Femoral revision with primary cementless stems: a systematic review of the literature

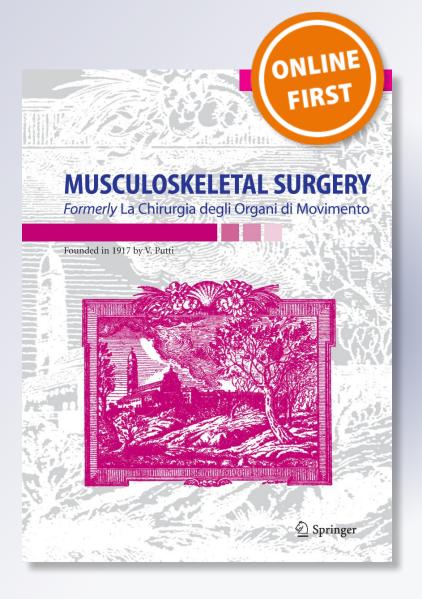
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REVIEW



Femoral revision with primary cementless stems: a systematic review of the literature

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Abstract The use of primary cementless stems in femoral revision has gained popularity, but no clear consensus about the correct indication is still present. The aim of our systematic review is to: (1) summarize the available literature focused on the use of cementless primary stem in revision total hip arthroplasty (THA); (2) evaluate whether the use of cementless primary stems could represent a feasible option in hip revision; (3) define the proper indication of this surgical approach. A systematic literature review was performed about the use of cementless primary stems in revision THA. The PRISMA 2009 checklist was considered to edit our review. A total of nine articles were included. The current evidence is primarily Level IV. A total of 439 patients (454 hips) underwent THA revision with primary cementless stem. Partial cementless porous coated stems were used in 246 hips (54.2%). The majority of patients were affected by type I or II Paprosky femoral defects. The mean stem-related survival rate is $95.6\% \pm 3.8$ with a mean follow-up of 4.7 years ± 1.3 . Poor standardization of methodological analysis was observed. Current literature shows lacking evidence about primary cementless stems in revision THA. Despite these limitations, we can affirm that primary cementless stems in femoral revision surgery represent a viable option in selected patients. The proper indication is a patient with femoral Paprosky defect types I or II, with low number of previous surgeries and a previous cementless stem.

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Keywords Total hip arthroplasty · Hip revision · Cementless stem · Primary hip stem · Review

Introduction

Total hip arthroplasty (THA) increases worldwide as stated by National and International register [1-3]. More and more young and active or high demanding patients undergo THA for end-stage hip osteoarthritis with excellent longterm results [4-10]. Meanwhile, revision THA is a currently major issue especially in this specific subgroup of patients. This represents one of the most difficult challenges for both patients and surgeons and tremendous socioeconomic burden for society [11, 12]. Facing THA revision, orthopedic surgeon needs to consider both acetabular and femoral side. Regarding femoral side, the surgical goal is to obtain an adequate primary stability with a stem that "fixes as proximal as possible and as distal as necessary" [13]. The aim is to spare diaphyseal bone stock and load the proximal portion of the femur in order to restore proper bone stock in metaphyseal region and allow future revision surgeries. Following these principles THA revision with primary stems could represent a feasible option. Cornerstones of this surgical approach are proper preoperative planning and patient selection. The use of primary stems in total hip revision is not new. First attempts did not lead to good results with a 44% of aseptic loosening at 4.5 years [14]. After these unreliable data, THA revision surgery moved to cemented stems that showed unacceptable results as well [15–17]. Some authors started to employ long cementless stem with distal fixation supported by encouraging results obtained with cementless stems in primary THA. These diaphyseal-engaging stems showed optimal mid- and long-term outcome and still



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represent the implant of choice in the majority of hip arthroplasty revisions [18–22]. Common surgical target is to bypass femoral defects by at least two cortical diameters [23]. However, this behavior is not well supported in the literature. Moreover, the use of revision stems increases complexity of the procedure, may increase the risk of intraoperative fracture [24], and reduces bone stock for future reconstructions. Recently, some good results have been achieved with primary cementless stem in revision setting. The aim of our systematic review is to: (1) summarize and critically analyze the available literature focused on the use of cementless primary stem in revision THA; (2) evaluate whether the use of cementless primary stems could represent a feasible option in hip revision; (3) define the proper indication of this surgical approach.

