was seen as Grade II in 17 hips (30.9%), Grade III in 3 hips (5.4%). Pedestal formation was seen in 9 hips (16.4%) which were statistically associated with varus alignment and CFI < 80. No stem revision was performed with stem survivorship of 100%.

Conclusion: The mid-term survival rates and good clinical-radiological outcomes of CLS stem in high demanding Indian population were excellent.

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1. Introduction

Cementless prosthesis was developed to achieve biological implant-bone fixation and reduce aseptic loosening rates which were the most common cause of long-term failure of cemented system.[1–3] Cementless prosthesis is now commonly used as the preferred modality of fixation and almost constitutes two-third of the Total Hip Arthroplasties (THA) in the United States.[4] Initial stability achieved during implantation and peri-prosthetic bone growth achieved later, are important factors responsible for long-term survival of cementless prosthesis.[5] The second generation of the cementless system has overcome the issues related with the first generation of cementless prosthesis like thigh pain, peri-implant osteolysis, stress shielding.[6] Excellent results have been seen with uncemented tapered titanium femoral components with minimum osteolysis and stress shielding.[7,8]

CLS femoral stem is a collarless, three dimensional tapered stem with fins on proximal anterior and posterior surface to achieve proximal stability. Various authors have reported excellent results using CLS stem with long term survivorship.[9–13] There are three studies published till date showing long term results of CLS stem in young and active population.[11,14–16] Younger population due to their highly demanding activities places greater loads on the joint reconstruction.[15] In Indian population, squatting and sitting cross-legged is an integral part of daily activities, with many patients from rural areas earn their daily livelihood through highly demanding physical activities like farming or manual labor placing excessive loads on the joint.

The goal of the study was to evaluate the mid to long term functional and radiographic results of cementless CLS stem in this high demanding Indian population and to evaluate the influence of age, gender, diagnosis, stem alignment and Canal fill index (CFI) on the outcome. Kaplan-Meier survival analysis was used to evaluate the CLS stem survivorship rate with femoral revision for any reason or for aseptic loosening considered as an endpoint.

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2. Materials and methods

We retrospectively evaluated the functional and radiographic features of 64 THA in 54 patients using an uncemented, tapered, collarless titanium stem (CLS Spotorno, Zimmer, Warsaw, IN, USA; formerly Sulzer Orthopaedics, Switzerland) between July 2000 to July 2011, after institutional review board approval. Informed consent was obtained from all the patients for inclusion in this study and in our center database. Mean age of the patient at the time of surgery was 46.80 (range 18–78) with 33 male and 21 female in the study with M/F ratio 1.57. Demographic data along with indications of replacement and components used in the study are mentioned in Table 1.

CLS stem is a rectangular wedge shaped, collarless stem which is tapered in all three planes with proximal anterior and posterior flutes (Fig. 1). Stem is implanted using the press-fit technique described by Spotorno et al.[17] Stem is made up of Ti6A17Nb alloy with Ra microporous treatment (Ra = 4.4 μm) and has grit blasting surface which incurs secondary osteointegration properties. This implant has remained unchanged except for a modification (i) in the shape of the flutes in 1992 with proximal sharpened edges to increase stem penetration property and to reduce fissure risk (ii) two offset options which were added in 1997(135^0) and 2004 (125^0).

Various sizes of 135^0 CLS stem used were 5 (6), 6 (6), 7 (13), 8 (11), 9 (9), 10 (12), 11.25 (5), 12.5 (2). The femoral stem was paired with 4 types of acetabular component. In 46 hips (71.9%) Durom® cup (Zimmer, Warsaw, IN, USA) was used, 11 hips (17.2%) received Plasmacup® (Aesculap, Tuttlingen, Germany), 6 hips (9.4%) were implanted using Trilogy cup (Zimmer, Warsaw, IN, USA) and in 1 case (1.5%) Birmingham cup ® (Smith & Nephew, Memphis, TN, USA) was used. The femoral head used was the metal head Protasul Cobalt Chrome Metasul alloy (Zimmer, Warsaw, IN, USA) in 46 hips (71.9%), 28 mm head of CoCrMo alloy (Sulzermedica) in 3 hips (4.7%) and 32 mm Al2O3 ceramic femoral head (Biolox®, CeramTec AG, Plochingen, Germany) in 15 hips (23.4%). Various sizes of the Metasul head used in 46 hips were 44–50 mm in 29 hips (63.1%), 52–56 mm in 14 hips (30.4%), >56 mm in 3 hips (6.5%). The bearing surface was metal on metal in 47 hips (73.4%), ceramic on ceramic in 12 hips (18.8%), ceramic on polyethylene (UHMWPE) in 3 hips (4.7%) and metal on polyethylene (UHMWPE) in 2 hips (3.1%).

