Is there a real difference between modular stems and monoblock implants in THA? A revision and comparison of tribological, clinical and radiological outcomes

# Francesco Manfreda<sup>1</sup>, Egzon Bufi<sup>2</sup>, Giuseppe Rocco Talesa<sup>3</sup>, Enrico Francesco Florio<sup>4</sup>, Auro Caraffa<sup>1,2</sup>

<sup>1</sup> Service of Orthopedics and Trauma Surgery, "S. Maria della Misericordia" Hospital, Perugia, Italy; <sup>2</sup>Department of Orthopedics and Traumatology, University of Perugia, Perugia, Italy; <sup>3</sup> San Matteo Degli Infermi Hospital, Spoleto, Italy; <sup>4</sup> Orthopaedic and Traumatology department, Infermi Hospital, AUSL Romagna, Rimini, Italy

### **SUMMARY**

Background. Total hip arthroplasty represents one of the most practiced intervention in orthopaedic surgery. In order to increase the durability of implants, several options have been proposed over the years. Probably one of the most important aspects for this purpose is the adequate restoration of the offset, limb length and femoral neck version. The appearance of modularity in implants seems to be the best help for orthopaedists to achieve these goals. However, in view of these advantages, some specific complications of modular prostheses have been reported, including increased release of metal particles from wear, fretting, implant failure and secondary osteolysis.

Aim. The aim of this study was to conduct a systematic review of the studies in the literature in order to compare modular implants with monolithic implants from a tribological, clinical and radiographic point of view and to establish specific indications or contraindications.

Methods. We set specific and clear inclusion criteria and selected 11 studies from a collection of more than 150 studies found in the principle scientific databases. We analysed the studies by dividing them by categories of outcomes and assessing any differences between them.

Findings. No significant differences were found in almost any of the outcomes examined. The only different trend was shown in the blood and urinary concentration of metal ions resulting from corrosion, which was increased in modular prostheses. However, this difference was not reflected in a cross-evaluation with clinical and radiographic outcomes. Conclusions. The literature is poor in valid scientific evidence that compares the two groups of patients. There is no unanimous opinion on any evaluable outcome. Further RCTs and meta-analyses on this much debated topic are needed.

Key words: Total hip arthroplasty, ion metal release, corrosion, neck modularity, monoblock versus modular

# Introduction

Total hip arthroplasty (THA) is one of the most successful and frequently executed orthopaedic procedures <sup>1</sup>. The most common indication for THA includes end-

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#### Correspondence

Francesco Manfreda Orthopedic and Traumatology department, "S. Maria della Misericordia" Hospital, Piazzale G. Menghini, 06129 Perugia, Italy.

E-mail: francesco.manfreda@libero.it

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stage symptomatic hip osteoarthritis (OA), hip osteonecrosis and congenital hip disorders including hip dysplasia. Much research has been carried out with the aim of increasing implant durability, reducing complications and improving the ability of the implant to reproduce native hip anatomy and function.

Analysing the history of hip arthroplasty, the first attempts began to appear at the end of the 19th century, when Themistocles Gluck attempted an ivory femoral head replacement in a human patient, and failed. During the 20th century, much progress has been made in new technologies and materials. We can cite Austin Moore's endoprosthesis, the first attempt of THA in 1937 by Philip Wiles, using stainless steel components which were fitted to the bone with bolts and screws <sup>2</sup> and McKee and Watson-Farrar<sup>3</sup> who adopted a metal-on-metal (MoM) articulation in the 1950s. Next, there is the concept of John Charnley: a "low-friction arthroplasty" <sup>4</sup> through the use of a metallic femoral stem and small femoral head articulating with a cemented polyethylene acetabular component. However, this was unsatisfying because of the friction between the components and the resulting debris caused an unacceptable incidence of mobilisation, pain and adverse reactions <sup>5,6</sup>. Over the years, Charnley's concept of low friction arthroplasty has established itself and the metal-polyethylene joint is now the standard in hip arthroplasty.