Materials and methods

We performed a systematic review of the literature to investigate the evidence about revision total hip arthroplasty with a primary cementless femoral stem. A primary search on Medline through PubMed distribution used the following search terms: (((revision[All Fields] AND ("arthroplasty, replacement, hip" [MeSH Terms] OR ("arthroplasty" [All Fields] AND "replacement" [All Fields] AND "hip" [All Fields]) OR "hip replacement arthroplasty" [All Fields] OR ("total" [All Fields] AND "hip" [All Fields] AND "arthroplasty" [All Fields]) OR "total hip arthroplasty" [All Fields])) AND (cementless [All Fields] AND ("plant stems" [MeSH Terms] OR ("plant"[All Fields] AND "stems"[All Fields]) OR "plant stems" [All Fields] OR "stem" [All Fields] OR "microscopy, electron, scanning transmission" [MeSH Terms] OR ("microscopy" [All Fields] AND "electron" [All Fields] AND "scanning" [All Fields] AND "transmission" [All Fields]) OR "scanning transmission electron microscopy"[All Fields]))) AND (cementless[All Fields] AND ("femur" [MeSH Terms] OR "femur" [All Fields] OR "femoral" [All Fields]) AND ("plant stems" [MeSH Terms] OR ("plant" [All Fields] AND "stems" [All Fields]) OR "plant stems" [All Fields] OR "stem" [All Fields] OR "microscopy, electron, scanning transmission" [MeSH Terms] OR ("microscopy" [All Fields] AND tron" [All Fields] AND "scanning" [All Fields] AND "transmission" [All Fields]) OR "scanning transmission electron microscopy"[All Fields]))) AND (primary[All Fields] AND ("femur" [MeSH Terms] OR "femur" [All Fields] OR "femoral" [All Fields]) AND ("plant stems" [-MeSH Terms] OR ("plant" [All Fields] AND "stems" [All Fields]) OR "plant stems" [All Fields] OR "stem" [All Fields] OR "microscopy, electron, scanning transmission" [MeSH Terms] OR ("microscopy" [All Fields] AND "electron" [All Fields] AND "scanning" [All Fields] AND "transmission" [All Fields]) OR "scanning transmission electron microscopy" [All Fields])).

The inclusion criteria were: studies providing clinical and radiological results about revision in total hip arthroplasty with a primary cementless femoral stem, papers in English without any restrictions on publication date, retrospective or prospective studies including randomized controlled trials, nonrandomized trials, cohort studies, case-control studies, and case series studies with minimum mean follow-up (FU) of 24 months. The criteria for exclusion were: a study population less than 15 patients, articles that did not provide clear clinical and radiological results of primary cementless femoral stem in total hip arthroplasty revision or papers not related to the research item and data derived from cohorts of patients in which both primary and revisions stems were used. Two reviewers (M.F.; L.C.) independently applied the previously determined inclusion and exclusion criteria to select potentially relevant papers. Papers were initially identified based on title and abstract. Full text copies of relevant trials were then obtained and independently evaluated by the reviewers. When a disagreement between reviewers occurred, it was resolved by a meeting held in consultation with another author. References from the identified articles were checked in order not to miss any relevant articles. The following data were extracted from the articles: number of patients, number of treated hips, type of revised stem (cementless or cemented), reason for revision, classification and type of femoral defect, use of femorotomy, type of stem used for revision, complications, stem survival rate, and mean follow-up. The Level Of Evidence (LOE) of a given study was assigned based on the 2011 Oxford Centre for Evidence-based Medicine Levels of Evidence [25]. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2009 checklist was considered to edit our review. Continuous variables were reported as mean \pm standard deviations (SD). Categorical variables were expressed as number of cases or percentage.

