The Zweymüller primary stem is a reliable, effective, and less invasive implant in revision hip arthroplasty for Paprosky type I and II defects

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Aims
Revision hip arthroplasty for femoral stem loosening remains challenging due to significant bone loss and deformities requiring specialized revision stems. The aim of this study was to evaluate the clinical and radiological outcomes, and survival, of a consecutive series of femoral revisions performed using a primary cementless stem with tapered geometry and rectangular cross-section at medium-term follow-up.

Methods
We retrospectively evaluated 113 patients (115 hips) with intraoperative Paprosky type I (n = 86) or II (n = 29) defects, who underwent femoral revision with Alloclassic Zweymüller SL stem for one-stage aseptic revision or two-stage septic revision from January 2011 to December 2020. The mean follow-up was 77.9 months (SD 33.8). Nine patients were lost to follow-up (deceased or not available), leaving 104 patients (106 hips) for the clinical and radiological analysis. Clinical assessment was performed with Harris Hip Score (HHS) and visual analogue scale (VAS) before surgery and at final follow-up.

Results
There were 60 males and 53 females with a mean age at time of surgery of 71.2 years (SD 12.6). The mean HHS and VAS significantly improved at final follow-up, from 33.7 (SD 13.0) and 5.8 (SD 1.8) preoperatively to 66.4 (SD 16.8) and 2.1 (SD 1.8) postoperatively, respectively ($p = 0.001$ and $p = 0.001$). Overall, 28 patients (25%) showed non-progressive radiolucent lines at the level of proximal femur without radiological or clinical signs of loosening. One patient had a recurrence of periprosthetic joint infection after a two-stage procedure requiring re-revision surgery. One patient underwent exchange of modular components for recurrent dislocation, and another case of dislocation was treated conservatively. The survival with aseptic loosening as endpoint was 100%, while stem revision for any reason was 99.1% at up to 152 months' follow-up.

Conclusion
Alloclassic Zweymüller SL primary stem showed favourable medium-term results and survival for revision total hip arthroplasty in Paprosky type I and II defects.

Take home message
- The Alloclassic Zweymüller SL stem is a viable option for revision total hip arthroplasty (THA) for Paprosky type I and II defects.
- Its utilization for revision THA is associated with excellent mid-term survival and clinical outcomes.

Introduction
Total hip arthroplasty (THA) is one of the most successful operations in orthopaedic

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surgery, with the estimated number of procedures performed annually expected to increase exponentially. An increasing proportion of these patients are also younger and more active, increasing the lifetime risk of implant failure and the projected number of revisions.[1,2]

The severity of femoral bone defect encountered during revision surgery varies widely, and several classification systems have been proposed. Paprosky's[3] classification remains one of the most commonly used,[4] and it is based on metaphyseal bone integrity and the amount of residual bone in the diaphysis. The classification is also used to provide guidance on the choice of femoral stems to optimize fixation, stability, and long-term osseointegration. Depending on the patient profile, index surgery, and remnant bone stock after explant, multiple options, such as cement filling of bone voids, cement-in-cement techniques, and impaction bone grafting, have been used, with excellent results in the hands of experienced surgeons.[5,6] Among cementless stem designs, bypassing femoral defects with cylindrical, diaphyseal-engaging, fully porous-coated, cobalt-chromium stems has been one of the most popular choices historically. However, due to the extensive proximal stress shielding and high incidence of thigh pain, their use has greatly declined with the introduction of fluted tapered titanium-alloy long stems.[7,8] In recent years, primary proximal fit THA stems have been used in revision THA, with encouraging results.[9] The idea of "staying as proximal as possible or as distal as necessary" is gaining popularity,[10] avoiding the need for unnecessary therapeutic escalation during femoral revisions.[11]

The Zweymüller stem (Zimmer Biomet, USA) is a titanium-alloy (Ti-6Al7Nb) tapered stem with a rectangular axial geometry and a grit-blasted surface. It was first introduced for primary THA in 1979 and underwent extensive modifications in 1986. Before the implantation, the canal is prepared using sharp-cutting rasps to provide a bone bed in the cancellous and cortical bone.[12] Primary axial stability is provided by the tapered geometry, whereas rotational stability is conferred by four-point contact of the rectangular implant along the femoral canal. The roughness of the surface provides a favourable surface for osseointegration.

