Original article

Third generation Dual Mobility Cups: could be the future in total hip arthroplasty? A five-year experience with dualis

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Abstract. *Background*: The concept of dual mobility (DM) is currently approved as a valid option for reducing the risk of dislocation, with an incidence ranging from 0% to 4.6%. The principle is to achieve a high joint stability through a large diameter polyethylene (PE) liner, and to reduce cutting forces due to a "low-friction" head-liner coupling mechanism. *Methods*: From March 2015 to March 2020, 138 patients were treated with Dualis Cup (Gruppo Bioimpianti–Peschiera Borromeo, MI, Italy) for a total of 141 implants (three cases were bilateral). The average age at the time of the surgery was 77. Patients' clinical and X-ray follow-up was at 1, 3, 6, 12 months and then once a year. *Results*: Seven patients (4.9%) had complications which required a second surgery, but only one case (0.7%) of intraprosthetic dislocation (which required cup revision), was directly ascribable to the DM cup. *Conclusions*: Improvements in design and materials of the third generation DM cups allowed both to reduce the rate of dislocations in high-risk patients (i.e., patients with neuro-muscular diseases and cognitive disorders, patients needing revisions, osteosynthesis failures, femoral neck fractures) and to achieve a survival rate similar to standard cups, ensuring a range of motion (ROM) very close to the physiological one. In our brief experience, Dualis Cups showed results comparable to those reported in the literature for Dual Mobility. If this data is confirmed by long-term studies, the use of DM cups could be extended even for young patients with high functional demands. (www.actabiomedica.it)

Key words: Dual Mobility Cup, Intraprosthetic Dislocation, Total Hip Arthroplasty, Hip Joint Stability

Introduction

The concept of Dual Mobility, introduced by Gill Bousquet and Andre Rambert in 1974 as a possible option both to reduce wear debris and to increase stability of the implant, underwent several design improvements over the years. Tests carried out on the first prototypes, where a PE cup directly rotated between the native acetabulum and a 22.2-mm metal head, failed due to the wide deformation of the PE cup. Starting from this failure, Dual Mobility has been progressively developed up to its current concept: a PE liner which moves between a metal head on the femoral side and a fixed cup on the acetabular side, creating a double sliding surface. In 2003, Noyer (1) underlined the crucial role of the femoral stem design in implant survival, mainly due to the macroscopic feature of the prosthetic neck which can conflict with the peripheral edge of the PE liner. It was thus defined the concept of "third articulation". DM cups consist of three joints: the small joint between the femoral head and the PE liner, the large joint between the metal cup and the PE liner, and the third paradoxical joint between the prosthetic neck and the peripheral edge of the PE liner. In 2010, third generation DM cups were launched. They consist of hemispherical anatomical metal cups which are able to avoid conflicts with the psoas muscle. They are made in cobalt-chromium alloy to resist wear and deformation, equipped with a mirror-polished internal surface without holes. The peripheral circumferential

