WORKSHOPS OF THE SOO (2010, LA ROCHELLE). SYMPOSIUM: THA ''BIG-HEAD''

Update - ''Big-head'': The solution to the problem of hip implant dislocation?

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Summary   New friction couples, initially intended to limit osteolysis risk due to debris, have enabled larger implant head diameters to be developed to resolve the problem of hip implant dislocation. The Symposium demonstrated that, whatever the configuration, increased head diameter significantly reduced the incidence of dislocation, but that none of the friction couples fulfilled the mechanical and/or biomechanical charge-book for consistently reliable use of large diameter heads. The greatest caution is therefore recommended in their implementation.
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Introduction

Total hip arthroplasty (THA) has been practiced for 50 years now. It is characterized by two complications — dislocation and sepsis — and by natural evolution toward loosening [1]. Larger implant head diameters have been developed to limit the risk of dislocation. The multifactorial nature of dislocation is well understood, but it is also clear that the ''bigger'' the diameter of the implant head, the greater the ''tolerance'' with respect to other dislocation factors, due to the increased dislocation distance and reduced risk of cam effect.

The problem of dislocation certainly deserves our fullest attention. Although lower for experienced operators working with implants with which they are perfectly familiar, THA dislocation rates in the literature consistently range between 1% and 10%, for a mean 4%; moreover, 50% of patients with postoperative dislocation will experience iterative recurrence, leading to revision surgery [2]. If these data are confirmed by the studies ongoing under the auspices of the French Hip and Knee Society (SFHG), then nearly 2% of first-intention THAs undergo revision for dislocation!

A diameter of 28 mm has become established as a compromise between 22 mm and 32 mm models. ''History'' relates that J. Charnley selected a 22 mm diameter to optimize low friction; the ''story'' has it that he made this choice before opting for cement as a means of fixing the cup in place: the small head reduced bone/cup-interface stress. According to the same ''story'', trochanterotomy, to restore gluteal hood tension, served to stabilize the hip with such a small head, whereas the ''official'' history is that trochanterotomy was performed to improve exposure. M. Muller, to avoid trochanterotomy, introduced the 32 mm head; but it rapidly became clear that this increased wear — and thus 28 mm came to be the diameter of choice.

Studies following the identification of ''polyethylene disease'' led to the development of new friction cou-

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ples. Hard/hard couples were quickly found to reduce alumina and metal insert thickness, and the principle was soon extended to highly cross-linked polyethylene. At the same time, the apparent reliability of dual-mobility cups extended indications, and dual-mobility alumina/alumina models emerged. Thus the large head diameters available to surgeons became *de rigueur,* and this ''round-table'' update seeks to answer the following questions:

- Are big-heads the solution to the problem of dislocation?
- How far does the specific tribology of each new-generation friction couple allow the use of a large head?

Are big-heads the solution to the problem of dislocation?

Increasing head diameter increases the head/neck ratio, delaying neck/cup contact and thus extending implant range of motion. Moreover, the jumping distance is increased, allowing greater range of motion in ''subluxation'' before true dislocation occurs [3]. In an experimental study, Burroughs [4] showed that diameters greater than 32 mm increased range of motion and reduced dislocation risk. Beaulé et al. [5] reported less than 10% recurrence after treatment of iterative dislocation using heads of 36 mm diameter or more. Mertl [6] reported a 1.8% rate of dislocation with wide-diameter metal-metal couples on a posterolateral approach.

These encouraging results, however, need to be taken with caution. Skeels [7] reported 17% dislocation recurrence in patients who had undergone THA revision using a 36 mm head. Clinical results for 36 mm and 40 mm head implants (polyethylene cup) in 61 patients at risk of dislocation showed no significant reduction in risk (4.6%) compared to previous series [8]. Finally, the stability benefit provided by increased head size is dependent on cup orientation and is lost in case of malpositioning in abduction [9]. In all cases, large heads increase jumping distance and certainly delay dislocation, but may mask hip dysfunction under hostile mechanical conditions: edge loading and cam effects aggravated by cup malpositioning. The harmful consequences are variable, depending on the interface of the friction-couple used.

How far does the specific tribology of each new-generation friction couple allow the use of a large head?