The aim of this study was to evaluate the clinical and radiological outcomes of a consecutive series of femoral revisions using a tapered rectangular primary stem by a single senior surgeon (LZ), with a minimum follow-up of three years.

Table I. Patient demographics and indications for revision (n = 113 patients, 115 hips).

Variable	Value
Sex, n	
Male	60
Female	53
Mean age, yrs (SD, range)	71.2 (12.6, 41.0 to 93.0)
Mean duration of follow-up, mths (SD, range)	66.0 (33.9, 24.0 to 140.0)
Paprosky Classification, n (%)	
1	86 (74.8)
2	29 (25.2)
Indications for revision, n (%)	
Aseptic loosening	51 (45.5)
Two-stage revision (PJI)	50 (44.6)
Painful prosthesis	6 (5.4)
Periprosthetic fracture	3 (2.7)
Failure resurfacing	3 (2.7)
Girdlestone	2 (1.8)

PJI, periprosthetic joint infection.

Methods

The study was conducted in accordance with the principles of the Helsinki Declaration,[13] and approval was obtained from the local institutional review board (IRCCS Istituto Ortopedico Galeazzi, Milan, Italy). All patients gave informed consent for data collection and analysis. The data were extracted from a prospectively collected hip arthroplasty registry, which included clinical, radiological, and surgical data that were anonymized according to the General Data Protection Regulation for research hospitals.[14]

We retrospectively reviewed data from a consecutive series of patients undergoing stem revision using the Alloclassic Zweymüller SL stem (Zimmer Biomet) in our department (Hip Department, IRCCS Istituto Ortopedico Galeazzi) from January 2011 to December 2020. Inclusion criteria included femoral revision using the aforementioned stem and Paprosky type I and II defects. Second-stage reimplantations for periprosthetic joint infection (PJI) or femoral periprosthetic fractures were also included in the study. The only exclusion criterion was Paprosky type III or IV bone defects, as there is inadequate bone stock in the proximal femur for stable fixation of a primary stem, and fixation at the level of femoral isthmus is preferable.

All surgeries were performed by a single senior surgeon (LZ). Preoperative planning was based on calibrated anteroposterior radiographs of the pelvis and a shoot-through lateral view of the hip. Digital templating was performed using IDS7 software (Sectra-Imtec AB, Sweden; Picture Archiving Communication Systems, Philips Medical Systems, USA). A CT scan of the hip was performed for all patients to evaluate preoperative implant position and bone stock. In cases where infection was suspected, a preoperative ultrasound-guided joint aspiration or a needle tissue biopsy for dry joints was performed.[15] All procedures were done using the posterolateral hip approach with transosseous repair of the capsule and short external rotators and/or scar tissues at the end of the procedure. Careful removal was performed of fibrous tissues, endosteal membranes, and cement if present. Intraoperative bone loss assessment was done according to the Paprosky classification,[4] and was noted on the operating registry after explant and prior to broaching. Progressive broaching of the femoral canal was performed according to the surgical plan, but the final size was determined when a firm press-fit and axial-rotational stability together with joint stability, correct soft-tissue tension, and leg-length correction were reached. At least six intraoperative samples were collected for microbiological cultures. After surgery, intravenous (IV) antibiotic