In recent years a new design for THA was introduced: the modular neck femoral stem (MNFS). This had the intention of giving the surgeon the possibility to restore the patients' anatomy more accurately in terms of neck anteversion, leg length and femoral offset. Duwelius et al. 7 evaluated two groups of patients undergoing THA: the first (284 patients) with a monoblock prosthesis and the second one (594 patients) with a modular prosthesis. They observed that the use of the modular neck improved the surgeon's ability to restore the femoral offset value on radiographic parameters, although the improvement was small and the clinical significance was questionable. Traina et al.<sup>8</sup> conducted a retrospective study of 61 MNFS prostheses, implanted between 1995 and 2004, in 47 patients with congenital hip dysplasia. With a mean follow-up of 117.2 months (range 52-162), the authors evaluated the ability of this system to restore femoral offset, the lever arm of the abductors and the length of the limbs, through X-ray images post-surgery. The mean survival of the implant was 97.5% at 11 years after surgery. The mean clinical score, estimated with the Harris Hip Score, was 74.7 (range 23-91). Limb length and femoral offset were restored in most cases. The data obtained support the use of MNFS prostheses as an effective alternative in the treatment of congenital hip dysplasia, using the standard surgical technique.

The modularity also makes it possible to replace the femoral neck during revision surgery, so as to recreate the above parameters, leaving the femoral stem in place if it is well fixed and positioned, reducing morbidity at revision and preserving the femoral bone stock.

However, these types of hip implants are associated with high complication rates, including fracture <sup>9</sup> and dissociation <sup>10</sup> of the

modular neck, modular junction corrosion and adverse local tissue reactions to metal, such as pseudotumours (PT)<sup>11,12</sup>. Many reports have indicated the bearing interface as the primary source of concern <sup>6,13</sup>. However, more recent reports have suggested the modular head-neck interface and modular neck-stem interface as significant sources of ion production resulting in adverse tissue reactions <sup>14,15</sup>. This corrosion involves the release of metal particles that induce pseudotumour formation and periprosthetic bone osteolysis <sup>16,17</sup>. Although it does not follow a linear connection, measuring metal ion levels in blood is an indirect way to estimate the ion release from implants. Since corrosion liberates metal ions, its measure may be estimated by quantifying the metal ion concentration in organic liquids <sup>18,19</sup>.

In this manuscript, we performed a systematic review comparing THAs with modular necks and monolithic implants in terms of urinary and serum levels of metal ions, prevalence of adverse reactions to metal debris, such as PTs, and clinical and radiographical features.

## **Methods**

Our purpose was to carry out a systematic review of studies in the literature that correlate, from a clinical, radiographic, or tribological points of view, patients with MNFS and patients with NFS THAs.

#### Search strategy

The research of the studies was carried out through PubMed, Cochrane Library and EuropePMC searching for the following key words: "Total Hip Arthroplasty", "Modular Neck Versus Nonmodular", "Ion Metal Release", "Corrosion", "Neck Modularity", "Monoblock versus Modular". No limit was set for the date of publication.

### **Inclusion criteria**

We choose only those studies that compared from a clinical, radiographic (presence of periprosthetic osteolysis and/or periprosthetic detachment), or tribological (serum and urine Cr-Co levels evaluation) point of view patients who had undergone a total hip replacement. Patients with modular and monoblock prostheses were included in the analysis; studies that analysed the presence of evidence in literature on the greater reliability of modular prostheses compared to non-modular prostheses; studies with a minimum mean follow-up of 9 months, studies with a minimum of 10 patients analysed.

### Data collection and analysis

After independent research, studies were classified by criticising the quality and risk of the presence of BIAS. The data were extracted taking into account all the outcomes present beyond the main one (Fig. 1).



Figure 1. Flow-chart for choice of studies included in the systematic review.

## Results

The search for keywords resulted in 11 studies that met the inclusion criteria (Tab. I).

Table II provides an overview of the main results of the studies for the several outcomes.

Gill et al. in 2012 were the first to compare the release of metal ions (CrCo) by MNFS prostheses and NFS prostheses made entirely of chrome-cobalt with clinical outcomes by means of evaluation forms (HHS)<sup>20</sup>. The results obtained after an mean follow-up of 9 months showed an average HHS in patients with modular prostheses of 80.7 points compared to patients with monolithic prostheses with 70.2 points; cobalt blood levels were on average 50.75 nmol/l in modular prostheses and 10.3 nmol/l in monolithic prostheses<sup>20</sup>.