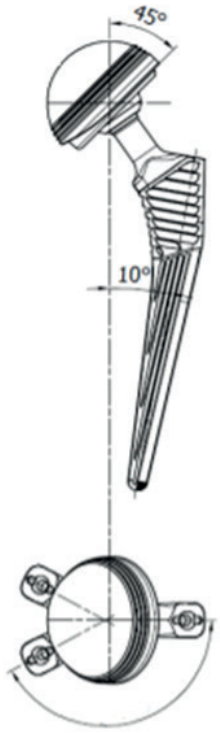
edge of the cup promotes primary stability and osseointegration through a double layer plasma spray of titanium and hydroxyapatite. The peripheral edge of PE liner has rounded internal edges to avoid impingement with the third joint. The first (or small) joint is a constrained joint between the femoral metal/ceramic head and the mobile PE liner. Head and liner are linked with a snap-type retention mechanism; however, the head freely rotates into the liner. The second (or large) is an unconstrained joint, where the PE liner serves as a "big head" articulated with the metal cup. The third joint, that one between the prosthetic neck and peripheral edge of the PE liner, is involved in the extreme movements of the hip. Large or wrinkled necks might facilitate wear and tear of the PE liner edge, resulting in debris formation, retention mechanism loss and an increased risk of intraprosthetic dislocation. The three joints are not simultaneously activated: the movement starts with the head rotation into the liner until the prosthetic neck conflicts with the liner. At this stage, rotation between the liner external surface and the acetabular cup internal surface begins. This mechanism allows to obtain a wider joint excursion, avoiding impingement between neck and liner peripheral edge (2). Intraprosthetic dislocation (IPD), described by Lecuire in 2004 (3), is an exclusive complication of DM cups and occurs when a worn PE liner is no longer able to retain the head. Three types of intraprosthetic dislocations exist: the first occurs as a result of a uniform wear of the external liner ring (46% of IPs); the second occurs due to an asymmetric wear of the liner ring leading to a progressive modification in the head center of rotation of the small joint (39% of IPs); the third is associated with a rapid wear of the retentive edge due to formation of abrasive intra-articular particles or metallosis. In 2013, Philippot described 81 cases with IPD among 1960 primary total hip arthroplasties (THA) performed between January 1985 and December 1998, identifying three different dislocation types (4). Type 1 (21 cases) was a pure IPD secondary to wear of the PE retentive rim and occurred at an average of 11 years after surgery. Type 2 (4 cases) was secondary to a mechanical blocking of the liner due to fibrotic tissue interposition or ossifications causing liner impingement and occurred at an average of 8 years after surgery. Type 3 was secondary to loosening and resulting cup migration. In 2018, Neri reported that the latest modifications in the design of the femoral neck, as well as the improvements in the mobile liner itself, have contributed to the nearly disappearance of this complication (5). The most recent cases of IPD reported in the literature consist of a liner disassembly during a bloodless reduction and are not real dislocations.

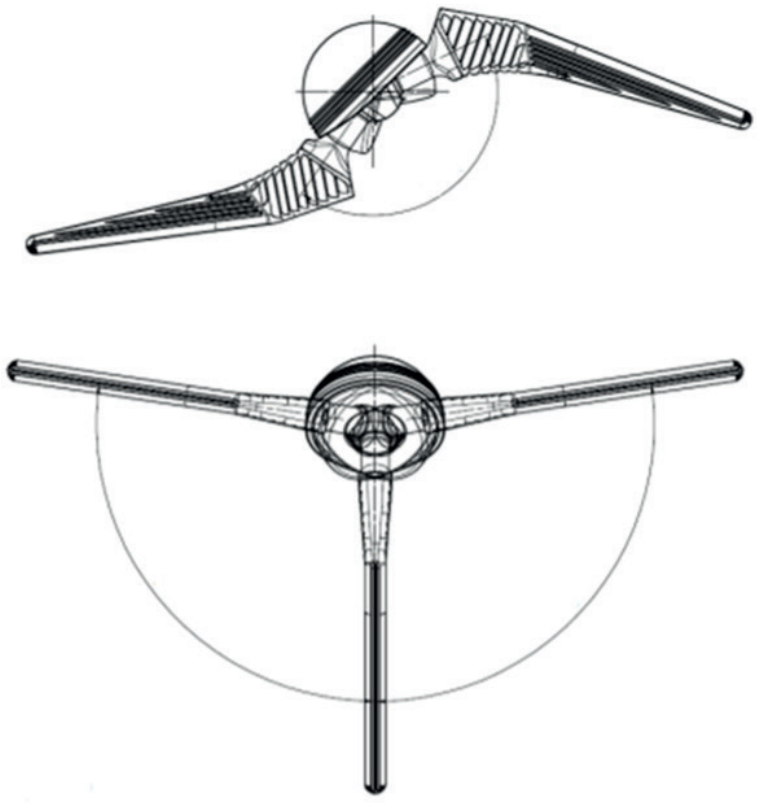
Patients and Methods

Authors report their experience in using Dualis cup (Gruppo Bioimpianti–Peschiera Borromeo, MI, Italy) during a 5-year period from March 2015 to March 2020.

