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Dual Mobility Cup Fixation Augmented by Pegs and Screws for Total Hip Arthroplasty in a Geriatric Population with Osteoporosis: Short- and Medium-Term Results of a Retrospective Series of 45 Patients

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Abstract

Introduction: Total Hip Arthroplasty (THA) requires stable primary fixation of the acetabular implant. The main objective of this study was to evaluate, in a geriatric population, the radiological results and the medium-term survival of a Dual Mobility Cup (DMC) with hydroxyapatite coating and tripod fixation augmented by 2 pegs and a screw.

Hypothesis: In a geriatric population prone to osteoporosis, this type of implant offers medium-term survival >95% and a complication rate similar to the data from the literature.

Methods: This single-center retrospective study included 45 patients (30 women and 15 men) with a mean age of 79.3±5.4 years. Patients included were over 70 years old, with this type of implant for any indication for a first-line THA (30 cases) or revision (15 cases), the initial indication was a proximal femoral fracture in 71% of cases. For each patient, X-rays, clinical scores (Oxford Hip Score, EQ-5D-5L, Parker score) and implant survival were evaluated at the last follow-up.

Results: The mean radiological follow-up was 25.4±16 months. Clinical follow-up was 39.9±14 months for 30 patients. For 15 patients (4 lost to follow-up and 11 deceased), clinical data were not available. For 3 patients, periprosthetic osteolysis was observed in zones I and II, as per the DeLee and Charnley system. The Oxford Hip Score was 41.1±8.8 (range: 16-48). The mean VAS was 0.9±1.6 and the mean EQ-5D-5L was 0.6±0.3.

Discussion: The use of DMC with fixation augmented by pegs and screws is safe and effective in the short and medium term for THA in a geriatric population.

Keywords: Arthroplasty; Replacement; Hip; Aged; Proximal femoral fractures.

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Introduction

Total Hip Arthroplasty (THA) is the indicated treatment for various pathologies affecting the hip joint; predominantly osteoarthritis, femoral neck fractures and osteonecrosis of the femoral head. There are different options for fixation of the femoral implant [1]. Cemented implants, initially criticized for high loosening rates [2], have given way to non-cemented implants. Although the recent literature does not report a better survival rate with cemented implants compared to uncemented implants [3,4], the latter have nevertheless become the gold standard.

Cementless implants require primary fixation to allow immediate rehabilitation without restrictions to weight-bearing. This stable primary fixation subsequently guarantees good osseointegration of the cup ensuring its long-term secondary fixation. Implants coated with hydroxyapatite have been developed to promote primary stability and osseointegration because of their osteoconductive properties observed in vivo [5]. While these implants have gained popularity, the effectiveness of the hydroxyapatite coating on long-term survival remains controversial [6,7].

There are different ways to obtain primary fixation [8]: Simple press-fit impaction and the combination of press-fit with the placement of screws or pegs through the cup to increase its stability (increased fixation). The type of primary fixation required has not been clearly established according to the indication. Increased fixation of implants is sometimes used when there is insufficient primary stability from press-fit alone, or when the bone quality is poor. Thus, these implants appear ideal for a geriatric population, prone to osteoporosis, and in the management of proximal femoral fractures.

Several studies comparing press-fit to augmented fixation do not show any superiority of augmented fixation in the short- or long-term [8-10]. Several series [11-15] report the results of acetabular implants with fixation augmented by screws and pegs (known as tripods) with excellent results and a survival greater than 90% at more than 15 years of follow-up [13]. The indication for THA is primary or secondary osteoarthritis, with cases of trauma excluded. Consequently, the mean age at surgery is less than 60 years except for one study specifically investigating the use of this type of implant in the context of acetabular revision [12].

No study, to our knowledge, presents the results of augmented tripod fixation in a geriatric population prone to osteoporosis and treated for proximal femoral fractures.

The primary objective of this study was to evaluate, in a geriatric population, the radiological results and the short- and medium-term survival of a Dual Mobility Cup (DMC) coated with hydroxyapatite with tripod fixation increased by 2 pegs and a screw. The secondary objective was to evaluate the clinical results and potential complications related to implant placement.

