Fall 10-17-2023

Corrosion of implant materials in the human body

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Introduction

Greeks and Egyptians used wood and animal bones to repair fractures. Developments in modern medicine and material science led to the evolution of biomaterials. The first synthetic material was a gold plate implemented for cleft palate repairment in 1546, and since that time metallic medical devices have been used in humans (Eliaz 2019). Due to a rise in the senior population and longer life expectancies, there have been substantial requests for the installation of medical devices in recent decades. The search for solutions to the health issues an ageing population faces is one of the most challenging jobs of our day.

Biomaterials have been used to augment, replace, and repair tissues and structures in the human body, although they are prone to corrosion (Table 1). Corrosion, an inherent phenomenon when considering metals, is the irreversible loss of metals brought on by their physical, chemical, or electrochemical contact with the environment via a variety of mechanisms, including biocorrosion, stress cracking corrosion, intergranular, galvanic, and pitting.

Table 1. Listing of metallic implants used today. (Gilbert 2017) © 2017, NACE International

List of Metallic Implants		
1	Orthopaedic	Hip, knee, shoulder, elbow, ankle, finger
2	Dental/ Oral/Cranial	Dental implant, crowns, fillings, bridges, temporomandibular joint (TMJ), cranial plates, screws
3	Spinal	Spinal fusion, spinal disk replacements, spacers, fillers, rods, screws, hooks
4	Cardiovascular	Cardiovascular or peripheral stents, heart valves, pacemakers, vena cava, filters, aneurysm stents, coils, ventricular assist devices
5	Neurological	Electrodes, deep brain stimulation and sensing
6	Gastrointenstinal	Esophageal stents, insulin pumps
7	Urological/ Gynecological	Stents, catheters, intrauterine device
8	Fracture Fixation	Rods, plates, screws, nails

Because corrosion plays a pivotal role in the release of metal cations into the body milieu and in the deterioration of the implant, it must be taken into consideration while evaluating the biocompatibility of biomaterials. Metal cations, complexes, and anions are produced by electrochemical corrosion and chemical dissolution processes, and metal particles can wear off the implant surface. These ions, proteins that have reacted with them, and particle debris on the implant-tissue interface may travel through the tissue and even enter the bloodstream, which may affect several biological parameters.

Temporary implants are often removed by surgical operation and are mostly made of stainless steel. Permanent implants are made of stainless steel, Ti-alloys, Co-alloys, and other comparable materials, which form a protective surface oxide (Singh and Sharma 2023). In a worst-case scenario, corrosion can disintegrate the implant, which will ultimately cause the implant to become brittle and fracture (implant failure). However, even relatively small amounts of released metal species can cause adverse clinical outcomes, such as infection, inflammation, and allergic reactions, requiring the revision of the implant. This second procedure causes greater stress for the patients and more costs (Song 2007).

Different types of corrosion in body

Tribocorrosion: Wear-Corrosion of Bearing Surfaces of Metal-on-Metal Devices: Tribocorrosion of bearing surfaces can be caused by a multitude of factors, including motion, the presence of particles and an electrolyte, hard-on-hard contact, and environmental influences, such as encountering chemicals and interacting with compounds produced by adhering biofilms and inflammatory cells (Mombelli, Dena and Norbert 2018).

Microbiologically influenced corrosion (MIC): Microbiologically influenced corrosion, also known as biocorrosion, is the term used to describe the metals' accelerated degradation because of biofilm formation on their surfaces, which is usually accompanied by other corrosion mechanisms (Beech and Sunner 2004). MIC develops as a localized attack in the form of pitting due to the morphology of biofilms, which typically appear as a heterogeneous, non-continuous deposit or coating on the metallic surface (Beech and Sunner 2006).

Galvanic: An accelerated corrosion of a metal driven by the presence of two different metals in a corrosive electrolyte are known as galvanic corrosion (Reclaru, et al. 2002).

Stress corrosion cracking: An external stress (often static and tensile) or residual stresses (from manufacturing) and a reactive environment operate together to cause stress corrosion cracking (SCC), which is the formation of cracks through the combined mechanical and chemical action in alloys, often involving chlorides (Shoji, Lu and Peng 2011).

Metallic Biomaterial alloys

In order to be used for the augmentation or replacement of body tissues, biomaterials need to be nontoxic, non-carcinogenic and possess sufficient mechanical and physical properties. Examples of metallic biomaterials with superior mechanical qualities, outstanding biocompatibility, and effective corrosion resistance are stainless steel, titanium and its alloys, and cobalt-chromium alloys (Wilson 2018).