Friction couples using polyethylene

In 2009, 63% of THAs in France used friction couples involving polyethylene (12% of cemented cups, 35% of fixed inserts in metal-back cups, and 16% of mobile inserts in metal-back cups). Polyethylene is the main cause of THA evolving toward loosening. The macrophage-dependent biological process implicated is well known, from debris production to osteolysis; but it must never be forgotten that the process is also ''patient-dependent'' [10]. The aggravating factors are perfectly clear. Certain, such as activity and offset, are not relevant to the issue of large-diameter heads; polyethylene

thickness, on the other hand, and thus head size and possible fixation in a metal-back cup, have a direct effect [11,12]. If one wished to be slightly provocative, one could say that the three key words in the domain of polyethylene are: thickness, thickness and thickness.

In the wear/solidity trade-off, the common denominator is polyethylene thickness.

Polyethylene wear is directly related to head radius: in polyethylene/metal couples, the optimal compromise between the stress exerted by the head on the cup and the area over which the stress is exerted (the ''low-friction'' principle) entails low wear volume with small-diameter heads [13,14]. Similar findings were reported with ceramic heads and polyethylene in vivo [15]. Wear is also related to the type of head and thus to interface tribology: a 22.2 mm cobalt—chromium head seems to produce less wear than a steel head, but as much as a 32 mm alumina head; beyond the immediate wear, alumina heads lead to 50% less wear than metal/polyethylene couples [16].

The causes of increased wear volume with increasing head diameter are related to increased contact distance and speed during movement and to reduced polyethylene thickness. This increases not only wear but also stress within the material, leading to mechanical degradation of the polyethylene (fracture, fatigue, delamination). A thickness of 8 mm is recommended, to limit these effects.

Thus, in the case of a classic cemented cup, to respect this thickness criterion of 8 mm, and in the hope of 20 years' survivorship, it would not be reasonable to use a head wider than 28 mm for a 48 mm cup or than 32 mm for a 50 mm cup.

Cementless fixation requires smaller polyethylene thickness for a given acetabular diameter; it has a negative impact on wear and thus on osteolysis, but protects the cup against the risk of loosening associated with cemented fixation [17], which in turn allows insert replacement with graft, which is impossible with cemented cups [18].

The cemented versus cementless polyethylene issue has not been solved, and the debate goes on between those who argue that ''you get more wear'' and those who reply that ''you get less loosening''.

For a metal-back insert, however, where the mean thickness is 3 mm, the 8 mm criterion implies using a 28 mm head with 50 to 52 mm cups or a 32 mm head with 54 to 56 mm cups.

Thus, although some teams remain faithful to a 22.2 mm diameter, 28 mm cobalt-chromium or ceramic heads are generally preferred for use with polyethylene cups. Any discussion should be between 22.2 mm metal and 28 mm alumina heads, as both are known to be strictly equivalent with respect to any given polyethylene cup, the 32 mm diameter being suitable only for large instrumented and cemented acetabular components.

If polyethylene thickness is the determining factor in THA longevity, it follows that increasing head diameter to improve stability will be at the expense of survivorship.

Highly cross-linked polyethylene is intended to counter the limitations of conventional polyethylene, allowing increased head size; clinical studies have shown increased head diameter to be preventive with respect to dislocation [19]. In-vitro [20,21] and in vivo studies [22—24] seem to confirm that wear volume and periprosthetic osteolysis are significantly reduced, although clinical follow-up remains

less than 10 years. Uncertainty persists concerning, on the one hand, the mechanical risks associated with less thick implants undergoing physical treatment (radiation and heat treatment), particularly when the cup is positioned vertically, and, on the other, tolerance for highly cross-linked polyethylene wear-particles, which are smaller than those of conventional polyethylene and hence have greater osteolytic potential.

Other approaches are being studied, such as ''vitamin-doped'' polyethylene.

In the present state of knowledge regarding polyethylene, any increase in head diameter is to be viewed with caution or indeed great reserve.

It is no doubt due to this impasse that, to keep polyethylene as part of the friction couple, dual-mobility cups are being deployed, in a true ''big-head'' strategy.

