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Original article

The use of dual mobility cups in primary total hip arthroplasty: A bicentric, retrospective study of 196 implants

Corrado Ciatti[1,2], *Pietro Maniscalco*[1,3], *Gianfilippo Caggiari*[2], *Ramón Vallenilla Fernàndez*[4], *Carlos Eduardo Marquez*[4], *Shamira Mohtar*[4], *Ruben Jaén*[4], *Andrés Mauricio Monasterios*[4], *Edoardo Bori*[5], *Fabrizio Quattrini*[1,3]

[1]Orthopaedic and Traumatology Department, Guglielmo da Saliceto Hospital, Piacenza, Italy; [2]Orthopaedic Department, Sassari University Hospital, Sassari, Italy; [3]University of Parma; [4]Centro Medico de Caracas, Venezuela; [5]Haute Ecole "ICHEC-ECAM-ISFSC", Brussels, Belgium

Abstract. This retrospective bi-centre study aims to present our experience with the use of dual mobility cups. The primary endpoint was the evaluation of outcomes after dual mobility hip replacement. The total cohort was composed of 196 THAs, operated between 2015-2021: 35.4% male, 64.6% female (64.6%), mean age 63.6 years. We used 3 different stems, the femoral head was composed of ceramic (93.9%) or metal (6.1%); the size was always 28 mm. The average Harris Hip Score was 34.3 ± 15.8 (min 4 - max 69) preoperative, and 91.2 ± 6.7 (min 61 - max 100) at 3 months follow-up. The Harris Hip Score grading was "Excellent" in 65.8% cases. The outcome was significantly better in young patients (p value < 0.001). We registered an overall dislocation rate of 0%, while we reported 8 revisions (4.1%), due to periprosthetic fracture (4), aseptic loosening (1), infection (1), component breakage (1) and pain (1). The dual mobility system is an effective solution within primary hip replacement: it reduces wear and loosening forces, increasing joint range and prosthesis stability, with a very low incidence of dislocation. In younger patients and in arthritic ones, even better results can be expected. (www.actabiomedica.it)

Key words: dual mobility, total hip arthroplasty, outcomes

Introduction

Total Hip Replacement (THR) is recognized as one of the greatest successes in orthopaedic surgery worldwide (1). The main objectives to be achieved in all hip replacements are to provide total (or at least partial) pain relief, to achieve good stability and to restore a satisfying range of motion (ROM), with minimal wear of the implant components.

In the pursuit of these objectives, various factor contributed to the historical development of said surgical procedure: these include the design of the implants, the materials used for their components, friction pairings, wear considerations and techniques employed in surgical implantation (2-4). Given both the improvement in life expectancy and the increase in functional demands of the elderly population, we are witnessing significant boosts in joint replacements and the figures are likely to continue to increase with time (5).

Post-surgical complications will always be feared by surgeons, despite the significant decrease in their incidence compared to the past. The main complications are involving infectious processes, dislocations, neurological sequelae, vascular lesions, leg

length discrepancies, periprosthetic fractures, heterotopic ossification and periprosthetic osteolysis with loosening.

The prevalence of hip dislocation following primary arthroplasty varies between 0.2% and 10%, representing also the most common cause of revision hip surgery (6,7). This complication generally occurs in the first months after surgery, and it is possible to distinguish dislocations into early (less than 3 months) and late (more than 3 months) ones, according to their time of onset. Most authors report that the incidence of early dislocations is more frequent (8-10). Moreover, the direct lateral approach seems to be associated with a higher rate of revision for dislocation if compared with the anterior approach, with the posterior-lateral approach being the one involving the greatest risk (11).

The list of risk factors for hip replacement dislocation is extensive and principally includes patient-related factors (such as gender, age, diagnosis, previous surgeries, neuromuscular dysfunction, non-compliance with prophylactic anti-dislocation guidelines, cognitive dysfunction, alcohol and drug abuse), surgery-related factors (such as approach, component orientation, soft tissue tension, surgeon's experience and perioperative infection) and implant-related factors (such as femoral head size, head-to-acetabulum size ratio and acetabular component design) (2,13).