Titanium

Due to its strong corrosion resistance, high biocompatibility, low specific gravity, high specific strength, and lack of magnetic characteristics, it is highly desirable for a variety of specialized applications, including medical implants, especially dental implants, particularly for people who are allergic to other common metals. The mechanical and chemical tensions that titanium implants experience inside the human body can cause physicochemical corrosion, which may contribute to implant failure, loosening or the release of titanium ions and particles. Additionally, corrosion results in the release of ions and oxides, which may cause titanium hypersensitivity and allergy (Fig. 1) (Chen and Thyssen 2018). Inflammatory responses and systemic consequences have been seen in specific situations.

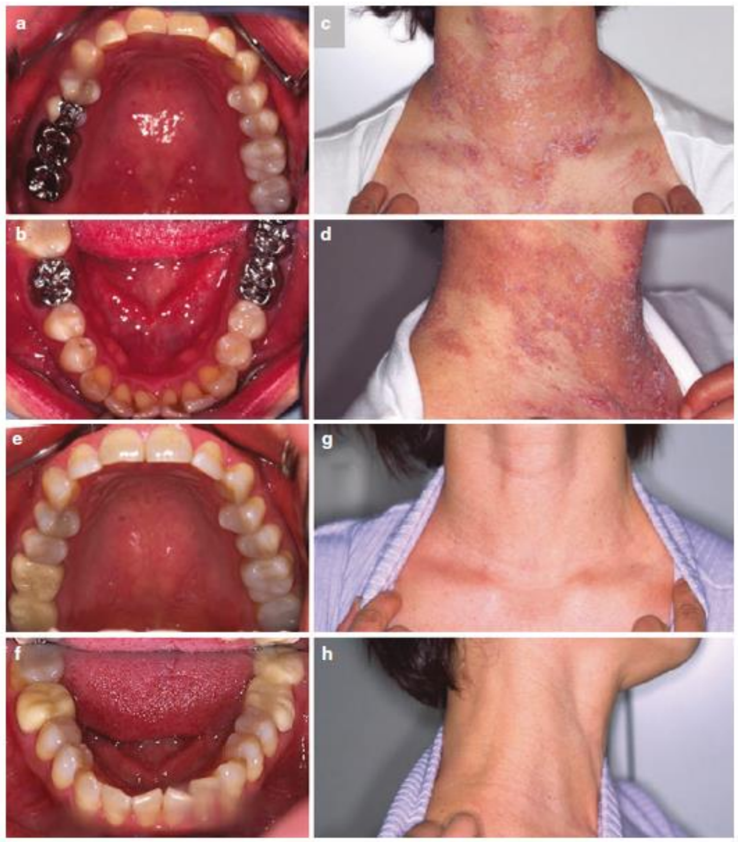

*Figure 1. Hypersensitivity to Titanium dental implant. (**a**) maxillary and (**b**)mandibular arches of a woman with titanium crowns. (Chen and Thyssen 2018) (c,d) after 9 months, she developed worsening eczema on her neck. (e,f) removal of implants. (g,h) after 3 months of removal all symptoms went away. © 2018, Springer International.*

As stated in the “Handbook on the Toxicology of Metals: Volume II: Specific Metals, chapter of Titanium.” (Nordberg and Costa 2021), titanium particles can suppress the osteogenic differentiation of human bone marrow stroma-derived mesenchymal stem cells. Also, there was a decrease in bone marrow cells, which undergo apoptosis, and simultaneously there was an increase in the levels of tumor suppressor proteins. The size of the titanium particle affects its in-vitro cytotoxicity toward human neutrophils; the smaller the size, the more poisonous the titanium particle (Nordberg and Costa 2021). Moreover, an increasing number of studies report that the release of titanium particles from the implant might cause inflammatory reactions, cytotoxicity, osteolysis, and bone resorption (Nordberg and Costa 2021).

Cobalt

Due to their great wear resistance and biocompatibility, cobalt alloys are frequently utilized to create prosthetic joints, such as knee and hip joints. Wear, corrosion, and processes, including fretting, tension, and fatigue, cause the release of cobalt ions and nanoparticles from prosthetic materials. The cobalt chapter of the “Handbook on the Toxicology of Metals: Volume II” has stated that during metal-on-metal total hip implant revision surgeries metallosis was seen, which is a negative local reaction to ions or particles released by the failed implant and can cause severe deterioration of bone and soft tissues, aseptic lymphocytic vasculitis, and pseudotumors in addition to asymptomatic tissue damage (Nordberg and Costa 2021). The elevated levels of cobalt in bodily fluids after hip implant surgeries have been seen in a variety of reports, causing different symptoms, including general ones (fatigue, weight loss), central neurologic symptoms (deafness and vision deficiency), polyneuropathy, hypothyroidism, cardiomyopathy, and dermatitis (Nordberg and Costa 2021).

