1 Large-Diameter Total Hip Replacement Bearings

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1.1 Large Heads in Hip Arthroplasty

The head size in total hip arthroplasty (THA) has always been a topic of controversy. Although it is undisputed that Charnley established the replacement of the hip joint as a standard procedure with his philosophy of "low friction arthroplasty" relying on a small head diameter (22.25 mm) [9], the use of larger heads has never lost its attraction for appealing reasons: greater stability and increased range of motion (Fig. 1.1). At the same time, the disadvantages of increasing the head diameter have always been recognized: higher friction moments and greater wear in hard-soft bearing articulations, which can lead to a higher revision rate. A comparison between the Charnley and Mueller prostheses more than 30 years ago reported better results for the Charnley type, "possibly due to the smaller head" [42]. Nevertheless, as long as the National Joint Replacement Registry of the Australian Orthopaedic Association reports "loosening / lysis and dislocation of prosthesis components" as the two most common reasons for revision (29 and 23 %, respectively [4]), the desire for larger heads will continue (Fig. 1.2). This became very clear by the rapid adoption of larger head sizes in England and Wales between 2003 and 2011: the use of the "traditional" head size of 28 mm decreased by nearly 50 % during this period, while the use of larger diameters increased (Fig. 1.3). This increase was driven by two achievements: the improvement of the wear characteristics of polyethylene (PE) by highly cross-linking (HX-PE) and the renewed popularity of hip resurfacing (HR) with large metal-on-metal (MoM) articulations, initiated by Derek McMinn and Harlan Amstutz [3, 32]. The design surgeons and manufactures were convinced that the problems that had led to failure of large MoM

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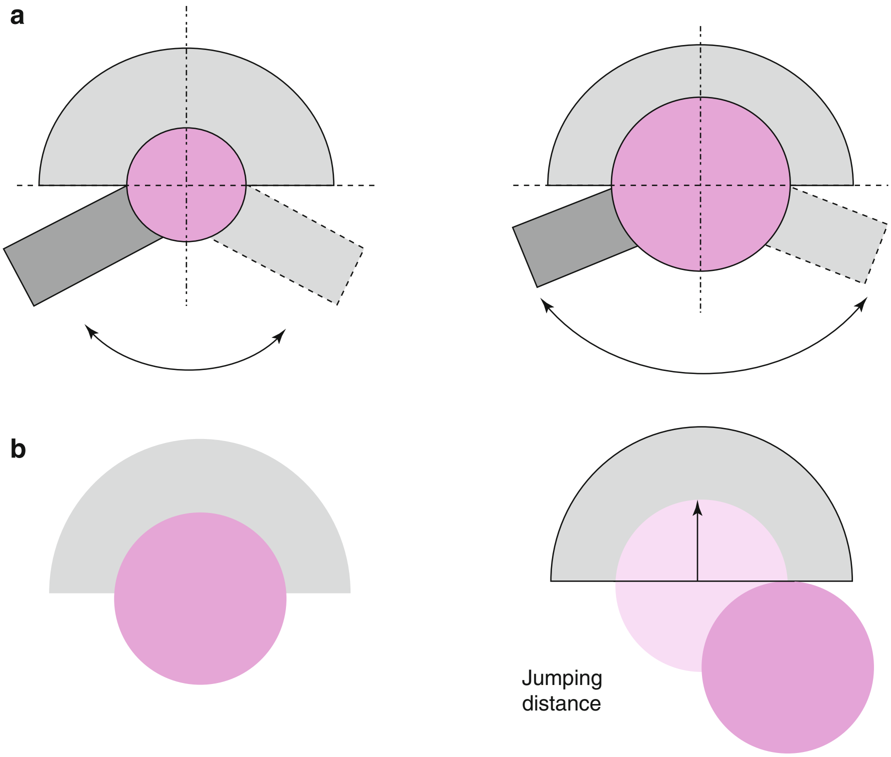

Fig. 1.1 (**a**) Increase in the technical range of motion with larger head sizes. (**b**) Illustration of the "jumping distance," which a ball head has to travel in order to dislocate (half of the diameter)

