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Wear-induced loss of mass in reversed total shoulder arthroplasty with conventional and inverted bearing materials

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ABSTRACT

The notching phenomenon is one of the major concerns with reversed total shoulder arthroplasty. Repetitive contact between the humeral implant and the scapula (mechanical notching) produces progressive abrasion of the implant if the moving part is made of polyethylene. Its debris may then lead to active osteolysis (biological notching). Inversion of bearing materials, i.e. Glenosphere made of polyethylene and humeral Inlay made of metal, aims at the reduction of this phenomenon. However, the question arises if the tribological behavior would then be different.

On an experimental setup, the gravimetric wear of both material configurations was measured after loading and moving over 500,000 cycles. The abrasion of the polyethylene Inlay due to mechanical notching was calculated by means of 3D CAD models with different notching stages.

The loss of mass due to gravimetric wear was compared to the loss of mass caused by mechanical notching.

After 500,000 cycles the measured amount of wear of the polyethylene components was between 8 and 10 mg for both tribological pairings.

The calculated loss of mass of the polyethylene Inlay caused by mechanical notching ranged from 73 to 3881 mg.

The results of this study indicate that the gravimetric polyethylene wear in the estimated life-time is very low and not significantly different between both material configurations. However, the polyethylene abrasion due to mechanical notching in the configuration with polyethylene Inlay is by far more important than any gravimetric wear. These results support the continued use of inverted bearings in reversed total shoulder arthroplasty.

1. Introduction

Reverse total shoulder arthroplasty (RTSA) is a common surgical procedure, mainly for cuff tear arthropathy. If the rotator cuff is torn, the humeral head may progressively migrate cranially, as a result of the cranially directed vector of the deltoid force. Conventional total shoulder arthroplasty in such a condition often yields limited functional results, since the missing rotator cuff is unable to stabilize the prosthetic head for the deltoid muscle to act as an abductor. Therefore, reversed shoulder arthroplasty has been developed in order to overcome this limitation (Grammont and Baulot, 1993; Boileau et al., 2005).

In RTSA the concavity (Inlay) is attached to the proximal part of the humerus and the convexity (Glenosphere) to the glenoid. This configuration stabilizes the humerus and increases the lever arm of the deltoid for initial glenohumeral abduction (Grammont and Baulot, 1993; De Wilde et al., 2004; Boileau et al., 2005; Terrier et al., 2008).

While functional results are promising (Boileau et al., 2006), clinical and radiological experience with RSA reveals several complications, above all the so-called notching phenomenon (Sirveaux et al., 2004; Lévigne et al., 2008; Stechel et al., 2010). In neutral position, the Inlay may come in contact with the long head of the triceps and/or with the scapula (Gutiérrez et al., 2008). Posterior and anterior contact may also occur (Simovitch et al., 2007). Repetitive contact leads to bone loss (*mechanical notching*) and if the humeral part is made of polyethylene (PE) to PE wear (Nyffeler et al., 2004). PE particles may then induce an active process of bone resorption (Goodman, 2007; Goodman and Ma, 2010; Green et al., 2000). On the inferior part of the glenoid, this process has been referred to as *biological notching* (Cazeneuve and Cristofari, 2009), a situation that may ultimately jeopardize

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the fixation strength of the prosthetic glenoid (Wirth et al., 1999, 2009). This type of notching has been reported as an early and very frequent phenomenon (Lévigne et al., 2008).

Mechanical notching may be reduced by improvement of the geometry and positioning of the prosthetic components (Chou et al., 2009).

In order to reduce or even avoid biological notching, an inversion of the mechanical bearings has been designed on some prostheses (Affinis Inverse/Mathys Ltd. Bettlach/Switzerland; SMR/Lima Lto./Italy; Mutars/Implantcast/Germany). The Glenosphere is then made of polyethylene and the Inlay of metal (inverted bearing reverse total shoulder arthroplasty, IB-RTSA). In this situation, there is no PE that can abut to the scapula.

Since metal and polyethylene switched their positions on IB-RTSA, the question raises whether the tribological behavior of the system would then be different. The present report addresses this question.

RTSA is a conforming prosthetic joint. For anatomical total shoulder replacement, conforming implants *in vitro* demonstrate significant greater wear than non-conforming implants (Swieszkowski et al., 2011). Even though it is not known if this would apply to conforming RTSA, the overall amount of PE wear is of concern. The second aim of this study is to compare the magnitude of wear in IB-RTSA and RTSA.