In France, Gilles Bousquet and Andrè Rambert developed the concept of Dual Mobility (DM), creating the so-called Dual Mobility Cup (14). This component consists of two concentric joints: a prosthetic head (22 or 28 mm) within a retentive polyethylene liner, which moves freely inside a highly polished metal acetabular cup (15). The diameter of the large head is usually 6 to 8 mm smaller than the size of the outer shell of the cup. Most of the movement occurs at the head-liner interface. A third joint is described, which is made up of the neck and polyethylene head (16).

This paper aims to present our experience with the use of the dual mobility system in primary THR (pTHR). The primary endpoint is to evaluate the patient's outcome after DM THA, assessed during the first 3 months post-surgery via both a clinical visit and the calculation of the Harris Hip Score (HHS) (17). The pre-operative HHS was registered and assessed in all the medical records reviewed.

Materials and methods

We conducted a retrospective bi-centre study, including all patients operated with a DM THA at "Centro Medico de Caracas" (Caracas, Venezuela) and "Guglielmo da Saliceto Hospital" (Piacenza, Italy). We considered the period between August 2015 and August 2021 (6 years). The spread of the Covid-19 pandemic throughout the world obviously influenced the data of the last few years, and consequently a decrease in the procedures performed in both Centres was recorded (18-20).

The inclusion criteria were: patients with symptoms, clinical evaluation and radiological imaging compatible with severe hip osteoarthritis (Figures 1 and 2); age between 40 and 99 years; causes of arthritis attributable to primary osteoarthritis, Developmental Dysplasia of the Hip (DDH), AVascular Necrosis of the femoral head (AVN), outcomes of femoral neck's fracture; preoperative evaluation of the patient through the HHS.

All surgeries in both Centres were performed using the direct lateral approach according to Hardinge, implanting a THA with a Dualis® DM cup (Dualis System® Gruppo Bioimpianti S.r.l., Milano, Italy) (Figures 3 and 4). All cups included in the cohort were cementless. DM cups were combined with several stems from different Companies: Korus (Gruppo Bioimpianti S.r.l., Milano, Italy), Fin (Gruppo Bioimpianti S.r.l., Milano, Italy), and Corail (DePuy Synthes, Warsaw, IN, USA).

During the immediate postoperative period, a control pelvis X-ray was requested and the position of the prosthetic components was evaluated. The patients received pain management therapy, which allowed the immediate start of physiotherapy exercises the day after surgery to restore the complete ROM (21). Using a walker or crutches, they started walking on the first or second postoperative day (at the latest), with partial and progressive weight bearing according to patient tolerance, except for those who had intraoperative complications.

