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Tribology of medical devices

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Abstract

Importance of tribology in a number of medical devices and surgical instruments is reviewed, including artificial joints, artificial teeth, dental implants and orthodontic appliances, cardiovascular devices, contact lenses, artificial limbs and surgical instruments. The current focus and future developments of these medical devices are highlighted from a tribological point of view, together with the underlying mechanisms.

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Keywords: Tribology; Medical devices; Artificial joints; Dental implants; Surgical instruments

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1. Introduction

Medical devices are widely used in daily life, ranging from simple bandages to complex imaging equipment. Medical devices are defined in different ways from various organizations, including the Food and Drug Administration (FDA), the European Union Directive (2007/47/EC) and ISO (13485). Examples of medical devices include instruments, apparatuses, appliances, materials, etc., intended to be used in human beings for the purpose of diagnosis, prevention, monitoring, treatment, or alleviation of disease, or compensation for an injury or handicap, investigation, replacement, or modification of the anatomy or of a physiological process etc.

Medical devices are heavily regulated because of their intended uses in human beings. Generally medical devices are classified into different categories depending upon the degree of potential risks and regulated accordingly. An increasing concern has been raised recently, following on the clinical withdraw of a number of medical devices [1]. The issue to balance the safety and effectiveness of a medical device is once again called into question. Strict and comprehensive pre-clinical testing has become even more important in the evaluation of new innovative medical devices.

Many medical devices are involved with relative moving parts, either in contact to the native tissues or within the biomaterials, and often under loading. Important issues, such as friction and wear of the moving parts, not only affect the functions of these devices but also the potential adverse effects on the natural tissues. Biotribology deals with the application of tribological principles, such as friction, wear and lubrication between relatively motions surfaces, to medical and biological systems. Biotribology plays an important role in a number of medical devices.

The purpose of this review is focused on the tribology of medical devices. Specific aims include the following:

- Review important medical devices that have received extensively tribological investigations.
- Identify the corresponding gaps in research and the new directions.
- Understand the underlying tribological mechanisms that are common among different medical devices.

It is beyond the scope of the present review to include all possible medical devices in which tribology plays an important role. Instead implanted medical devices are mainly considered and only musculoskeletal, dental, and cardiovascular systems are focused. Other important medical devices for ocular and skin systems as well as medical instruments are also included. This paper is organized with an overall introduction, followed by the literature review of medical devices in each system, and finally a summary. In each section of the literature review on a biological

system, a general introduction to the use of the medical device and the potential clinical problems are firstly outlined and then the important tribological issues are discussed.

2. Literature review

1920

1940

A search was performed in Pubmed on 8th October 2016, using the following keywords "(Medical device or (Joint AND implant) or (Dental and Implant) or Contact lens or Medical instrument or Contact lens OR Cardiovascular devices OR Fracture fixation or (Artificial AND limb)) AND (tribology or friction or wear or lubrication)" and a total of 41,090 records were found. Fig. 1a shows the increasing trend of these records, particularly after the 1980s.

A narrowed down search using the keywords "Medical device AND (tribology OR friction OR wear OR lubrication)" returned a total record of 15,966, as shown in Fig. 1b.

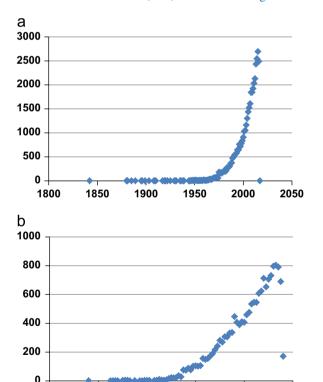


Fig. 1. (a) Number of records searched in Pubmed on 6th October 2016 against year published using keywords "Medical device or (Joint AND implant) or (Dental AND Implant) or Contact lens or Medical instrument or Contact lens OR Cardiovascular devices OR Fracture fixation or (Artificial AND limb)) AND (tribology OR friction OR wear OR lubrication)".

(b) Number of records searched in Pubmed on 6th October 2016 against year published using keywords "Medical device AND (tribology OR friction OR wear OR lubrication)".

1980

2000

2020

1960

The records in each specific search of the sub-areas are shown in Table 1:

It is clear that joint implants have received by far the most attention, followed by dental implants and cardiovascular implants, fracture fixation devices and artificial limbs. Contact lenses and medical instruments are widely used, however the tribological research is relatively limited. There are clear limitations of the above search because of the selection of the keywords. Nevertheless, the above search does give an indication of the important medical devices that have received important considerations of tribology.

2.1. Artificial joints

Artificial joints are one of the most successful medical devices used in human beings. There are 206 bones and over 300 joints in the body. Of the joints in the body that allow a relatively large motion are the hip, the knee, the shoulder etc. Smaller joint implants such as the ankle, the elbow, the wrist and the finger are also increasingly introduced into clinical practices. Joint implants also include the spinal disc (total disc) replacement and the temporomandibular joint (TMJ) prosthesis. These joints provide a range of complex three-dimensional

Table 1 Number of records searched in Pubmed on 8th October 2016 for different areas with different keywords.

Keywords			
Joint And implant AND (tribology OR friction OR wear OR			
lubrication)			
Dental AND implant AND (tribology OR friction OR wear OR	429		
lubrication)			
Cardiovascular devices AND (tribology OR friction OR wear OR	387		
lubrication)			
Fracture fixation AND (tribology OR friction OR wear OR	295		
lubrication)			
Artificial AND limb AND (tribology OR friction OR wear OR	157		
lubrication)			
Contact lens AND (tribology OR friction OR lubrication)	114		
Medical instrument AND (tribology OR friction OR wear OR	50		
lubrication)			

motion and yet at the same time undertake a significant amount of loading. It is estimated that currently there are well over one million artificial joints implanted yearly into patients worldwide. Fig. 2 shows a typical hip implant and a typical knee implant.

Tribological issues at the articulating surfaces as well as at the connection between modular components and the fixation to bone are important considerations. Friction, wear and lubrication play important roles in the successful function of artificial joints and the potential clinical problems.

2.1.1. Articular surfaces

Various biomaterial combinations are used for the articulating surfaces of artificial joints. These can be broadly divided into soft-on-hard and hard-on-hard combinations. Soft-on-hard combinations mainly include ultra-high molecular weight polyethylene (UHMWPE) against cobalt chromium alloys or alumina/zirconia toughened alumina composite ceramics (ZTA). Titanium alloys are sometimes preferred, particularly for total disc replacements in the spine, due to its lower elastic modules and improved imaging quality, but surface treatments to improve its wear resistance are necessary. Hard-on-hard bearing surface combinations for a hip implant include metalon-metal, ceramic-on-ceramic and ceramic-on-metal [2]. The major issue currently associated with the bearing surfaces of artificial joints is wear and subsequent wear debris which can cause adverse tissue reactions and the loosening of the prosthetic components. Therefore improving the wear resistance of the bearing surfaces has been one of the main drivers in the development of artificial joints [3].

The major source of wear debris in the soft-on-hard combination is from the UHMWPE bearing surface. Therefore improvements of the UHMWPE bearing surface are essential. Recent developments in this area include highly cross-linked UHMWPEs, and further addition of vitamin-E and other antioxidants [4]. Compared with the conventional UHMWPE, these new polyethylene bearing materials have been shown to reduce wear considerably and to improve clinical outcome. Furthermore, the role of the hard counterface is also very important since its scratch can lead to a marked increase in







Knee implant

Fig. 2. A typical hip implant and a typical knee implant, showing the joint components (a) hip: metallic femoral head, plastic cup and metallic backing shell; (b) knee: metallic femoral head, plastic tibial insert and metallic tray). a) Hip implant. b) Knee implant.