2. Materials and methods

2.1. Wear tests of two different tribological pairing

The experimental setup compares the common material pairing of the first prosthesis generation—UHMWPE Inlay and CoCr Glenosphere—to the reversed pairing—UHMWPE Glenosphere and CoCr Inlay (Fig. 1a and b). The design of the samples was identical for each pairing.

The polyethylene specimens were made from conventional UHMWPE and were not artificially aged.

The wear tests were performed on the basis of standardized gravimetric wear tests for hip prosthesis (ISO 14 242-1, 2002; ISO 14 242-2, 2000) at the test laboratory IMA GmbH Dresden, Germany. Two hip joint simulators type “E-sim” (KUPA Präzisionsmaschinen GmbH, Grambach, Austria) were used. The test parameters are demonstrated in Table 1 and Fig. 2. For each kind of pairing four identical specimens were tested. To minimize the influence of fluid uptake, the polyethylene components were pre-soaked according to ISO 14 242-2.

For the UHMWPE components of each pairing, an identical control specimen was stored in tempered fluid test medium as passive soak controls without axial load, in order to take into account the fluid uptake.

The gravimetric wear of the polyethylene is measured by the loss of mass in each situation with an electronical scale (Sartorius, type RC210P-0D1, Göttingen/Germany) with an accuracy better than 0.1 mg.

Both the tested PE components and the control specimens were checked for surface alterations and weighted before the test, after $N_n=113{,}000$ cycles and after $N_n=500{,}000$ cycles.

Fig. 1. (a) Test samples—pairing 1: PE–Inlay versus CoCr–Glenosphere. (b) Test samples—pairing 2: PE–Glenosphere versus CoCr–Inlay.

Table 1

Test parameter		Maximum	Minimum
Normal force	F_N (N)	−1000	−250
Flexion/extension	$\alpha_{F/E}$ (deg.)	+25	−18
Abduction/adduction	$\alpha_{Ab/Ad}$ (deg.)	+7	−4
Internal/external rotation	$\alpha_{Int/Ext}$ (deg.)	+2	−11
Temperature	T (°C)	37 ± 2	
Frequency	F (Hz)	1	
Test medium		Bovine serum solution	
Content with protein	(g/l)	30[a]	

[a] The protein content was chosen in accordance with other test labs.

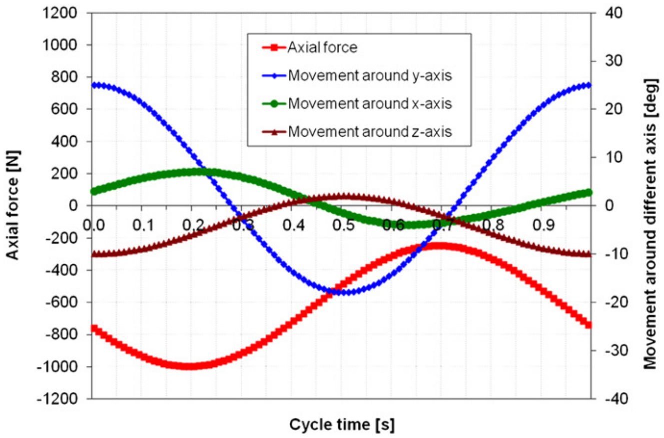

Fig. 2. Synchronization of the load and motion curves at the simulator adapted for shoulder conditions.

Actually the in-process inspection was intended at 100,000 cycles. Then the first inspection happened at 113,000 cycles and all following inspection were done at this point.

According to ISO 14 242-2 following values for determination of the gravimetric wear were used:

m_0…mass of the tested specimens at $N=0$.
m_{v0}…mass of the control specimens at $N=0$.
m_n…mass of the tested specimens at $N=N_n$.
m_{Vn}…mass of the control specimens at $N=N_n$.

The gravimetric wear W_n (true mass change of the tested specimens) at a defined number of cycles N_n was calculated from the mass loss of the tested specimens W_{an} ($=\Delta m$) and the mass change of the control specimen S_n by

$$W_n = W_{an} + S_n = (m_n - m_0) - (m_{Vn} - m_{v0})$$

The value a_G represents the wear rate in milligram after 1 million cycles (mg/10^6 cycles) using the equation for the least squares linear fit relationship between W_n and the corresponding number of loading cycles n: $W_n = a_G n + b$. The zero time point is not used in this calculation (ISO 14 242-2, 2000).

In a pilot study it was tested before, on separate specimens, that the characteristic line of the wear remains linear between 500,000 cycles and 1,000,000 cycles.