Dualis cup (Fig. 1) is a press-fit uncemented cup (the cemented model is also available) made of high-nitrogen steel according to ISO 5832-9. It has an hemispherical shape with a 3-mm cranial protrusion to reduce dislocation, an anatomical aperture in the caudal section to avoid conflict with the stem neck, and two circumferential grooves to increase a greater primary press-fit. The cup is 3 mm in thickness with a mirror finishing on the inside to reduce wear of the PE liner. The liner has two spherical surfaces: the convex surface perfectly articulates with the inside of the acetabular cup, while the concave one articulates with a 28-mm prosthetic head. The circumferential grooves located at the equator of the cup ensure its primary stability; the outside double coating in Plasma Spray Ti SPS and Osprovit® hydroxyapatite promotes biological response guaranteeing osseointegration. Dualis cup is available in

Figure 1: Dualis Cup





	Minimun Value (ISO 21535)	Size 44	Size 56	Size 64
γ internal/external rotation	90°	268.2°	303°	360°
ε abduction/adduction	60°	138.8°	147.1°	150.9°
δ flexion/extension	100°	172.6°	188.8°	197°

Figure 2. Dualis Cup range of motion gradually increases from the smallest (44 mm) to the largest (64 mm) Cup size

a single model, which allows it to be implanted in both right and left joint. It comes in 11 different sizes, from 44 mm to 64 mm, to fit the needs of different patients (Fig. 2). The ultra-high molecular weight crosslinked PE liner also comes in 11 different sizes to be coupled with the corresponding cup sizes. The internal surface of the PE liner is finished with a retention mechanism, consisting of a collar narrowing, which counteracts the risk of prosthetic head dislocation.

From March 2015 to March 2020, 138 patients were treated with Dualis Cup for a total of 141 implants (three cases were bilateral). At our Institution, criteria for preferring the use of the DM system include all those clinical features which may lead to a

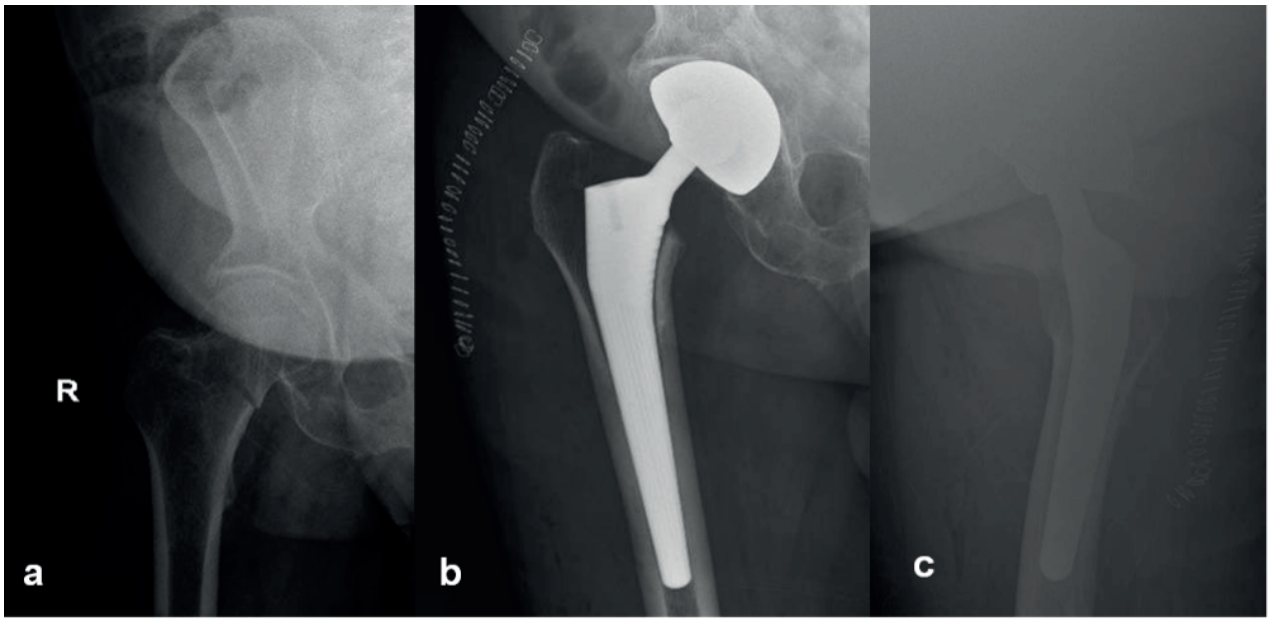


Figure 3: a) Femoral neck fracture in a patient with functional post-traumatic lower limb weakness; b-c) Post-operative x-ray