Table 1
Patient demographics and distribution of implant used.

	Number of hips
Diagnosis	
AVN	32 (50%)
Fracture neck and head femur	11 (17.2%)
Osteoarthritis	6 (9.4%)
Post-traumatic arthritis	5 (7.8%)
Ankylosing spondylitis	4 (6.2%)
Rheumatoid arthritis	4 (6.2%)
OtherS	2 (3.2%)
Gender	
Male	33 (61.1%)
Female	21 (38.9%)
Male/Female ratio	1.57
Side	
Right	25
Left	19
Bilateral	10
Mean age at the time of surgery	46.80 (range 18–78)
Acetabular components used	
Durom cup	46 hips (71.9%)
Plasmacup	11 hips (17.2%)
Trilogy cup	6 hips (9.4%)
Birmingham cup	1 case (1.5%)
Bearing used	
Metal on metal (MOM)	47 hips (73.4%)
Ceramic on ceramic (COC)	12 hips (18.8%)
Ceramic on polyethylene (COP)	3 hips (4.7%)
Metal on polyethylene (MOP)	2 hips (3.1%).
Femoral head used	
Metasul head	46 hips (71.9%)
Biolox ceramic head	15 hips (23.4%)
CoCrMo alloy metal head	3 hips (4.7%)

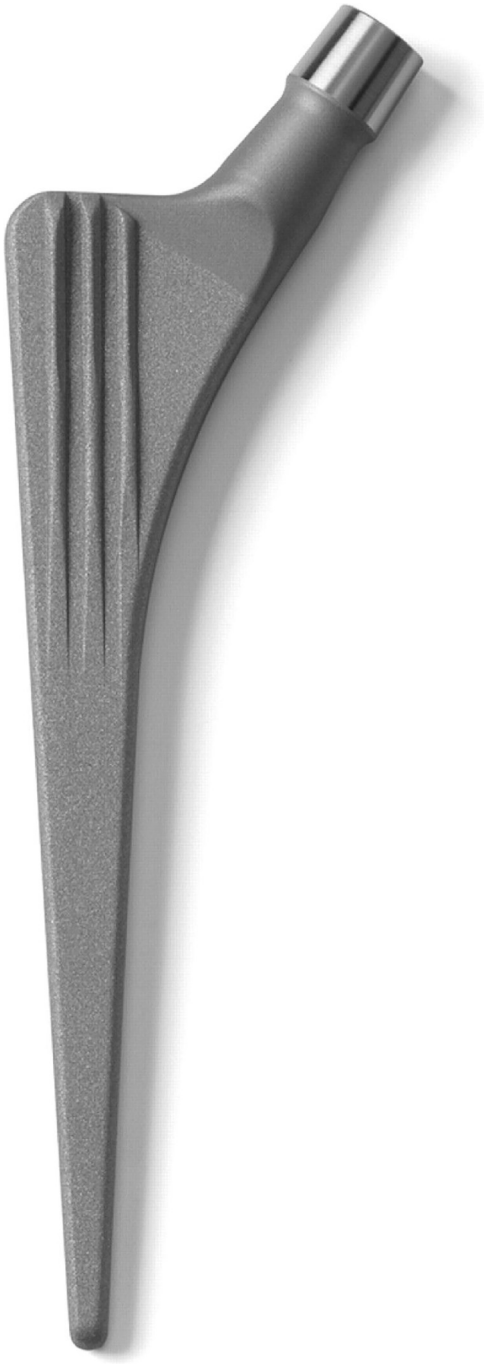

Fig 1. Photograph of CLS femoral stem (Zimmer, Warsaw, IN, USA).