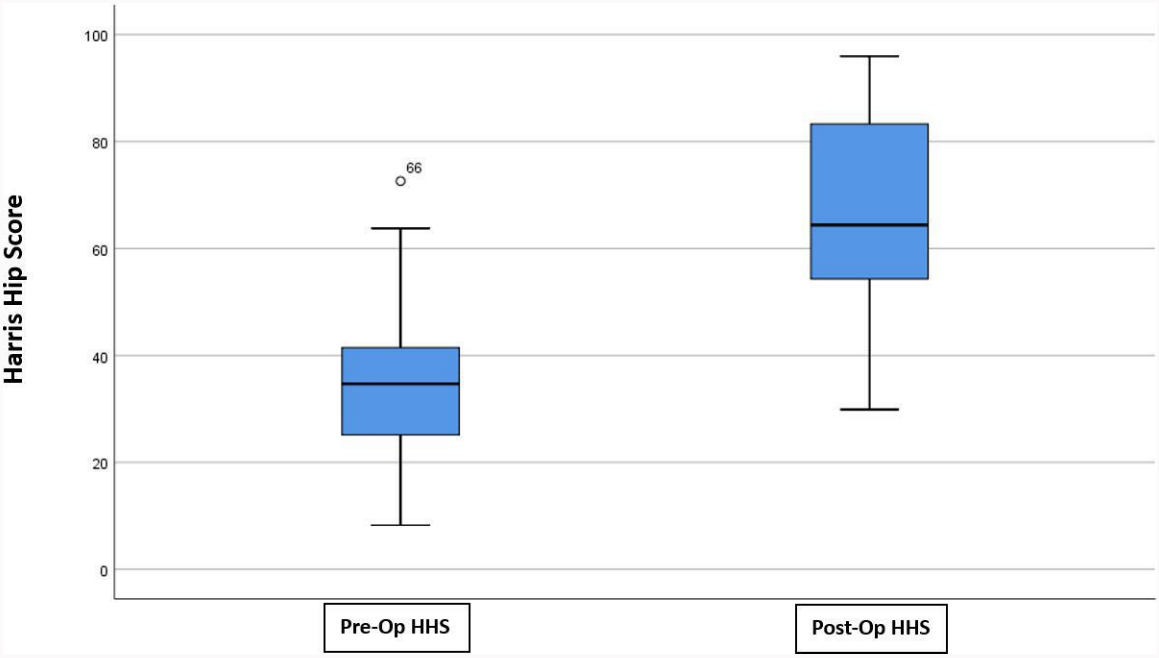

Fig. 1
Box plot showing the variation of Harris Hip Score (HHS) preoperatively and at final follow-up.

Table II. Detailed list of complications.

Complication	Frequency	Treatment	Comments
Intraoperative fracture	2	Intraoperative cabling and stem retention	1 subtrochanteric and 1 greater trochanteric fracture
Postoperative prosthetic hip dislocation	2	1 treated conservatively and 1 revision to constrained liner	
Recurrent PJI	1	Two-stage revision	Extended trochanteric osteotomy to remove well-fixed stem
Limb length discrepancy	8	Conservative	Range between 1 and 1.5 cm
Postoperative thigh pain	22	Conservative	
Radiolucent lines	28	Conservative	Non-progressive osteolysis

PJI, periprosthetic joint infection.

therapy was continued until negative cultures were obtained for staged procedures for PJI and in patients with a high index of suspicion for infection intraoperatively. Postoperative antithromboembolic prophylaxis protocol for all patients included low molecular weight heparin and stockings for five weeks. Patients were allowed to stand and walk with crutches from postoperative day one, with partial weightbearing restrictions on the operated leg. They were discharged three to 15 days postoperatively depending on their rehabilitative progress, ambulatory independence, and general postoperative condition. Full weightbearing and weaning off walking aids were permitted from eight to 12 weeks postoperatively.

Clinical and radiological evaluation was performed before surgery, at postoperative two, four, and 12 months, and yearly thereafter. Patient demographics and patient-reported outcome measures (PROMs), including Harris Hip Score (HHS)[16] and visual analogue scale (VAS),[17] were collected. Radiological evaluation included an anteroposterior view of the pelvis. A single independent orthopaedic surgeon (AGB), not involved in the surgeries, evaluated the radiographs. Component subsidence was evaluated as described by Callaghan et al,[18] and a difference of > 2 mm between immediate postoperative and follow-up was considered as the cut-off value for vertical subsidence. All radiographs were assessed for loosening and stability using the criteria described by Engh et al.[19] If present, the location of osteolysis and radiolucent lines was noted according to Gruen zones.[20]

Statistical analysis

Statistical analysis was conducted using GraphPad Prism v5.0 (software Prisma; GraphPad, USA). The data distribution was evaluated with the Shapiro-Wilk test; the Wilcoxon signed-rank test was used to compare preoperative and postoperative