UHMWPE wear [2]. Surface coatings of the metallic counterface or the use of harder materials such as ceramics are introduced to maintain a low wear level. However, the strength and the potential long term durability associated with these coatings remain problematic [5]. Highly cross-linked UHMWPEs are now mainly used in the majority of artificial hip joints, while their use in artificial knee joints is also receiving attention [6].

The current hard-on-hard combinations for artificial joints are mainly for the hip, including metal-on-metal and ceramicon-ceramic. The wear in a metal-on-metal articulation can be low, but can be increased drastically under adverse operating conditions when the lubrication breaks down [7]. This has largely led to the high revision rate and clinical withdraw of a number of hip implants with a metal-on-metal articulation and the use of these types of devices is greatly reduced [8]. Nevertheless, well designed and accurate position may still allow metal-on-metal articulations, particularly of the resurfacing type, to be used in selected patients [9]. Only ceramic-onceramic bearing combinations are now mainly used in routine clinics, including alumina and ZTA. In particular, the introduction of ZTA has improved both wear resistance and toughness [10]. As a result, the combination of ZTA-on-ZTA has reduced the wear of the bearing surfaces considerably, particularly under adverse conditions when the edge of the acetabular cup comes into contact with the femoral head [11] and in younger patients [12]. One of the potential complications with ceramic-on-ceramic articulations is squeaking, and a number of factors have been suggested and yet the squeaking mechanism is still unclear [13]. Squeaking has been reported to range from 0.5% to 10%, but occasionally up to 25%. Patient, implant and surgical factors can all contribute to the squeaking. This is further complicated by lack of a clear definition. At the present time, the squeaking in ceramic-on-ceramic implants cannot be eliminated completely.

New bearing surface combinations are being increasingly introduced to reduce wear and improve the longevity of joint implants even further. Polyether-ether-ketone (PEEK) has been extensively investigated as a potential material to replace UHMWPE, in particular against a ceramic counterface for the hip [14], the knee [15] and the spinal disc [16]. In addition, PEEK-on-PEEK combinations have been investigated for smaller joints such as the spinal disc [17]. More recently, UHMWPE-on-PEEK bearing combination has been suggested as a candidate for knee implants [18-20]. All these new materials and combinations are currently investigated in laboratories and extensive pre-clinical testing is still required before potential clinical applications. Apart from the improvements of the wear resistance of the bearing materials, other factors such as implant designs, patients and surgeons are also important considerations. The key parameters in the implant design include the radius (size) of the bearing surfaces as well as the conformity between the two articulating surfaces. It is often necessary to balance the contradictory design requirements between biomechanical and tribological functions. For example, an increase in the femoral head radius in the hip implant improves the biomechanical functions such as the range of motion and stability, and yet the wear of the bearing surfaces is also increased as a result of the increased sliding distance [21]. In the knee implant, an increase in the conformity between the articulating surfaces reduces the contact stress, but may limit the range of motions and also potentially increase wear [22]. Furthermore, patient activities can affect wear greatly, for example, stair climbing may double wear in a knee implant, compared with level walking [23]. Surgical techniques can affect how the components of artificial joints are positioned and aligned, and consequently the load transmission and wear.

Wear testing of artificial joints is carried out extensively in laboratories using simulators with various degrees of complexity before the implants are considered for approval for clinical applications. A number of standards for wear testing of artificial joints have been introduced from both ISO (14242; 14243; 18192) and ASTM (F2025). Currently, the major focus is to improve the laboratory based testing in order to be more closely representative of clinical settings. These include introduction of more adverse conditions to reflect a wide-spectrum use in patients and by surgeons [24,25].

2.1.2. Modular junctions

Modular connections are introduced in artificial joints in order to facilitate their use in patients and by surgeons. For example in the hip joint, modular head-neck combinations and modular neck stems allow for restoration of anatomy and optimization of joint biomechanical functions. Different biomaterials are often involved in the modular connection as well as in direct contact with bone, including cobalt chromium alloy/titanium, ceramics/titanium etc. Therefore, the potential problem of corrosion has long been recognized [26]. However, fretting corrosion has only received significant attention recently, following on the extensive clinical problems and recalls reported with a number of hip implants with metal-onmetal articulations initially and then subsequently with modular conjunctions [27]. The problem of fretting corrosion at the modular connection has been found particularly to be associated with the synergistic mechanical and electrochemical effect [28]. A number of terms have been introduced to describe the related clinical problems, including pseudotumor, adverse local tissue reaction (ALTR), acute lymphocytic vasculitis associated lesions (ALVAL), adverse reaction to metallic debris (ARMD), taperosis, trunnionosis etc., mainly as a result of metallic wear debris and released metal ions. Furthermore, the clinical problems associated with fretting corrosion in different artificial joints are common. Initially the focus was on the articulation of metal-on-metal bearing surfaces, particularly in resurfacing prostheses and large diameter total hip implants. Subsequently, a number of modular femoral stems in the hip implant were identified as problems and consequently recalled [29,30]. Similar problems have also been found at the femoral head and stem junction [31], and at the bearing linear and backing shell connection [32]. Fretting corrosion at the taper interface was found to be particularly severe in the articulation of metal-on-metal bearing surfaces with a large diameter [33]. Now it is generally

accepted that fretting corrosion also occurs widely in the femoral taper connection in total hip implants associated with UHMWPE-on-metal and UHMWPE-on-ceramics bearing surfaces [34]. Similar problems have been identified in modular components in the knee implant [35] and in the shoulder implants [36]. Currently a lot of efforts are devoted to the understanding of the tribo-corrosion mechanism at the modular junction and the identification of implant factors that are mainly responsible through clinical studies, laboratory testing and computational modelling.

Extensive clinical studies have been conducted to correlate the factors that are related to fretting corrosion, through monitoring joint fluid and blood metal ions [37,38] and analysing retrieval components [39]. The most important factor in fretting corrosion has been found to be associated with the material combination of the modular connection. Cobalt chromium alloy against titanium alloy or stainless steel has been shown to produce more extensive fretting corrosion at both the head-neck junction and the modular stem connection than against itself [39]. The use of a ceramic femoral head in conjunction with a titanium alloy appears to be the best combination in terms of reducing fretting corrosion, but cannot eliminate the problem completely [40]. In addition, these authors have shown that a low modulus titanium alloy (titanium-molybdenum-zirconium-iron alloy, TMZF) led to increased fretting corrosion damage in the ceramic heads but no differences in the cobalt chromium alloy heads. A PEEK stem has been shown to produce less fretting corrosion [41]. Surface coatings may have the potential of reducing fretting corrosion, however this has not been demonstrated in a clinical study for an oxidized zirconium head [42]. Furthermore, the coating strength and long term durability are yet to be established.