We formulated the hypothesis that, within a population prone to osteoporosis, this type of implant offers satisfactory short- and medium-term efficacy and a complication rate similar to the data in the literature.

Materials and methods

This monocentric retrospective cohort study was carried out in accordance with the Declaration of Helsinki. The Ethical Review Board of the *Ile de France IV* (IRB 00003835) approved this study on March 19, 2019 (registration number: 2019-A00229-48). The data collection was carried out after the study was declared to the relevant French National authorities (The Agency for the Safety of Medicines and Health Products and The Commission on Informatics and Liberty). All patients included gave their informed consent.

The series (Figure 1).

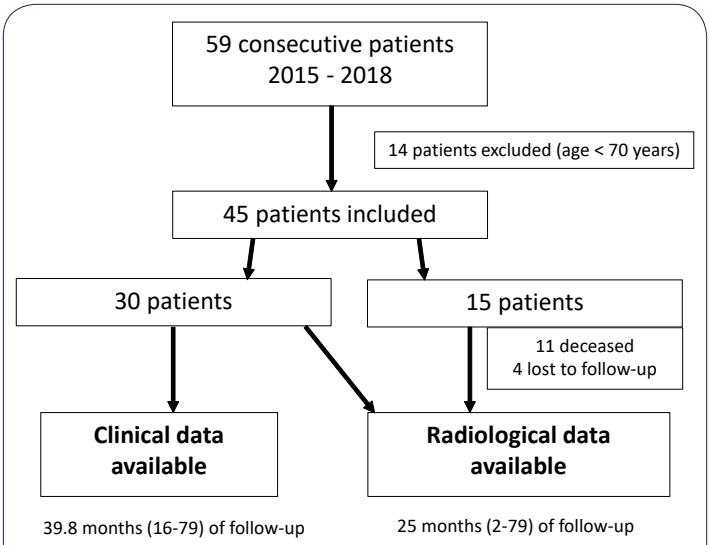

Figure 1: Flowchart.

This consecutive series of 45 patients (14 men and 31 women) originated from a consecutive series of 59 patients operated on between January 1, 2015 and October 31, 2018 at the Savoie metropolitan hospital center. The operators were the department's senior orthopedic-trauma surgeons. The inclusion criteria were age over 70 years at the time of surgery, and placement of the Cupule Avantage 3P plasma TIHA implant (Zimmer laboratory) regardless of the surgical indication. The different surgical indications are detailed in Table 1.

The exclusion criteria were refusal to participate in the study, loss of acetabular bone substance greater than or equal to stage IIA of the Paprosky classification [16].

Table 1: Surgical indications.

Pathology	Surgery	n=45	%
First-line surgery		**30**	**66.6**
Femoral neck fracture	Total hip prosthesis	21	46.6
Coxarthrosis	Total hip prosthesis	8	17.7
Femoral head osteonecrosis	Total hip prosthesis	1	2.2
Revision surgery		**15**	**33.3**
Acetabular PTH Loosening	Acetabular unipolar revision	5	11.1
Gamma nail failure in a pertrochanteric facture	THA	3	6.6
Aseptic bipolar THA loosening	Bipolar revision	3	6.6
Chronic THA Infection	1-stage bipolar revision	3	6.6
Dislocation of intermediate hip prosthesis	THA revision	1	2.2

The characteristics of the population are summarized in Table 2.

Table 2: Preoperative characteristics of the population.

		Number	%	Mean ± SD	Range
Number		45			
	Males	14	31.1%		
	Females	31	68.8%		
Age (years)				79.3±5.4	70 - 91
Height (cm)				67.2±16.9	38 - 115
Weight (kg)				164.7±8.4	147 - 183
BMI (kg/m^2)				24.6±5.1	14 - 42
Pre-op Parker score				7.4±2.6	0 - 9
Comorbidities					
Hypertension		21	46%		
Atrial Fibrillation		12	26%		
Cancer		10	22%		
Heart failure		8	18%		
Diabetes		5	11%		
Hypercholesterolemia		5	11%		
CVA		4	9%		
Renal failure		2	4%		
Respiratory failure		1	2%		
Myocardial infarction		1	2%		
Parkinson's disease		1	2%		

Surgical technique

The implant used was the TIHA Avantage 3P plasma cup, Zimmer laboratory (Figure 2).