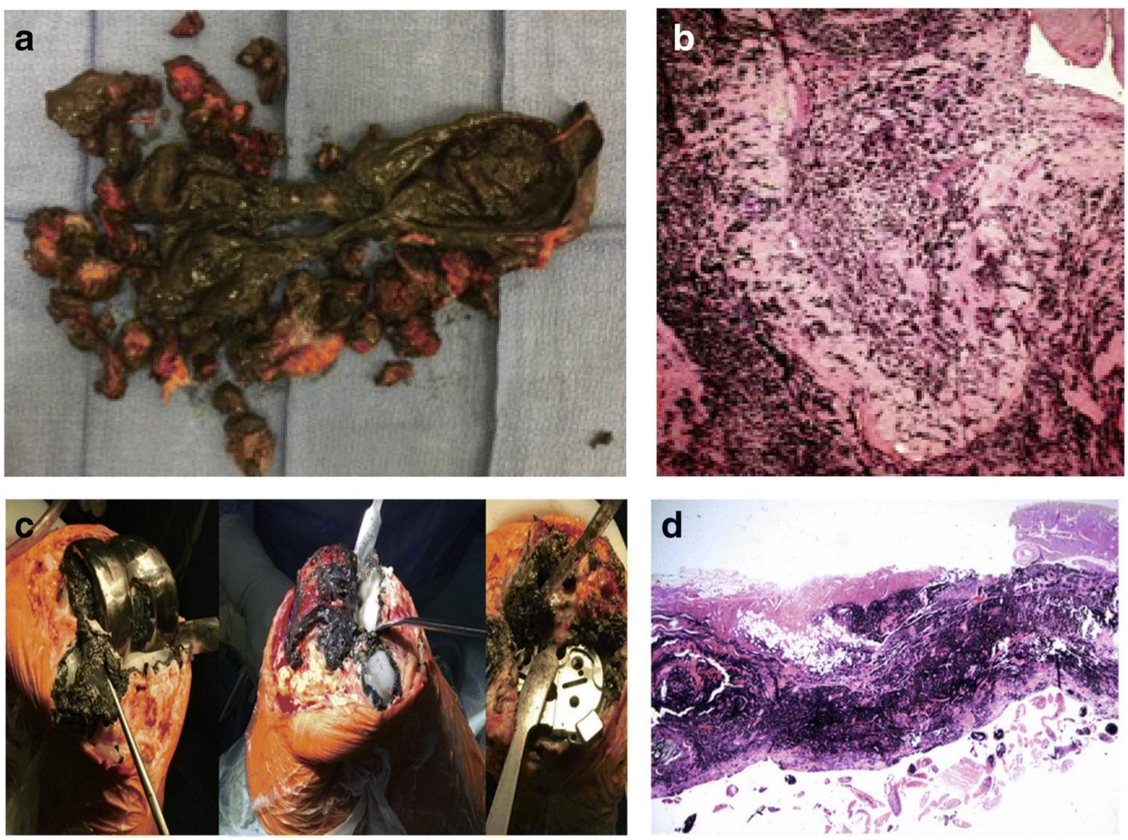

Figure 2. a) Intraoperative pseudo-tumor in hip arthroplasty, b) Microscopic findings of pseudotumor indicating metallosis, c) Intraoperative photograph of black staining in knee arthroplasty, d) Microscopic photograph of metallosis from knee arthroplasty (Ude, et al. 2021). Copyright © 2023 Springer Nature.

Chromium

Chromium alloys make up a large portion of orthopedic implants. Chromium forms a passive film which is crucial for all corrosion-resistant chromium alloys such as stainless steel, Inconel (nickel-chromium alloy), and cobalt-chromium alloys (dental implants and artificial joint prostheses) (Chen and Thyssen 2018).

After nickel and cobalt, chromium (Cr) has historically been the third most frequent metal allergy; however, depending on the country and the location, it can vary from the first to the fifth most common metal allergen. In general, the likelihood of developing allergic Cr contact dermatitis rises with age (Chen and Thyssen 2018). The formation of hexavalent Cr, the most toxic and a carcinogenic form of Cr, is unlikely in the implant environment in the human body unless there is a highly oxidative environment due to disease, electrochemical oxidation, or electric devices (Hedberg and Odnevall Wallinder 2014, Swiatkowska , et al. 2018).