The design and manufacturing parameters at the modular junction can affect the relative micro-motion and therefore the fretting corrosion. Narrower and shorter stem designs with different offsets are introduced to restore the joint centre, to increase the range of motion, and decrease the risk of impingement and dislocation. However, a stem design directly affects its flexural rigidity and the head offset is directly related to the frictional torque, all potentially influencing the micromotion at the taper. The effect of the taper designs from different manufacturers on fretting corrosion was investigated by Tan et al. [42] for a given polyethylene-on-cobalt chromium alloy articulation with a 28 mm diameter bearing and significant differences were found. However, there are many parameters associated with a taper design, which can all potentially affect fretting corrosion. Taper geometry (crosssectional dimensions and lengths) from different retrieved implants was measured and used to calculate the flexural rigidity and a wide range of values were found [43]. Three taper designs with different angle, distal diameter and contact length were examined and compared for a metal-on-metal articulation [44]. A further study revealed the effect of the taper length, and fretting corrosion was increased with longer head lengths [45]. However, this has not been demonstrated in another study [46]. The effects of the increased medio-lateral offsets and longer neck moment arms have been shown to lead to increased taper damage at the modular interfaces for metalon-metal articulations [32]. The effect of the taper angle has been shown to be inversely correlated with stem fretting, but not with head fretting and head-neck corrosion [47]. Different surface topographies and textures are introduced to increase the fixation at the modular interface [48]. One study in [49] showed an increased fretting corrosion in the rougher tapers under normal loading and an even worse performance under high loading. The surface topography was also shown to be related to the damage scores on retrieved head-neck modular iunctions and furthermore to affect different materials combinations of cobalt chromium/titanium and titanium/titanium differently [50]. Currently it is still not clear what the best surface topography should be for a modular connection. In addition to the design parameters, manufacturing parameters of the taper interface can also influence fretting corrosion significantly. Langton et al. showed that any deviations from the design specifications resulting from the manufacturing process can significantly increase the problem of fretting corrosion [51].

The bearing surfaces of the articulation between the femoral head and the acetabular cup can also affect the fretting corrosion at the modular taper interface. The resultant frictional torque at the bearing surfaces plays an important role in this process. Metal-on-metal bearing surfaces, particularly with a large diameter and under adverse conditions, can produce a high friction torque, leading to severe fretting-corrosion problems at the taper interface. Nevertheless, different bearing surfaces currently used for total hip implants have all been shown to produce fretting corrosion at the taper junction. Head diameter affects the friction, particularly for metal-on-metal articulations, however for UHMWPE-on-metal articulations, no effects were found [52].

The effect of the length of implantation in patients on fretting corrosion is not clear, with contradictory findings [38,44]. In addition, patient weight was found to be a predictor of fretting corrosion damage at the taper-neck junction in a retrieval series [53]. Furthermore, in a study of retrieved modular femoral components, female patients were identified as high risk factors for failure [54]. However, such a finding may be confounded by the smaller size of the implants.

While the above findings have been found mainly from clinical studies, laboratory experimental measurements have also been conducted to understand the underlying mechanism of fretting corrosion from various perspectives. Some of these studies have combined a number of factors such as fretting corrosion under a cyclic load and a corrosion environment [55]. While Panagiotidou et al. [49] have examined the effect of friction torque (bending moment) and corrosion. The surface contact area in a taper was measured and found to depend on different assembly forces [56]. Micro-motion and pull-out force were measured under different conditions to simulate different surgical techniques and conditions [57–61]. The effect of impaction force was considered to represent surgical factors [55,62]. A fretting corrosion testing was set up to investigate the effects of fretting amplitude and pH levels

and the importance of the materials paring/contacts was found [63]. Similar to the clinical finding [41], a laboratory based study has also revealed the potential benefit of using a PEEK component to reduce fretting corrosion [64].

A limited number of computational studies have been conducted to understand the fretting corrosion, particular focusing on the contact area, the contact stress and the micro-motion at the taper junction [65,66]. In general these modeling studies have shown how the articulation of the bearing surfaces and the modular interface designs affect the parameters associated with fretting corrosion.

Despite a number of clinical, experimental and computational studies in this area, the biomechanical environment at the modular junction has not been fully characterized. There remains lack of fully integrated computational studies and fully coupled tribo-corrosion testing where both the articulating surfaces and the modular connections are addressed. A number of compounding parameters of implant designs as well as patients and surgeons can all influence the fretting corrosion, and therefore the effect of isolated parameters may not been easily identified. The underlying fretting corrosion mechanism in the modular junctions in artificial joints remains to be elucidated.

2.1.3. Fixation

Artificial joints are fixed to bone, either using bone cement (cemented fixation) or press-fitting through bone in-growth (cementless fixation). The micro-motion at the implant-cement and cement-bone interfaces is inevitable and can result in fretting and wear [67]. Important factors include stem designs and surface finish/texture and cement types [68]. Furthermore, galvanic coupling was found to significantly increase the rates of corrosion [69].

While for the cementless fixation, the micro-motion at the implant-bone interface affects the primary stability (mainly achieved through press-fit and friction) and consequently the long term secondary stability (bone in-growth). Stem designs and particularly coatings affect friction and therefore the primary stability [70]. Sufficient friction is required to limit the micro-motion [71,72].

2.1.4. Challenges

Significant effort has been devoted to the improvement of the materials and designs for artificial joints. As a result, the clinical outcomes of current hip and knee implants have been improved considerably. Despite these attempts, there are still a number of challenges. Wear testing using simulators is increasingly performed, prior to the approval of new artificial joints into clinical use. This is generally time consuming and costly. Accelerated testing does not represent clinical use and is not feasible. Consequently, development of computational models may be complementary and necessary [73]. Despite a large number of experimental and computational studies as well as clinical investigations, the biomechanical environment at the modular taper junction has not been fully characterized. There remains lack of fully integrated and coupled studies. Furthermore, the biomechanics of the joint at the muscular-skeletal level is often decoupled from the tribology of the bearing surfaces at the joint

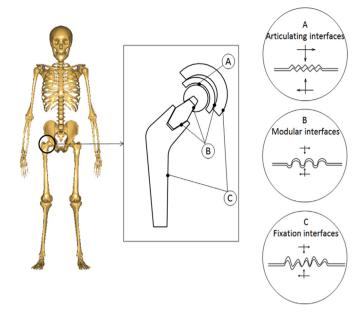


Fig. 3. Multi-scale and multi-physics interactions illustrated for a typical medical device of a hip implant.

level, such that the corresponding interactions are often ignored [74]. Fig. 3 illustrates such potential interactions at the articulating, modular and fixation interfaces.

Whilst major advancements have been made for the hip and the knee, smaller joints such as the total disc replacement and the TMJ implant remain to be improved. Future use of artificial joints will demand even more functions, as implanted in younger and more active patients with increased life expectancy. New bearing surface combinations with wear reduced even further will be required.

2.2. Fracture fixation

Bone fractures are common, with over 1.7 million fractures in the hip alone worldwide [75]. Various constructs are used clinically for different fractures at different sites and with different indications. The purpose of the fracture fixation is to restore stability and promote healing at the fracture site. The micro-motion (strain) at the fracture site plays a pivotal role during this process [76]. In some hip fracture fixation devices such as an intramedullary nail, modular constructs are sometimes preferred and for example, sliding of the lag screw is important to the fracture consolidation and transmission of forces through the fracture site. In addition, fracture plates or nails are fixed to the bone through screws, cables etc. and often with different materials. Galvanic corrosion and fretting corrosion are often involved between the components of the construct as well as between the constructs and bone [77,78]. Fretting corrosion is often present in the modular junction of an intramedullary nail [79]. Friction and lubrication are important considerations in the relative sliding of the lag screw and hence the load transmission to the fracture site [80]. All these may contribute to potential clinical failures such as pain, non-union, osteolysis etc. However, unlike the modular

junction in the hip implant, the effect of using dissimilar materials for the fracture constructs does not appear to be significant [81].