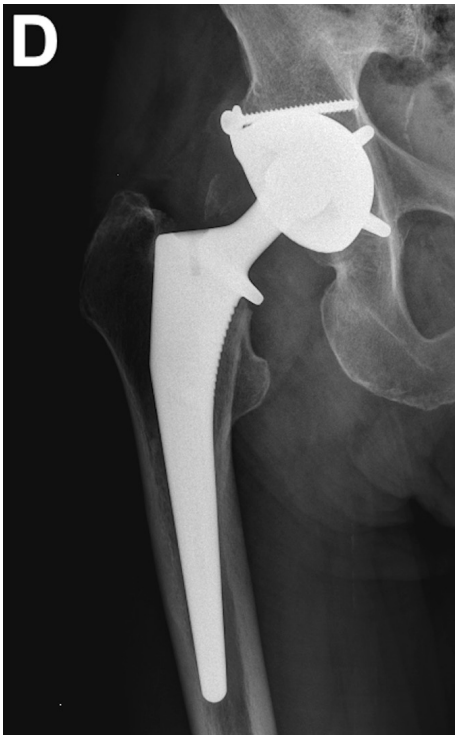

Figure 2: Radiograph of the implant.

The intervention was systematically carried out with the patient positioned in lateral decubitus, using a posterolateral (Moore) approach. The preparation of the acetabular cavity was done with motorized acetabular reamers of increasing size until there was satisfactory reaming of the subchondral bone. The final implant was chosen to have the same diameter as the last acetabular reamer used, and it was impacted in to the press-fit. The 2 pegs and the fixation screw were then added. For all patients the Advantage E1® insert was used.

The sizes of the implants used and the characteristics of the femoral stem are detailed in Table 3.

Table 3: Acetabular implant size and femoral stem type.

		N	%
Implant size	48	1	2.2
(mm)	50	8	18
	52	16	35.5
	54	7	15.5
	56	4	8.8
	58	6	13.3
	60	2	4.4
	62	1	2.2
Femoral stem	AURA II®	1	2.2
	Standard EXCEPT	15	33.3
	Varied EXCEPTION	1	2.2
	TARGOS™	18	40
	Complete UPTION®	5	11.1
	Unknown	5	11.1

Evaluation method

Patient data was collected from the medical file and verbally via a telephone call. This included all the pre- and intra-operative data, radiographs post-operatively and at the last follow-up, the functional scores (Oxford hip score, EQ-5D-5L, Parker score), possible complications and any revision of the implant at the last follow-up.

The interpretation of the radiographs was carried out by 2 evaluators (CH and RP). The interpretation of the radiograph at the last follow-up was done independently and then in comparison with the immediate postoperative radiograph. The areas of periprosthetic osteolysis were classified according to their location (DeLee and Charnley [17]).

In the event of the patient's death, the next of kin was contacted and asked about the cause of death and whether further surgery on the affected hip had taken place before the death.

The primary endpoint was the clinical and radiological survival of the implant. The secondary endpoints comprised functional scores and reported complications.

Statistics

A sample size calculation was performed using SAS® 9.4 Proc Power software. The study was designed for an alpha error risk of less than 0.05. Based on the assumption of 98% survival at 2

years, a sample size of 40 had at least an 80% chance of obtaining a lower limit of the 95% Confidence Interval (CI) for implant survival, with a CI of 9% for the margin of error.

The description of the series and the results were carried out through descriptive statistics. Survival was calculated using the Kaplan-Meyer technique.

Results

The mean age was 79.3±5.4 years (range: 70-90). Clinical and radiological data were complete for 30 patients with a mean follow-up of 39.9±14 months (range: 16-79 months). Among them, only 3 patients had a follow-up of less than 2 years.

