Technology and Handling of Ceramic Implants

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1.1 Ceramic Implants for Joint Arthroplasty: Where Do We Stand?

Ceramic bearing articulations were introduced in the 1970s by Boutin and Mittelmeier with the goal of minimizing wear particles and preventing aseptic osteolysis – to fight “the particle disease” caused by polyethylene (PE) wear (Kobayashi et al. 1997), especially in the younger and more active patient (Mittelmeier 1984). Since their introduction, ceramic materials have been greatly improved by reducing grain size and increasing density and by the successive introduction of composite ceramics (Fig. 1.1). With these improvements, the resistance of the materials to crack growth and uncontrolled phase transition was greatly improved (Stewart et al. 2003; Oberbach et al. 2007; Affatato et al. 2012), which is reflected by the material properties (Table 1.1). Controlled phase transition is now even used to limit crack growth (Fig. 1.2).

Considering these material improvements in conjunction with the undoubtedly superior wear characteristics of ceramics and the good biocompatibility of ceramic wear products, the question why ceramic components are not used all the time arises (Mehmood et al. 2008). This can probably be attributed to three issues: fractures, noises, and revision difficulties.

1.1.1 Fractures

Fracture rates in the literature vary quite substantially around a low value. They range from 0.004 % of revisions (Willmann 2000) to 0.1 % (Santavirta et al. 2003) and up to 1.7 % in an Asian study (Park et al. 2006). The most reliable numbers are

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Fig. 1.1 The three generations of ceramics used in hip arthroplasty as bearing materials: (*top left* to *bottom right*) first-generation BIOLOX® threaded cup Ø 38 mm, second-generation BIOLOX®*forte* Ø 28 mm (*thick* and *thin inlay*), third-generation ceramys® Ø 28 mm (*thick* and *thin inlay*), BIOLOX®*delta* Ø 44, 40, 36, 32, 28 mm

Table 1.1 Properties of different ceramic materials used for bearing components in THA

Name	Manufacturer	Generation	Four-point bending strength [MPa]	Biaxial bending strength [MPa]	Toughness [MPa*m^{½}]
BIOLOX	Ceramtec	First	500		3.0
BIOLOX® forte	Ceramtec	Second	631		3.2
BIOLOX® delta	Ceramtec	Third	1,384		6.5
Bionit	Mathys	Second	–	438	3.4
ceramys	Mathys	Third	–	1,160	7.4
Al_2O_3 Bio-Hip	Metoxit	Second	550		4.0
ATZ Bio-Hip[a]	Metoxit	Third	1,600		8.0

Values are determined according to ISO6474 (where applicable). Values from different manufacturers cannot be compared directly since they were acquired with different tests

[a] Not commercially available

probably those reported in the annual publications of the national joint replacement registries. The Australian registry attributes 0.4 % of all revisions to head fracture and 0.6–0.9 % to insert fractures (Australian Orthopaedic Association 2012). These include all ceramics (old and new materials) as well as PE components. The registry of the UK and Wales reports slightly higher values (respectively <1 % and 1 %;

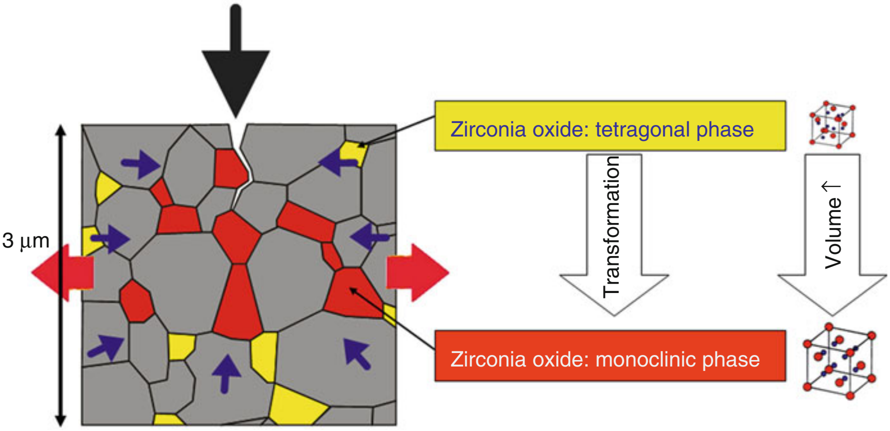

Fig. 1.2 Stress-induced phase transformation of zirconium oxide ceramic grains stopping or slowing down crack growth by volume increase (Adapted from Kuntz et al. 2009). Phase transformation of zirconia from the tetragonal to the monoclinic phase is an undesired event in pure zirconia ceramic components since it is combined with this volume increase and roughening (If it occurs on the surface; Morlock et al. 2001)