Tribological problems are clearly present in fracture constructs and fixations. However, the scope of the investigation in this area is much limited, compared with artificial joints. The main reasons for this may be the relatively short period of *in vivo* implantation and different biomechanical environments of fracture constructs.

2.3. Dental artificial tooth

Human teeth are not only the important masticatory organ but also closely associated with both the pronunciation and the facial esthetics of human being. Due to ageing, various pathologic factors and traumas, tooth lesion such as caries, partial or overall tooth tissue loss will occur unavoidably. Generally the lesion of human teeth is restored and treated with dental restorations and/ or implants in dental clinic, which are called artificial dental tooth. Dental restorations include dental restorative materials used to restore the function, integrity and morphology of missing tooth structure and the replacement of missing tooth structure that is supported by dental implants. Due to oral physiological functions, dental restorations and implants inevitably suffer friction and wear in the mouth every day. Nowadays, metals and alloys, ceramics and composites materials are most widely used for dental restorations and implants [82]. Fig. 4 illustrates dental restorations and implants commonly used in clinic. Normally different dental materials encounter different tribological problems in their clinical uses, as shown in Table 2 [83]. Excessive wear could result in the failure of dental restorations and implants. Thus, much work has been done to investigate the tribological behavior of artificial dental teeth and then to improve their anti-wear properties.

2.3.1. Tribology related to dental restorations

Dental restorations are classified as either direct or indirect. Direct restorations are made directly inside the mouth of the patient, while indirect restorations are made outside of the patient's mouth and then placed inside. Restorations include filling, (composite filling and amalgam filling), crown (composite crown, metal-ceramic crown and full ceramic crown),

veneer, inlay, onlay (mainly made from ceramic), and bridge (mainly made from stainless steel). Most tribological studies related to dental restorations focused on dental composite, ceramic and amalgam.

2.3.1.1. Dental composite. Due to good aesthetics, the ability to bond to tooth structures and the need for an amalgam alternative, resin-based dental composites have been used increasingly widely in the field of restorative dentistry recently [84]. The most widely used dental composites are composite resin fillings (also called white fillings), which contain filler particles (borosilicate glass, colloidal silica, etc.) in a polymer matrix (Bis-GMA, TEGDMA, etc.) generally. Composite resin fillings are commonly utilized to restore cavities, replace the missing tooth tissue that has been worn away by grinding, and resemble the appearance of the natural tooth [83,85,86]. A main problem of dental composites in clinic is their weak wear-resistance [83]. Therefore, many new technologies and methods have been developed to optimize the composites in order to improve their wear resistance [87].

The wear resistance of dental composite is closely associated with its material characteristic [88]. The material factors of resinbased dental composites are normally related to particle size, shape and hardness, the filler content, the inter-particle spacing, the filler distribution, the degree of conversion, the interfacial bond strength between filler and matrix, the nature of the matrix, and the surface hardness [89].

The size of inorganic fillers has been found to be enormously essential for the wear resistance of the dental composites. Microfilled materials had a better wear resistance than traditional macro-filled materials [90]. Micro-filled and hybrid materials possessed similar wear resistance [90]. Although a few earlier studies revealed that composites containing smaller spherical particles showed better wear resistance [91], nano-filled materials seemed to experience more or equal wear to micro-filled materials [92]. It was indicated that there was a critical value of filler particle size $(1.2-1.5 \,\mu\text{m})$, under which the strait-line relation was different from that above the value [89].

Aside from particle size, the content of filler particles also could affect the wear resistance of dental composite significantly. As the filler volume increased, wear was reduced regardless of the filler treatment [88]. The wear resistance of

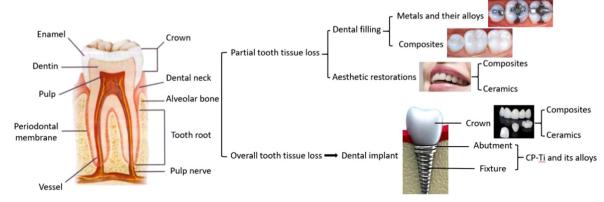


Fig. 4. Dental restorations and implants commonly used in clinic.

Table 2 Dental materials and their tribological problems in clinic [2].

Materials	Main tribological problems	Influencing factors
Metals and their alloys	Wear-corrosion, friction in fixed orthodontic appliance systems, fretting wear.	The nature of metal, alloying, oral factors.
Ceramics	Abrasive potential to the opposing enamel, brittle fracture.	Ceramic microstructure and surface characteristics, oral factors.
Composites	Excessive wear in posterior composite restorations.	Characteristics, content and distribution of filler, the degree of conversion and the nature of matrix, the interfacial bond strength between filler and matrix, oral factors.

the micro-filled composites containing ground glass filler particles ($1 \sim 5 \, \mu m$) was enhanced remarkably with an increasing of the filler volume from 25 to 30 vol% [83]. However, the composites with only colloidal silica particles (50 nm) showed diminished wear resistance when the filler concentration was more than 50 wt% [93]. Additionally, P.V. Antunes et al. investigated the wear behavior of the dental composite reinforced with SiC particle filler and found that in an abrasive slurry medium, its abrasion resistance decreased with the increase of the particle volume fraction [92]. Another study suggested that an optimum content of seashell nanopowder used to reinforce the PMMA based denture composite was 12% [94].

Other filler characteristics, such as the inter-particle spacing and the filler distribution, also play an important role in the wear process of dental composites. Filler particles situated very close can protect the softer resin matrix from abrasives, thus reducing wear. And the critical distance between particles was found to be between 0.1 and 0.2 μm [88]. Meanwhile, the use of finer particles for a fixed-volume-fraction of filler was reported to cause decreased inter-particle spacing and then reduce wear [90]. Moreover, well-distributed fillers can achieve good wear resistance for small-particle hybrid composites [83].

Additionally, good stress-transfer ability could enhance the wear resistance of composites. Given that well-bonded microfillers in the resin matrix can protect the matrix and interfere from crack propagation at higher filler levels, improving the bond between the filler and the matrix could achieve a good stress-transfer ability [95]. Silane coupling agents are thought to play a major role in enhancing the adhesion of the interface between the inorganic filler and organic resin. Nihei et al. [96] found that the resin composites containing fillers modified with a novel hydrophobic silane presented high resistance to wear, and the composites with the higher amounts of silane showed better interfacial adhesion between filler and matrix and thus showed better wear resistance.

It should be noted that the characteristics, such as the strength and the toughness, of resin matrix must be considered. A weak, incoherent matrix can bring up phenomenon such as getting rid of filler particles and thus reduce the abrasive capacity of the composite [97]. Meanwhile, urethane-based materials with an excellent toughness are suggested to be the most abrasion resistant [97].

2.3.1.2. Dental ceramics. Due to their natural appearance and durable chemical and optical properties, dental ceramics are widely used as restorations. However, there are two main

disadvantages with the dental ceramics in clinic. Firstly, their brittle fracture nature could cause disastrous results clinically. Secondly, dental ceramics have relatively high wear resistance normally, but most ceramic restorations may be abrasive and then create opposing occlusal surface wear of natural or artificial dentition [83,98].