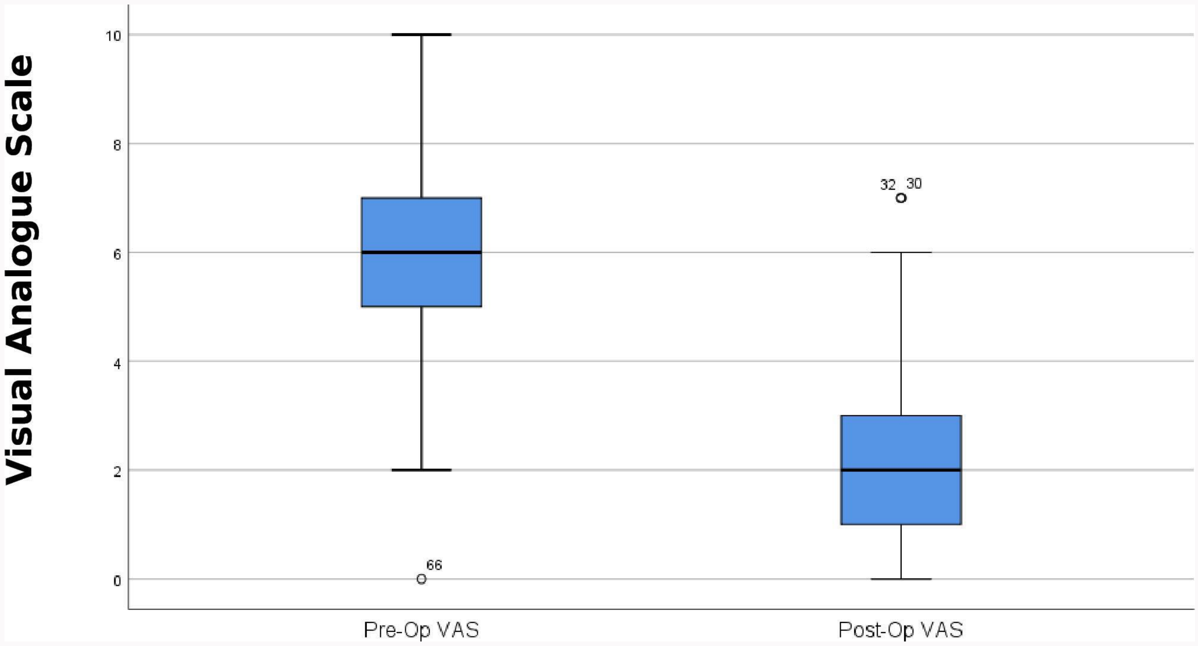

Fig. 2

Box plot showing the variation of visual analogue scale (VAS) preoperatively and at final follow-up.

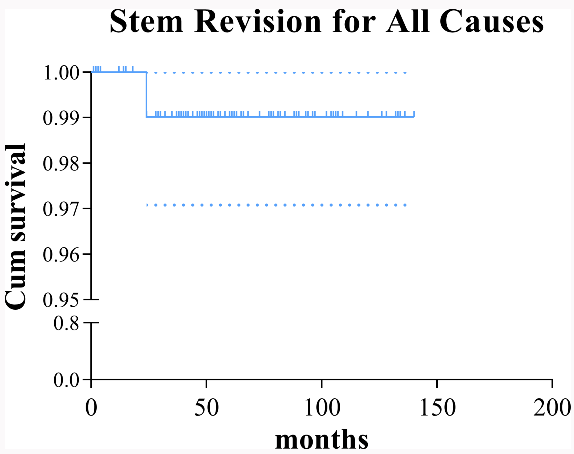

Fig. 3

Kaplan-Meier plot for stem revision for all causes with 95% CI.

scores. Survival was estimated and demonstrated using the Kaplan-Meier curve.[21]

Results

A total of 113 patients (115 hips) underwent femoral revision using the Alloclassic SL stem for Paprosky type I and II defects. There were 60 males and 53 females, with a mean age of 71.2 years (SD 12.6; 41.0 to 93.0) at revision surgery. Nine patients were lost to follow-up (deceased or not reachable at the minimum follow-up), leaving 104 patients (106 hips) for the analysis and a compliance rate of 92.0%. The mean follow-up was 77.9 months (SD 33.8; 36 to 152). A total of 86 (74.8%) of the hips had Paprosky type I defects and 29 (25.2%) had Paprosky type II defects. Aseptic loosening (51 hips; 45.5%) and reimplantation for a two-stage protocol for PJI (50 hips; 44.6%) were the most indications for revision surgery. Patient demographic details and indications for revision are summarized in Table I.