Results

Following the research protocol, a total of 153 articles were identified. The PRISMA flow 2009 diagram illustrates the number of studies that have been identified, included, and excluded as well as the reason for exclusion (Fig. 1). A total of 9 articles were included in our systematic review.

The first paper about this topic was published in 2000, the last one in 2016. Due to the heterogeneity and low quality of the included studies, it was impossible to pool and standardize the demographic and surgical data from the whole population and each group. All studies were rated as



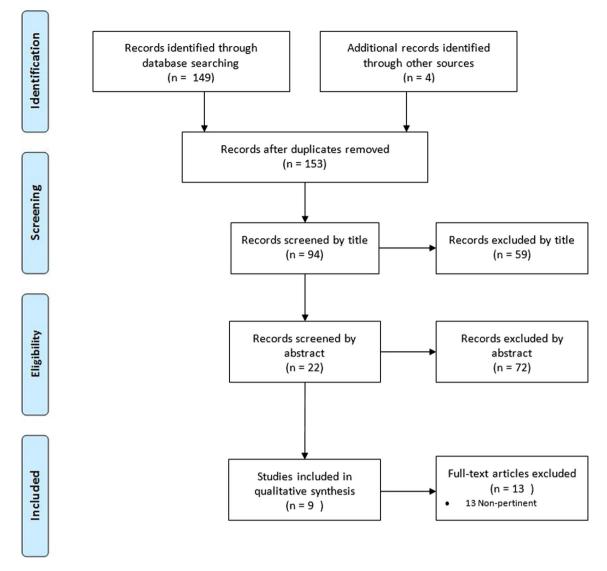


Fig. 1 PRISMA flow 2009 diagram illustrates the number of studies that have been identified, included, and excluded as well as the reason for exclusion

level IV (retrospective non-controlled studies) according to the 2011 Oxford Centre for Evidence-based Medicine Levels of Evidence.

Pooling the available data from the included studies, 439 patients (454 hips) underwent THA revision with primary cementless stem, 413 patients (428 hips) completed the follow-up protocol. One paper included 5 patients (5 hips) in which a primary cemented stem was employed [26]. Only one study achieved a relevant number of patients (139 patients/144 hips) [27]. In 5 of the 9 included studies [28–32], a partial porous coated stem was used. A complete hydroxyapatite (HA) coating stem was employed in two studies. One study combined 10 full porous coated stems with five cemented ones [26] and in another study partial to complete porous coating stems were implanted [27]. Globally, partial cementless porous coated stems were used

in 246 hips (54.2%). Full porous coated stems were employed in the remainders [33, 34]. Femoral defects were classified according to the Paprosky classification [35] in four studies. One study employed the SOFCOT [36] classification of bone femoral defect and one paper included both classification systems [32]. Gustilo and Pasternak [37] along with Endo-Klinik classification [38] system were used in one paper [31]; AOSS classification was the preferred one in the study of Kelly et al. [28]. One article did not declare the type of classification used [34], but suggested the use of primary cementless stems in femora with good metaphyseal bone stock. According to the type of revised stem three studies [28, 30, 32] did not state whether the revision was performed on a cemented or cementless implant. One study [27] declared that revision procedures were performed on cemented and cementless stems,