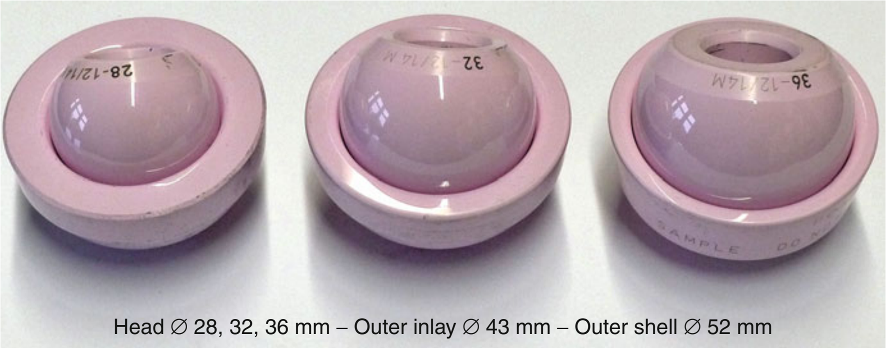

Fig. 1.3 The thickness of the insert depends on the size of the head. For a given outside diameter Ø of the inlay at the entry plane of 43 mm, liner wall thickness varies between 7.5 and 3.5 mm for 28 and 36 mm heads, respectively (*left* to *right*)

(National Joint Registry 2011)). Considering the material improvements over the years, it can be expected that these failure rates will further decline. However, due to the improved material characteristics, inlay components are made increasingly thinner to accommodate larger heads, possibly partly offsetting the improvement (Fig. 1.3).

Reasons for failure are multiple and include impingement, subluxation, rim loading, or loosening of the head on the stem taper (Nassutt et al. 2006; Park et al. 2006; Poggie et al. 2007; Schlegel et al. 2011). Very few problems are reported for ceramic heads against PE cups. Trauma can be associated with ceramic fractures if

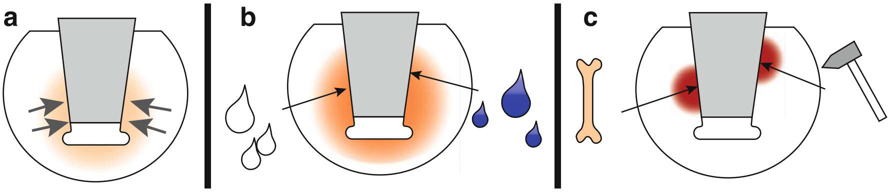

Fig. 1.4 Situation at the taper interface between stem and ball head taper during assembly. (**a**) Clean metal taper: stresses (indicated in *red*) are distributed equally and close to the tip of the stem taper deep within the ball head (area of desired stress transfer indicated by *arrows*); (**b**) wet metal taper (water, blood, fat): stresses in the ball head are higher due to lower friction during assembly resulting in deeper penetration of the stem taper; (**c**) point loads (bone particles)/damaged taper (scratches, wear): stresses in the ceramic ball head are strongly increased locally

the ceramic head becomes subluxated or the cup is rim loaded (Salih et al. 2009; Fard-Aghaie et al. 2012). If the head remains inside the cup, failure is not observed despite high external forces (Salih et al. 2009). Material issues are rarely the reason for fractures with exception of a unique recall by the manufacturer St. Gobain Desmarquest in 1998, when, due to a change in manufacturing procedure, the material properties were altered, which caused a high fracture rate and caused a recall by the company.

The majority of ceramic head or insert failures can be linked to handling (assembly) issues or component positioning.