Mihalko et al. <sup>21</sup> performed a systematic review of the main arthroplasty registers and literature studies to determine if modularity or type of contact material could influence the longevity of the implant and thus the revision rate. The results showed that MNFS prostheses had a significantly lower survival rate at 10 years in both the major international registries and published clinical studies; moreover, MoM bearing couples with large head diameters had a lower survival rate in both the literature and in registries than other bearing couples.

In 2014, Gerhardt et al. <sup>22</sup> performed an X-ray comparison of 95 patients with MNFS hip arthroplasty and 95 patients with

NFS hip arthroplasty. They looked for significant differences between the two patient groups with regards to the following parameters: AMA (Abductor Arm Moment), BMA (Body Arm Moment), limb length and implant dislocation. The result was that there was no statistically significant difference between the two groups in any of the parameters examined. Therefore, the conclusion of the authors was that in patients diagnosed with primary hip OA, without particular hip deformities, modularity does not bring any advantage <sup>22</sup>.

Duwelius et al. <sup>7</sup> analysed 284 patients with NFS prosthesis (Zimmer M\L T aper) and 594 patients with MNFS prosthesis (Zimmer M\L Taper Kinectiv) between August 2005 and December 2009. The outcomes were followed-up for 2.4 years: HHS, SF-12 and radiographic evaluation of limb length and offset. The results were as follows: no difference between the groups regarding clinical evaluations (no significant difference between the 2 groups for HHS and SF-12); patients with modular hip prosthesis had a higher percentage of equal limb length (89%) than monolithic THAs (77%) as well as higher accuracy in offset recovery (47% MNFS versus 38% NFS). The authors concluded that the use of modular necks does not improve the scores evaluated with clinical evaluation scales <sup>7</sup>.

Carothers et al. <sup>23</sup> considered 463 patients with first MNFS THA implant (Zimmer M\ L Taper Kinectiv) from January 2008 to October 2013, determining the position of the centre of rotation of the head and then comparing it with NFS implants (Zimmer M\L T aper). If the centre of rotation did not correspond between the two implants, then the difference in length and offset was measured. The results were as follows: 56% had no difference in the position of the centre of rotation or there was a very small difference; 29% had a different centre of rotation of less than 4 mm in length and 2 mm offset; only 15% had an elongation of more than 4 mm and a difference of 2 mm offset in the case of controls. The authors concluded that in most cases the use of NFS prostheses can give the same results in restoring the centre of rotation of the femoral head as MNFS prostheses <sup>23</sup>.

Laurencon et al. <sup>24</sup> in 2016 analysed from a clinical (Oxford Hip Score) and tribological point of view 40 patients with MNFS prostheses, 10 patients with NFS prostheses and 10 patients with primary hip OA but without surgery. In blood analysis, all the metal ion values investigated (Cr, Co, Ti, Al, Va, Mb) were much higher in MNFS prostheses than in controls. Serum analyses, on the other hand, did not show significant differences between the 3 groups. Patients with blood levels of Cr and Co > 2 mg were subjected to MRI of the hip and only one patient was found to have a pseudotumour. This patient was clinically asymptomatic <sup>24</sup>.

Gofton et al., in 2015<sup>25</sup>, conducted a prospective evaluation of metal ion release in patients undergoing MNFS prostheses and compared them with the values reported in the literature, and in particular with the study by Omron et al. The 47 patients had 2 years of follow-up. The detection of metallosis, for titanium metal ions and chrome and cobalt metal ions, averaged 2.76 for

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## Table I. Schematic review of selected articles.