Some high-toughness dental ceramics have been developed in the last decades, aiming to minimize the damage by brittle fracture. Yttria-stabilized tetragonal zirconia polyscrystal (Y-TZP), a high-toughness zirconia ceramic, has been increasingly accepted to overcome the issues and can be used as an alternative to porcelains or glass-ceramics in posterior restorations [99]. Amaral et al. evaluated the influence of surface treatments on the low-temperature degradation (LTD) of a Y-TZP ceramic, and they found that LTD may be suppressed by smoother surfaces or the presence of an initial amount of mphase on zirconia surface [100]. The results of Nakamura et al. indicated that even though LTD increased the monoclinic phase, resulting in lower strength, the fracture resistance of the monolithic zirconia crowns was still sufficient to withstand the loading conditions in the molar regions [101]. The hydrothermal aging of zirconia caused a statistically significant decrease in the flexural strength of thin bars of zirconia, which was the result of the transformation from a tetragonal to monoclinic crystal structure [102].

Most ceramic restorations may be abrasive and then result in opposing occlusal surface wear of natural or artificial dentition [83,98]. Hence, much research work has been done to investigate how to reduce the wear of enamel against various ceramics. The wear of enamel and ceramics was reported to be associated closely with ceramic type, microstructure and surface characteristics [103]. Compared with feldspathic porcelains, low-fusing feldspathic dental porcelains was found to cause less wear of opposing teeth [104]. Zirconia ceramics was reported to yield superior wear behavior and lower antagonistic wear than conventional ceramic [105,106]. Wear of zirconia and standard ceramics showed different wear performances, strongly influenced by surface treatments as well as number of wear cycles [107]. Ceramic surface glazing and/or polishing treatment may reduce enamel wear caused by dental ceramics to some extent at the early stage of contact [105], however the positive effect would be lost quickly when the material is placed unctionally in mouth. Comparing to well-polished zirconia ceramics, a newly developed grade of self-glazed zirconia ceramic showed similar friction and wear performance against natural tooth while provides sufficiently improved aesthetic appearance [108].

The chemical attack in the mouth may result in the surface degradation of dental ceramics [103], and then accelerate its wear process. The highest degradation of Y-TZP dental ceramics occurred in acidic environment [109]. Generally ceramic surface is prone to degradation by acidulated fluoride, that can increase wear rates. The results of Guilherme Teixeira Theodoro et al. suggested that ceramic type and fluoride gel affected the wear and roughness of worn surface, but the type of failure was only affected by ceramic type [109].

2.3.1.3. Dental amalgam. Considering the color being very different from that of dental tissue, metals and alloys are mainly applied to orthodontic appliances and dental implants nowadays, and only amalgam filling is used as dental restoration. Amalgam, commonly called amalgam alloy, is composed from a mixture of mercury and powdered alloy made mostly of silver, tin, copper and so on [110], and has been successfully used as one of the most popular direct restorative materials by dental profession for more than 200 years.

The major attraction of amalgam alloy is the proven longevity due to its high wear resistance from the metallic character in clinical service and ease of clinical use [111]. Thus, many researchers use the amalgam as a comparator to evaluate other dental materials in earlier studies. Hu et al. [112] compared the relative wear resistance of a selection of current dental composites and amalgam to assess their relative potential clinical wear resistance under variable masticatory loads, and finally they divided the tested composites into two degrees of wear resistance including better and worse than the amalgam. Additionally, it was found that an increase in the hardness value of amalgam usually led to improved abrasion resistance [111].

However, there are still some disadvantages about the amalgam, such as its aesthetics and the high toxicity of mercury, the weak corrosion-resistance, the low fracture toughness and tensile strength, the brittleness, and so on [111]. It has been widely accepted that ions, especially mercury and some other heavy metal, of the constituent elements are released into the body during the corrosion of dental amalgam in the long run [113,114]. Given that the corrosive characteristics of dental alloys are of both fundamental and applied interest, because corrosion not only affects the functionality of dental constructions but may also cause pathological phenomena, related research work mainly focused on the corrosion of amalgam in the last decade [115]. Much has been done on the corrosion of dental silver amalgam from different point of views, such as the release of mercury and other metals, the electrochemistry under sliding wear condition, the metallography, the discoloration and other aspects. From the aspect of electrochemistry, a recent research proved that the existence of an electrically insulating layer, which is probably composed of non-metallic corrosion products, biofilms, and dental calculus, could reduce galvanic corrosion rates to small or negligible values [116]. While from the aspect of metallography, considering both the corrosion and the strength, the results of Chung et al. [117] indicated that the corrosion resistance of high-copper single-composition amalgam, whose mechanical properties could be significantly improved by a certain amount of steel fibers [118], could be improved by Ag-Cu nanoparticle-doping.

2.3.2. Tribology related to dental implants and orthodontic appliance

2.3.2.1. Dental implants. Pure titanium (CP-Ti) and its alloys have been widely applied to dental implants due to excellent biocompatibility, corrosion resistance and light weight. However, CP-Ti is inferior to conventional dental alloys in tribological characteristics [119,120], and its wear resistance can be improved by alloying [121].

Nowadays, although CP-Ti and its alloys are the most commonly used materials for dental implants, the release of toxic elements (e.g. Al and V) due to tribocorrosion in the mouth and the so-called stress-shielding effect are still a concern. Recently, β and near-β titanium alloys with reduced elastic modulus and biocompatible alloying elements have been developed to overcome these issues [122]. Golvano studied the tribocorrosion behavior of the near-\beta Ti13Nb13Zr alloy in oral environment, and their results revealed a negative influence of the increase of fluoride concentration and the acidified artificial saliva on the material degradation [123]. It was suggested that both the cast and sintered Ti6Al4V alloys exhibited same tribocorrosion mechanisms, and there existed a critical fluoride concentration above which corrosion and tribocorrosion rates of Ti6Al4V alloys increased [124]. Copper in titanium-copper biomedical alloy was proven to increase the amount of eutectoid in the grain boundary, favouring the formation of Ti₂Cu intermetallics and increasing the hardness of the alloys, and thus total material loss due to the wear and corrosion decreased with the increase in the Ti₂Cu intermetallics [125]. In order to improve the tribocorrosion resistance of Ti alloy implant surface, Oliveira et al. focused on the incorporation of magnesium, together with calcium and phosphorous, in the structure of titanium oxide films produced by micro-arc oxidation, and they found that the addition of magnesium would support the formation of rutile which could improve the tribocorrosion properties of the surfaces [126]. The results of Mathew et al. indicated that the lipopolysaccharide in saliva could negatively affect the corrosion/wear behavior of titanium, which may contribute to the failure of dental implants [127].

It should be noted that fretting wear may result in the failure of dental implants [128]. Yu et al. investigated the tangential fretting behavior of titanium alloy (TC4) against human cortical thighbone to understand the fretting behavior of the fixation interface of dental implants [129]. Their results indicated that during the long service process of dental implants, the repeated action of occlusal load would result in a variation of the initial contact condition of the bone-implant interface with the accumulation of surface damage, and thus loosening occurs to dental implants. That is the non-medicinal reason why the failure rate of dental implants' fixation interface increases over time after osseointegration.

2.3.2.2. Orthodontic appliance. It has been accepted that increased friction between mucosa tissue and the surface of

metallic brackets can cause pain and discomfort of oral mucosa [130,131]. The friction behavior of orthodontic metallic bracket-wire combinations is associated with such factors as archwire and bracket materials, their size and shape, width and slot dimensions, surface composition, roughness and cleanliness, bracket-to-wire positioning in a 3-dimensional space, the ligature force and the type of ligation, interbracket distances, and lubrication.