The interest of dual-mobility in terms of stability is incontrovertible [25]. Indications, long reserved for revision for dislocation, were then extended to revision for whatever cause [26], given the increased dislocation risk in revision. The most recent studies seem to find it also a reliable solution for implant longevity in primary THA in patients over the age of 70 years.

J. Bonnan's regionally-based series comprised 1038 implantations, with only three dislocations, confirming the reliability of the ''big-head'' attitude in terms of dislocation risk; in the light of these satisfactory results, the author recommends this configuration for ''out-of-the-ordinary'' cases (elderly female, neurologic background, etc.) at risk of dislocation in leisure or occupational activity (fishermen, athletes, etc.). Are such indications to be adopted?

Cup design and acetabular fixation are nowadays certainly reliable; if ''big-head'' indications are to be extended, it is the polyethylene that needs working on.

There have been few studies quantifying polyethylene wear volume in the dual-mobility configuration [27,28]. Distribution analysis in terms of the three origins of wear seems to point to very little convexity wear and lower concavity wear, but with no study of the culprit cam effect (other than serious cup malpositioning) in intra-implant dislocation. Bonnan's regionally-based series included 16 cases of revision for intra-implant dislocation at 7 to 22 years' follow-up, none of which concerned THAs performed during the last 10 years. The solution lies partly in association to a ''friendly'' neck and partly in the choice of polyethylene. No studies, however, demonstrate the interest of highly cross-linked polyethylene in this kind of implant.

Before extending indications for true ''big-head'' implants, this issue of the choice of polyethylene surely needs addressing.

Ceramic-ceramic friction couples

Conventional 28 to 32 mm diameter alumina/alumina couples long carried two stigmas: alumina acetabular fixation failure and head or insert fracture risk. Both problems now seem solved: fixation of a titanium cup able to receive an alumina insert has been made reliable by developments in coatings: pure alumina has improved, with 3rd-generation ceramic fine-grain sizes and density, bringing the rupture rate down from 1/2000 to 1/10,000 [29]. Results [30] confirm the remarkable performance of this friction couple in terms of wear and debris biocompatibility [31]. This makes the 28 to 32 mm configuration a proven solution in terms of wear in young and/or active patients in whom a hard/hard couple is indicated [32]. Studies show that, to improve stability significantly by increasing head size, a diameter greater than 36 mm is needed [33], so that insert thickness needs to be very significantly reduced. It can be seen that these conventional diameters need to be respected if such patients are not to be put at risk. Implant revision for head or ceramic insert fracture is known to be associated with non-negligible failure rates [34].

Apart from the instability risk inherent to 28 to 32 mm diameters, limitations are related to the risks, inherent to hard/hard configurations, of cam effect (70 out of 176 explants reported by Shon [35]) and poor decoaptation or dislocation tolerance leading to edge loading and resultant wear and fracture risk. In alumina/alumina couples, the cam effect releases metallic particles liable to induce squeaking [36].

It therefore seems interesting — especially as theory (Achard's equation) points this way — to develop this material, with its low friction coefficient and high degree of hardness, for use in larger diameters.

The development of so-called ''composite matrix'' ceramics, reinforced by zirconium oxide and strontium oxide particles that limit and orient fissuring, will allow greater diameters, as reinforced insert resistance and solidity allow thickness to be reduced [37]. Microseparation and cam effect are known to be associated with smaller diameter heads, and a 36 mm head in composite ceramic induces no more wear than a 28 mm head in pure alumina [38]. A larger head diameter, moreover, increases head offset in the cup, which is zero for a diameter of 36 mm. This reduces the height of the conical fixation area of the insert, which, for a conical fixation angle of 18°, enables a larger insert to be adapted in a cup in which the thickness is resistant to impaction, allowing reliable insert positioning [39].

An increased diameter with correct cup positioning reduces the risks of cam effect [4] and of dislocation (4.5% for 28 mm versus 1.8% for 36 mm [40]). This escalation in diameters, however, is not a panacea, and is subject to certain reserves:

- subluxation, inducing the microseparations and edge loading underlying fracture, persists;
- increased bone/cup-interface stress, correlated to friction moment, may reintroduce the problem of acetabular fixation in cups receiving ceramic inserts;
- insert rupture with reduced thickness [41] is a distinct complication in insert fracture by malpositioning due to cone slope [42], and is sufficiently well known for manufacturers to have developed solutions (pre-assembly, or an intermediate metallic part — which further reduces ceramic thickness), the efficiency of which remains to be shown.