Fig. 1.2 Head sizes available for metal and ceramic head components. The diameters range from 22 mm to above 50 mm in either material

bearings more than 30 years previously had been recognized and resolved with the new designs. Due to the advantages of large heads early postoperatively, many surgeons followed this rapid development. The consequence of this "hype" is now hitting the orthopedic community hard: MoM articulations and HR have nearly

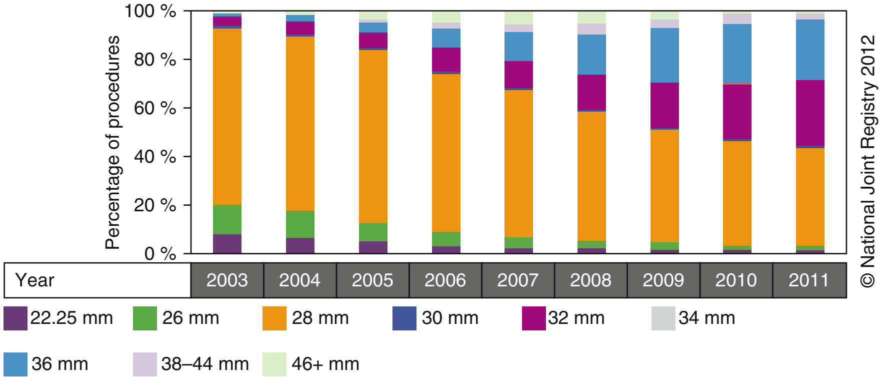

Fig. 1.3 Increase in the use of larger head sizes between 2003 and 2011 as documented in the National Joint Registry Report of England and Wales 2012 [36]

disappeared from the market as a consequence of high revision rates in the registries in comparison with conventional THAs. Adverse responses to metallic debris arising from wear and corrosion, generated either at the bearing articulation and/or the taper interface between head and stem or elevated metal ions in blood or serum, are the dominant reasons for these revisions.

This chapter discusses the potential advantages of large-diameter heads in THA, critically weighing clinical observations with the potential benefits.

1.2 Head Size and Metal-on-Metal Bearing Articulations

Three different prosthesis types can be differentiated for MoM bearings (Fig. 1.4): modular small heads (≤32 mm) THA, modular large heads (≥36 mm), and hip resurfacing arthroplasty. The definition of 36 mm as a cutoff between small and large is somewhat arbitrary and some sources also categorize 36 mm as the largest small head. The three different types show quite different performance in clinical application (Fig. 1.5). The small head modular MoM bearings have been used quite successfully for the last 25 years and show revision rates similar to other conventional bearing articulations. Large head modular MoM bearings demonstrate poor performance, and several authors suggest omitting them completely in the future based on the registry results [44]. A European consensus statement explicitly warns against this type of MoM bearing [18]. Larger modular heads have also been shown to exhibit more fretting and crevice corrosion at the head taper interface [13]. This seems to occur if the head is not sufficiently fixed on the stem taper. This seems to be the origin of the increased serum metal ion concentrations and revision rates observed for large-diameter modular MoM bearings in comparison with large-diameter HR [4, 15]. In the worst case, this can result in fracture of the stem taper, typically close to the open end of the head taper (Fig. 1.6). High friction moments in the joint articulation in adverse lubrication situations may generate micromotions

Fig. 1.4 The three different types of MoM THA: (**a**) Modular small-diameter head (≤32 mm). (**b**) Modular large-diameter head (≥36 mm). (**c**) Hip resurfacing arthroplasty (Note: the definition of 36 mm as large is somewhat arbitrary; some sources categorize it as the largest small head)

at the taper junction between head and stem [7] or cup loosening [30, 33]. This friction increase with head diameter is pronounced for MoM and ceramic-on-ceramic (CoC) articulations and further enhanced by the negative effect of resting periods on start-up friction (Fig. 1.7) [7, 8, 35].