Subjectively, the HHS increased significantly from 33.7 (SD 13.0) preoperatively to 66.4 (SD 16.8) at final follow-up (p = 0.010, Wilcoxon Signed-rank test) (Figure 1). VAS decreased significantly from 5.8 (SD 1.8) preoperatively to 2.1 (SD 1.8) postoperatively (p = 0.010, Wilcoxon Signed-rank test) (Figure 2). The survival rate for aseptic loosening as endpoint was 100%, whereas survival for revision surgery for all causes was 99.1% (Figure 3). The Kaplan-Meier plots and the observed cumulative survival for aseptic stem loosening and revision surgery for all causes at endpoint show a high rate of implant survival (99.1%), considering a cumulated total risk over a period of 152 months.

Three patients had prophylactic cabling as they had cortical thinning, history of osteoporosis, and were at increased risk of intraoperative fractures. There were two intraoperative fractures (one subtrochanteric and one of the greater trochanter) that were treated intraoperatively with cables without stem exchange. Two patients had postoperative prosthetic hip dislocations; one was treated conservatively and one required liner revision to a constrained liner. One stem was re-revised in a patient with recurrent PJI associated with cup loosening, and an extended trochanteric osteotomy was needed to remove the well-fixed stem. Eight patients (7.1%) had leg-length discrepancies between 1 cm and 1.5 cm. Overall, 22 patients (19.5%) reported postoperative thigh pain up to six months. All the patients with leg-length discrepancies and thigh pain were treated conservatively. None of the patients had stem migration or subsidence. In 28 patients (24.8%), asymptomatic non-progressive radiolucent lines > 1 mm were detected, mostly in Gruen zone 1. The list of complications, treatment instituted, and location of radiolucent lines are summarized in Table II and Table III.

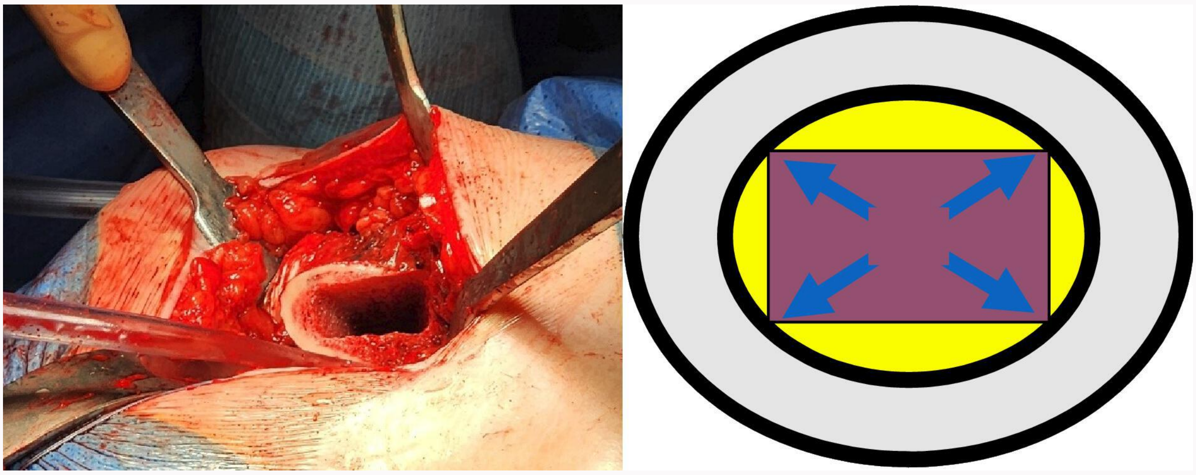

Fig. 4
Intraoperative photograph and accompanying diagram showing the rectangular track at the end of femoral broaching.