The optical appearance of the articulating surfaces and the surface roughness was assessed before and after the wear tests (ISO 7206-1, 2008; ISO 7206-2, 2008).

2.2. Calculation of PE abrasion caused by contact with the scapula

The abrasion models of the polyethylene Inlay due to mechanical notching were designed by 3D CAD software (Siemens PLM NX5). The loss of mass was calculated for three abrasion stages by the loss of volume and the density of polyethylene.

The 3D CAD models are based on a common polyethylene Inlay design with three typical rim offsets (Fig. 3), usually referred to as ∅36+0; ∅36+3; ∅36+6.

Inspection of the pattern of wear on the rim of retrieved glenoids reveals that the line of abrasion is mostly not straight, but curved. The abrasion patterns of typical explants are shown in Fig. 4a and b.

Since the severity of the *in vivo* PE abrasion is assumed to be variable, three different levels of abrasion were defined (stage 1–3).

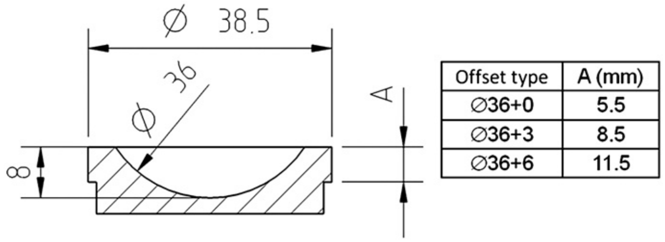

Fig. 3. Basic design of the PE Inlay, as plotted in the CAD. The distance *A* represents the height of the PE rim that exceeds the margin of the metallic implant.

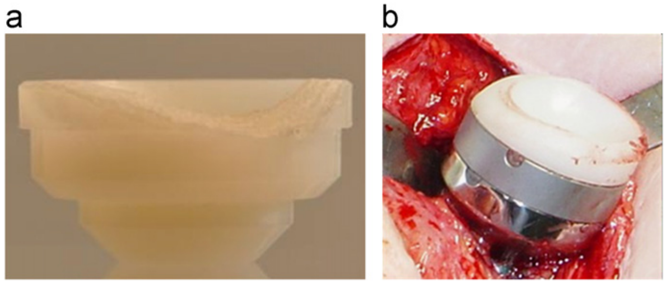

Fig. 4. (a) Photograph of a retrieved specimen. (b) Photograph of a worn epiphysis at revision surgery.

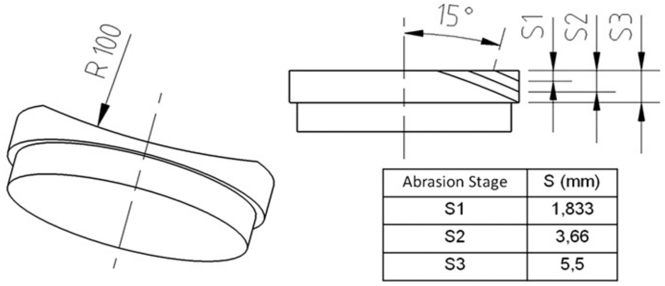

Fig. 5. Design parameter of the 3D-model with recess radius and abrasion stages 1–3.

The dimensions of the derived recess and the 3 abrasion stages are shown in Fig. 5.

The loss of mass was calculated with the simulated loss of volume of the 3D models and the density of polyethylene; $m=V\rho$ ($\rho_{\text{polyethylene}}=0.963$ g/cm^3).

3. Results

3.1. Detailed measurement of gravimetric wear

At the first inspection after 113,000 cycles, the mean amount of gravimetric wear was 3.29 mg for the PE Inlay and 2.69 mg for the PE Glenosphere.

After 500,000 cycles the mean amount of wear was 9.78 mg for the PE Glenosphere and 8.40 mg for the PE Inlay (Fig. 6).

The calculated wear rate a_G according to ISO 14 242-2 after 1 million cycles is 18.56 mg/10^6 cycles for the pairing UHMWPE Glenosphere/CoCr Inlay and 13.21 mg/10^6 cycles for the pairing CoCr Glenosphere/UHMWPE Inlay.

In initial state the articulating surfaces of the set of test specimens were free from embedded particles and from scratches and score marks other than arising from the finishing process. After the tests the articulating surfaces showed a normal appearance. The articulating surfaces of the polyethylene components were smooth and highly polished in the loaded area. They showed a defined changeover from the loaded to the unloaded area. The surface roughness was in the range stipulated in ISO 7206-1/-2.