In HR, the tendency is the opposite: smaller-diameter resurfacing components show an increased risk for revision [21] and higher blood Co and Cr ion concentrations [38]. Two primary factors are cited to explain the contrasting behavior between HR and large head modular MoM THA: firstly, a smaller angle of coverage for smaller monoblock acetabular cups resulting in a higher risk of edge loading and increased wear [16] and secondly different failure mechanisms in women, who tend to have smaller femoral head diameters [20].

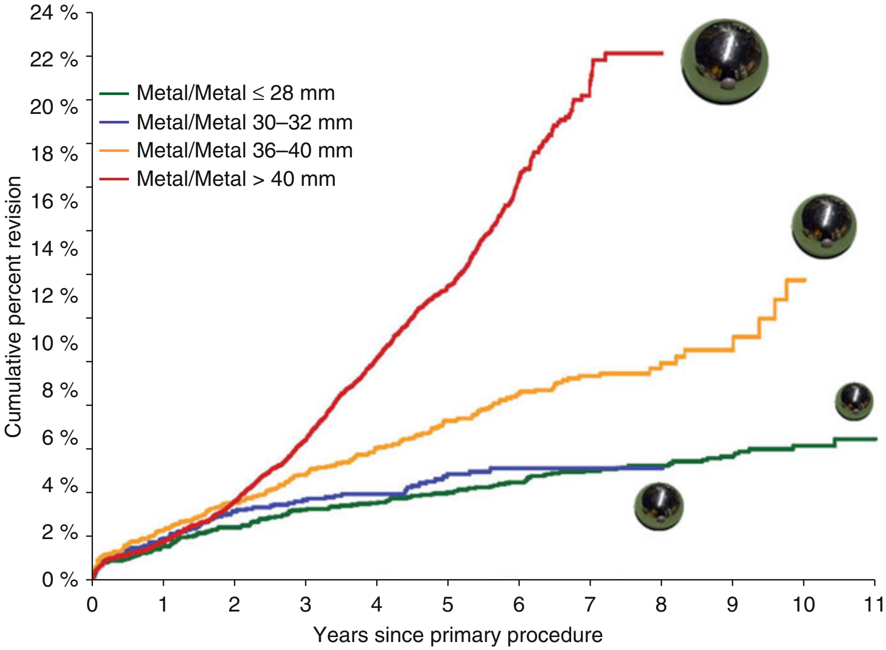

Fig. 1.5 Revision rate for MoM bearings of different head diameters from the Australian Joint Arthroplasty Register [4]

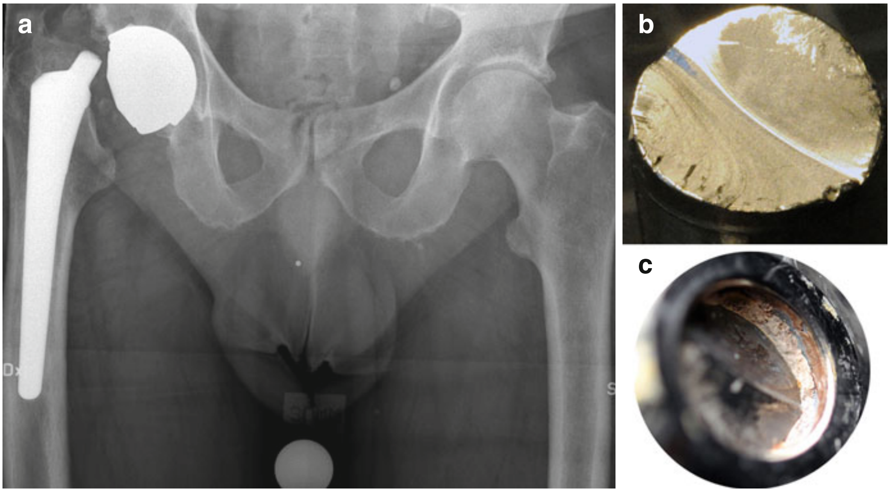

Fig. 1.6 (**a**) Fractured titanium stem taper in a modular large head MoM THA with a titanium adapter sleeve. (**b**) Fracture surface on the stem side. The lines characteristic for fatigue fractures can easily be identified. (**c**) Fracture surface on the broken taper end still sitting inside the female head taper. The white deposits were identified as titanium oxide, characteristic for continuous re-passivation of titanium under fretting or crevice corrosion (Courtesy Ake Hamberg)