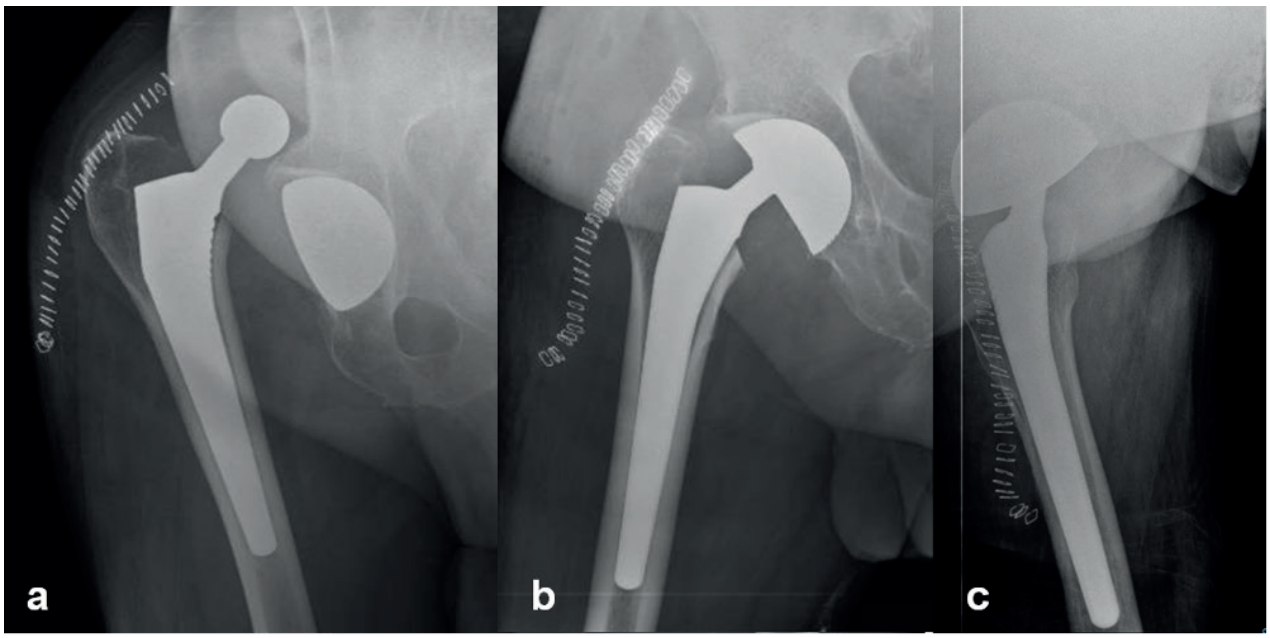


Figure 4: a) Intraprosthetic dislocation occurred 12 days after the surgery; b-c) Post-reduction x-ray

higher risk of prosthetic dislocation or to an increased risk of new falls:

- Failure of previous osteosynthesis devices
- Recurrent THA/hemiarthroplasty dislocations
- Avascular necrosis of the femoral head
- Previous lumbar spine fusion
- Femoral neck fractures in elderly patients (within 80 years of age; hemiarthroplasty for the over 80)
- Femoral neck fractures in patients affected by neuro-muscular or cognitive disorders.

The study population consist of 90 females (65.2%) and 48 males (34.8%). The average age was 77 (ranging from 46 to 94) at the time of the surgery. The average follow-up was 27 months (ranging from 1 to 60). 107 cases (75.9%) were femoral neck fractures: this group included a case of neck fracture on amputated limb, a neck fracture following nail removal, 2 inveterate fractures of the neck. 26 cases (18.5%) were osteoarthritis of the hip, 3 cases (2.1%) were failures of osteosynthesis devices, 3 cases (2.1%) were recurrent prosthesis dislocations; 2 cases (1.4%) were avascular necrosis of the femoral head. Dualis cup was combined to a Korus stem in 138 (97.8%) hips. The remaining three hips required the implant of one Arcos Modular Revision Stem (subtrochanteric nonunion); one ADR stem (neck fracture following nail removal); one Polarstem (neck fracture on amputated limb). 121 hips (85.8%) received a 28-mm chrome and cobalt alloy prosthetic head, 20 hips (14.2%) received a Biolox Delta ceramic head. 75 (53.2%) were left hips and 66 (46.8%) were right hips. A postero-lateral approach was used for all cases and full weight-bearing was allowed after surgery. Clinical and X-ray follow-up was at 1, 3, 6, 12 months, and then once a year.