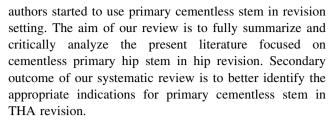


without specifying the distribution within these groups. In the remainders, 132 cemented and 44 cementless stems were revised. Regarding the reason for revision all studies stated the reason for revision surgery. Even if the reasons for revision are not fully declared, a total of 303 (69.8%) cases of aseptic loosening (AL) were observed. Periprosthetic joint infection (PJI) is the second common cause of revision (91 patients), 21% followed by periprosthetic femoral fracture (PPFF) (13 patients, 3%), component malposition (8 cases), dislocation (7 patients), stem breakage (3 patients), mechanical problems (3 patients), poly wear (1 patient), failed resurfacing (1 patient), and metallosis (1 patient). Three cases were classified as "other." Transfemoral approach was used in five hips; 31 extended trochanteric osteotomy (ETO); 2 linea aspera osteoclasies; and one cortical window were performed. Five studies did not employ femorotomies to explant the loosened stem [26, 28, 31, 32, 34]. One study did not declare whether cortical window was used [30]. The most frequently observed complication was perioperative femoral fracture (24 patients, 5.6%) followed by dislocation (23 patients, 5.4%), deep infection (11 patients, 2.6%), AL (6 patients, 1.4%), false route (2 patients), nerve palsy (2 patients), and acetabular loosening (1 patient). Only one manuscript did not report any intra- or postoperative complication [26]. Analyzing the stem-related survival rate, we observe a mean value of 95.6% \pm 3.8 with a mean follow-up of 4.7 years \pm 1.3. None of the included studies reported a survival rate lower than 90% at the last followup. Only one studies reported a comparison between groups with different femoral bone defects [33] concluding that no significant differences could be detected between groups in terms of clinical or radiological outcomes. None of the included papers compared results obtained from septic versus aseptic patients. Moreover, no comparison was performed between results obtained from patients with or without femorotomies. Only the study performed by Miletic et al. study [26] extensively argued about deescalation procedure (Table 1).

Discussion

Hip revision surgery is often affected by femoral bone defects, both on the femoral and acetabular side [39–43]. Several attempts have been performed in femoral revision using primary cementless or cemented stem with poorquality results.

On the other hand, encouraging results have been obtained using cementless long stem. These stems have shown better results if compared with primary cemented stem in hip revision. Supported by these data and by the advancing knowledge on implant manufacturing some



In 2014, Tetreault et al. [27] published the results obtained from the most important cohort of patients treated with primary stems in revision settings. One hundred and forty-four patients were reviewed at a mean follow-up of 4 years, in order to assess the percentage of femoral revisions (that could be managed with primary stems. Although they reported optimal clinical outcomes and 96% of stem integration, the rate of re-revised stems was 9.8% with 5 intraoperative and 3 postoperative femoral fractures and 8 dislocations. The authors succeeded in using primary stems in about a half of the selected patients. They suggested the use of this approach in patients with 4 cm of isthmus available for distal fixation and canal diameters smaller than 19 mm.

The use of a primary stem in hip revision surgery is not new. In 1987, Pierre Vives firstly developed the idea of "de-escalation" which involved changing a long stem by a standard length primary one [44]. In 2012, Miletic et al. [26] published the mid-term results obtained with this surgical technique. Fifteen patients underwent femoral locked stem revision with a standard primary one and were followed clinically and radiographically for a mean of 55 months. In all patients a femorotomy was used to extract the locked stem. The standard stem employed for revision was a cementless one in 10 cases and a cemented one in the remainders. Four revisions were performed for septic loosening. The authors reported optimal clinical data with good restoration of the proximal femoral bone stock and without further bone loss. No mechanical or septic failures were reported at final follow-up with 100% of stem survivorship.

The problem of iatrogenic escalation in stem revision is highlighted by Pinaroli et al. [33]. According to these authors, the correct patient selection defines the proper indication of first intention implants in femoral revision surgery. Forty-one stem revisions were performed with a fully HA-coated primary stem (Corail, Depuy, Johnson & Johnson, Leeds, UK) and evaluated at a mean follow-up of 30.4 months. Six septic revisions (4 treated with a two-stage technique and 2 with one-stage approach) were included with the majority of surgeries performed for a failed cemented implant. All femoral bone defects were classified as II or I according to Paprosky classification except 1 patient with a IIIA bone defect. The authors reported optimal mid-term clinical and radiological data with an overall complication rate of 9.6%, none of them