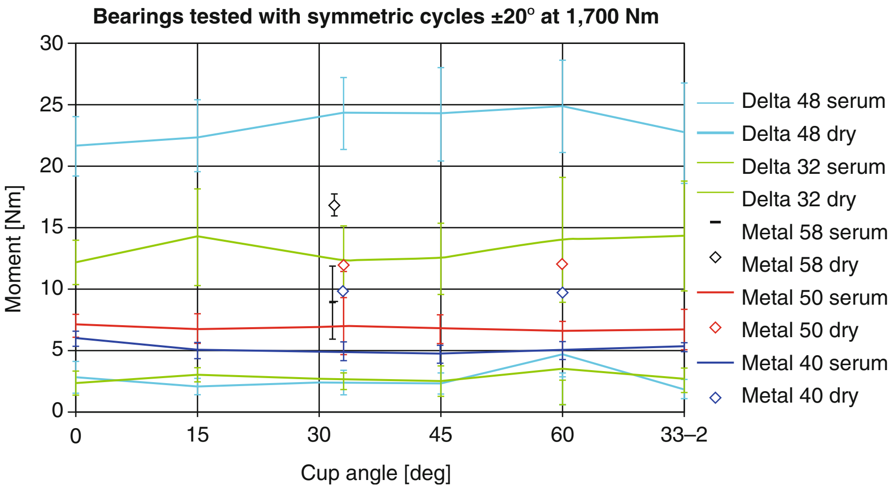

Fig. 1.7 Friction joint moment for different diameters of hard-on-hard articulations in normal (serum) and extremely adverse (dry) conditions (Adopted from Bishop et al. [7]). A cup angle of 33° corresponds to an anatomical cup inclination of 45°

In preclinical testing, larger MoM heads outperformed smaller ones. The resulting design objective was to minimize clearance and increase diameter to optimize wear behavior [12]. The partial success of these HR designs in preclinical testing were misleading, since the overall clinical revision rate for HR is much higher than for small-diameter modular MoM THAs. A recent study voices concerns even for well-functioning HR bearings. Differences in bone and cardiac function between patient groups suggest that chronic exposure to low elevated metal concentrations in patients with well-functioning HR prostheses may have systemic effects [41]. Furthermore, patients with unexplained hip pain leading to revision of a metal-on-metal hip arthroplasty sometimes exhibit satisfactory acetabular cup orientation and low wear rates, which are the factors typically associated with problems [19]. This is the basis for Hart's speculation that patient-specific factors may have been responsible for the failure in a large proportion of these patients. With all these problems, large THA MoM bearings, be they modular or HR, have more or less disappeared from the market.

1.3 Range of Motion

Some of the most commonly claimed reasons for the use of large heads are the improved range of motion (RoM) and function. During normal daily activities, the RoM utilized is quite substantial: flexion/extension can reach up to 124°, abduction/adduction up to 28°, and internal/external rotation up to 33° [23]. During athletic activities such as running, cycling, kick boxing, alpine skiing, wrestling, or free climbing, which are being practiced by some patients with THA (as claimed on the homepages of the respective companies), the RoM is most certainly higher.

The achievable range of motion is limited by impingement between femoral neck and acetabular rim and is determined by prosthesis design as well as component positioning. Head size directly influences this technical RoM. Component positioning determines the "zero" point of the RoM, i.e., how much of the RoM in flexion-extension is actually usable for flexion. Increasing the head size from 28 to 36 mm yields an increase of 13° in the technical RoM (from 123° to 136°). This applies to a hemispherical cup with a modern 12/14 mini taper completely embedded in the head and a slender neck design (proximal neck diameter smaller than the distal diameter of the taper). The technical RoM is not directly related to the active or passive RoM achieved by the patient. The "true" RoM of the patient is heavily influenced by the orientation of the components, the muscular and soft tissue situation. The limit to the RoM is reached, when the neck of the stem impinges on the cup or pelvic bone or when bony impingement occurs somewhere else between femur and pelvis.