1.1.1.1 Assembly

The assembly of ceramic heads and inserts onto metal tapers dictates the stress direction and distribution at the interface. Ceramic materials have excellent properties under compression but rather poor properties under tension. A sudden stress increase in tension can lead to critical crack growth, causing the component to fail rapidly (“my hip exploded”). It has to be appreciated that every ceramic has cracks, which do not cause any problems, as long as they are prevented from critical growth (compression is desirable). If due to the assembly a local stress increase occurs, a dramatic decrease in the overall strength of the component (up to 90 % reduction) can result (Weisse et al. 2008). This stress rise can be caused by all situations that prevent a clean circular contact between the ceramic head (or insert) and the taper: contamination (water, blood, fat, bone debris) or taper surface damage (scratches, wear; Fig. 1.4). When the head is removed, the metal transfer from the stem on the female ceramic taper gives an indication of the status of the connection between the ceramic component and the metal taper (Fig. 1.5). It is of crucial importance to clean and dry the metal taper as much as possible before assembling the ceramic components to it.

Following the assembly, the ceramic head (or insert) must be impacted onto (into) the mating metal taper in order to achieve a mechanically stable connection between the two components. Turning the head onto the taper prior to impaction prevents tilting. Inserts should only be assembled using appropriate tools and additional care should be taken to ensure that they are flush with the entrance plane

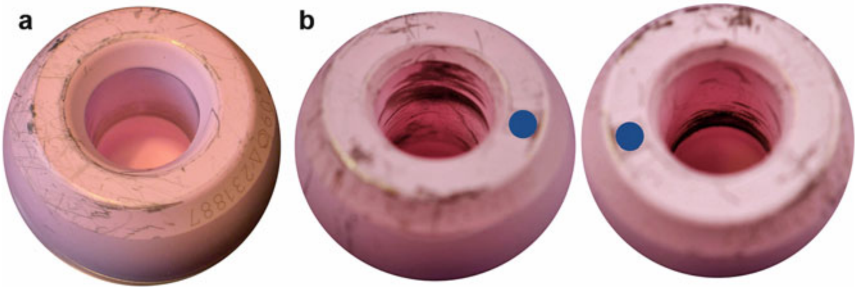

Fig. 1.5 Metal transfer on the female taper of explanted ceramic heads. (**a**) Circular light metal transfer close to the undercut as indication for proper assembly (Fig. 1.4); (**b**) heavy local metal transfer at different depths of the female taper, noncircular but opponent at different levels, indicating a poorly assembled head with toggling during loading and wear of the stem taper (*blue dot* for reference of orientation)

of the metal shell. Once tilting has been ruled out, a firm stroke (~4,000 N peak force) using the appropriate impaction tool should be applied to the ceramic component in order to "lock" it onto (into) the taper (Rehmer et al. 2012).

Assembly of ceramic inserts can be difficult if the metal shell was implanted with a high interference press fit, i.e., excessively underreamed (Langdown et al. 2007). Due to the inhomogeneity of the acetabular stiffness, the metal shell deforms into a noncircular shape (Fig. 1.6a). This makes it difficult to center the insert prior to impaction. If the insert is impacted in a tilted position or not properly impacted (which can lead to tilting of the implant during reduction of the joint; Fig. 1.6b), chipping of the insert rim is to be expected (Fig. 1.6c).

Mismatch between taper and ceramic component must be prevented under all circumstances since this will lead to stress concentrations, which can result in failure of the component (Hohman et al. 2011). The "don't mix and match" precept is crucial. Since the exact taper dimensions cannot be visually identified and labeling can differ between manufacturers, ceramic components should always be obtained from the manufacturer of the metal components. Mismatch between the ceramic components themselves is always an indication for a failed quality assurance during surgery and can have other similarly dramatic consequences (Fig. 1.10). It is hard to believe that as many as 1 % of revision procedures are due to such a size mismatch (National Joint Registry 2011).