Four patients were lost to follow-up and 11 died before the last follow-up. For these 15 patients, radiological data were available with a mean follow-up of 12.1±9.2 months (range: 2-39 months). For the 11 deceased patients, none had necessary iterative surgery or implant revision before death and no death was related to a direct complication of the surgical intervention.

Implant survival

Short-term survival was 100%, no revisions were observed.

Radiological results

For the whole series, the last radiological evaluation was made with a mean follow-up of 25.4±16 months (range: 2-79). For 3 patients, peri-prosthetic osteolysis was observed (Figure 3) in zones I and II, as per DeLee and Charnley. For the 42 other patients, no radiological complication (implant mobilization, screw breakage, periprosthetic lucencies, osteolysis) was identified. No radiological changes between the immediate postoperative image and the image at the last follow-up was visible.

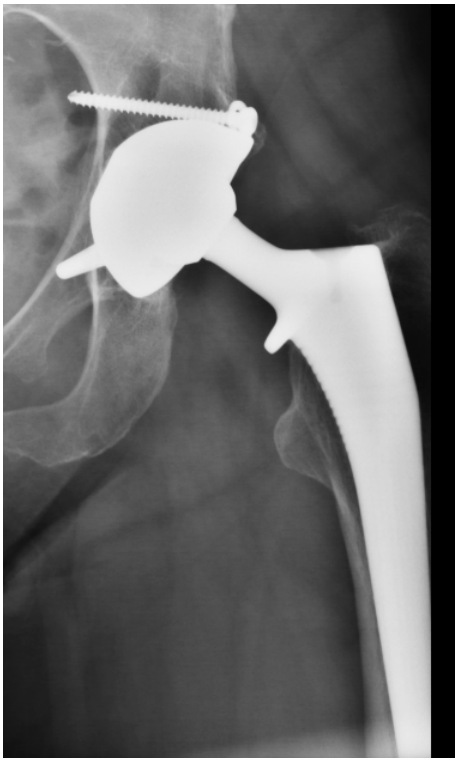

Figure 3: Periprosthetic osteolysis at 5.8 years of follow-up.

Functional scores

Concerning the clinical data available for the 30 patients, the Oxford Hip Score was 41.1±8.8 (range: 16-48). The mean VAS was 0.9±1.6 (range: 0-7) and the mean EQ-5D-5L score was 0.6±0.3 (range: -0.1-1). The mean preoperative Parker score was 7.4±2.6 (range: 0-9) and the mean score at the last follow-up was 7.47±2.07 (range: 3-9).

Complications

One patient presented with an intraoperative Vancouver B fracture requiring the addition of cerclage wiring. Four patients presented with postoperative anemia requiring blood transfusions. One patient presented with moderate postoperative pain consistent with psoas impingement but did not wish to prolong the assessment, nor consider surgical management. Finally, 2 patients presented with peri-prosthetic femoral fractures following falls after surgery (Vancouver A G and B1) requiring functional treatment and plate osteosynthesis respectively. No prosthetic dislocation was observed in the series and there were no complications related to the placement of the acetabular implant.

Discussion

This study supports our hypothesis as to the short-term efficacy of the use of a DMC with increased fixation by pegs and screws for total hip arthroplasty in older adults for various indications. No serious radiological complications or implant revisions were observed. This is the first series studying this type of implant in this population.

Our results corroborate those of the literature with a very low rate of radiological complications and a survival rate close to 100% in the short and medium term. Philippot et al. [14] reported 96% survival at a mean follow-up of 17 years in the largest series in the literature, including 438 patients with a tripod acetabular implant, not coated with hydroxyapatite or macrostructure. The causes of revisions were aseptic loosening, polyethylene wear, intra-prosthetic dislocations and sepsis. Boyer et al. describe the radiological results of 62 patients at 20 years of follow-up reporting 13% peri-prosthetic osteolysis, corresponding to our medium-term observations.

The risk of periprosthetic osteolysis associated with this type of implant remains a controversial subject. Certainly, surface irregularities between the liner and the cup related to the locations of the pegs and screws are considered to be a cause of wear and polyethylene debris ultimately responsible for osteolysis [18]. Various authors [19-21] corroborate this hypothesis, while Taniguchi et al. [22] did not report a higher rate of osteolysis for this type of implant after CT evaluation at more than 7 years of follow-up.