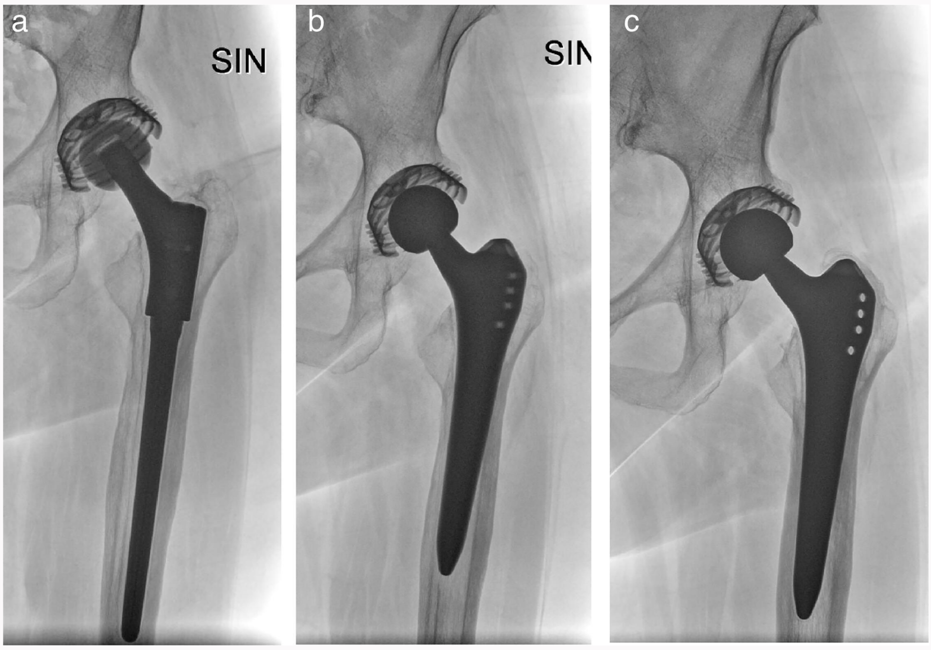

Fig. 5
a) Preoperative anteroposterior (AP) radiograph of a 57-year-old female with aseptic loosening of modular revision stem three years after surgery. b) Postoperative AP radiograph of stem revision from a modular revision stem to a primary Zweymüller stem. c) Follow-up AP radiograph at seven-year follow-up showing osseointegration and stable implants.

Discussion

Long cementless tapered fluted titanium-alloy stems are considered a standard of care in the treatment of femoral revisions, as they are designed for distal fixation bypassing proximal femoral bone loss. Primary stems are an attractive option because of the avoidance of diaphyseal canal violation, reduction of stress shielding, reduced cost, and easier stem removal in the event of further revision for any reason, or due to infection or recurrence of infection, after two-stage procedures for PJI. The literature suggests that primary stems represent a viable option for patients with Paprosky type I and II defects. The presence of good metaphyseal bone quality allows for primary stability and revision surgery to be performed with an endofemoral approach.[22] This assumption is, however, based on a small number of studies with limited sample sizes,[9] which shows the reluctance of surgeons to use this technique.[22] More recently, short conical stems have been proposed as a valuable option for Paprosky type I and II defects, with good results reported in larger cohorts of patients and at a longer follow-up.[23,24]

Excellent long-term results have been reported for the Alloclassic Zweymüller SL stem in primary THA, with survival ranging from 95% to 99% at 15 to 30 years of follow-up.[25–28] According to the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), the combination of this stem and the Trilogy cup (Zimmer Biomet) has the lowest 15-year cumulative percent revision (2.7%).[29] Stem geometry and surface finishing are likely contributors to the reported