1.1.1.2 Positioning/Impingement

Component positioning is a further critical factor for proper operating conditions for ceramic bearings in THA. If the positioning of cup and stem leads to implant-implant impingement or subluxation due to bone-implant impingement, permanent damage can be caused to the ceramic and/or the metal components (Fig. 1.7). Furthermore, if significant forces are exerted on the hip while the head is in rim contact, dramatic stress rises are the consequence, possibly exceeding the fracture strength of ceramic, especially the liner side (Elkins et al. 2012). Fracture risk can

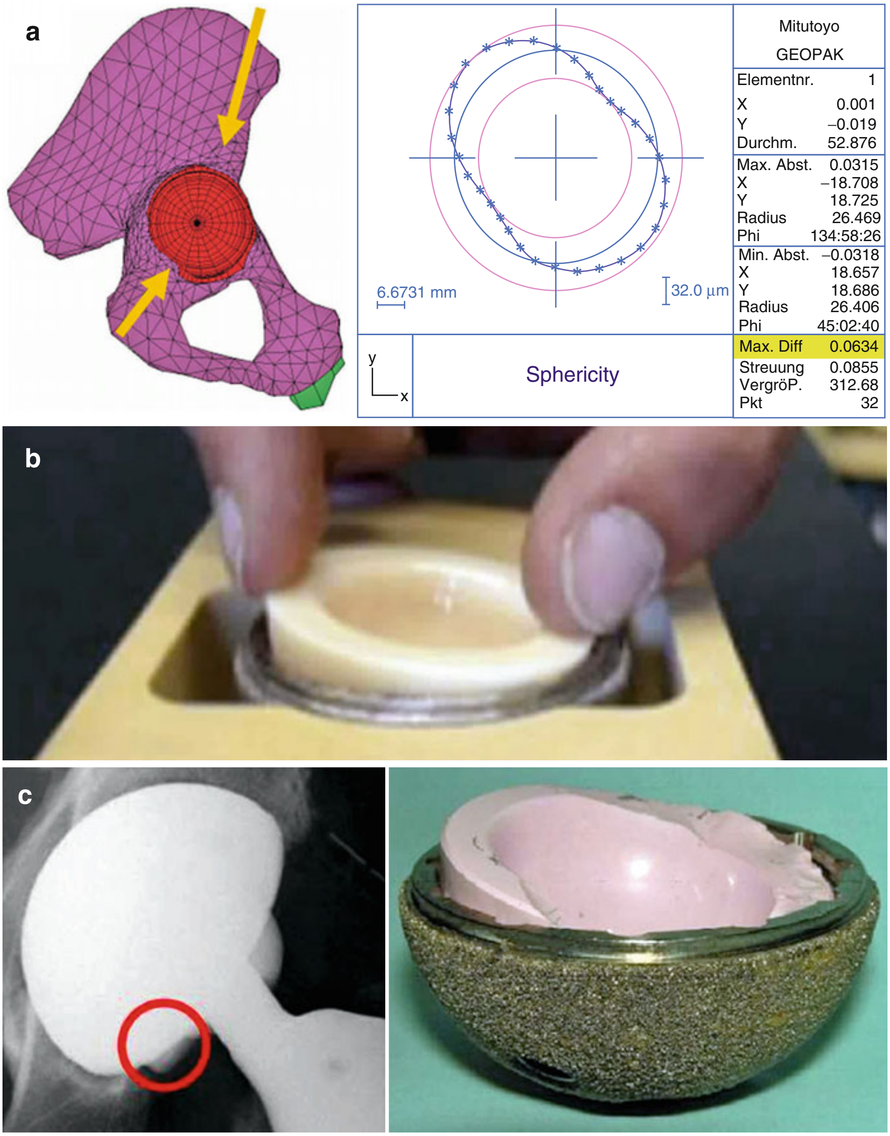

Fig. 1.6 (**a**) Elliptical deformation of metal shells during press-fit implantation due to the inhomogeneous bone stiffness at the acetabulum (Hothan et al. 2011a); (**b**) problem of ceramic liner seating due to excessive underreaming; (**c**) not fully seated insert resulting in chipping of the rim (same implant)

be reduced by surgeons decreasing cup abduction and by patients avoiding specific activities (Elkins et al. 2013).