2.1. Surgical technique

All operations were done in lateral position by a single surgeon (VS) using Modified Hardinge approach in 53 hips, posterior approach in 4 hips and Ganz approach in one hip. Final stem size was considered adequate when a series of hammer blows did not change the position of the stem and stem fixation was regarded as stable if there is no relative movement between femur and stem on applying axial and rotational torque. Three doses of intravenous Cefazolin was given peri-operatively, first dose in the preoperative period and two doses in the postoperative period. Drain was removed at 2nd postoperative day and suture removal was done at 12th day. Full weight bearing was started for all patients on the 1st postoperative day. No prophylaxis for heterotopic ossification was given. Patient controlled analgesia for pain management and low molecular weight heparin with venous foot pumps for DVT prophylaxis was given to all patients.

2.2. Clinical and radiological evaluation

The evaluation was done at regular intervals at 6 weeks, 3 months, 6 months, 1 year and annually thereafter. Clinical assessment was done using Harris Hip Score[18] at the last follow-up. Radiological assessment was done on weight bearing pelvis radiograph in anteroposterior and lateral view. It was evaluated by 2 observers for alignment, osteolysis, heterotopic ossification, stress shielding, subsidence, pedestral formation. Varus or valgus malalignment was defined as a deviation of 3^0 or more between femoral and stem axis.[19] Osteolysis was defined as localized or endosteal bone resorption as proposed by Willert et al.[20] Radiolucent lines, osteolysis, cyst and cortical hypertrophy were evaluated as per the zones defined by Gruen et al.[21]

Engh criteria[22] was used to evaluate stress shielding and femoral component fixation. Rounding off the medial femoral neck which is graded as Grade I stress shielding in Engh classification was not considered as a sign of stress shielding but stability.[11,15] Heterotopic ossification was evaluated using Brooker classification.[23] Subsidence was defined as an increase in the distance of >3 mm between the tip of greater trochanter and shoulder of the prosthesis on comparing previous and recent radiograph.[24] Pedestral is defined as the presence of partly or completely bridging new endosteal bone in the medullary cavity.[25] Canal width index (CFI) was calculated on immediate post-operative AP radiograph as the ratio between implant width to canal width at 3 cm distal to lesser trochanter.[26] Our cut-off to define undersized stem was CFI $\leq$ 80%.

2.3. Statistical analysis

Statistical analysis was performed using SPSS Version 20.0 (SPSS Inc, Chicago, IL, USA) software by a statistical consultant with P values of $<.05$ considered significant. Kaplan Meier survival analysis was performed to estimate the overall survival rate of the stem using MedCalc Statistical Software version 16.8 (MedCalc Software bvba, Ostend, Belgium). The worst-case survival analysis was also evaluated on the assumption that all the cases which were lost to follow-up and all the patients who had died failed and had been revised. The time to revision was classified as the time duration between the date of implantation and that of revision. Multivariate survivorship analysis for age, gender, diagnosis, stem alignment and Canal fill index (CFI) was performed using Cox regression model with femoral revision for any reason as an end point.

3. Results

Mean follow-up was 10.3 years with a minimum follow-up of 5 years and a maximum of 14.9 years. Forty-five patients with 55 hips out of 64 operated THA were available for final follow-up (Fig. 2). Four patients (4 hips) died and 5 patients (5 hips) lost to follow-up. In all the patients who died, the average time between last review and death was 1.5 years. In all the 4 patients who died, the stem was in situ at the time of death and patients were asymptomatic.

3.1. Clinical assessment

Mean Harris Hip Score (HHS) in 55 hips that were available for follow-up was 89.4 (range 72–100). HHS shows excellent outcome in 33 hips (61.9%), good outcome in 12 hips (23.6%) and fair outcome in 8 hips (14.5%) (Table 2). Subgroup of patients with fair outcomes (8 hips) include 3 patients (4 hips) with Ankylosing spondylitis, 1 patient (2 hips) in advanced HIV with myelopathy and spasticity, 1 patient each of chronic Lumber canal stenosis and rheumatoid arthritis. Thigh pain was reportedly seen in 4 hips (7.3%) which was mild and required no further intervention.