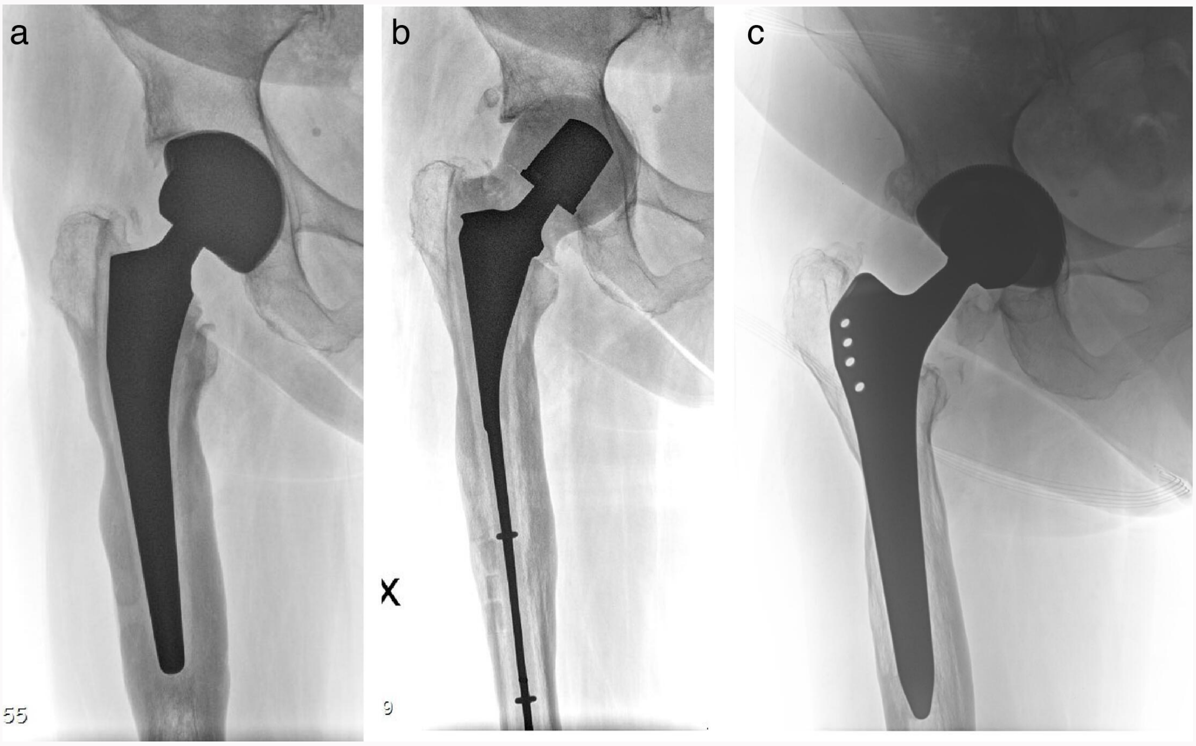

Fig. 6

a) Preoperative anteroposterior (AP) radiograph of a 72-year-old female with infected total hip arthroplasty with gross stem loosening. b) Postoperative AP radiograph showing implant removal through a cortical window and implantation of a custom-made spacer. c) Seven-year follow-up AP radiograph after staged revision to a Zweymüller stem showing osseointegration and stable implants.

Table III. Location of radiolucent lines around the stem.

Gruen zone	Patients with radiolucencies, n (percentage of overall hips)
I	91 (79.1)
II	3 (2.6)
V	3 (2.6)
VI	3 (2.6)
VII	15 (13.0)

excellent long-term results. The rectangular cross-sectional geometry together with the tapered shape provides excellent primary stability even in the case of large canals and bone loss. Despite significant bone loss, the four-point cortical engagement controls rotational stability and prevents subsidence. Moreover, a shorter stem length avoids the issue of procurvatum of the femur and anterior cortex perforation during insertion and the 'three-point fixation', which are typical issues of long taper conical stems in revision. Oetgen et al[30] reported the use of the Zweymüller stem for femoral revision in 24 cases, with no failures at 7.5 years' follow-up. 'Make a revision like a primary' is an attractive option. Miletic et al[31] described the use of the Zweymüller stem as second revision for replacing long locked revision stems in ten cases, with no failures at 4.5 years' follow up. This is concordant with our study, which demonstrated excellent survival for stem loosening as endpoint at minimum three years' follow-up.

In our 104 patients (106 hips), the survival of the stem was 99.1% at a mean follow-up of 77.9 months. This is similar to data reported for primary conical stem at five years in 74 patients with Paprosky type I and II defects,[24] and compares favourably with those recently reported for conical primary cementless stems (PCS) (n = 29) and a modular revision stem (n = 30) at five years in a comparative study for type II defects, reporting a survival of 97% and 87%, respectively.[10] A systematic review about the use of primary cementless stems in femoral revision showed a mean stem-related survival of 96% at a mean follow-up of five years.[9]

From a subjective point of view, all patients had statistically significant improvement in HHS and VAS scores at final follow-up. Despite this, the final HHS rating remained within the 'poor' category when compared with other studies on primary THA and revision THA.[10,24,32] This may be secondary to the extremely poor scores that the majority of patients already had prior to revision surgery, and a large proportion of the cases being PJI, which are known to have poorer outcomes after revision arthroplasty.[33] A trained research coordinator (AGB) was responsible for HHS scoring and calculation, and this was performed in a rigorous manner rather than by patient self-administered questionnaires. In addition, previous studies have shown that the floor and ceiling effects of the HHS limit its utility for arthroplasty research,[34] and likely more so in revision arthroplasty research.