Another issue related to component positioning is metal transfer from the cup to the ceramic head (Fig. 1.8). Insert designs with an elevated rim, or ceramic insert

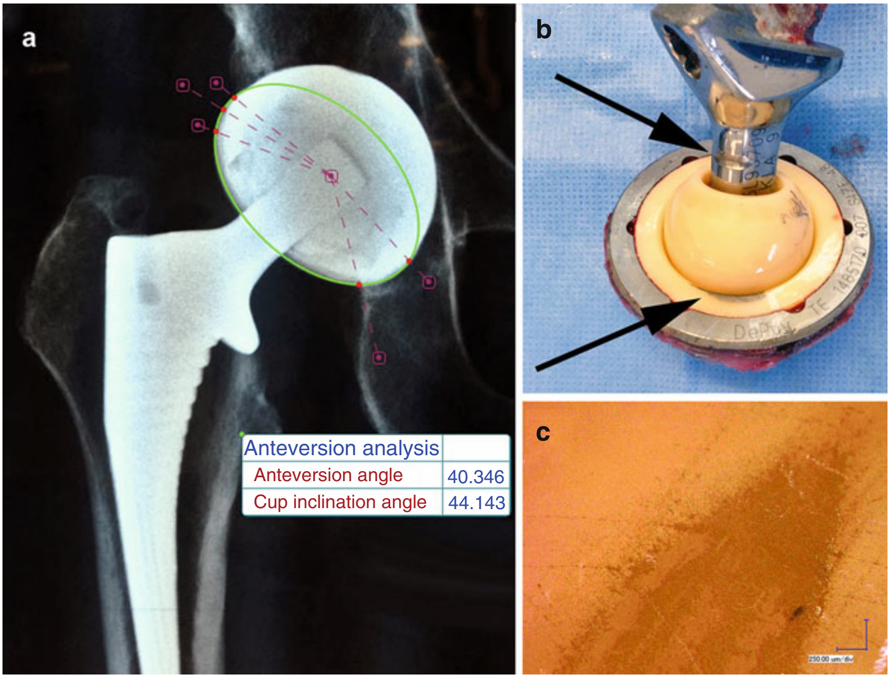

Fig. 1.7 Impingement situation. (**a**) The X-ray shows a large cup anteversion (estimated with the IMATRI.org software). (**b**) Due to the large anteversion of the cup, the neck of the prosthesis stem impinges on the inferior edge of the ceramic inlay during full extension. This causes metal transfer to the insert (*bottom arrow*) and damage to the stem (*top arrow*). (**c**) Stripe wear (grain breakout on the bearing surface) on the top of the ceramic head caused by the subluxation due to the impingement between stem and cup (Courtesy of Tarik Aït Si Selmi)

Fig. 1.8 Examples for metal transfer to ceramic heads (Courtesy of Hartmut Kiefer)

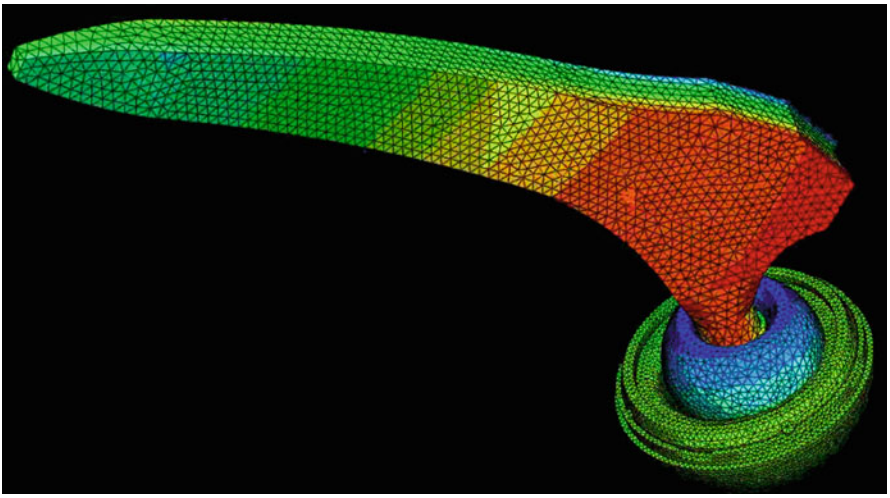

Fig. 1.9 Finite element model of a vibrating THA system. Different colors correspond to different movement magnitudes; warmer colors represent larger movements (Weiss et al. 2010). The frequency of the noise is determined by the natural frequency of the stem (Hothan et al. 2011b)

fracture, or contact of the head and the rim during reduction can partly explain such transfers. The wide variety of patterns observed is not yet fully understood. It is important to note that metal transfer always contaminates the ceramic surface and increases friction (Bal et al. 2007). This is suspected to be the reason for the frequent association of that metal transfer with the occurrence of joint noises in vivo.