Table 1 Summary and main features of the included studies

Author Year Level of Type of stem N° of largement Femoral defect Type of revised Reason for revision Femorationny C Tauther et 2000 IV CLS Spotomo (Zimmer) 22/24 / 24 Cemented 23 AL No 2 Kidron Complete HA coating 29/24 / 24 Cemented 25 AL No 2 Kedly 2006 IV Securit plusTM (Stryker) 29/32 AAOS type I, II Not declared 25 AL No 3 Thorey 2006 IV Partial HA coating 2 ADOS type I, II Not declared 6 PII No 3 Thorey 2008 IV Bermial HA coating 1 Paprosky I, II 20 cemented 6 PII No 9 129] Partial HA coating 1 Partial HA coating 1 Partial HA coating 1 1 Pan 1 Pan 1 Pan 1 1 Pan 1 Pan 1 ADOP 1 1 Pan 1 <th>1 222</th> <th></th> <th>-</th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th>	1 222		-									
1	Author	Year	Level of evidence	Type of stem	N° of patients/ hips	Femoral defect	Type of revised stem	Reason for revision	Femorotomy	Complications	Stem survival (%)	Follow-up (years)
2006 IV Security plusTM (Stryker) 29/32 AAOS type I, II Not declared 26 AL No Partial HA coating 19/79 Paprosky I, II 29 cemented 69AL S Transfemoral 1	Tauber et Kidron [34]		2	CLS Spotomo (Zimmer) Complete HA coating	22/24	,	24 Cemented	23 AL 1 PJI	No	2 false route 2 perioperative fractures 1 dislocation 1 nerve palsy	96	4.5
100 10 10 10 10 10 10 1	Kelly et al. [28]	2006	2	Securfit plusTM (Stryker) Partial HA coating	29/32	AAOS type I, II or III	Not declared	26 AL 6 PJI	No.	3 perioperative fractures 1 dislocation 3 deep infection	91	v
Partial HA coating	Thorey et al. [29]	2008	≥	Bicontact (B-Braun) Partial HA coating	<i>9</i> 1/ <i>9</i> 1	Paprosky I, II	29 cemented 50 cementless	69AL 3 PJI 2 PPFF 1 Pain 3 Other	5 Transfemoral approaches	2 perioperative fractures 2 deep infection	95	٢
2009 IV Corail 38/41 Paprosky I, II 26 cemented 30 AL 1 ETO	Salemyr et al. [31]	2008	≥	Bi-Metric (Biomet) Partial HA coating	60/62	Gustilo and Pasternak type I, II, III Endo-Klinik type I,II,III	53 cemented 9 uncemented	62 AL	°Z	9 dislocations 8 perioperative fractures 1 deep infection 1 nerve palsy	93.6	6.1
2012 IV Alloclassic (Zimmer) [10] 15/15 SOFCOT I et II 15 locked stems 14 AL No full porous (cementless) 1 stem coating + cemented stems (Stryker and Zimmer) (5)	Pinaroli et al. [33]	2009	2	Corail (Depuy, Johnson & Johnson) Complete HA coating	38/41	Paprosky I, II	26 cemented 15 cementless	30 AL 6 PJI 2 PPFF 3 mechanical problems	1 ETO 2 linea aspera osteoclasies 1 cortical window	2 dislocations	100	2.5
	Miletic et al. [26]	2012	2	Alloclassic (Zimmer) [10] full porous coating + cemented stems (Stryker and Zimmer) (5)	15/15	SOFCOT I et II	15 locked stems (cementless)	14 AL 1 stem breakage	No.	No	100	4.5



100

2 dislocations

N_o

27 AL

Paprosky I and Not declared IIA

43/43

Linea (Tornier) Partial HA coating

2016 IV

Gastaud et al. [32]