Clinically, the theoretical advantage of larger head sizes is not really reflected. Prosthetic design has been shown to be unlikely as a limiting factor to the range of motion, provided that the positioning of the acetabular component is adequate [29]. One year after surgery, increased head size was shown not to improve function [1, 17], and range of motion was not increased at 2 years postoperatively [39]. The benefit of increased RoM of larger heads seems to be limited by the bony anatomy [25]. Extra-large-diameter femoral components may cause iliopsoas impingement, which might be the cause of postoperative pain [10]. These reports demonstrate that the increased technical RoM of larger heads is not directly related to the clinically observed RoM and function and therefore an improved RoM is not a sufficient argument for the use of large heads.

1.4 Dislocation Risk

Nearly all publications document a decrease in the dislocation rate for an increase in head diameter (Fig. 1.8). The absolute numbers, however, are quite different. For heads with a 28 mm diameter (Fig. 1.5), they range over 0.6 % [5], 2.0 % [24], 2.5 % [40], 3.0 % [6], 3.1 % [2], and 3.6 % [37]. For smaller head diameters, the range is even greater: 3.8 % [6] to 18.8 % [37] for a 22 mm head. For larger head diameters, the rates are very low: for heads with 32 mm diameter only 0.5 % [2], and even 0.0 % for 38 mm [40]. This indicates that the head diameter itself is only partly responsible for the dislocation rate. Implant position and soft tissue tension achieved by the surgeon are probably equally, or even more, important: "The theoretical gain in stability obtained by using a large femoral head (above 36 mm) is negligible in cases where there is a high cup abduction angle [43]." Already in 2004, Roy Crowninshield stated that the use of larger femoral heads contributes little to joint stability but elevates the stress within the polyethylene with high abduction acetabular component orientation [11]. The role of combined anteversion [34] and

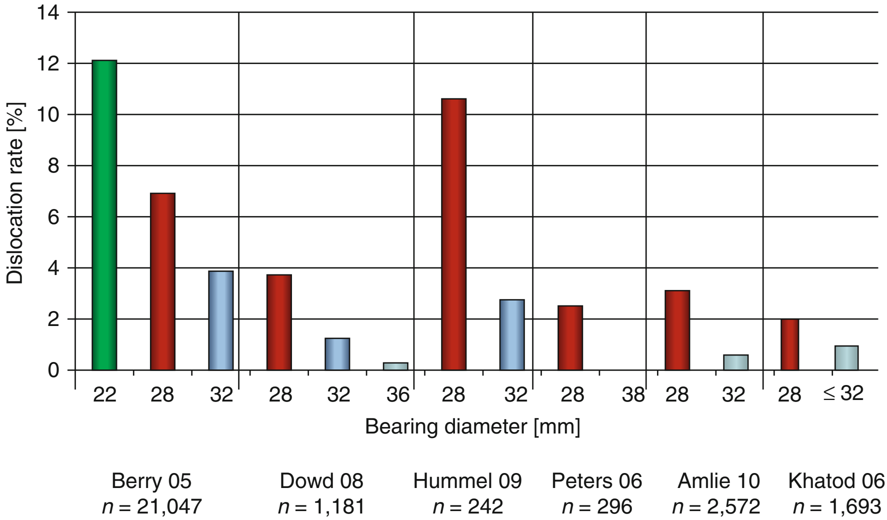

Fig. 1.8 Dislocation ratio vs. head diameter in six different studies [2, 5, 6, 24, 37, 40]

high preoperative range of motion [27] as well as several other factors besides head size was shown to be important for dislocation risk (Paprowsky acetabulum classification, hip abductor deficiency [46]). In excessively obese patients, it was even shown that a reduced cup abduction angle more effectively reduces dislocation risk than head diameter [14].

Considering the advantages and disadvantages of large heads, the important question becomes: How large does it have to be? The 2013 annual joint registry report of the Australian Orthopaedic Association makes a very clear statement in this regard: "Smaller head sizes (less than 32 mm) have the highest rate of revision for dislocation in all age groups. Increasing head size from 32 to 36 mm or larger does not appear to confer any additional protection against revision for dislocation."