1.1.2 Noises

Several different kinds of noises have been reported in the literature since squeaking of artificial hip joints suddenly received intense attention in the USA and Australia. The noises are referred to as popping, snapping, knocking, clunking, clicking, grinding, scraping, crunching, grating, cracking, squeaking, rolling, or even as “the sound of a rusty door hinge” (Glaser et al. 2008). From a technical point of view, two types of noises should be differentiated since they arise from two different mechanisms: squeaking (tonal sounds) and clicking (transient noise). All the different terms used can (and should) be assigned to one of these two types. Squeaking noises are caused by friction-induced vibrations of the whole prosthesis system (Fig. 1.9). A prerequisite for this to occur is high friction in the joint articulation. The frequency of the resulting sound is influenced heavily by the natural frequency of the stem (Hothan et al. 2011b). Clicking noises result from short and “hard” contact events occurring after subluxation when the head locates back into the cup or during impingement.

Theoretically, any bearing couple can be involved, when either the friction in the articulation is high enough or two hard components of the prosthesis system come into “hard” contact. Practically, however, noises are observed nearly exclusively in

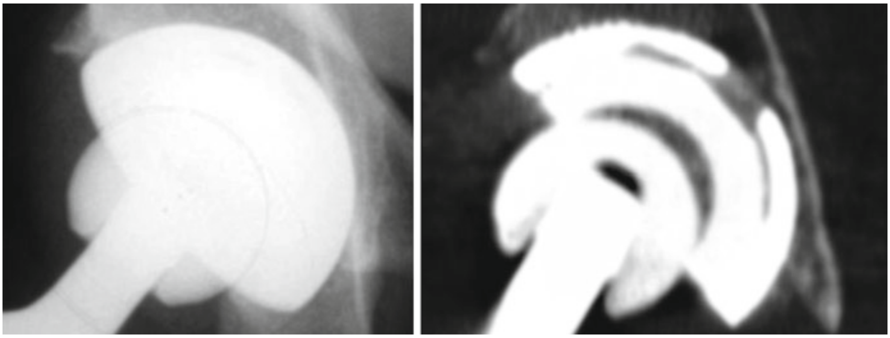

Fig. 1.10 Mismatched ceramic head and ceramic insert. Patient complained about loud squeaking which led to a CT scan (*right*) since mismatch is not easily recognized from the X-ray (Courtesy of Dr. Tarik Aït Si Selmi)

hard-on-hard articulations, namely, metal-on-metal or ceramic-on-ceramic bearings. The superior wear characteristics of these bearing materials are due to their ability to achieve fluid film or mixed lubrication during movement, effectively separating the bearing surfaces and, as such, reducing wear and friction. If the fluid film breaks down, the advantage of hydrodynamic lubrication is completely lost and high friction and wear result. This can be easily imagined by thinking of a car engine without oil. Hard-on-soft bearings with polyethylene always operate in the boundary lubrication mode (the surfaces are in contact) due to the poor wettability of the material. This makes them rather insensitive to the presence or absence of fluid.

The patient himself or herself has nearly no influence on the occurrence of the noise phenomenon. High ranges of joint motion and/or high body weight can be minor factors due to their association with cup edge loading or higher wear (Walter et al. 2007). The major factors, however, are prosthesis design and the surgical procedure, especially those aspects that have the potential to increase friction (Walter et al. 2007; Hothan et al. 2011b; Weiss et al. 2010). Friction is increased mostly due to edge loading, metal transfer (probably caused by impingement or subluxation; Fig. 1.2), mismatched materials (Morlock et al. 2001), the combination of wrong sizes (Fig. 1.10), or by third-body particles. Edge loading and metal transfer can cause a breakdown of the fluid film with the consequences mentioned. Both are related to component positioning, which is probably the most important single factor for the incidence of noises in THA. In some designs the positioning of the components is particularly critical due to certain design features (Chevillotte et al. 2012b). The majority of squeaking events have been reported for one particular THA design using a titanium alloy with a lower stiffness than usual (Stanat and Capozzi 2011). Furthermore, in this system the rim of the ceramic liner is protected by a metal sleeve, facilitating metal transfer to the head, which causes a higher incidence of squeaking occurrence than in other designs.