In nearly one in five patients, early postoperative thigh pain was reported. This was resolved in all patients within six months, and was not associated with poorer HHS scores in patients with either Paprosky type I or type II defects. Temporary postoperative thigh pain has been widely described for this type of cementless stem even in primary THA.[25,28] The eight patients that showed a leg lengthening between 1 cm and 1.5 cm had two-stage procedures for PJI. The leg-length discrepancy was in relation to spacer insertion at the first stage and was not correlated with poorer results.

None of the patients exhibited evidence of stem subsidence or migration. However, one-quarter of the patients showed non-progressive radiolucent lines > 1 mm, mainly in Gruen zones 1 and 7. Radiolucent lines have previously been reported in other studies of diaphyseal fitting versions of tapered rectangular stems, mainly from other manufacturers.[30,35,36] Radiolucent lines around Zweymüller standard stems are also well known in primary THA, and have been reported in up to 45% of cases with no clinical relevance.[28] At ten-year follow-up, these lines do not progress and have not been shown to be associated with an increased risk of aseptic loosening.[37] Long-term radiological and clinical evaluation is recommended to ascertain if this is true for revision cases as well.

The tapered geometry of the stem might explain the absence of significant subsidence. This can be achieved by ensuring the implanted stem is correctly sized through preoperative planning with calibrated markers and avoiding varus positioning of the stem during canal preparation. A perfect rectangular track at the end of the broaching is part of the assessment of a good femoral preparation (Figure 4). The rectangular cross-section ensures that the femoral version of the stem is rigidly fixed with sequential broaching, but occasionally a compromise between femoral anteversion and endosteal engagement may be required to achieve optimal press fit and hip stability. Care should also be taken to avoid proximal femoral fractures, by the log-splitting mechanism, during broaching and insertion of the wedge shape components.[30] Adequate exposure of the proximal femur and occasional prophylactic cerclage cabling should be performed prior to broaching or stem implantation in patients at high risk of fracture due to cortical thinning, or in case of previous extended trochanteric osteotomy during the first stage or complete segmental cortical bone loss. Compared to long modular revision stems, other advantages of a short tapered rectangular stem include bone preservation at the isthmus, less bulky proximal body, and lower potential distal femur fracture or perforation risks. Moreover, the monobloc stem avoids all the issues related to modular junctions.

Figure 5a illustrates a case where a patient had aseptic loosening of a modular revision stem three years after the index surgery. The revision stem was de-escalated to a primary Zweymüller stem (Figure 5b) and the patient continued to have stable implants on radiographs at seven-year follow-up (Figure 5c). The Zweymüller stem can be an option for revision for PJI as well. Figure 6a shows the preoperative radiographs of a patient with PJI that was explanted through a cortical window and staged with a custom-made articulating spacer (Figure 6b). Figure 6c shows the seven-year follow-up radiographs after implantation with a Zweymüller stem showing good osseointegration and stable implants at long-term follow-up.

This study has several limitations. First, the retrospective nature of the study is associated with its inherent biases. This includes selection bias, as a larger proportion of the patients had Paprosky type I defects. This also limits the generalizability of the study and direct comparison with other diaphyseal engaging stem designs which are used for the management of more severe bone defects. A longer version of the rectangular stem than can be used for Paprosky type III defects should be used for comparing outcomes and complication rates.[30,35,36] In our practice, fluted tapered revision stems, cement-in-cement technique, and occasionally cemented stems were used for Paprosky III and other atypical defects, but these techniques were not part of the study. The variety of indications for revision may also be a factor in overall outcomes, as the patients may continue to experience pain or further complications due to reasons other than implant loosening. Additionally, as there was no control group, we were unable to compare the outcomes against other stem designs. Further follow-up would also be warranted to look at long-term survival and outcomes for such stems.

In conclusion, the Alloclassic Zweymüller SL stem demonstrated excellent medium-term radiological outcomes in revision THA for Paprosky type I and II defects with a 100% survival rate for aseptic loosening at a minimum three-year follow-up, along with significant improvements in clinical outcomes. Further studies with a longer follow-up are warranted to see if these results are sustained in the long term.

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Data sharing

The data that support the findings for this study are available to other researchers from the corresponding author upon reasonable request.