2.3.3. Challenges

Significant effort has been devoted to improving the tribological properties of dentalmaterials. As a result, the clinical outcomes of current artificial dental teeth have been improved considerably. Nonetheless, there are still a number of challenges. Ideally, the tribological properties of artificial dental teeth should be similar to those of human tooth enamel. To date, these properties may only befound in dental ceramic materials and particular metal alloys [82], and the wear of many dental resincomposites is still considerablein vivo in the long run. Moreover, most in vitro studies have only focused on providing comparative ranking of various dental materials, but not aimed at revealing their wear mechanism. Given that an understanding of the fundamental underlying wear mechanisms involved will lead to a better understanding of in vivo failure patterns, the lack of these aspects may be one of the main obstacles hindering the development of dental materials.

2.4. Surgical instruments

Surgical instruments can be generally divided into six classes by function. These classes are: cutting instruments, grasping or holding instruments, haemostatic forceps, retractors, clamps and distractors, accessories and implants. In recent years, Minimally Invasive Surgery (MIS) and gastrointestinal endoscopy are generally popular surgical operations, which is accompanied by some tribological problems occurred at the interface between minimally invasive grasper or endoscopy and tissues.

2.4.1. Friction at minimally invasive grasper-tissue interface

Minimally Invasive Surgery (MIS) is almost self-evident

that minimally invasive procedures have clear clinical benefits to patients when compared to "open" procedures. By virtue of the minimal invasion, performing any procedure less invasively results in less soft tissue disruption, with the effects of reduced pain, faster healing and better recovery [132]. As a byproduct of minimally invasive techniques, patients require shorter hospital stays and return faster to normal activity [133]. However, these minimally invasive procedures have also incorporated the disadvantages of limited dexterity, lack of 3D visualization, poor ergonomic design and lack of haptic feedback, which reduce the accuracy of force feedback to the surgeon from the tool-tissue interaction [134–136]. As the

surgeon is no longer in direct contact with the patient or

surgical tools and must use only their visual sense to

approximate the tool-tissue interaction forces, the surgeon's

perception of the tool-tissue interaction forces may be higher

or lower than the actual force at the tool tip. Higher force usually induces tissue trauma, while lower force can cause grasper and tissue slipping when dragging tissue, reducing operation efficiency [137,138]. The function of laparoscopic graspers is to realize clamping, gripping and dragging organ or tissue. There exists friction behavior at the laparoscopic grasper-tissue interface, which would usually result in tissue damage. Excessive pressure during organ and tissue retraction with laparoscopic graspers is one of the causes of intraoperative injury in laparoscopic interventions [139,140]. It is reported that grasper-related traumaduring laparoscopic procedures has a 2-4% risk of injury to the bile duct, bowel, vascular structures, significantly higher than in open abdominal surgery [140-143]. An observational study by Tang et al. [144] found that 66% of human errors identified during laparoscopic cholecystectomy were related to graspers, 13% of which, in turn, were related to excessive force exertion.

On the investigation of the pressure distribution of graspertissue interaction, Payandeh et al. [145] has shown that the average magnitude of the grasping force in a typical palpation task is approximately 12.5 N. Similar research studies have foundthe maximum grasping force was 16 N [145,146]. Cartmill et al. [147] found that the pinch force required to prevent tissue slipping out of the grasper, while hanging from the tissue a 250 g load at a direction perpendicular to the plane of the end effector, generated localized peak tissue stresses as high as 800 kPa, which was beyond the safety threshold of 200 kPa estimated by De et al. for cell apoptosis in abdominal organs [148,149]. Some researchers designed a laparoscopic grasper equipped with strain gages or sensors and then conducted *in vivo* and in situ experiments with different tissues to measure forces during grasping [135–137,150].

On the investigation refered to the friction between laparoscopic grasper and soft tissues interfaces, Frank et al. [151] preliminarily tested the friction behavior between the clamp and the small intestine in laparoscopic operation, the result showed that the friction coefficient was $0.6 \sim 0.9$ and 7 N of sealing force was recommended to prevent leakage. Li et al. [152] studied the friction behavior at minimally invasive grasper-liver tissue interface under different clamping forces and dragging speeds. The results revealed that the injury degree of the liver gradually increased with increasing clamping force. The maximum static friction force increased with increasing clamping force and dragging speed, and dragging displacement before sliding increased with increasing clamping force and decreasing dragging speed, which indicated that low clamping force and high dragging speed may be more likely to cause slipping at the jaw-liver interface. Oldfield et al. [153] examined tool-tissue interactions, strain energy release rate and deformation by using blade insertions into a gelatin soft tissue phantom experiments and accompanying finite element simulations.

In most of the studies above, the compressive stress was measured and computed by finite element analysis, however, the tractive force or friction force during dragging tissue was still rarely studied. The combination of critical pressure values and friction force which neither induced tissue injury nor cause tissue slipping out of the grasper are not clear. Little current data is available to suggest stress magnitudes that are safe for tissue manipulation, which is an important safe threshold for doctors during grasping task in MIS.

Moreover, modern laparoscopic graspers usually have a tooth structure at the end effector to improve the efficiency of clamping. However, this structure may cause non-uniform pressure distribution, and the obvious damage appeared in the tissue site contacted along the jaw edge, which suggested that the tissue damage is not only associated with excessive clamping force, also related to the structure of the grasper [152]. Thus the pressure distribution from graspers with different structures is important for analysis of tissue damage mechanisms, which should be done as future work by using numerical simulation.

2.4.2. Friction at endoscopy and esophagus or colon interface

For gastrointestinal diseases, conveying gastrointestinal endoscope through the digestive tract, such as, to the lesion location, and conducting operation such as checking, ablation, removing or stripping the diseased tissue, are the most basic clinical treatments in digestive system (Fig. 5). For example, endoscopic submucosa dissection [154] and endoscopic mucosal resection [155,156] are the proper treatment of early gastrointestinal tumors. However, either diagnosis or treatment of gastrointestinal tract is a kind of invasive operation through the narrow single port of digestive tract. During gastrointestinal endoscopy, endoscopy is pushed into human digestive tract with the aid of outside force, which may cause a series of complications such as throat abrasion, bleeding, mucosal tearing and perforation of digestive tract due to repeatedly inserting, rotating, pushing and retrieving operation. Nevertheless, these are serious friction damage problems that few studies have focused on.

On the investigation of friction behavior of the digestive tract tissue surface, Accoto et al. [157] first acknowledged and proposed that it was very difficult for minimally invasive devices to pass through the collapsed and bended digestive tract in the initial stages of NOTES (Natural orifices transluminal endoscopic surgery). They measured the variation of

friction coefficient by using the constant weight blocks sliding on the surface of digestive tract at different speeds and found that it increased proportionally with speed. Since then, the study of friction behavior on the digestive tract surface was mainly concentrated on the small intestine. Kim et al. [158] tested the friction coefficient of intestinal surface in closed and open cavity and put forward a five-element viscoelastic model to establish the friction model of small intestine. Li et al. [159] investigated the friction trauma mechanism of small intestine caused by the pulling operation of endoscopy under different normal force and friction time in the process of surgery, and found that the total friction energy dissipation on the small intestine increased with the increasing normal force and friction time, which induced the damage degree of the small intestine aggravation. For the friction between capsule endoscopy and digestive tract surface, some studies examined the influence of capsule shape, dimension, weight, contact area and speed parameters on the friction coefficient of small intestine, and found that the friction coefficient changed between 0.08 and 0.2, which increased with the increasing speed, and decreased with the increasing normal load. The influence of capsule weight and contact area on the friction coefficient was trivial [160-164].