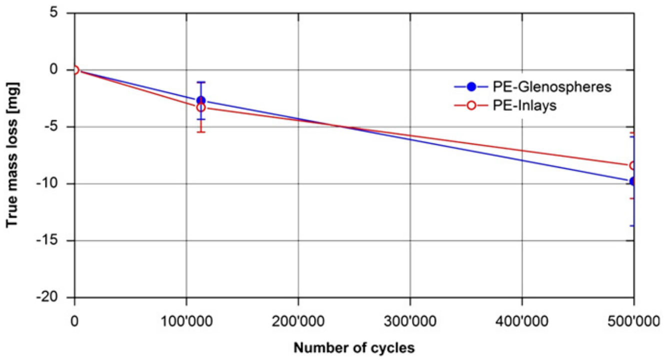

Fig. 6. Mean values of gravimetric polyethylene wear on Glenospheres and Inlays.

Table 2

	Loss of mass/mg		
	PE Inlay 36+0	**PE Inlay 36+3**	**PE Inlay 36+6**
Stage 1	73	181	333
Stage 2	304	735	1.399
Stage 3	691	1.768	3.881

3.2. Detailed calculation of PE abrasion

Table 2 shows the CAD-calculated loss of mass on Polyethylene Inlays with different rim offsets and three stages of PE abrasion.

On a 36+0 Inlay, the calculated loss of mass ranges from 73 mg to 691 mg for the three stages of PE abrasion. On a 36+6 mm Inlay, the loss of mass range from 333 mg to 3881 mg.

4. Discussion

In order to reduce or even avoid biological notching, an inversion of the mechanical bearings has been designed on some RTSA. However, before widespread use of IB-RTSA could be considered, the gravimetric wear of IB-RTSA needed to be assessed and compared both to the gravimetric wear and to the wear resulting from contact with the scapula, in conventional RTSA.

The gravimetric wear of every polyethylene component was in the range of 5–15 mg after 500,000 cycles (mean $<$ 10 mg). There was no significant difference between the two tribological pairings.

The calculated loss of mass of the polyethylene Inlay caused by mechanical notching ranged from 73 mg to 3881 mg. This is up to 462 times higher compared to the gravimetric loss of mass.

In Fig. 7, the gravimetric wear is compared with the calculated amount of abrasion due to notching, for the three different stages of notching, both on Ø36 mm PE-Inlays.

Concerning gravimetric wear tests, following statement is given in the "Standard Specification for Shoulder Prostheses" (ASTM F 1378–05, 2005): "*No device specific wear test is specified in this specification. It is felt that, at this time, wear is not a major issue in existing or potential implant designs, that presently there are no techniques available to do device specific wear tests…*". In the absence of special shoulder standards, the tests were performed on the basis of standardized gravimetric wear tests for hip prosthesis (ISO 14 242-1, 2002; ISO 14 242-2, 2000). We assume this to be reasonable since the radius of the ball and the socket are identical, and the center of rotation does not move, creating a very similar kinematical condition as for the hip joint.

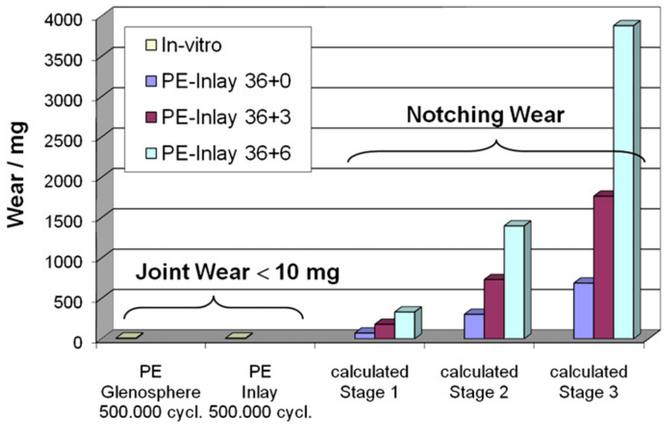

Fig. 7. Loss of mass due to gravimetric wear and calculated notching wear.

Existing standards for the shoulder joint require a total of 100,000 cycles with maximum loads of 750 N (ASTM F2028-08, 2008). Although 100,000 cycles is low compared to hip and knee testing, this value is justifiable because the test does not investigate component strength, because high-load activities occur much less frequently at the shoulder than in the lower limb, and because people with shoulder prostheses would be expected to load their arms even less often. This number of cycles represents approximately 25 high-load activities a day (such as getting out of a chair or lifting a suitcase) for 10 years (Anglin et al., 2000). To adapt these conditions to usable wear testing parameters, we increased both the amount of cycles up to 500,000 and the load up to 1000 N.