We are aware of the limitations of our study, which include having a retrospective study design, not having any functional score collected and not having any comparative arm.

This study was conducted under the principles of the Declaration of Helsinky. Written informed consent was obtained from each patient at the time of the surgery for any future potential data publication.

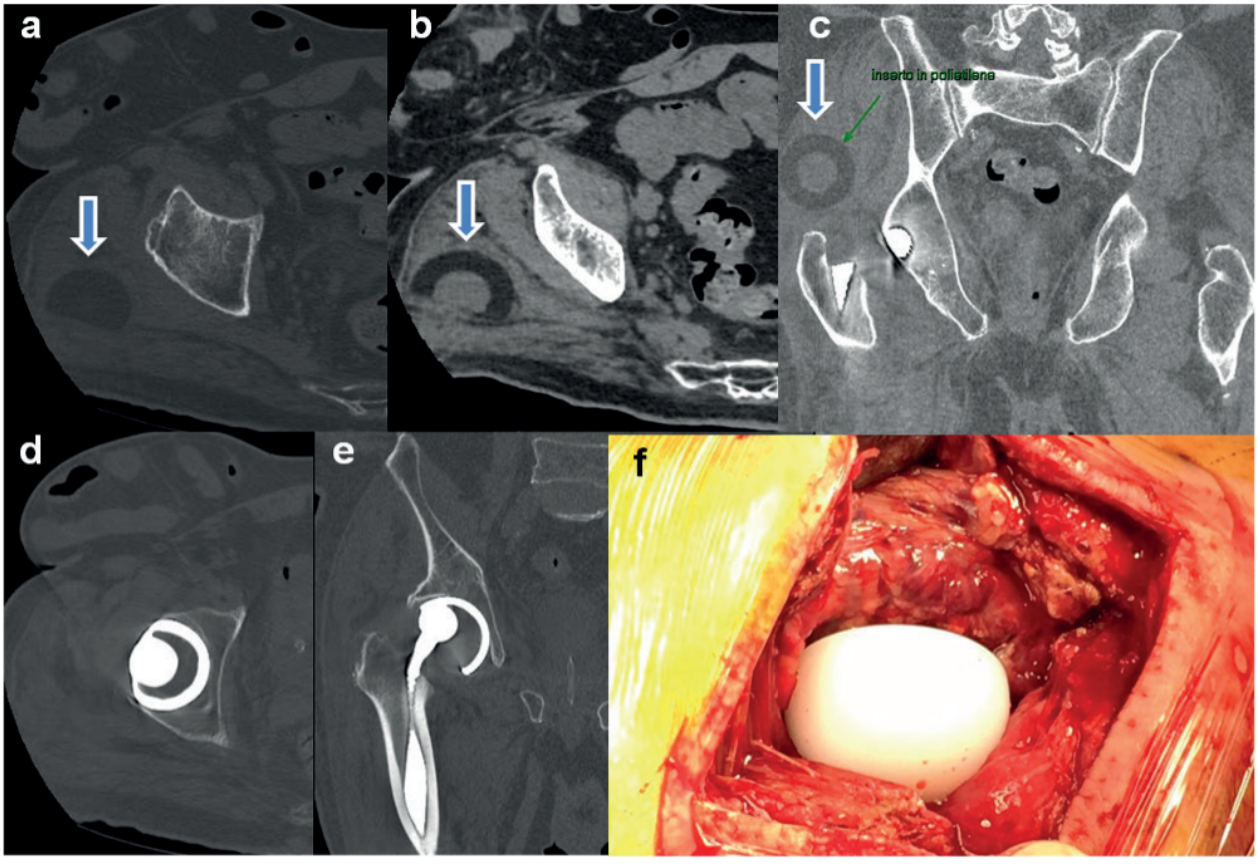


Figure 5: a-b-c) Metal head – PE liner dissociation with liner dislocation into the periarticular soft tissues; d-e) Femoral head/Cup relationship after reduction; f) Intraoperative image of the disassembled liner dislocation

Results

All cases were retrospectively reviewed to assess complications. Eight patients were lost due to death. Nine patients had less than six-month follow-up, so they were excluded from the mid-term evaluation of cup survival, which was carried out on the remaining 124 hips. Seven patients (4.9%) had complications which required a second surgery, but only one (0.7%) was directly ascribable to the DM cup: a case of intraprosthetic dislocation which required cup revision. This occurred 12 days after the surgery in a 71-year-old patient with a femoral neck fracture (Fig. 3), a functional post-traumatic lower limb weakness, and poor compliance with post-operative recommendations (Fig. 4a). Post-reduction X-ray showed a head residual asymmetry within the cup (Fig. 4b).