3.2. Radiologic assessment

As per Engh criteria, stable fixation by bony ingrowth was seen in 53 hips (96.4%), stable fixation by fibrous ingrowth was seen in 2 cases (3.6%) and no case of unstable implant fixation was seen. There was no radiographic evidence of definite loosening of the femoral stem seen in any case. The femoral component was implanted in neutral position in 36 hips (65.4%), in varus position in 13 hips (23.6%) and in valgus position in 6 hips (10.9%). There was no change in varus/valgus alignment of any of the stem seen as compared to immediate postoperative radiographs. There were 31 hips with CFI $\geq$ 80 and 24 hips with CFI $<$ 80. There was a statistically significant association seen with varus alignment of the stem to pedestal formation (p value = .02).

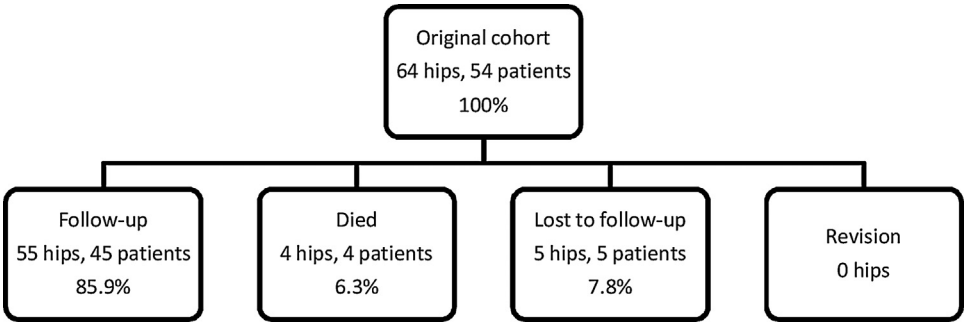

Fig. 2. Flowchart showing distribution of hips at final follow-up.

Table 2
Clinical and radiological outcome at final follow-up.

	No of THA
Harris hip score	
Excellent (90–100)	34 (61.9%)
Good (80–89)	13 (23.6%)
Fair (70–79)	8 (14.5%)
Poor ≤70	0
Thigh pain	4 hips (7.3%)
Engh criteria	
Stable bony ingrowth	53 hips (96.4%)
Stable fibrous ingrowth	2 cases (3.6%)
Unstable implant	0
Heterotopic ossification	
Grade I	17 (31%)
Grade II	11 (20%)
Grade III	3 (5.5%)
Grade IV	1 (1.7%)
Stress shielding	
Grade II	17 hips (30.9%)
Grade III	3 hips (5.4%)
Grade IV	0
Stem alignment	
Neutral	36 hips (65.4%)
Varus	13 hips (23.6%)
Valgus	6 hips (10.9%)

Heterotopic ossification was seen in 32 out of 55 hips (58.2%) and as per Brooker classification was graded as Grade I (17 hips), Grade II (11 hips), Grade III (3 hips) and Grade IV (1 hip). Mean canal fill index was 86% (65–100%). Twenty one stems (38.2%) had a CFI <80% and were classified as undersized. Stress shielding was graded as Grade II in 17 hips (30.9%), Grade III in 3 hips (5.4%). No case of Grade IV stress shielding was reported. Rounding of the medial femoral neck was seen in all the stems. Radiolucent lines were limited to only zone 1 and 7 however there was no case reported with progressive radiolucent line or osteolysis. Pedestal formation was seen in 9 hips (16.4%) and cortical hypertrophy in 5 hips (9.1%). There was a statistically significant association seen with CFI < 80 to pedestal formation (p value = .032).

3.3. Complications

Trochanteric non-union with screw breakage was seen in one case wherein two 4 mm partially threaded cannulated cancellous screws were used to fix greater trochanteric fragment during Ganz approach. One case of superficial wound infection was seen in the immediate post-operative period which healed eventually with antibiotics. Osteomyelitis of distal femur was reported 17 months post-THA in a patient with HIV on immunosuppressive agents. Debridement and intravenous antibiotics was given and it healed eventually without any affect on femoral component. One patient had dislocation at the 11th postoperative day which was successfully treated by closed reduction and knee immobilizer for 3 months. No revision of femoral or acetabular component has been performed out of all the patients available for follow-up.

3.4. Stem survival

Kaplan-Meier survivorship analysis at 7 years using the revision of the femoral stem for any reason and for aseptic loosening as the end point is 100% (Fig. 3A). Assuming that all patients lost to follow-up be failures describes a stem survival rate of 88% (95% confidence interval [CI], 78–98%) (Fig. 3.B). The worst-case scenario survival rate of the CLS stem assuming that all patients who died and all patients lost to follow-up be failures was 76% (95% CI, 61–94%) (Fig. 3C).