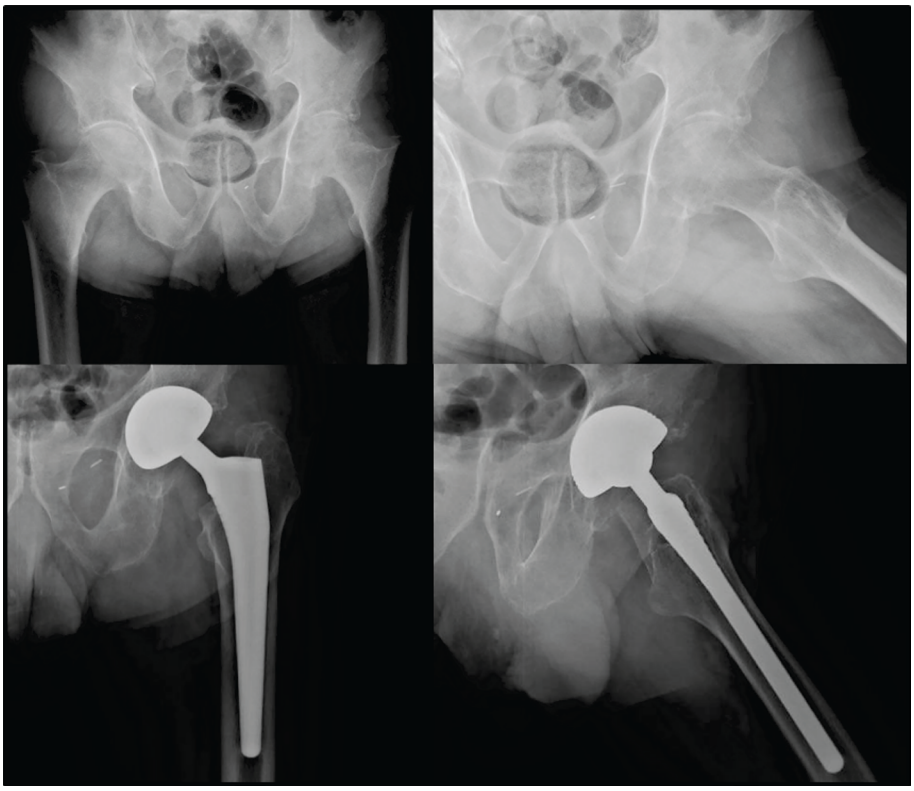

Figure 1. Case report: male, 67 years old, osteoarthritis of the left hip; operated with THA with Dualis dual mobility cup.

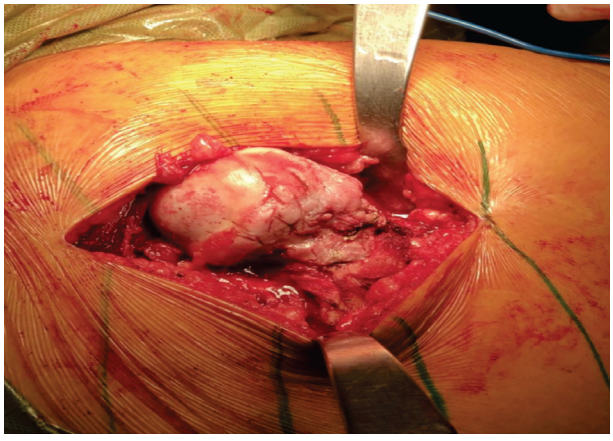

Figure 2. Intraoperative image, direct lateral approach of Hardinge; severe femoral head osteoarthritis.

Figure 3. Dualis system, Gruppo Bioimpianti S.R.L.

We analysed the medical records of the selected patients, looking for information related to surgery (type of implant, fixation method, surgical approach, intraoperative complications), hospitalisation (length of stay, blood transfusion), and postoperative course (thrombosis, pulmonary embolism, haematomas, nerve injury, anaemia, and complications inherent to the operative wound).

Outcome assessment after hip replacements was determined with the HHS (administered 3 months after surgery), and the occurrence of any complications in the first two postoperative years.

Figure 4. Head and liner implantation.

After being discharged from the ward, patients were evaluated weekly during the first month to check the operative wound and patients' advances in ROM and pain control. Subsequently, a follow-up (FU) evaluation was carried out postoperatively at 1 - 3 - 6 - 12 and 24 months after surgery. The patients who did not comply with the last consultation were contacted by telephone and then searched for any major complications. Patients who did not complete this FU evaluation or died before the end of the FU were excluded from the study.

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Statistical analysis

Continuous variables were expressed by the mean and standard deviation (SD) and were evaluated by Student T-test or Mann-Whitney U test. The categorical data were expressed as number and percentage (%) and were evaluated by chi-square or Fisher's exact test. The statistical test level was set as $p<0.05$. SPSS version 23.0 (IBM, Armonk, NY, USA) was used to perform all the tests.

Results

During the examined period, 213 patients were operated with a DM THA. According to the inclusion/exclusion criteria, the total cohort was composed of 196 THAs and 189 patients (7 of the patients had a bilateral hip replacement); 67 were male (35.4%), while 122 were female (64.6%). The mean age at the time of surgery was 63.6 years ± 7.3, the median was 66 years. Concerning the components used, only Dualis cementless cups (Gruppo Bioimpianti S.r.l., Milano, Italy) (Figures 3 and 4) were implanted, while the femoral stem was cemented in 7 cases (3.6%) and cementless in the other 189 (96.4%). In terms of femoral components, we used Korus stems (Gruppo Bioimpianti S.r.l., Milano, Italy) in 153 cases (78.1%), Fin stems (Gruppo Bioimpianti S.r.l., Milano, Italy) in 6 cases (3.1%) and Corail stems (DePuy Synthes, Warsaw, IN, USA) in 37 cases (18.9%). The femoral heads were made of ceramic in 184 cases (93.9%) and of metal in 12 cases (6.1%); the size of all the implanted heads was 28 mm.