CT scan showed a metal head-PE liner dissociation with liner migration into periarticular soft tissues (fig.5). Intraoperatively, a vertical migration of the acetabular cup in the coronal plane was found; therefore, it was decided to replace the cup with a new one, adding screws and a constrained liner.

No other Dualis cup showed x-ray evidence of loosening, obtaining a cup survival rate of 99.2% at 5 years. Other complications found are common to all THA, regardless of the implant used. One patient suffered from a periprosthetic fracture following a new trauma, treated with plate fixation. One patient needed a periprosthetic ossification removal one year after the first surgery. Four patients underwent debridement and liner-head replacement due to early infection.

Discussion

In literature, the dislocation rate in hip surgery is reported to range from 0.2 to 7% after primary hip replacement, and up to 21% in revision surgery (6). The excellent results obtained with the use of DM Cups in terms of limiting dislocations, have progressively enlarged their indications both for elective surgery and for the treatment of femoral neck fractures (6-8).

Authors consider the DM system a suitable option both for cases requiring high functional demand, such as young patients with degenerative or post-traumatic osteoarthritis of the hip or avascular necrosis (9), and for cases with an increased risk of dislocation, such as patients affected by neurological diseases (10), cognitive disorders (8), failure of previous osteosynthesis devices (11), recurrent THA/hemiarthroplasty dislocation, previous lumbar spine fusion (12-14).

A peculiar population is represented from elderly patients affected by femoral neck fractures. Elderly are often affected by several comorbidities or cognitive disorders, which may facilitate new accidental falls and runaway motions with a resulting increased risk of prosthetic dislocation (8). Furthermore, it needs to be considered that elderly patients, who do not suffer from comorbidities or cognitive disorders at the time of the surgery, have a concrete risk to develop them in the near future. For this reason, Authors believe that DM system should be taken into consideration as a valuable alternative to standard THA or hemiarthroplasty for elderly patients with femoral neck fractures. Indeed, with their increased stability, DM cups do not compromise clinical results, implant survival, and costs (6). Dual mobility system combines the Charnley 'low friction' principle, of a small femoral head articulated with a high-density (UHMWPE) PE liner, to the McKee Ferrar theory of a large prosthetic head, similar to the native femoral head in size, which articulates with the cup, increasing stability (15). The combination of two real joints with the third paradoxical functional joint allows to increase the implant stability maintaining a ROM similar to the physiological one. However, having a double sliding surface may slightly increase wear and tear, which might be present both inside and outside the PE liner surface. When deteriorating, PE liner progressively loses its constraining capacity. Consequently, higher risk of dislocation and abnormal wear may occur (16). First assessments on head-liner-cup wear were driven on the cups removed. Loving et al. (17), using a hip simulator, evaluated the wear performance of DM hip bearing under three different conditions: impingement, abrasion and when the mobile liner becomes immobilized at either the inner or outer diameter. In all these tested conditions, DM wear was comparable to those of conventional cups. The same Loving found there were no significant differences in volumetric loss and PE liner wear, positioning DM cups at two different inclination an-