4. Discussion

Uncemented tapered titanium femoral stems have reported excellent long term survivorship with decreased rates of stress shielding and osteolysis.[7,8,26] Various studies have reported long term survivorship of CLS stem into the second decade (Table 3). Streit et al[27] have reported excellent outcomes of the CLS stem into the third decade with revision for any reason as an endpoint comparable to the best reported series of cemented THA. Most of the studies reporting excellent survivorship include western population, where squatting and sitting cross-legged is not a part of daily routine activities. Our study therefore, evaluating the clinical and radiological outcome of CLS stem in Indian population where they place increased demands on their replaced joints.

4.1. Clinical assessment

Mean Harris Hip Score of 89.4 in our study is comparable to mean HHS of 88 at 10 years in the study conducted by Schramm et al[28] and a mean of 86 at 17 years by Muller et al.[13] Biemond et al[11] have reported mean HHS of 94 after CLS stem fixation in patients less than 50 years of age. Due to the younger cohort of patients, their outcome in terms of HHS was better than ours.

We reported a total of 4 hips (7.3%) with thigh pain which is slightly less than 25% cases of thigh pain reported by Muller et al.[13] We found no correlation with undersized or tight fit of the stem as the reason for thigh pain (p value = .489) as is reported by Muller et al.[13] Various authors have reported the absence of distal reaming or press-fit as the reason for the absence of thigh pain in their study.[28,32,33]

4.2. Radiological assessment

There were no cases of radiologically evident loosening reported with stable bony ingrowth seen in 53 cases and stable fibrous ingrowth in 2 cases. Radiolucent lines were reported in 16 out of 55 hips (29.1%) and were limited to Zone 1 (RL <2 mm = 12 hips, RL >2 mm = 2 hips) and Zone 7 (RL <2 mm = 3 hips, RL >2 mm = 1 hip). Radiolucent lines were reported in 35% of the hips at 10-year follow-up by Biemond et al[11] and in 10% cases by Streit et al.[27] In both the studies, radiolucencies were seen in Zone 1 and 7 only with no radiolucency in zone 3, 4, 5 and 6. There were no cases of progressive osteolysis and severe stress shielding which is being explained by the fact that the more proximal metadiaphyseal loading provided by the CLS stem prevents severe stress shielding.[10] Also, titanium which is more flexible prevents stress shielding as was seen with cobalt chrome cementless stems.[34]

Rounding of the femoral neck which was previously being described as Grade I stress shielding in Engh classification is seen in all the hips (100%). There is a strong association between the stability of the CLS stem with rounding of the femoral neck and we suggest that this radiological feature should be considered as a sign of good implant fixation rather than of stress shielding. Radiolucent lines more than >2 mm were found in 3 hips (5.4%) and Pedestal formation was seen in 9 hips (16.4%). Although both of them are considered as signs of instability, they have not affected the clinical outcomes and will be monitored closely. Undersizing (CFI ≤ 80%) was seen in twenty-one stems (38.2%). There was no association of CFI ≤ 80% with aseptic loosening rates in our study as seen in other studies.[12,13] Streit et al[27] have concluded that undersizing of the stem does not have any effect on aseptic