Although a few studies referred to the friction between endoscopy and digestive tract tissue surface, the viscoelastic characteristics of the internal organs and the frictional resistance of the endoscope inside the body are still not clear. These are definitely necessary since the power consumption and position control of the endoscope are largely affected by these characteristics [165]. Moreover, it is hard to perform experimental investigations inside the human body because of the cost and safety, whenever the data are required for the endoscope design. In addition, complex digestive tract environment has been one of the greatest obstacles of the development of the endoscopy and capsule robot. Different parts of the digestive tract have different diameters, wall thickness, lengths of villi and so on. The influence of the biodiversity of the digestive tract on the frictional resistance can be revealed by a lot of experiments, which can provide the basic data for safety operation and damage control during gastrointestinal endoscopy.

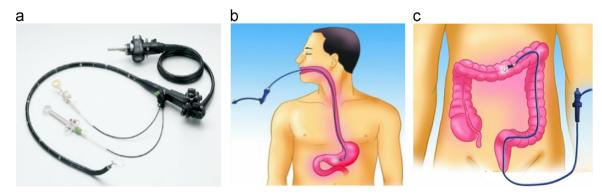


Fig. 5. Schematic diagram during gastrointestinal endoscopy, (a) Gastrointestinal endoscope, (b) Endoscopic diagnosis and treatment through upper gastrointestinal tract and (c) Endoscopic diagnosis and treatment through lower gastrointestinal tract.

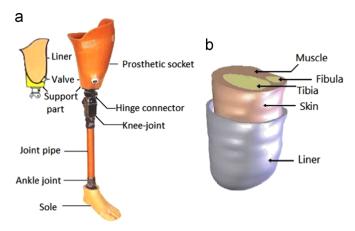


Fig. 6. Artificial limb, stump and prosthetic socket, (a) prosthesis structure and (b) stump and liner.

2.5. Artificial limbs stumps/sockets

In recent years, the prevalence rate of people with amputations has risen due to production safety accidents, traffic accidents, diseases, aging, etc. Artificial limbs enable amputees to retain upright mobility capabilities and restore appearance. The suspension system and socket fitting of artificial limbs have major roles and vital effects on the comfort, mobility, and satisfaction of amputees [166,167]. Coupling between the prosthesis and trans-tibial stump is typically achieved by a socket (Fig. 6), which is a critical component for prosthetic performance and the sole means of load transfer between the prosthesis and the stump in current prosthetic practice [168– 170]. Several systems are employed to secure the stump inside a socket and connect the suspension system to the pylon (adaptor) and the foot. These systems include the belt and suprapatellar cuff [171], figure-of-8 belt [172], sleeve suspension [173], supracondylar-suprapatellar suspension [174], supracondylar suspension, thigh corset silicon liner suspension, and distal locking pin, lanyard, and suction suspension [175,176]. The residual limb-socket interface is filled with a liner and is in direct contact with the skin and socks. Unfortunately, the skin and underlying soft tissues of the stump are not well-suited for load bearing, although the liner works as a cushion for the residual limb and alleviates shock from the contact between the prosthesis and the residual limb. The interfacial friction between stump skin and prosthetic socket materials and liners is very execrable [177,178], which usually causes elevated internal friction injury and pain in the epidermis and muscle tissues of the stump, such as pressure ulcers, blister, cysts, edema, skin irritation and dermatitis [177,179]. In addition, the frequent friction between residual limb and prosthetic material can cause the prosthetic material wear, aging and failure. Thus, the tribological factors are very important in the limb skin-prosthetic socket interface design and fitting.

Concerning the interface interaction between the stump skin and the prosthetic devices, most studies paid attention to the interface pressures and resultant shear stresses in trans-tibial amputee in the last 40 years. The most common method is a

patient-specific modelling approach which involved an MRI scan, interface pressure measurements between the residual limb and the socket of the prosthesis and three-dimensional non-linear large-deformation finite-element (FE) modelling to quantify internal soft tissue strains and stresses during static or quasi-dynamic load-bearing [180–188]. The information gained has been used for the assessment and improvement of prosthetic socket design and fitting. For example, Zhang et al. studied the pressure, shear stress and frictional action at residual limb-prosthetic socket interface [168,169,177,180]. The results reveal that the fiction applied to the stump skin produces stresses within tissues and the these stresses may damage the tissues and affect their normal functions. The combination of normal and shear stresses is considered to be a critical factor leading to amputee's discomfort and tissue damage. However, the friction plays a critical role both in supporting the load of the amputee's body during the support phase of the gait cycle and in preventing the prosthesis from slipping off the limb during swing phase. A larger pressure was produced at the lubricated interface than at the normal interface. A proper choice of coefficient of friction will balance the requirements of relief of load stress and reduction of slip with the general ability to support loads. From the perspective of the residual limb skin damage caused by friction, Li et al. researched the frictional behavior and comfort sensations of the limb scar skin and prosthetic wearing skin against prosthetic socket material [189]. Due to the changes of skin histological structure and surface roughness, higher friction coefficient with higher fluctuation has been obtained for the scar skin and it is sensitive to the comfortless sensations induced by friction contact with prosthetic socket material. By comparison, the prosthetic wearing skin has lower friction coefficient and is tolerant to the comfortless sensations. They also investigated the rehabilitation and adaptation of lower limb skin to friction trauma during long prosthetic wearing process [190,191]. There would exist optimal critical friction parameters, such as normal load, friction frequency and time, which would avoid the trauma. These results would be useful for the new amputee to arrange the best policy of capability training. Moreover, the interaction between different prosthetic socks and residual limb skin was studied by Li et al. [192]. The results showed that the weave parameters, surface features and material composition of socks fabrics have the crucial effect on the tribological behaviors, mechanical irritations and comfort sensations of stump skin. The friction coefficients were higher when the wool and nylon socks slid against skin due to their coarse knitting weave surfaces and hard protruding textile fibers, causing clear microscopic trauma to the skin, accompanied by skin irritations and discomfort.

Other than that, tribological factors could not be revealed adequately in the limb skin-prosthetic socket interface design and fitting, the effective transfer of tangential and normal load at residual limb-prosthetic socket interface is also need to analyze accurately, and the studies on the stump skin trauma under the friction condition of prosthetic socket are still very limited, which are the key factors in future prosthesis design and fitting.

Moreover, the improper prosthetic materials often cause skin damage from the tribological point of view. Therefore, it is necessary for prosthetic limb manufacturers to improve prosthetic socket design and fitting, and choose better biocompatible materials with the skin such as silica gel, etc, which can improve the contact comfort and avoid the skin damage.

2.6. Ocular contact lenses

Contact lenses are used widely to correct vision. Currently over 140 million contact lenses are used worldwide [193]. Despite the improvements of new lens materials and care systems, clinical problems such as dryness and discomfort are still widely reported and more severe complications such as contact lens-induced lid-wiper epitheliopathy and lid-parallel conjunctival folds are still present [194]. The insertion of a contact lens forms two interfaces with the natural eye, one with the lid wiper (pre-lens) and the other with the ocular surface (post-lens). Both relative motion and loading are involved at these two interfaces and therefore tribology plays an important role in the blinking of the eye as well as the successful function of a contact lens.