Taken together, these doubts as to the long-term reliability of larger head diameters may cancel out the benefit expected from composite ceramics and oblige us to stay with conventional diameters.

These reservations doubtless underlie the development of ceramic-ceramic dual-mobility cups, a very recent concept intended to solve the various problems raised by increased head size.

The system uses the delta composite ceramic with 32 mm and 36 mm cups and 22 mm and 26 mm heads, with retention assured by a polyethylene ring. Head medialization ensures cup self-centering, improved mobility and reduced dislocation risk [19,43—45]; dual-mobility reduces friction wear and microseparation [46]; the insert design prevents any contact with the implant neck, and dual-mobility reduces bone/cup-interface stress.

Clinical results are as yet few: P. Viale's regionally based series comprised 166 implants in 160 patients, with a mean age of 60 years and a mean 2.3 years' follow-up. Results were identical to those on conventional THA at comparable follow-up: Merle d'Aubigné score, 17.8; Harris score, 98.4; Oxford score, 12.52. Radiology shows very irregularly reconstructed femoral offset, but good cup osseointegration, and no signs of osteolysis and no dislocation. The author believes that the ceramic-ceramic dual-mobility configuration solves the problem of microseparation, and that the availability of a 26/36 mm model, possibly associated to a modular neck, should resolve that of femoral offset reconstruction.

As can be seen, results are too recent for this concept to be considered a reliable ''big-head'' solution to the problem of dislocation.

Metal-metal friction couple

J. Charnley dug the grave of K. McKee's metal-metal fiction couple. Even before the failure of 1st-generation metal-metal designs could be explained by manufacturing defects in sphericity tolerance [47], the metal-polyethylene concept had been enthroned. B. Weber revived a second generation of metal-metal couples, with a high carbon-content alloy and optimized joint freedom [48]. This tribology quickly replaced all of the rival metal-metal configurations, and notably low carbon-content alloys [49]. Cemented metal inserts soon showed their limitations [50] without metal reinforcement [51]; but a cementless polyethylene sandwich configuration demonstrated real mechanical, biological and clinical reliability, on 15 years' follow-up. The clinical results reported for 28 mm and 32 mm diameters were very interesting in young and/or active patients, and imaging follow-up appeared to be very reassuring in terms of osteolysis [52—54]. Certain follow-up images of osteolysis, moreover, did not definitely implicate the metal-metal friction couple, and there were many reasons to attribute them to the polyethylene [55].

Metal-metal friction couples always raised doubts as to the risks entailed by a permanently elevated rate of circulating metallic ions, even when the friction couple was operating correctly. To date, however, no complications have been specifically attributed to this cause, and it seems clear that the doubt applies to any metal implant [56] and not just to metal-metal THA friction couples.

The limitations of small-diameter metal-metal couples are two-fold: biological and mechanical.

Biologically, the problem is a type IV allergy — i.e., late and unpredictable — perfectly described by Willert as aseptic lymphocyte-dominated vasculitis-associated lesion (ALVAL) [57]. Clinical manifestations are very varied, from simple joint discomfort to a pseudo-septic pattern [58]; all include hip effusion (sterile puncture) and a thickened capsule on ultrasound and CT. Only histology provides definitive diagnosis, but radioclinical patterns are now sufficiently suggestive for experienced physicians, enabling early revision. The result in that case is quickly satisfactory, without complications specific to this kind of revision, which, if performed early, involves only the friction couple. The incidence of ALVAL is 0.3%.

Mechanically, the limit is set by the cam effect. The risk is certainly greater with large neck diameters — but also with greater mobility. Cam effects are detectable radiologically as notching on the neck and elevated metal (Cr, Co, Ti) ion levels, and are mainly due to positioning the cup too vertically, often associated with defective positioning in the anteversion sector [59].

