Chapter 1

Bio-Tribological Demands

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1. Description of the Bio-Technical System

From an engineer’s point of view, an artificial joint represents a technical system with well-defined components under individual boundary conditions that are difficult to predict. History has shown that materials which were demonstrated to have considerable potential as biomaterials for joint reconstruction under in vitro conditions, failed in vivo after a short period due to a bad mechanical or biological outcome. Examples of this are polytetrafluoroethylene (PTFE, or ‘teflon’) and zirconia ceramics (Charnley, 1961, 1963; Derbyshire et al., 1994; Dowson, 2001; Haraguchi et al., 2001; Hernigou and Bahrami, 2003). Bio-engineers and surgeons often must wait for years to discover if a new material or implant design will have a proven clinical outcome.

Materials are used for joint prostheses according to their function. For example, a distinction can be drawn between materials made for components used to achieve the best possible long-term fixation within the bone stock and those that are made for reconstruction of the deceased joint articulation function. The latter are included in the present book. This chapter explains the choice of materials used today and what the bio-tribological demands for a new bearing material are.
2. Factors Influencing Longevity of Joint Replacements

Surgical intervention to replace a deceased natural joint with an artificial one has proven to be very successful (Learmonth et al., 2007), even though early as well as long-term failures are reported by national joint registries and numerous clinical studies (Park et al., 2005; Swedish Hip Arthroplasty Register, 2010; Willert et al., 1990) (Figure 1-1). The main reason for long-term failure is aseptic loosening of the fixating components, which is associated with a biological reaction that wears debris, resulting in osteolysis. Special attention is therefore paid to the tribological performance of articulating components so as to minimise the biological potential of the bulk materials and wear products. Registry data from Sweden (Figure 1-1) reveals

![Hip implant survival rates from Swedish registry data (Swedish Hip Arthroplasty Register, 2010).](image-url)
a clearly increased survival rate for modern implant systems compared to total hip replacements that were implanted more than 20 years ago.

The main factors that influence a joint’s short- and long-term performance are the actual implant, which is the product of investigation at the manufacturer, the orthopaedic surgeon, who significantly influences the boundary conditions under which the implant is working and, often underestimated, the patient who receives the artificial joint and defines the loading conditions and kinematics by his/her individual lifestyle (Figure 1-2).

2.1. Implant

The tribological components of an implant for joint reconstruction (e.g. head and insert of a THA) are defined by their material and technical design. Nowadays, the components are generally made of metals, ceramics and polymers and are advanced products designed by highly experienced engineers. They are developed under boundary conditions that are provided by standardisation organisations such as the International Organization for Standardization (ISO) or ASTM International, for example, surface specifications (Table 1-1)
## Table 1-1. Topological specifications for articulating surfaces given by the ISO 7206-2 and ISO 7207-2.

<table>
<thead>
<tr>
<th>Surface finish</th>
<th>ISO 7206-2: Hip</th>
<th>ISO 7207-2: Knee</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(total joint replacement)</strong></td>
<td><strong>Implants for surgery — partial and total hip joint prostheses — Part 2:</strong> Articulating surfaces made of metallic, ceramic and plastic materials</td>
<td><strong>Implants for surgery — components for a partial and total knee joint prostheses — Part 2:</strong> Articulating surfaces made of metal, ceramic and plastic materials</td>
</tr>
<tr>
<td>Surface finish</td>
<td>Metal: $R_{a,max} = 0.05 \mu m$</td>
<td>Metal: $R_{a,max} = 0.1 \mu m$</td>
</tr>
<tr>
<td></td>
<td>Ceramics: $R_{a,max} = 0.02 \mu m$</td>
<td>Ceramics: $R_{a,max} = 0.1 \mu m$</td>
</tr>
<tr>
<td></td>
<td>Plastics: $R_{a,max} = 2 \mu m$</td>
<td>Plastics: $R_{a,max} = 2 \mu m$</td>
</tr>
<tr>
<td>Radial sphericity</td>
<td>Femoral component: Max. $10 \mu m$</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Acetabular component: Max. $100 \mu m$</td>
<td>—</td>
</tr>
</tbody>
</table>

or pre-clinical tribological testing (Chapter 3). The general aim of these standards is to guarantee a high and comparable product quality under the control of independent testing laboratories and Notified Bodies.

Regarding their function during articulation, today’s materials are evaluated according to their wear resistance, mechanical strength and biocompatibility of the bulk material and wear products, but also economic factors. Most of today’s articulation materials follow the principle of hard and smooth surfaces that wear off at a very low rate (Figure 1-3). However, besides low wearing properties, implant materials are also evaluated according to their aging resistance in an oxidative environment \textit{in vivo} and during sterilisation processes (Kurtz \textit{et al.}, 2003; Muratoglu \textit{et al.}, 2003).

The contact conditions within the bearing are determined by the contact area and pressure that are a function of the material, the design and the loading conditions. The synovial fluid plays a major role in the lubrication of the bio-tribological system. This is,
however, dependent on the material combinations: While hard-on-hard bearings ideally build up a separating fluid film between the articulating surfaces by (elasto-)hydrodynamic effects, bearings using polyethylene as an articulating partner are meant to be completely or partly in physical contact during articulation (boundary or mixed lubrication conditions) (Jin et al., 2006; Sonntag et al., 2013). Based on the height of these fluid films, frictional forces and moments are generated. From a technical point of view, the physiological periprosthetic environment presents a challenging condition for biomedical engineers, as the implant is working under a corrosive environment and dynamic loading conditions. High punctual stresses may act on the surface of a bearing, for instance under adverse alignment of the articulating components, such as edge loading or impingement of the femoral neck to the cup rim in total hip arthroplasty (Habermann et al., 2006; Park et al., 2006) (Figure 1-4). Under these conditions, lubrication of the joint may be limited.