Lubrication between the contact lens and the eye is critically important [194]. Fluid film lubrication in the presence of the tear film ensures minimum friction, smooth motion and negligible damage in the eye during blinking. However, at the beginning, end, and return points of the blinking cycle where there is relatively small motion between the lid wiper and a contact lens, boundary lubrication may be dominant, and a complementary surface-brush boundary lubrication mechanism comes into operation. At the back of the contact lens in contact with the ocular surface, the speed is relatively low and the brush lubrication mechanism is also dominant. Therefore a synergistic lubrication mechanism is expected for a contact lens to function normally in the eye. Important considerations include the lens materials, the wetting agents etc. as well as the tear film, and particularly their interactions [195]. The structure of the tear film and composition (proteins, lipids, and mucin) are critically important in the tribological and clinical functions of a contact lens [196,197].

New soft contact lens materials with high water content surfaces or incorporated wetting agents such as poly(vinylpyrrolidone) (PVP) or poly(vinyl alcohol) (PVA) have been developed to reduce friction between the contact lens surface and the lid-wiper [194]. The coefficients of friction in these new materials have been shown to be much lower, than those of the first-generation soft, silicone-hydrogel contact lenses [215]. The tribology of the pre-lens interface in these low friction soft materials can be expected to be similar to the normal eye [194]. Under this ideal condition, the effects of the contact lens on the tribology of the eye may not be important. However, a high friction contact lens or lack of the tear film in dye eye patients may induce high shear stress and may negatively impact the brush lubrication, potentially leading to wear. Wetting agents such as water-soluble surface-brushes are

introduced, particularly for dry eye patients [198]. It has been further revealed that adding a wetting agent is important to maintain low friction even when the contact lens was aged and worn [199]. In addition, the elastic modulus of the soft contact lens materials may also plays an important role [200]. The tribology of the post-lens interface may influence the overall function of a contact lens, particularly the brush lubrication mechanism, because of a much reduced speed [201]. The surface topography of a contact lens is another important factor in the tribological function [202].

The successful clinical function of a contact lens depends critically on the tribology of the two interfaces formed with the eye. Both fluid film lubrication and brush-type boundary lubrication mechanisms are important to maintain low friction and minimum shear stress. The material composition and structure of a contact lens are important considerations.

2.7. Cardiovascular devices

Cardiovascular disease includes conditions that affect the structures or function of the heart or blood vessels, such as coronary artery disease, heart failure, heart valve disease, vascular disease (blood vessel disease) etc. It is the leading cause of death globally among noncommunicable diseases. Sometimes mechanical interventions using medical devices are necessary for end-stage diseases. These include blood vessel prosthesis, heart valve, pacemaker, stent, catheter, heart assist devices etc. These devices interact with blood in relative motion and must be designed to avoid blood damage in contact, while at the same time, allowing sufficient washouts. Blood damage can lead to thrombosis, coagulopathy etc. [203]. Furthermore, mechanical cardiovascular assist devices often exhibit relative motions between components. Tribological principles of cardiovascular implants are therefore important considerations in the design of these medical devices.

Mechanical circulatory support medical devices include left ventricular assist devices and total artificial hearts [204,205]. One of the key elements in the design of these devices is the bearing of the rotating components [206]. It is important to maintain an adequate lubricant (blood) film to avoid blood damage and provide sufficient washout. This is usually achieved through the optimization of the bearing geometry [207,208].

Mechanical heart valves are still used extensively to treat aortic valve diseases [209]. Erosion and wear of heart valve components is often present [210]. New coatings are constantly developed to minimize the formation of thrombosis while at the same time to improve the wear resistance of the leaflets [211].

Friction is important when a vascular stent is inserted [212] and at the contact between the stent and the blood vessel [213]. The passage of a lead in tissues and in the cardiovascular system, such as a pacemaker or a defibrillator, may trigger wear, particularly when a combination of two or more materials is used [214].

3. Summary

Medical devices are extensively used in current clinical practices to treat various diseases. There are a number of limitations of current medical devices, some of which are closely associated with tribological problems. The future requirements for medical devices are even more challenging, as a result of more active and younger patients and increased life expectance of patients. It is also important to consider medical devices in the context of patients and surgeons. It is being increasingly recognized that the design of a medical device must be considered in conjunction with patients and surgeons. Although patient specific designs have been advocated, only the patient anatomy is mainly addressed. More important considerations in the development of patient specific implants should include the functions, particularly the biomechanics of loading and function. Improvements of the medical devices should help develop more natural physiology, while at the same increase durability and longevity. Compromises may have to be thought. Furthermore, while innovations in medical devices are important, increased regulations are also required to balance the potential risks and the safety [1].

Biotribology considerations are important for a number of medical devices involving relative motions currently in clinical use. While a fluid film lubrication mechanism is preferred, as accompanied with minimum friction and negligible wear, such an ideal lubrication regime is often difficult to achieve inside the body. Furthermore, intermittent motion and adverse conditions must also be addressed, as the break of the fluid film lubrication may significantly increase friction and wear. Effective boundary lubrication mechanisms and intrinsically wear resistance properties of the bearing surfaces are also required. While this is feasible in a contact lens, difficulties in artificial joints are still present.

Modularity is an important design consideration of medical devices to balance patient specificity and cost. Different materials are often used in a modular connection for different purposes. Galvanic corrosion and more importantly fretting corrosion is common at these interfaces of a medical device implanted in the body. It is important to choose appropriate biomaterials as well as to optimise designs. The patient and surgical factors are also important considerations.

Medical devices are working in the human body as a system. It is increasingly important to address the multi-scale and multi-physics problems encountered in a medical device. As illustrated with a typical medical device of a hip implant (Section 2.1.2), coupling the biomechanics of the joint at the skeletal level and the tribology of the bearing surfaces at the joint level is essential to address the effects of the patients and the surgeons on the performance. The interactions between the biomechanics of the jaw and the tribology of the tooth can also be expected to be true and should be investigated together. Furthermore, it is important to investigate the interactions between the tribology at the bearing surfaces and the fretting corrosion at the modular junctions. Such interactions are also expected to be present in other medical devices.

Realistic *in vitro* simulation of the operating environment is becoming more important as part of pre-clinical evaluation of the safety and effectiveness of a medical device. Extensive development has been made in the area of artificial joints. However, for other medical devices such as dental implant and contact lens, full *in vitro* simulation of the working environment is still lacking. Furthermore, more robust testing under even more severe conditions is required in order to capture the worse-case scenario and to ensure the safety of medical devices

New materials and medical devices are constantly being developed to improve the treatment of existing and new clinical problems. There is also a paradigm shift for medical treatments to be more conservative and more minimally invasive, such as more natural healthy tissues are kept. This has been the case in dental care, however, in the joint, cartilage repair and regeneration has only received significant attention recently. As a result, the natural tissue may become an integral part of a medical device or the scaffolds may become natural tissues ultimately. Design and testing of such devices is challenging, since not only the mechanical environment but also the biological environment need to be simulated. Furthermore, new technologies, such as 3D printing, are being pushed into the field of medical devices and allow patient-specific implants and custom-made devices to be made. Design and manufacturing as well as testing and evaluation of these innovative medical devices may require specific considerations.

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