Interestingly, the rate of noise observations depends on the heritage of the type of bearing materials used. In countries in which ceramic articulations are well established (e.g., France, Germany, Italy), squeaking of THA is rather an anecdotal event, probably since the surgeons are aware of the overwhelming importance of component positioning. In countries, in which ceramics have been introduced more recently, where more forgiving hard-soft bearings were used previously, the squeaking rates reported are higher. This may in part be due to the use of the particular THA system mentioned. Furthermore, the local legal situation might also influence the situation. Realistically, the squeaking frequency of ceramic-on-ceramic articulations in these regions probably lies between 1 and 3 %. Squeaking of metal-on-metal articulations has also been frequently reported. However, this squeaking subsides as the articulation has the ability to wear, such that the increase in contact surface improves lubrication and decrease friction. The substantial metal debris resulting from "bedding in," however, can lead to biological reactions. Since ceramic does not wear easily, the noise phenomenon is usually persistent.

Joint noises should be interpreted as a diagnostic flag since they are an indication of a high-friction situation in the joint, which might otherwise remain unidentified. The surgeon should carefully evaluate the joint functionally and radiologically in order to identify the source of the problem such as extensive cup anteversion, joint laxity, or impingement. In this context it should also be carefully determined how frequently this complication occurs. If the occurrence is rather rare (e.g., "only after 3 h of walking uphill"), the phenomenon might not have a prognostic significance (Chevillotte et al. 2012a). If the phenomenon occurs regularly during daily activities (e.g., stair climbing, lifting objects), the surgeon should use the opportunity to closely examine the mechanical situation in the joint. Repetitive clicking noises are a particular indication for hard contact in small areas resulting in high stresses in the material and potential failure.

1.1.3 Revision

For the revision after failure of a ceramic bearing, it is imperative that certain precautions are observed meticulously (Traina et al. 2011). Three aspects have to be considered: (1) the metal tapers of cup or stem could be damaged due to wear with the ceramic components or fragments; (2) some ceramic particles will always remain in situ after a ceramic fracture; and (3) identify the reason for the failure.

1.1.3.1 Taper Damage

If, prior to fracture, the ceramic head component loosens on the taper (heavy metal transfer can be an indication, Fig. 1.5) or if the patient loads the joint after fracture has occurred, damage to the metal taper interface is to be expected (Affatato et al. 2000). Whether a new ceramic component can be placed onto or into the remaining metal taper depends on the severity of the damage. If the contact area for the new ceramic component is reduced or uneven (Fig. 1.4), stress concentrations might lead to failure once more. In order to prevent the necessity of removing well-ingrown components, titanium adapter sleeves with a 16/18 taper on the outside and a taper matching that of the stem in situ (most of the time also a titanium alloy) were developed (Fig. 1.11). These sleeves are just only in combination with special ceramic