The arguments against developing larger head diameters in this friction couple are thus well-founded; however, there are also contrary arguments, in favor of increasing head diameter in order to reduce dislocation risk.

Theoretically, in vitro, ion release after the running-in period is less [60]. It is clear that, given good cup positioning, mobility is better and the risk of cam effect is lower [61].

These arguments led to the development of anatomic heads (large head diameter, LHD).

It should be remembered that these were originally developed to treat neck fracture complicating resurfacing! Not changing the cup is, tribologically, a very debatable attitude.

M. Colmar's two regionally-based series totaling 200 implantations in 162 patients at five years' FU confirmed the interest in terms of stability, with zero incidence of dislocation! These results are very encouraging.

Implantation is indicated only in well-centered osteoarthritis of the hip: Merle d'Aubigné and Harris scores, 16.3 and 85, respectively; UCLA score, 6.5; corrected WOMAC score, 77.2%. Radiology, performed by independent operators (Medical Metrics Inc., Houston, TX, USA), confirmed absence of migration, with 91.5% entirely intra-osseous cups, accounting for their relative verticality (45.4—52.3, depending on the series). Ion levels were well below toxic (Cr, 1.95 μg/L; Co, 2.2 μg/L), but higher than those found with 28 mm heads [62]; this is due to the cross-piece used to adjust neck length, which introduces an extra interface.

Since the first report, follow-up on this series disclosed one case of pseudotumor, initially seen as dislocation by joint distension due to effusion. Pseudotumor was occasionally associated with anatomic heads [63,64]. What Langton categorized as adverse reactions to metal debris (ARMD) [65] does not only concern resurfacing.

Published results for LHD series have not always been so encouraging [66—68]. Before this type of implant can be considered a definitive solution to the problem of dislocation, it will be necessary:

- to optimize the coatings, given the shear stress at the bone/implant-interface, and improve design so as to have a structural and a functional angle providing cover [69];

- to analyze ARMD and understand the cause(s) of pseudo-tumor.

Regarding what may be called intermediate diameters (lying between 28—32 mm in a polyethylene sandwich and anatomic heads of 36 mm or 40 mm as of 50 mm cup-size), it is too early to say whether they induce specific complications. Such configurations are standard for all manufacturers of ''3-in-1'' systems (three friction couples in the same cup), the debatable mechanical interest of which has been overshadowed by the commercial interest. As far as metal-metal couples are concerned, however, they have allowed polyethylene, with its osteolytic potential, to be eliminated and larger head diameters to be introduced since smaller metal thicknesses can be used without risk. It remains to be seen whether these intermediate diameters will achieve the ''small large-diameter head'' that will solve the problem of dislocation.

Conclusion

In THA, large head diameter is an effective and attractive response to one of the two most frequent causes of revision: dislocation. To date, however, the solutions on offer induce new problems or heighten existing but hitherto marginal ones. For example:

Mechanical situations in which large head diameters reduce tolerance:

- increased bone/cup-interface stress, to which dual-mobility implants may provide an answer;
- reduction, but not elimination, of cam effects, for which the tolerance of the new materials required by large diameters represents a limitation;
- subluxation processes or, to a lesser extent, microseparation inducing edge loading at the expense of material longevity;
- early mechanical impact of cup malpositioning.

New technical requirements to reduce insert thickness:

- new polyethylenes and composite ceramics, for which clinical follow-up is as yet short;
- assembly of ceramic inserts in metal cups.

Poorly understood biological reactions to ''new'' types of wear debris from materials specific to large diameter heads (highly cross-linked polyethylene, metallic ions, etc.).

To date, no combination solves all of these problems. Opting for a large head diameter instead of a conventional interface of which the limitations are thoroughly documented is to venture into the unknown on behalf of the patient. One unknown shared by all of the options discussed above is long-term clinical longevity. To limit the impact of these unknowns, we need, individually, to assure prospective follow-up, enter our patients in the implant registry, fill in the materials vigilance documents in case of failure and in all cases facilitate interaction between clinicians, research laboratories, manufacturers and authorities.

Disclosure of interest

Several Symposium participants act as consultants for manufacturers and/or distributors of orthopedic material, but none have received or will receive personal and/or professional benefit from the present study.

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