gles (50° and 65°, respectively). This suggest that DM system is less affected by imperfections in acetabular cup positioning than conventional cups. Laende et al. (18) analyzed migration and wear of the cup using the radiostereometric analysis. Movement patterns and micro-displacement of the cup after surgery provide for the risk of future mobilization, especially in a metal component without holes, where the real contact with the acetabular bone is difficult to assess and fixing the cup with screws is not possible. In such event, a sub-optimal fixation between bone and metal cup might be possible. Purpose of their study was also determining migration of the anatomical DM cup (ADM) in the first three years after surgery, assessing PE-liner wear, establishing a relationship between migration and wear, analyzing changes in functionality after surgery. Tantalium landmarks were placed during the surgery in 30 patients. X-ray follow-up at 6 weeks, and at 3, 6, 12, 24, 36 months showed no signs of cup migration and no dislocations. This proved that the anatomical DM cup does not present a greater risk of wear and mobilization. Recently, several studies in the literature have been discussing the problem of the possible release of metal ions in the DM cups (19-23). Koper et al. (19) reported an increase of Co and Cr serum levels in a 75-year-old patient with an interprosthetic dislocation at the two-year follow-up. After cup revision, there was a progressive reduction of Co and Cr serum levels. Therefore, they concluded that the ions release was caused by the direct rubbing of the metal head against the metal wall of the cup. The PE liner molecular weight increase, the liner edge rounding, the introduction of smooth necks (trapezoidal, elliptical or circular in shape) reduced the incidence of IP dislocation and together limited the problem of the metal ion level increase due to friction between the metal head and the bottom of the cup (16). Modular DM cups, in which a cobalt-chrome liner is inserted into a standard titanium cup, have been recently introduced. This makes it possible to simplify the cup positioning and to use screws for implementing cup fixation. However, the potential wear and tear between the cobalt-chromium liner and the titanium cup raised again the problem of metal ions release. This is mostly critical for cobalt ions, which can cause adverse local tissue reactions (ALTR) and the consequent need for revision surgery (20). Regarding the safes serum cobalt ion levels, it was established to refer to a paper by Cooper et al. (21), which reported the need of revision surgery due to ALTR in a patient with a cobalt ions level of 1.6 μg/L; this has been established as threshold value. Matsen Ko et al. (22) completed the first study on serum metal ion levels following THA with modular DM components in 100 patients. At an average follow-up of 27.6 months, serum cobalt levels were 0.7 μg/L (0-7 μg/L), while serum chrome levels were 0.6 μg/L (0.1-2.7 μg/L). Nine patients (9%) showed cobalt ion levels above the the Cooper threshold value (more than 1.6 μg/L), but in 5 of them additional possible sources of metal ions were found. Three patients (3%) showed high chrome ion levels; one patient showed an increase serum level of both ions. Chalmer et al. (23) have recently reviewed 24 patients treated with modular DM cups, but using ceramic heads for both primary and revision THA. At the four-year follow-up no patients with high metal ion levels were found. Authors concluded that the use of ceramic heads avoided the phenomenon of 'trunnionosis' as source of metal ion increase. Equally, Mary-Hardy et al. (24) did not found any serum metal ion levels post-operative increase in their population of 16 patient, who underwent primary THA using ceramic heads. All these studies support the hypothesis that the increase in ion levels occurs with metal-metal surfaces (cup-liner) and not in the other surfaces (23-24). Finally, first Ehlinger et al. (25) and later Sappey-Marinierel et al. (26) reported an increased risk of periprosthetic fractures in patients with DM cups. Both Authors concluded that the increased cup stability leads to a greater load transfer to the femur, increasing the risk of periprosthetic fractures.

Conclusions

The use of DM cups in primary THA is associated with a low rate of prosthetic dislocation, ranging from 0% to 4.6%, both for patients with a higher risk of dislocation and for unselected patients (27). A remarkable decrease in dislocation rate is also reported for revision surgery, ranging from 0% to 1.5% (25). Therefore, the DM represents the most effective system in reducing

the post-operative risk of dislocation and revision surgery, followed by the use of large femoral heads, constrained liners and conventional single mobility prostheses (28). DM cups are a suitable option especially for those patients who have an intrinsic higher risk of dislocation (i.e., patients with neuro-muscular diseases and cognitive disorders, patients needing revisions, osteosynthesis failures, femoral neck fractures). Furthermore, reducing the need of revision surgery, DM cups also allow to reduce costs (6). In our brief experience, Dualis cups have showed results comparable to those reported in the literature for Dual Mobility. If this data is confirmed by long-term studies, the use of DM cups could be extended even to young patients with high functional demands. Moreover, long-term studies would clarify whether dual mobility can influence periprosthetic fractures, and whether the use of dual mobility cups can actually cause an increase in metal ion levels and define the related risks.

Conflict of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, pa-tent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article. Institutional Review Board approval is not applicable for this retrospective study.

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