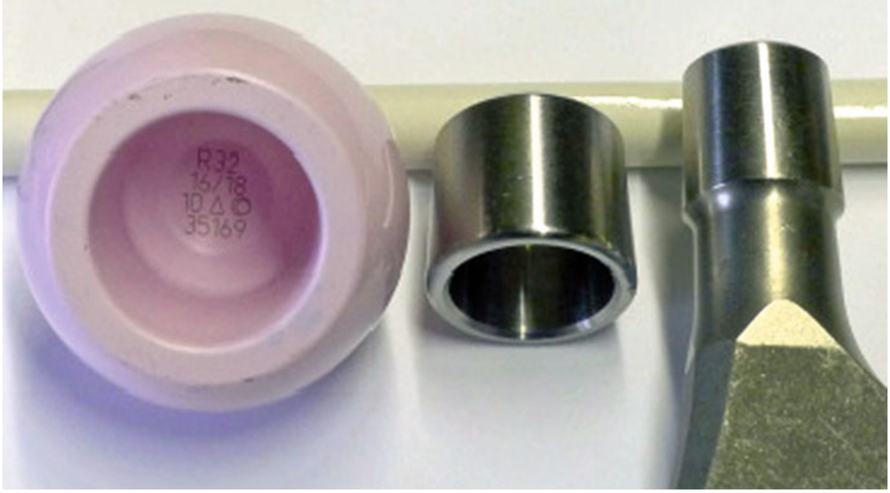

Fig. 1.11 Adapter sleeve for revision of slightly damaged tapers (*middle*). The sleeve has a taper matching the stem taper (e.g., 12/14) on the inside and a 16/18 taper on the outside, which is used in combination with an appropriate ceramic head

heads with a 16/18 taper. This solution creates one more modular junction in the system, which is highly undesirable but cannot be omitted, if the existing stem is to be retained. If damage to the stem taper is too extensive, these adapter sleeves should not be used but the stem revised (Traina et al. 2011).

The question of how to deal with taper damage on the acetabular shell is unanswered. Some designs with ceramic inserts encased into a thin titanium shell are available. These designs allow a new inlay to be inserted into a slightly damaged shell taper. However, these designs are also related to the highest incidence of joint noises (metal transfer) in the patient and the "ease of revision" should not be the dominant factor for the choice of a specific design. The manufacturers do not support replacement of the ceramic insert into a used metal shell, especially after fracture of the insert. If the surgeon is convinced that the shell taper is undamaged, he can keep the shell but under his own responsibility. This is a highly unsatisfactory situation. However, ceramic components do not fail without reason (see 1.3.3).

1.1.3.2 Ceramic Particles

After fracture of a ceramic component, a ceramic-on-ceramic bearing articulation is the bearing of choice from a tribological point of view. The use of a metal-on-PE bearing is contraindicated since any remaining ceramic particles will embed into the PE and rapidly wear the metal head with possibly catastrophic sensorineural consequences including loss of hearing, sight, metallosis, pseudotumors, massive weight loss, and several others (Gallinaro and Piolatto 2009; Pelclova et al. 2012; Kohn and Pape 2007; Hasegawa et al. 2006; Kempf and Semlitsch 1990). In a ceramic-on-ceramic articulation, the remaining particles will be reduced to smaller particles without greatly damaging the bearing surfaces. In a ceramic-on-PE articulation, the ceramic particles will also embed into the PE and increase the wear rate of the ceramic head and the PE cup, but not in a dramatic manner. This option can be used, if other factors do not allow the use of an all ceramic bearing.

1.1.3.3 The Real Problem

Ceramic component fractures are always due to a major stress rise out of whatever reason. Replacing the ceramic component without removing the source of this stress increase (impingement, rim loading, taper contamination or damage, etc.) will most probably result in a very frustrating situation with a renewed fracture event. This applies especially to problems related to component position. Exchange of a ceramic-bearing component alone should, therefore, be the exception, since this will not fully solve the problem.

1.1.4 Final Remarks

Some surgeons call total hip arthroplasty the most successful surgery in the history of orthopedics. This certainly seems justified looking at the growing number of surgeries performed every year and the success rates in the registries. From a biomechanical point of view, the problem of THA is under control, as long as patient and surgeon act carefully and responsibly. Established implants and bearing materials have clinically been shown to be successful in the vast majority of patients over periods in excess of 15 years.

The registries do not show great differences between any bearing materials presently used (Australian Orthopaedic Association 2012). The proven advantage of all ceramic THA bearings with respect to wear does not manifest in a reduced revision rate after 8–10 years. It might be that handling and positioning errors counterbalance the wear and biocompatibility advantages. It might also be that 10 years are insufficient to draw a final conclusion.

The ceramic materials used in joint replacement today are high-performance materials, quite comparable to the materials used in Formula I motor racing. Highest performance comes at the price of reduced tolerance to errors. The engineers will try to develop materials that are more forgiving to suboptimal handling and positioning but probably will only be successful within limits. The general rule “high performance comes with little error tolerance” will remain in the foreseeable future. This association clearly demonstrates how the situation for the patient can be improved: better education for involved parties and centers of excellence for challenging surgeries or designs.

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