Authors	Gill et al. <sup>20</sup>	MIhalko et al. <sup>21</sup>	Gerhardt et al. <sup>22</sup>	Duwelius et al. <sup>7</sup>	Carothers et al. <sup>23</sup>	Laurencon et al. <sup>24</sup>
Study	Corrosion at the neck-stem junction as a cause of metal ion release and pseudotumour formation	How have alter- native bearings and modularity affected revision rates in total hip arthroplasty?	Modular necks in primary hip arthroplasty without anatom- ical deformity: no clear benefit on restoration of hip geometry	Modular vs non- modular neck femoral implants in primary total hip arthroplasty: which is better?	Modular vs nonmodular femoral necks for primary total hip arthroplasty	Systemic metal ion levels in pa- tients with mod- ular-neck stems: a prospective cohort study
Year of publication	2012	2014	2014	2014	2015	2016
Level	Level IV	Level I	Level III	Level III	Level IV	Level III
Design	Case control	Systematic review of the Lecterature	Case control	Case control	Case series	Case control
N°Pz	35 modular\7 nonmodular		95 modular\95 nonmodular	197 nonmodu- lar\459 modular	463	40 modular\10 nonmodular
Mean Follow- up	9 months	//	1 years	2,4 Years	//	1 years
Stem/neck	Eska GHE/s ShortStem Mod- ular - Eska	//	Alloclassic Zweymüller (Zimmer) - Profemur Z, Wright Medical	Zimmer M\L Taper - Zim- mer M\L Taper Kinectiv	Zimmer M\L Taper - Zimmer M\L Taper Kinectiv	SPS Stem whith modular neck- SPS Stem
Acetabulus	Spongiosa Metal II	//	Zweymüller CSF	Trilogy	Metal Acetab- ular Component	//
Metalls	Stem\Modular Neck\Neck\ Metal Head: CrCo Acetabu- lar: TiNb	//	//	//	//	Stem: Ti -Modu- larNeck: CrCo
Dimensions of heads	Modular = 32 mm in 33 pt.\28 mm in 2 pt Nonmodula r = 32 mm in 4 pt.\36 mm in 3	//	//	Modular = 32 mm 56 pt.; 36 mm 302 pt.; 40 mm 236 pt. Nonmodular = 32 mm 169 pt. 36 mm 110 pt.; 40 mm	//	//
Outcomes	HHS - Crand Co Blood Levels	Determine if femoral compo- nent modularity (using another implant connec- tion other than the head-neck taper con- nection) have decreased the revision rates after at least 5	BMA(Body Arm Moment) - AMA (Abductor Arm Moment) - Radiologic limb lenght	HHS-SF-12-Ra- diologic limb lenght and offset	Compared the Head Centers ofa modu- lar-neck system with that of its nonmodular counter part	OHS - Crand Co Blood and Serum Levels

## Table I. Schematic review of selected articles.

Authors	Gill et al. <sup>20</sup>	Mlhalko et al. <sup>21</sup>	Ge et	rhardt al. <sup>22</sup>	Duwel et al.	us Carothers <sup>7</sup> et al. <sup>23</sup>			Laurencon et al. <sup>24</sup>	
Result	The mean blood I levels of cobaltin the study group were higher in the control group (nonmod- ular). Dual or Single modular CoCr hip pros- theses should be used with caution due to these concerns	ncreased modu- arity of the fem- oral component appears to have not improved mplant revision rates. Registry data show an increase in revision rate for exchangeable femoral neck modular stems	In con we fee did not a cleat from t modu on re of hip or dis rate ir THA fo with a an of anate	nclusion, el that we t establish ar benefit he use of lar necks storation geometry slocation n primary pr patients rthritis of therwise pomically mal hip	Use of mo neck sten not imp hip score reduce likelihoo complicati reoperat	odular ns did rove s nor the id of ons or ions	Use of a modu stem results in head centr positions also achievable wi a non-modula stem	ilar se ji o u th ar	Corrosion at the neck-stem junction of mod- ular-neck stems is a reported phenomenon, which is in part reflected by el- evated systemic ion levels. The use of such im- plants should be restricted to a minimum, and screening algorithms of patients with	
Authors	Gofton et al. 25	Nam et al. <sup>2</sup>	6	Chi et	llemi al. <sup>27</sup>	Mikkelsen et al. <sup>28</sup>			Barry et al. <sup>29</sup>	
Study	Serum metal ions with a titanium modular neck tota hip replacement system	Metal ion le in young,a patients rece modular, o mobility tot arthropla	evels ctive iving a dual al hip sty	Serologic graphic c total hip a with CoC neck at follo	and radio- outcome of orthroplasty Cr modular mid-term ow-up	Modular neck vs nonmodular femoral stems in total hip arthroplasty clinical outcome, metal ion levels, and radiologic findings		Effect of femoral stem modular neck's material on metal ion release		
Year of publication	2015	2016		20	016	3 2017		2017		
Level	Level III	Level III		Level IV		Level III			Level IV	
Design	Case control	Case con	trol	Case	series	Ca	ase control		Case series	
No. Patients	47 (24 MoM 23 MoP)	26 (+17 cor	ntrol)	2	22	33 modular - 30 non modular			36	
Mean follow-up	2 years	1 year	1 year		1 year		2.3 years - 3.1 years		1 year	
Stem/neck	Profemur TL	ACCOLAE	ACCOLADE II		Stryker ABG II		ABG II		Profemur preserve	
Acetabulus	Lineage <sup>®</sup> (MoP)	Modular Dual Mo- bility (Stryker)		//		Trident		Ma	axera cup (Zim- mer)	
Metals	Stem-neck: titaniun Head: CoCrMo (MoM)Acetabular	Stem: Ti Head: CoCr 22 mm, ceramic 28 mm Acetabular: Ti		Neck: CoCrHead: CoCr		Stem: Ti Neck: CoCr Head: CoCr		Sten Hea	n: Ti Neck: 22Ti, 14CoCr ad: CoC Acetab- ular: Ti	
Dimensions of heads	44-49 MoM 28-32 MoP	22 mm – 28	3 mm	, 	//	30	3 mm LFIT	36	6 mm – 40 mm	
Outcomes	Serum metal ions level with HR-ICP- MS.	Serum meta levels with resolutio sector field ductively co plasma mass trometr	al ion high on d in- upled s spec- y	Serum i levels co clinical, ra a biomeo parar	metal ion rrelated to adiological nd chanical meters	MRI, ion le	Serum metal vels, Harriship score	Ser M high tor- ly- c	rum levels with IAT Element 2 h-resolution, sec- field, inductive- coupled plasma mass ctrophotometer	