SOFCOT I and II

7 component malposition

6 PJI 3 PPFF

_	Table 1 continued	ontinued	_									
	Author	Year	Level of evidence	Year Level of Type of stem evidence	N° of patients/ hips	Femoral defect	Type of revised stem	Reason for revision	Femorotomy	Complications	Stem Follow survival (years)	Follow-up (years)
	Tetreault et al. [27]	2014 IV	N	Versys (Zimmer) Versys Epoch (Zimmer) Echelon (Smith & Nephew) Solution (Depuy) Partial to complete porous coating without HA	139/144	Paprosky I, II, IIIA	Cementless and cemented (number not declared)	54 PJI 48 AL 7 dislocations 6 PPFF 2 stem breakage 1 poly wear 1 failed resurfacing 1 metallosis 1 component malposition	30 ETO	6 revisions for AL 5 deep infections 8 perioperative fractures 8 dislocations	90.2	4
	Khanuja et al. [30]	2014 IV	≥	Accolade TMZF (Stryker) Partial HA coating	19/19	Paprosky I, II	Not declared	15 PJI 4 AL	Not declared	1 acetabular loosening 1 deep infection 1 perioperative fractures	94.8	v

AL Aseptic loosening; PII periprostetic joint infection; PPFF periprosthetic femoral fracture; ETO extended trochanteric osteotomy



was related to the stem. The first authors who attempted the use of a primary stem in THA revision were Tauber et al. [34]. In 2000, they published a retrospective evaluation of 24 hip revision performed with a fully coated HA stem (CLS, Zimmer Biomet, Warsaw IN, USA). The reason for revision was aseptic loosening of a cemented stem for all patients except one septic revision. No femoral bone defect classification was obtained. A clinical ad radiological follow-up was recorded at a mean of 57 months. The authors reported a good/excellent result in 20 out of 24 cases with one revision for recurrent dislocation (95.8% of stem survivorship) and 3 poor results due to intraoperative fracture (1 patient), postoperative subsidence (1 patient), and lowgrade infection (1 patient). The higher specific complication rate (16.7%) reported in this study could be partially explained by the fact that all revisions were for cemented stems and complete cement removal is often technically demanding and not always possible. Nevertheless, the authors concluded that CLS-Spotorno stem lead to satisfactory outcomes in the majority of revised patients at mid-/long-term follow-up. The best results were obtained when sufficient bone collar were present at the time of revision (i.e., Paprosky type I and II femoral defects). The majority of our data (54.2%) are extrapolated from proximally coated stems.

The first author employing partially HA-coated stems was Kelly [28]. He reported the clinical and radiographic outcomes of a cohort of 33 THA revisions (29 patients). The main reason for revision was aseptic loosening (43%). Other indications were painful arthroplasty (16%), PJI (18%), unstable hip (6%), and other unspecified reason (13%). The mean follow-up was 60 months. According to the authors, the main parameters to consider when using this stem in revision setting were sufficient methaphyseal bone in the region of lesser trochanter and approximately 4 cm of diaphyseal fit of the implanted stem. Following this algorithm, they observed optimal clinical and radiological outcomes. Despite these excellent mechanical data, 3 stems were revised for septic failure (stem survivorship: 91%), 1 implant was revised for recurrent dislocation with constrained acetabular liner, and a periprosthetic fracture distal to the stem occurred 4 years postoperative. Two prostheses subsided more than 2 mm with no radiographic signs of stem instability. If a general agreement upon the proximal methaphyseal bone stock availability is present, no clear consensus is detectable regarding the amount of diaphyseal fit. Two years later, Salemyr et al. [31] published their results with another cementless proximally HA-coated primary stem (Bi-Metric, Biomet Inc., Warsaw, IN, USA) in 62 aseptic hip revisions. Although the 94% of stem survival at a mean follow-up of 73 months, they reported excellent/good results only in 38.3% of patients. Moreover, the overall local complication rate was 41.9 with 9 dislocators, 13.3% of tight pain, and 19 subsided stems. These data could be partially explained by the high number (53 of the 62 revisions) of cemented stem revised. Khanuja et al. [30] reviewed 19 patients who underwent hip revision surgery with a proximally coated cementless stem (Accolade TMZF—Stryker Orthopaedics, Mahwah, New Jersey) at a mean follow-up of 49 months. Stem survivorship was 95% with one aseptic loosening. Three complications (1 aseptic loosening, 1 septic failure, and 1 intraoperative periprosthetic femoral fracture) were reported. Despite the low number of patients, the authors concluded that in a selected subgroup of patients (Paprosky type I and II femoral defects) the use of a primary cementless stem provides optimal clinical and radiological mid-term results.