The HHS applied to each patient before surgery yielded an initial value that in all cases was "Poor", with an average score of 34.3 ± 15.8 (min 4 - max 69).

In 3 of the patients (1.5% of all procedures), an incomplete fracture of the medial cortex of the femoral shaft was reported during the surgery; the issue was however resolved without major complications. Weight-bearing support was deferred for 3 weeks with the subsequent incorporation of progressive weight bearing until full recovery and incorporation of walking without support. The other cases did not report intraoperative complications and it was possible to start physiotherapy on the first postoperative day.

The average hospital stay was 5.9 ± 2.4 days (min 2 - max 9). During the immediate postoperative

period, 63 patients (32.1%) required a red blood cell transfusion due to a decrease in the haemoglobin level. No neurological or vascular complication was registered. Out of the total, 5 patients (2.6%) showed an organised haematoma, which did not require surgical drainage; 3 (1.5%) wound dehiscences and 2 (1.0%) pulmonary embolisms were recorded; 1 patient (0.5%) underwent second surgery one week post-operatively due to dehiscence of the fascia lata suture, resulting in no further complications; finally, a superficial infection of the wound was ruled out, but conservative treatment with targeted antibiotic therapies was sufficient to treat it and in any cases no surgery was necessary.

When the HHS test was performed during the late postoperative period (at the 3 months outpatient visit), the scores presented increases compared to the starting ones in all the cases, with a mean growth of 56.9 points (min 35 - max 82). The average HHS was 91.2 ± 6.7 (min 61 - max 100). The HHS grading was "Poor" for 2 patients (1.0%), "Fair" for 12 patients (6.1%), "Good" for 53 patients (27.0%) and "Excellent" for 129 patients (65.8%).

If we focus only on the 164 patients operated for osteoarthritis (86.2% of the total cohort), the average HHS values increase to an average of 93.2 ± 4.6 (min. 77 - max 100) (Figure 2). Within this subgroup, the HHS grading was "Fair" for 3 (1.8%), "Good" for 31 (18.9%) and "Excellent" for 130 (79.3%). "Poor" grading was not reported for any patient.

Using the median age of the cohort, our patients were divided into two equal groups to evaluate the difference outcome based on age. Results showed significantly better HHS in young patients (p value < 0.001): the mean HHS of the 98 younger patients is indeed 95.9 ± 2.8, while the one related to the 98 older patients is 86.5± 6.2.

Radiographic analysis revealed a mean acetabular tilt of 49° (range 31-65°). There were no osteolysis or radiolucent lines around the acetabular component of the whole cohort during the 2 years FU period. Moreover, at the end of the FU, no complications or revisions due to dislocation or instability were recorded, with an overall dislocation rate of 0%. On the other hand, we reported 8 revisions (4.1%): the main cause was periprosthetic fracture (4 cases, 2.0% of total THAs, 50.0% of revision surgeries), followed by aseptic loosening (1 case, 0.5% of total THAs, 12.5% of revision surgeries), infection (1 case), component breakage (1 case) and pain (1 case). In 3 cases (37.5%) the failure of the prosthesis occurred in the first 3 months, in 2 cases (25.0%) it occurred between 4 and 12 months, while in the remaining 3 cases (37.5%) it occurred after the first year. Failure of a Dualis-Korus fit prosthesis occurred 5 times (62.5%), 1 time (12.5%) for Dualis-Fin and 2 times (25.0%) for Dualis-Corail fit. Consequently, the coupling Dualis-Korus reported a failure rate of 3.3% (5/153), Dualis-Fin of 16.7% (1/6) while Dualis-Corail of 5.4% (2/37).