Knee and hip replacement

Total knee arthroplasty (TKA) and total hip arthroplasty (THA) are effective procedures for patients with hip and knee osteoarthritis suffering from pain. Tilbury *et.al* (2015) studied patients under 65 years for 3 years (2010-2013) to assess the return-to-work period in patients receiving TKA and THA in the Netherlands (Tilbury, et al. 2015). They demonstrated that a significant majority of working patients were able to return to work after 1 year and the mean time to return to work was 12 weeks. About 20% of the patients could work less hours compared to their work status before surgery. According to the Canadian Joint Replacement Registry (CJRR) annual report of the Canadian Institute for Health Information (CIHI) for hip and knee replacements in Canada, there were about a combined 117,000 and 110,000 joint replacement surgeries for both joints for 2021–2022 and 2020-2021, respectively (Hip and knee replacements in Canada: CJRR annual report 2020–2021 2022, Hip and Knee Replacements in Canada: CJRR Annual Report, 2021–2022 2023).

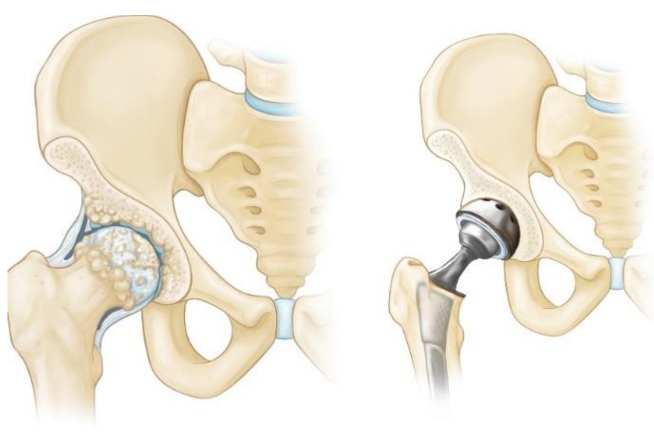

Figure 3. (Left) A hip with osteoarthritis. (Right) The head of the femur and the socket have been replaced with an artificial device (Foran 2021). ©1995-2023 by the American Academy of Orthopedic Surgeons.

Revision Knee and hip replacement

A knee or hip implants are expected to last for 15-20 years in 85-90% of patients who receive them, but even advanced implant bearings and securely fastened parts have a limited lifespan that is more likely to be exceeded in the younger, more active patients (Schwartz, et al. 2020). Meaning that younger patients who received these implants will need another operation to clean the bone surface and refixate the implant or even replace them with a new one which is known as revision total knee or hip replacement. Revision TKA and THA (rTKA and rTHA) surgeries come with extensive preoperative planning, specialized implants and tools, prolonged operating times, and mastery of difficult surgical techniques, and are characterized by higher health complications, risk of infections, and more costs of care (Knee Revision 2020). Schwartz *et al.* (2020) investigated the rates of revision arthroplasty from 2002 to 2014 for rTKA and rTHA. They indicated that there was an increase of 36% and 102% for rTHA and rTKA in 2014 compared to 2002, respectively. They also estimated that rTHA would increase between 43%-70% and rTKA would escalate to 78%-182% until 2030 (Schwartz, et al. 2020).

Infection, instability, stiffness, fracture, wear, and loosening could lead to revision TKA and THA surgeries. Bhandari *et. al.* demonstrated that the most important reasons for revision TKA surgeries are infection and instability (40 & 20%, respectively), while pain, aseptic loosening, and arthrofibrosis are other causes of rTKA (Bhandari, et al. 2012). According to CIHI annual report, the three top reasons for revision (both TKA and THA) during 2020-2021 in Canada were infection (31.3%), aseptic loosening (15%), and instability (14.8%) (Hip and knee replacements in Canada: CJRR annual report 2020–2021 2022).