Despite these cheering data, limitations of this study are the heterogeneity of indication for revision and the variety of the stems used for the revision surgery. Thorey et al. [29] observed same conclusions in 2008. The authors published clinical and radiological data from 79 stem revision with partially coated primary implant at a mean of 6.8 years. A proper patient selection is of a paramount importance as confirmed by Gastaud et coll. [32]. The authors carried on a retrospective analysis on 43 patients with a previous femoral stem revision with a primary anatomical partially HA-coated implant (Linéa stem, Tornier, Montbonnot, France) after a mean 47 months follow-up. Nineteen cases had a previous cemented stem. The overall complication rate was 4.7% with no mechanical failures of the stem and good-to-excellent clinical and radiological results. The authors suggested that only implant revisions with endofemoral approaches are eligible for primary stem usage. According to the available literature, we cannot completely agree with this statement.

Considering the low level of evidence of the included studies, we cannot draw any comparative data between partially coated stems versus fully coated ones or between the results obtained from surgeries performed in different bone loss settings. Although supported by weak statistical analysis, only Pinaroli et al. [33] stated that clinical and radiological data observed in Paprosky type I or type II femora were comparable. Similarly, few definite conclusions can be drawn about how the previous stem fixation can influence the postoperative outcome. Three studies do not declare the preoperative kind of stem [28, 30, 32]. Observing the mean stem survival rate, it seems that no differences are detectable between cemented and cementless stem revision. In their study of 62 THA revisions (53 cemented stems), Salemyr et al. [31] showed 94% of implant survival rate with only 38% of good results and a 31% of complication rate. Although it is not supported by statistical analysis, the high number of cemented stems may have influenced the poor results obtained in this study as confirmed also in our experience. AL is the most



frequent cause of revision. No studies compared outcomes derived from AL versus other diagnoses. Even though some literature studies show that hip revision for different diagnoses achieved comparable results [45], we do not firmly conclude about how preoperative diagnosis can influence the final outcome.

Our data confirm that one of the most frequently related complications with cementless stems is periprosthetic fracture [46–48]. Few correlations can be observed between type of complication and preoperative setting. The highest perioperative fracture rate is reported by Salemyr et al. [31]. The cement removal and the subsequent bone loss can partially explain this data.

Lacking evidence is present regarding the use of femorotomies. Tetreault et al. [27] reported the lower implant survival rate (90%) with an extensive use of ETO. Based on these data, we could hastily conclude that the use of femorotomy is a contraindication for primary stem usage in revision THA. Actually, a big difference is present between ETO [49, 50] or Wagner transfemoral approach [51] and cortical windows. Indeed, if the first ones can firmly be considered contraindications, controlled cortical window allows for primary stems usage in revision THA.

In conclusion, the critical analysis of the current literature shows lacking data about the use primary cementless stems in revision THA. The current evidence is based on level IV studies, and it is affected by poor-quality evaluation, high amount of biases, and short-to-mid-term follow-up.

Despite these limitations, we can affirm that primary cementless stems in femoral revision surgery represent a viable and feasible option in selected patients. Accurate patient selection is a cornerstone of this potential approach. According to the most recent data, the proper indication is a patient with femoral Paprosky defect types I or II, with low number of previous surgeries and a previous cementless stem. Following these easy-to-use principles, a deescalation procedure is a possible. We advise a proper standardization of the methodological analysis in order to compare the available data and achieve definitive results. Lastly, we strongly advocate further high-quality long-term studies to better clarify the role of this promising approach in revision THA.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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