Authors	Gofton	Nam	Chillemi	Mikkelsen	Barry
	et al. <sup>25</sup>	et al. <sup>26</sup>	et al. <sup>27</sup>	et al. <sup>28</sup>	et al. <sup>29</sup>
Result	Titanium ion levels in a modular system using a titanium-titanium stem-neck junction were similar to Omlor's study and those of other non- modular total hip arthroplasty systems reported in the literature	Patients in the dual mobility cohort did have a slightly increased 1-year postoperative mean cobalt level versus the conven- tional cohort and an in- crease in the change in cobalt level from preoperatively to 1-year	Absolute variability of ion release and clinical outcomes relating to offset recovery and pro- cedure, instead of implant choice	Serum cobalt and chromium levels higher in the MNFS group. Prevalence of Pseud tumors twice as high in the MNFS group, but difference insignificant	Higher Co concen- trations observed in the CrCo modular neck group, a nd higher Ti concen- trations observed in the Ti modular neck group

#### Table I. Schematic review of selected articles.

Ti, 2.07 for Cr and 2.52 for Co, which was not higher than the NFS prostheses described in the literature <sup>25</sup>.

Nam et al. <sup>26</sup> conducted a study with 43 patients at a one-year follow-up. They showed that modularity greatly increased metal ion release. In particular, the study showed an increase of metal-release corresponding to the increase in joint interfaces. In fact, the double modularity at the acetabular level showed a further increase in ion release. However, this difference had no correspondence with clinical evaluations, which were absolutely indifferent for the different implant types <sup>26</sup>.

Chillemi et al. <sup>27</sup> conducted a laboratory evaluation of metal ion release in both blood and urine at a minimum follow-up of one year. Cross-assessments between ion concentrations and recovery of offset and limb length led the authors to conclude that any difference between patients in ion concentrations was more related to the biomechanical variability between offset and limb-length than to the choice of implant. In addition, since there are no cut-off parameters for the elevation of metal debris, even if some cases presented very high blood and urinary values, no prosthetic revision was carried out <sup>27</sup>.

The case-control study by Mikkelsen et al. <sup>28</sup>, included in our systematic review, had the longest follow-up. More than 60 patients divided into 2 groups (MNFS vs. NFS) were evaluated according to the release of ions in serum, and clinically with HHS and MRI to assess the presence of pseudotumours. Although there were no significant clinical differences, 2 pseudotumours were detected in patients with modular implants. They also found higher levels of serum metal ions in the same group (66.8 vs 23.2 of Cr; 14.3 vs 6.73 of Co)<sup>28</sup>.