Discussion

The DM design embraces the following concepts: low friction and minimal Charnley wear, a large head to restore anatomy and increase stability proposed by McKee and Farrar, meaning that this design includes a joint that minimises wear issues and a large joint to prevent instability (22). In fact, with the increase in the "head to neck ratio", the "jump distance" will increase as well, thus reducing the risk of dislocation.

The objectives of this design are to reduce wear and loosening forces, to use a physiological system and to increase joint range without compromising intra-prosthetic stability (22,23).

A review of comparative results, where the main parameter to be evaluated is stability, showed that dual mobility cups have excellent short- and medium-term results compared to standard implants in pTHR (23). In a prospective cohort study of 143 dual mobility versus 130 standard implants at 4-year FU, Epinette reported a statistically significant difference in the dislocation rate in favour of dual mobility (0% vs. 5.4%) (24); in all cases, the same stem and a cementless cup were fitted with a 28 mm head; there were no cases of mechanical cup loosening in any of the cohorts. Similarly, in a case-control study comparing 105 dual mobility and 215 standard prostheses with a 22 mm head in pTHR, Caton et al. observed a statistically significant difference in both the dislocation rate (0.9% versus 12.9% respectively) and the revision rate (2.1% versus 12.9% respectively) at 10-year (25). Prudhon et al. found no significant differences in aseptic loosening, infection, or periprosthetic fracture between the two cohorts. The main significant difference

was the higher revision rate due to dislocation on the standard bearing cups (17.7%) when compared to dual mobility (4.7%) (26).

Most of the literature on DM is based in France, where the use of this kind of implants is more common. In fact, for a total of 45397 primary THAs (from January 1st 2006 to December 31st 2019), in 39.3% of cases a DM cup was implanted (27). Data on DM from other global national registers is more limited, even if we are witnessing a progressive increase in its use, as recently stated by the American Joint Replacement Registry (AJRR). The 2021 AJRR Annual Report reported indeed a statistically significant increase in the use of DM cups for elective pTHR when comparing 2012 to 2020, especially in young patients (< 50 years) (28). In addition, encouraging early results have emerged from some European national joint registries: comparing 620 dual mobility prostheses with 2,170 standard cemented cups with a 28 mm head in the "Lithuanian Arthroplasty Register", the 5-year cumulative revision rate was 3.9% in the dual mobility group and 5.2% in the cemented standard prosthesis group (29). In addition, in the "Dutch Arthroplasty Register", analysis of 3,038 dual mobility and 212,915 standard hip replacements showed that 0.2% of hip replacements with dual mobility prostheses underwent a revision for dislocation at 5-year FU compared to 0.5% in the standard primary prostheses group (30). Our cohort, even if limited in number, seems to confirm the very low dislocation rate of dual mobility THA, since after 2 years follow-up we did not recorded even one.

The results of contemporary DM THA have been even more interesting in high-risk patient populations, such as obese patients (defined as a BMI greater than 30 kg/m2). Hernigou et al. reported a statistically significant difference between obese patients who underwent a pTHR: at 7-year FU the dislocation rate of THAs with DM (or constrained liners) was 2%, whereas that of THAs with standard cups was 9% (31). Furthermore, the use of DM was more effective than preoperative bariatric surgery in reducing the risk of dislocation (dislocation rate of 14% at 7-year FU) (31). Patients with cerebral palsy or other neurological diseases are also at high risk of instability after THR. This is likely to be secondary to persistent coxa valga, increased femoral anteversion, and associated unbalanced forces generated by the adductor, internal rotator and hip flexor muscles. The review published by Raphael et al. about the use of THR with standard support in patients with cerebral palsy showed a dislocation rate of 14% with a mean FU of 9.7 years (32). Subsequently, DM was used with promising short-term results: Sanders et al. reported no dislocations in dual mobility hip joint replacements for patients with cerebral palsy at a mean FU of 39 months (33). Similarly, Morin et al. report that there were no aseptic loosening or dislocations in dual mobility THR performed in 40 patients with cerebral palsy at a mean FU of 5 years (34).