1.5 Final Remarks

Considering the pros and cons of large and extra-large heads, it is proposed that the head diameter should be limited to about 36 mm in primary hip arthroplasty – the "36 and under club" founded in 2008 by Carsten Perka from the Charité in Berlin and the first author of this paper is still appropriate; in hard-on-soft bearings utilizing polyethylene, the limit should possibly be 32 mm, since for hard-on-soft bearings wear increases with head diameter. The superior wear characteristics of cross-linked PE reduces but does not remove the increase in wear with increasing head diameter [28]. Larger heads also require thinner inserts, which have shown higher PE wear rates in simulators [22]. In CoC bearings, wear is not influenced by head diameter, but larger heads have been found to generate a greater rate of noises. A recent study of large ceramic-on-ceramic designs reported 21 % squeaking [31].

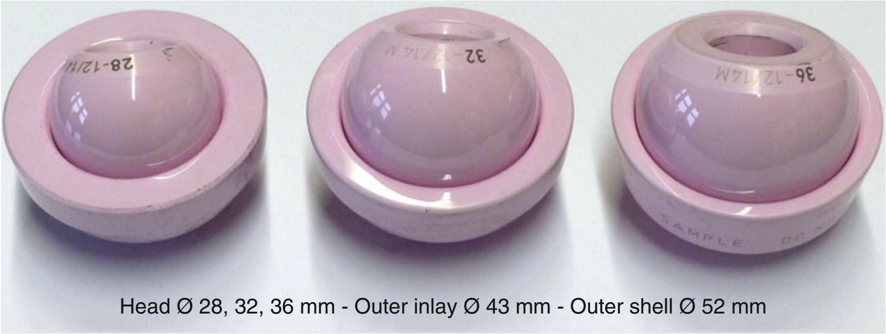

Fig. 1.9 The different head sizes (28, 32, and 36 mm) possible for the same metal back acetabular cup (inner diameter 43 mm, outer diameter 52 mm). The thickness of the inserts (7.5, 5.5, and 3.5 mm) is decreasing with increasing head diameter

Thinner ceramic liners have not been reported to have a higher fracture risk than thicker liners if implanted correctly (Fig. 1.9).

Larger heads reduce the early dislocation rate due to dislocation. However, in the long term, larger heads have been shown to have a greater cumulative revision rate after 9–21 years [45]. An analysis of the Finnish Arthroplasty Register recently showed a reduced risk for dislocation (−90 %) but a higher revision rate (+2 %) after 10 years for head diameters above 36 mm [26].

Total hip arthroplasty is the most successful surgical intervention in the history of orthopedics. The growing number of surgeries performed every year and the success rates in the registries confirm this. From a biomechanical and materials point of view, established prosthesis designs are safe and have the potential to achieve good results in the vast majority of patients over periods in excess of 15 years, as long as patient and surgeon act carefully and responsibly. There is a continuing need to improve implants and utilize newly available materials, but in this process, the risks and side effects of new developments must be carefully considered without focusing purely on the benefits. Continuous surgeon education and training for new implants and procedures is an essential requirement for the introduction of any new development into the clinics. The present problems with large MoM bearings and taper issues have once more demonstrated that successful preclinical testing does not guarantee clinical success but rather comprises a minimal requirement. Novel failure mechanisms, which never appeared in the past, cannot be prevented by preclinical testing, which is based on known problems. The international standards should be extended to include testing of adverse implant conditions rather than considering only the optimal situation. However, even this will not remove the need for a stage-wise clinical introduction of new designs. The challenge in the future will be to differentiate designs that should be categorized as "new."

In summary, there is compelling evidence that larger heads can effectively reduce the early dislocation and revision rates and that smaller heads reduce late revision due to osteolysis and loosening. A sensible choice of the optimum head diameter for the individual patient (as outlined before: not above 32 with X-PE or 36 mm with CoC in primary THA) combined with accurate component positioning will help to further improve the results of total hip arthroplasty.

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