Figure 1-3. Volumetric wear rates after *in vitro* testing of conventional hip bearings (Sonntag et al., 2012).
2.2. Surgeon

The surgeon plays a significant role in the clinical outcome as malalignment, for example, may lead to an early implant failure. It is the surgeon’s expert opinion in the first instance that determines whether the patient should receive an artificial joint or not and, if an artificial joint is given, the choice of the appropriate implant system. These decisions, together with the operating theatre team’s experience and skills, define the clinical starting conditions that are crucial for the quality of implantation and create the framework for the longevity of the implant.

In several studies, it has been shown that a malalignment, for example of the acetabular cup/insert in total hip arthroplasty, can result in catastrophic wear or mechanical failure that may subsequently lead to early revision (Fisher, 2011; Waewsawangwong and Goodman, 2012). In 1978, Lewinnek et al. defined a so-called ‘safe zone’ based on clinical observations. Within an acetabular cup inclination between $30^\circ$ and $50^\circ$ of abduction and $5–25^\circ$ in anteversion, the implant showed less risk of dislocation due to impingement between stem and cup (Lewinnek et al., 1978). In that context, recent clinical data give a more distinct correlation between cup inclination, metal ion level and the formation of pseudotumours after metal-on-metal hip resurfacing with a recommended maximum inclination angle of $55^\circ$ (De Haan et al., 2008; Grammatopoulos et al., 2010). These findings have further promoted pre-clinical adverse testing
protocols to mimic critical situations that may occur in the patient’s daily use and are particularly crucial for these hard-on-hard bearings (Fabry et al., 2013).

In addition, the volume of implantations per surgeon is a critical factor that is purported to influence the outcome of the artificial joint, as low-volume surgeons are associated with an increased risk of early revision (Losina et al., 2004; Manley et al., 2008). These facts have opened up the discussion in the orthopaedic community about a minimum number of implantations per year for a surgeon.

2.3. Patient

The endoprosthetic patient addresses the orthopaedic specialist because of pain, decreased function and quality of life. In general, the surgical intervention using a joint replacement enables the patient to recover and resume a quality of life regarded as ‘normal’. From this point on, it is the patient’s responsibility to take care of the new joint. Gait analysis and studies on instrumented artificial joint components have shed some light on the bio-mechanics of artificial joints during daily activities (Bergmann et al., 2001; Damm et al., 2010; D’Lima et al., 2006; Kutzner et al., 2010). The most important aspects are:

- Relevant loading conditions act during most daily activities such as normal walking (approximately 300% of the body weight) and vary between other activities (Bergmann et al., 2001; Kutzner et al., 2010) (Figure 1-5).
- The highest loads have been measured under conditions that have not been previewed before (spontaneous stumbling with up to 900% of the body weight) and, more importantly, that were not possible to reproduce under controlled conditions (Bergmann et al., 2004).

These findings need to be addressed to verify the implant’s performance in pre-clinical testing (Fabry et al., 2013) and will be part of future adaptations of the testing standards developed by the ISO and ASTM International organisations.
A meta-analysis by Prokopetz et al. (2012) revealed some factors that affect patient outcome by increasing the risk of a revision surgery after total hip replacement. These include male and younger patients. The register data confirm this as well (Australian National Joint Replacement Registry, 2013) (Figure 1-6). Furthermore, greater comorbidity and a diagnosis for avascular necrosis as compared to osteoarthritis have been shown to be risk factors for an early revision.

3. Approaches for New Bearings

New approaches for bearing materials may be classified according to the scheme of Sonntag et al. (2012) (Figure 1-7).

The approaches can be summarised as follows:

- New bulk material, for example ceramics:
  One or both articulation components are made of a new material that wears off at a very low rate and presents a minimal risk of a biological reaction on the bulk material as well as the wear products.
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Figure 1-6. Cumulative percent revision of primary total hip replacement by patient age (Australian National Joint Replacement Registry, 2014).

- Cushion bearings, in order to replicate the physiological situation: Soft bearing materials that attempt to mimic the natural joint, which is covered by a smooth cartilage. They are intended to work under better lubrication conditions than the established hard materials used for artificial articulation.

- Surface coatings, for example implants for patients suffering allergies: Surface properties are adapted (e.g. metal ion release) without changing the properties of the underlying substrate material. Adhesion of the coating on the substrate under high punctual loads is a limiting factor and needs to be addressed during development by the manufacturer.

- Surface modification, such as controlled oxidisation processes: Compared to coatings, no material is added to the substrate but the bulk material is chemically modified by diffusion into the outer layers of the substrate.
Based on these theoretical approaches, new bearing materials have been developed. Some are still under consideration in the laboratory, while others have already been introduced in the clinic. The aim of this book is to give a detailed overview on the material science aspects as well as the in vitro and in vivo performances of these new bearings so that a more rigorous evaluation of them can take place.
References

Material for Total Joint Arthroplasty: Biotribology of Potential Bearings