The control specimens are commonly referred to as passive soak controls. Alternatively, loaded or active soak control specimens can be used (Kurtz, 2009). Both, passive and loaded soak controls are described and allowed in ISO standards (ISO 14243-1, 2009; ISO 14243-2, 2009). The difference of passive and active soak controls is not significant to the overall wear rates of conventional UHMWPE implants (Kurtz, 2009).

The polyethylene specimens were made from conventional UHMWPE (not cross-linked) and were not artificially aged. It is to be assumed that cross-linked polyethylene would reduce the gravimetric wear. Therefore conventional polyethylene is used in this shoulder prosthesis system.

Artificial aging could increase the gravimetric wear in general, that means in both material configurations. In our opinion the basic comparison of the two tribological pairings is sufficient with the primary material.

4.1. *Limitations of the study*

Even though the gravimetric wear testing conditions are assumed to be close to the reality, differences between in vitro and in vivo loading conditions may have a significant influence on the results. Compression forces of 1000 N should not be reached in normal use of the arm with inverse shoulder prosthesis (Terrier et al., 2008), not either 500,000 cycles (Anglin et al., 2000).

Partial subluxation leading to asymmetric rim wear may occur, for example in the cases where the components have not been implanted with enough tension. The gravimetric wear setup with a conforming joint does not simulate such eccentric wear situations. However, to our best knowledge, there are to date no published reports about retrieved PE Glenospheres. Thus, this situation remains hypothetical.

It has been shown (Wirth et al., 1999; Mabrey et al., 2002) that the size of generated PE particles is different in hips and in knees, probably in relation to the different mechanics of these artificial joints. The characteristics of the particles generated in reversed shoulders remain to be determined.

We tested implants with diameters ∅36 mm. The difference between gravimetric and notching wear would be even higher with larger diameters (Anglin et al., 2000).

Relatively few components were tested. By increasing the number of specimens, a statistical distribution could be assumed and, based on this, significance testing could be performed.

The assessment of the articulating surface was important to exclude deviating gravimetric wear results due to abnormally surface injuries. Further specific surface inspections were not done.

The calculation of the mass loss with simulated notching stages does not represent specific examples from reality. Nevertheless the precise density of polyethylene and the simulated loss of volume should deliver appropriate reference values.

The polyethylene wear of conventional shoulder arthroplasty has been studied in some detail (Swieszkowski et al., 2011; Wirth et al., 2009, 1999; Cheung et al., 2007; Scarlet and Matsen, 2001; Hasan et al., 2002). However, to our best knowledge, no such reports are available for RTSA.

Despite these limitations, we believe this report to be the first published report about gravimetric wear in RTSA, be it on conventional or reversed bearing materials. Even though our results could not be compared to published results in the literature, they strongly suggest that PE wear due to mechanical abrasion in a standard configuration is by far more important than any gravimetric wear.

The gravimetric PE wear in the estimated life-time is very low and not significantly different between both prosthetic designs. From a tribological point of view, both designs may be used in clinical practice. If biological wear is considered to be of concern, these results support the continued use of the inverted bearing reverse total shoulder arthroplasty (IB-RTSA), with metallic Inlay and PE Glenosphere, since this configuration avoids any abutment of PE against the scapula (or tendons) and therefore is expected to avoid PE wear at this interface, thus to avoid biological notching.

On IB-RTSA, the metallic Inlay is harder than the bone of the scapula. Therefore, depending on the geometry of the artificial joint and the shape of the scapula, this Inlay could theoretically produce significant bone loss and eventually lead to loosening of the implant. However, in our clinical experience with the Affinis Inverse prosthesis (Mathys Ltd. Bettlach/Switzerland), where any contact between the humeral Inlay and the fixation pegs or screws of the metaglene is excluded, such a loosening has to date never been observed.

In the future, some other materials may be used on both sides of the artificial joint (Wirth et al., 2009). However, we would be very cautious about using a PE Inlay, as long as its abutment against the tendon of the triceps and/or the scapula is not completely excluded by any geometrical configuration.

Conflict of interest statement

GK and UI are consultants for Mathys Ltd. Bettlach and have received consultant payments from Mathys. DF is employee of Mathys Ltd. Bettlach, Switzerland.

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