Berry et al. <sup>29</sup> evaluated more than 35 MNFS prostheses comparing the release of Cr, Co and Ti ions with the values reported in the literature for NFS prostheses. In comparisons, no significant differences were found for any of the metals considered. Furthermore, no indications of any kind were given for re-interventions <sup>29</sup>.

## Discussion

The use of THAs with modular necks was introduced in the orthopaedic landscape and the surgeons' instrumentation in order to have an advantage for recovery of offset, limb length and neck version. After all, for recovery of the centre of rotation and consequently of the limb length, the offset and a correct antiversion are considered the most important aspects for the success of a THA <sup>30</sup>. The modular femoral neck can make the recovery of all these parameters by offering more options and greater flexibility in the surgical actions, especially in the case of a future revision of the implant <sup>31</sup>. These probable advantages have been always opposed to a monolithic prosthesis. However, over the years there has been evidence for the disadvantages of this type of implant. These include corrosion, adverse local tissue reactions and increased release of metal ions into blood and urine <sup>32,33</sup>.

Physicians, over the years have often related metallic-ion release to mechanical failure of the implant and possible systemic toxicity. As the technology improved the longevity of implants, problems emerged due to debris from the joint surfaces. The production of wear debris, which is primarily generated by the contact surfaces of the prosthetic components, represents the major causal factor of peri-prosthetic osteolysis, and thus for reduction of implant survival <sup>34</sup>. Accordingly, the use of modularity in hip replacements remains one of the most controversial discussions in orthopaedic surgery <sup>35</sup>.

As already mentioned, in recent years, several studies on prostheses with CoCr modularity have shown that corrosion at the stem-neck junction is a significant cause of production of the metal ions. This leads to high levels of Co (10 times higher than NFS prosthesis) and adverse reactions of soft tissues <sup>27,36</sup>. In our systematic review, however, the hypothesis of higher release of metal particles due to prosthetic modularity was only partially confirmed. Five studies compared to 2, actually showed a tendency for higher blood or urinary metal ion levels. However, the extreme variability in the weight of the studies

Outcomes	References	Main results	
Clinical evaluation at HHS	Gill et al. 20	Positive for difference: bet- ter for Non-modular	
	Duwelius et al. <sup>7</sup> Chillemi et al. <sup>27</sup> MIkkelsen et al. <sup>28</sup>	No differences	
Clinical Evaluation at SF-12	Duwelius et al. <sup>7</sup>	No differences	
Biomechanical Evaluation: BMA(Body Arm Moment) - AMA (Abductor Arm Moment)	Gerhardtet al. 22	No differences	
Radiographic evaluation of offset-recovery	Davey et al. 22	No differences	
and lengths of limbs - recovery	Duweliu et al. 7		
	Carhoters et al. 23		
	Chillemi et al. 27		
Complications (revision rate; dislocations; failures)	Mihalko et al. <sup>21</sup>	No differences.	
	Gerhardt et al. 22		
	Duwelius et al. <sup>7</sup>		
	Chillemi et al. 27		
Metallic Ion release	Gill et al. 20	Higher	
Positive for differences:	Laurencon et al. <sup>24</sup>	concentrations in modular stems	
	Nam et al. <sup>26</sup>		
	Mikkelsen et al. <sup>28</sup>		
	Barry et al. 29		
	Gofton et al. <sup>25</sup>	No differences	
	Chillemi et al. <sup>27</sup>		

Table II. Overview of the main results of the studies for several outcomes.

and the different measurement methodologies make it almost impossible to perfectly weigh the various studies and make a proper statistical evaluation.

In addition, a cross-evaluation with clinical or radiological evaluations highlighted the absolute irrelevance of the same concentrations with respect to complications or clinical aspects. In fact, none of the studies reporting a higher concentration of metal ions reported evidence of a significant increase of the events of osteolysis or pseudotumour. Additionally, it is clear from the various studies reviewed that the increase in modularity, when it fails to restore the required biomechanical requirements such as offset, likely creates the conditions for a deflection of all measurable outcomes, regardless of whether it is a modular implant. Regarding clinical evaluation measured in the various studies in our review with tools such as subjective and objective questionnaires, no significant differences were found between the two types of implants. Only one of the studies (Gill et al. 20) showed an improvement in HHS for the group with MNFS prostheses compared to those with NFS implants.