The interpretation of the results should be made with consideration to the limitations of the study. This study used a small cohort, with a high rate of deceased patients. The follow-up was also limited and did not make it possible to make conclusive results beyond the medium term. However, this limitation is specific to the population studied given the low life expectancy of this population of geriatric patients (with a mean age of nearly 80 years old), presenting with numerous comorbidities who underwent treatment for proximal femoral fractures. About 30% of geriatric patients die within a year of a femoral neck fracture [23], which

corresponds to our results. The evaluation of very long-term results for this type of population is therefore not feasible and ultimately not very useful since the majority of patients die in the short- or medium-term after surgery.

Assessment of the degree of osteoporosis by bone densitometry was not available, making it impossible to make a precise decision on the level of bone quality of the patients in the study. Nevertheless, 89% of patients were initially treated for a proximal femoral fracture (71%), and/or were older postmenopausal women (68%), making the probability of an advanced osteoporotic state very high in the majority of patients in this series.

The stability of the Parker score between the pre- and post-operative data is explained by cases of revision and of initial failure of proximal femoral osteosynthesis, in which surgery tends to improve autonomy, unlike cases of femoral neck fracture treatment which generally leads to a loss of autonomy in the postoperative months.

The effectiveness of a cup with augmented tripod fixation is therefore well established. Both in subjects under the age of 60 undergoing arthroplasty for osteoarthritis [14], and in patients over the age of 80 treated in the context of proximal femoral fractures, as exemplified by the results of this study. Nevertheless, the usefulness of this type of implant compared to cemented or simple press-fit implants remains debatable. Indeed, for several authors [8,9], the increased fixation does not improve the stability of the implant over the long term compared to press-fit alone. Brulc et al. [24] even argue that the primary stability of a press-fit cup depends almost exclusively on the surgical implantation technique, with no significant influence on the type of implant or patient characteristics. They conclude that failures of intraoperative primary fixation do not exceed 5% of cases when performed by surgeons who are experienced in the simple press-fit implantation technique.

Tripod cups do not exclude the need for press-fit implantation. Improved implant stability, in a setting where sufficient press-fit has not been obtained, does not appear to adequately address the technical challenge posed. In fact, the addition of a screw and 2 pegs does not offer sufficient biomechanical support to completely compensate for inadequate primary fixation, as suggested by Goodnough et al. [25].

Conclusion

DMC with augmented fixation by screws and pegs is safe and effective in the short- and medium-term for THA in a geriatric population. Additional studies, allowing a comparison with press-fit fixation alone or cemented fixation, are needed to assess the benefit of augmented fixation combining screws and pegs as an additional option in the surgeon's therapeutic armamentarium.

Declarations

Compliance with ethical standard: This monocentric retrospective cohort study was carried out in accordance with the Declaration of Helsinki. The Ethical Review Board of the Ile de France IV (IRB 00003835) approved this study on March 19, 2019 (registration number: 2019-A00229-48). The data collection was carried out after the study was declared to the relevant French National authorities (The Agency for the Safety of Medicines and Health Products and The Commission on Informatics and Liberty). All patients included gave their informed consent.

This study complies with the current laws from the French legislation

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Conflict of interest: CH: Clinical trial: as co-investigator of this study for the Zimmer laboratory.

BG: No conflict of interest.

PR: Education consultant- B. Braun.

BRD: No conflict of interest.

MS: No conflict of interest.

PR: No conflict of interest.

EM: Clinical trial: as principal investigator of this study for the Zimmer laboratory.

Authors contribution

CH: Collection of clinical data, drafting of the manuscript.

BG: Writing of the manuscript.

RP: Radiological analysis, data collection.

MS: Proofreading of the manuscript, referencing.

BRD: Proofreading and editing.

PR: Proofreading and editing.

EM: Study methodology.

Ethical approval : Obtained the 19th of June (CPP ile de France) Document in the attached file called "Ethic committee".

Informed consent: Mentioned in the manuscript

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