Dislocation represents one of the most insidious and feared complications for neurological patients (35). Within our cohort, there were 4 patients with neurological disease; 3 of them suffered from Parkinson's disease, while 1 had a diagnosis of multiple sclerosis. Despite this issue, we have not reported cases of dislocation within our cohort. It is to be mentioned that these patients reported lower scores both on preoperative and postoperative HHS, showing however a substantial improvement in the score.

Several studies testified to the greater risk of postoperative instability among THRs for femoral fracture compared to those implanted for other causes (36-39). This could be secondary to a combination of muscle failure and a propensity for recurrent falls, representing a life-threatening complication (39). Consequently, several centres started to employ DM system THAs for femoral neck fractures, with promising initial results. In a population of 105 patients, Tarasevicius et al. reported a statistically significant reduction in the dislocation rate of dual mobility THAs (0/42) compared to standard cups (8/56) during the first postoperative year (40). Similarly, in a prospective multicentre study of 214 femoral neck fractures treated with DM THAs, Adam et al. reported a dislocation rate of only 1.4% at 9-month FU with 70% of patients returning home without increased dependency (41).

Dual mobility hip replacements have also performed favourably compared to hemiarthroplasty (HA). Bensen et al. retrospectively compared 171 bipolar HAs with 175 dual mobility arthroplasties performed in patients with displaced femoral neck fractures (42). There was a statistically significant

difference in the rate of dislocation, with an incidence of 14.6% among bipolar HAs and of 4.6% for DM arthroplasties (42). Patient outcome studies are also promising: in the cross-sectional study by Tabori-Jensen et al. 89% of the 124 patients with dual mobility arthroplasties after a femoral neck fracture were satisfied with their surgical outcome, using health-related quality of life questionnaires comparable to the population norm with a mean FU of 2.8 years (43).

In a few cases, clear improvement in the HHS score was not achieved or, in any case, an improvement comparable to the other subjects of the cohort was obtained. This was especially due to other osteoarticular pathologies affecting several patients, such as severe osteoarthritis of the contralateral hip or knee osteoarthritis. Whereby, despite having a hip replacement and greatly improving their quality of life, hip replacement alone did not lead to complete resolution of the patients' pain and disability, and they remained with an assisted gait or were unable to walk for a prolonged time or perform other activities unassisted, such as walking up and down the stairs. Therefore, we are expecting to achieve lower postoperative HHS in these patients when compared to patients who prior to surgery only suffer from osteoarthritis.

We found that younger patients achieve better results in their postoperative outcome. This issue is not surprising and indeed goes to support what previous studies had already underlined (44,45,46).

Two limitations are however to be mentioned: the small number of patient and the use of the same surgical approach for all the procedures. All the prostheses included in the cohort were implanted with the direct lateral approach of Hardinge, and previous studies have shown that this surgical approach is less prone to postoperative dislocations than others: the posterolateral approach, with or without re-attachment of the short external rotators and/or the posterior joint capsule, is characterized by a higher dislocation rate (11,47).

Conclusions

The results of this study allow us to conclude that the DM design implant is an effective solution for primary THA. The objectives sought with the dual mobility system are focused on reducing wear and loosening forces, increasing joint range of movement and prosthesis stability. This prosthetic design indeed succeeded in providing excellent results, with a very low incidence of dislocation. In younger patients, and arthritic ones, even better results can be expected.

Conflict of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

Author's Contribution: Conceptualization, CC and FQ; methodology, CC, GC, FQ; software, CEM; validation, PM, RVF. and AMM; formal analysis, SM, RJ; investigation, CC; resources, GC; data curation, FQ; writing—original draft preparation, CC, EB and FQ; writing—review and editing, CC, PM, GC, RVF, CEM, SM, RJ, AMM, EB and FQ; visualization, CC; supervision, PM; project administration, FQ; funding acquisition, PM All authors have read and agreed to the published version of the manuscript.

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Correspondence:
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Prof. Pietro Maniscalco, MD
Orthopaedic and Traumatology Department, Guglielmo da Saliceto Hospital, Piacenza, Italy
University of Parma
Via Taverna 49, Piacenza, 29121 Italy
Phone: 0523303120
E-mail: p.maniscalco@ausl.pc.it
ORCID: 0000-0002-5637-6774