In this case, there was no specific correlation between these clinical improvements and the restoration of specific parameters such as offset etc. Only one (Chillemi et al. <sup>27</sup>) of the

studies (the other negative results) that showed a lack of significant differences in clinical evaluation conducted a parallel evaluation of the radiographic parameters of offset restoration, showing no substantial differences between MNFS and NFS prostheses.

Only one of the studies conducted clinical evaluation by an additional evaluation scale, SF-12, which did not show any difference <sup>7</sup>. Only one study conducted, in addition to other measurements, functional biomechanical evaluation, measuring BMA (Body Arm Moment) and AMA (Abductor Arm Moment)<sup>22</sup>. No differences were found between the two implants. With regards to radiographic parameters such as offset restoration and limb length, several of the studies included in our review had a follow-up of at least one year, showing no specific differences <sup>7,22,23,27</sup>.

It is precisely this aspect, from the onset of the MNFS implants, that has represented the workhorse of these types of implants. In our opinion, therefore, based on our experience and supported by the available scientific evidence, surgical technique and adequate planning of the intervention should be much more important. The restoration of the offset is therefore not exclusive of MNFS implants. At the same time, it is not certain that a more adequate improvement of these parameters can be achieved as modularity increases. Our review can only disprove the hypothesis of a gain in terms of offset restoration with the use of modular systems, also in their most recent and technological expressions. One of the weaknesses described in the literature relating to modular prostheses has always been the rate of complications. Among the various reasons, as mentioned above, one of the hypothetical causes has been the hypothesis of higher rates of periprosthetic osteolysis due to corrosion phenomena that theoretically should induce a higher rate of disconnection or failure <sup>37</sup>. Another hypothesis belongs to the same modularity; in fact, in the literature there is some doubt about the possibility of increasing the rate of disassembly of the various components <sup>38</sup>. A higher number of interfaces would correspond to a higher risk of the various parts of the modular system becoming detached. In the analysis of the various complications, including that of painful prosthesis re-intervention, no significant difference was demonstrated in our study. The re-intervention rate in the various studies, including Mihalko's revision<sup>21</sup>, does not show any significant differences between the two implant types.

Indeed, the few cases of pseudotumour described in the various studies <sup>23,28</sup> were found only in modular implants, but almost all patients were asymptomatic. Moreover, because of whether the weight of the studies or the very low frequency of this complication, no significant differences were found for the two types of implants. Our systematic review has underlined that in reality, despite differences in the specific purpose, there is no univocal dissimilarity between the two types of prosthesis in any outcome. Even with an apparent trend towards lower metal ion release in NFS prostheses, there are no correlated differences in hypothetical adverse reactions or complications. At the same time, the hypothetical clinical and biomechanical advantage of MNFS THAs is not really reflected in the systematic review.

Our study has some limitations. The first of these regards the sampling of patients, which was not perfectly uniform in the studies examined. It is impossible to conduct an analysis on the same brand or type of prosthesis. There is no doubt that each type of prosthesis has different characteristics, at least minimal, compared to others, ranging from assembly techniques, stem measurements, implant methodology, etc. The various studies were analysed for different categories of outcomes, but not all of which can be included in all categories. Finally, none of the revised studies reported long-term follow-up, with all reporting short- or medium-term results.

## Conclusions

It is evident that in the literature there is a serious lack of studies that compare from a clinical, radiographic, or tribological point of view modular prostheses with monolithic implants, regardless of the coupling of metals and non-metallic material (ceramic; polyethylene) used in their modularity. The few studies in the literature do not allow for statistical comparison. In fact, in the literature, there are no studies that take into account radiographic, clinical and tribological parameters in the same group of patients. Thus, it is clear that other prospective, randomised, comparative studies are needed to assess the actual incidence of modularity in the survival of the prosthetic implant, as well as the choice of materials for all components of the hip prosthesis.

### Ethical consideration

No experimental procedures have been conducted. All procedures performed in the study 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.

### Authors' contributions

All the Authors contributed equally to this work; MF and FEF designed the research and collected the data; TGR analysed the data; MF and BE wrote the paper; CA contributed to manuscript revision; all Authors approved the final version of the manuscript.

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### Conflict of interest

The Authors declare no conflict of interest.

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