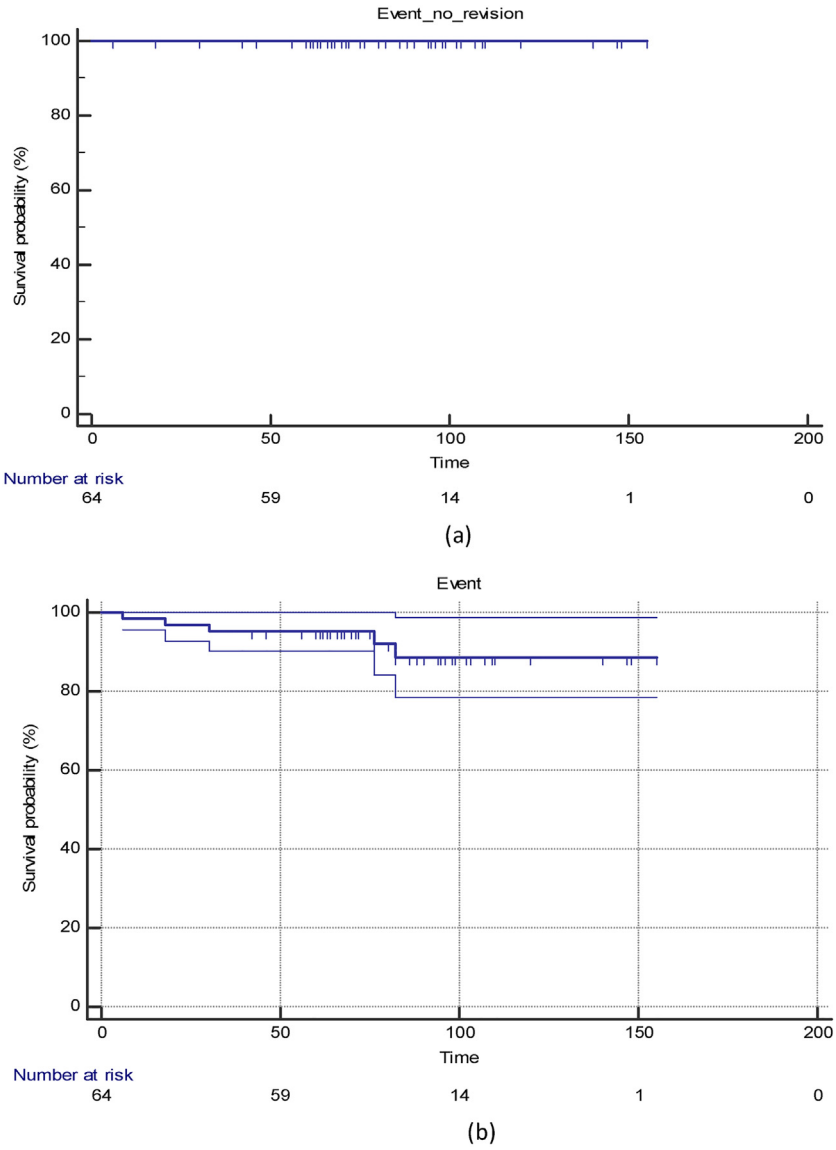

Fig. 3. (a) Kaplan-Meier survivorship curve with 95% CI with revision for any reason as the end point is 100% (b) With patients lost to follow-up as failures gives stem survivorship of 88% (95% confidence interval [CI], 78–98%) (c) Worst case survival rate is 76% (95% CI, 61–94%).

loosening rates in the short-term and mid-term, however long term aseptic loosening rates were higher for the undersized stem. Multivariate Cox regression analysis showed no association of age, gender, diagnosis, canal fill index and stem alignment on the survival of the stem.

Our study demonstrates a good mid-term survival rate of CLS stem in young high demand Indian population. Our results are consistent with studies on CLS stem showing excellent survivorship into the second decade[9,14,27–31] and studies on other cementless femoral stems with good long term outcomes.[8,34–36]

Table 3
Various studies showing survivorship of CLS stem.

Study	Mean follow-up (years)	Number of hips	Stem Survivorship for any cause (%)	Stem survivorship for aseptic loosening (%)
Schramm et al[29]	10	107	100 at 10 years	100 at 10 years
de Witte et al[32]	12	102	–	99 at 15 years
Streit et al[11]	12	89	96 at 12 years	99 at 12 years
Siebold et al[15]	12	298	94 at 12 years	–
Hwang et al[13]	12	227	97 at 16 years	100 at 16 years
Biemond et al[12]	12	100	97 at 13 years	98 at 13 years
Aldinger et al[10]	12	354	92 at 12 years	95 at 12 years
Mueller et al[14]	17	107	99 at 17 years	100 at 17 years
Aldinger et al[30]	17	354	88 at 17 years	94 at 17 years
Terre et al[31]	18	171	97 at 21 years	–
Streit et al[28]	22	354	86 at 22 years	93 at 22 years
Current study	7	64	100 at 7 years	100 at 7 years

5. Conclusion

In conclusion, the high survival rates and good clinical and radiological outcomes after uncemented THR using CLS stem in our Indian population are encouraging.

Conflicts of interest

The authors received no financial support for the research, authorship, and/or publication of this article and there are no conflicts of interest.

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