Revision and gender

Several reports have stated that in comparison to male patients, female patients receive more total hip arthroplasties (THAs) since females are more likely to suffer from osteoarthritis, rheumatoid arthritis, and developmental abnormalities (Caicedo, et al. 2017). Women who receive metal-on-metal THA have a greater rate of implant failure, according to studies using the National Joint Registry for England and Wales. Additionally, the Canadian Arthroplasty Society further established that the failure rate is influenced by gender (Society 2013). Different studies have found that the risk of aseptic revision following metal-on-metal and metal-on-polyethylene THA, including dislocation and periprosthetic fractures, was 32% higher in females than in males (Caicedo, et al. 2017). Caicedo *et. al*. discovered that females with unexplained joint pain after Total Joint Arthroplasty had a higher rate and greater severity of metal sensitization to soluble nickel ($NiCl_2$), cobalt ($CoCl_2$), and/or chromium (Caicedo, et al. 2017). Another study also confirmed that 60% of patients who underwent implant failure, were females (figure 2.) (Onuoha , et al. 2019). Aseptic implant failures have been linked to several biological variables that have previously been identified and characterized. Aseptic lymphocyte-dominated vasculitis-associated lesions, metal toxicity, and excessive innate and adaptive immune responsiveness to implant debris are examples of biological pathways that have been demonstrated to affect aseptic implant failure rates. Furthermore, it is well known that delayed-type hypersensitivity to metal can result in excessive aseptic inflammatory reactions around the bone-implant interface, which may be the cause of a subgroup of patients who need revision surgery for pain that cannot be explained (Caicedo, et al. 2017).

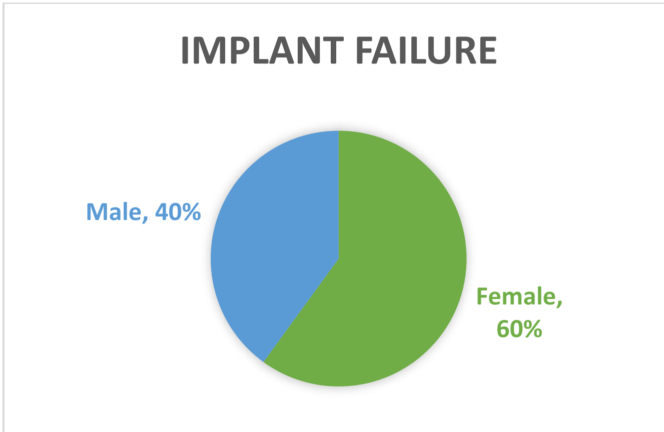

Figure 4. Gender distribution of patients with implant failure (Onuoha , et al. 2019)© All rights are reserved by Onuoha K M.

Cost analysis for hip or knee revision arthroplasty

World view

Joint arthroplasty is a primary surgical procedure involving the replacement of a joint with the goal of restoring its function. It normally involves the articulating joint components being replaced with metallic implants (which could also be made of high-density polyethylene) (Solomon 2017). More primary implant installations during arthroplasty are usually successful and patients recover quickly based on differences in their health statuses and the quality of the procedure. However, there may also be complications in others requiring revision surgeries. In developed countries (e.g., Canada, the US, Britain, and Australia), these procedures are designed so that patients are usually not susceptible. However, there may also be lifetime risks associated with hip or knee revision arthroplasty. In fact, these risks are relatively low in Australia, making it less than 2 in 100 patients for both hips and knees (Ackerman, et al. 2020). During these revision arthroplasty surgeries, implants are carefully replaced with similar ones after removal. However, revisions are technically difficult when compared to primary arthroplasty surgery because intricate implant parts are replaced in such a way as to avoid another repeat procedure. With revision comes longer hospital care, the tendency for infections, and even death. The orthopedic associations of individual countries are responsible for providing comparative numbers for primary vs. revision arthroplasty surgeries per year, countries like Australia and Canada have observed lower admissions due to the suspension of elective surgeries during the COVID pandemic (Morgan and Page 2023). However, this gradually changed when hospitals returned to their normal operations. According to the 2022 annual report of the Australian Orthopedic Association (Australian Orthopaedic Association, 2022. Hip, Knee & Shoulder Arthroplasty: 2022 Annual Report

2022), there were about 73% more patients undergoing primary hip than knee arthroplasty surgeries in 2021. This number stood at 600,000 (hip) and 820,000 (knee), with 7.6 (83,206 cases) and 7.4% (78,373 cases) revision cases needing replacement procedures, for hip and knee, respectively. In Canada, the request for revision continues to increase despite a relatively low number of primary procedures being performed, compared to Australia (Ackerman, et al. 2019).

Cost analysis - Focus on Canada

According to the Canadian Joint Replacement Registry (CJRR) annual report of the Canadian Institute for Health Information (CIHI) for hip and knee replacements in Canada (Hip and Knee Replacements in Canada: CJRR Annual Report, 2021–2022 2023), there were about a combined 117,000 replacements for both joints for 2021–2022. This number is 5.9% more than in 2020–2021, however, lower than pre-pandemic. More than $2.46 billion was expended on hospital costs (excluding rehabilitation fees) between 2020 and 2022, with $60 million more spent in 2021–2022 and double the replacement procedures the year prior. More than 14,700 replacement procedures were performed in 2021–2022. There were 6.0% hip and 5.7% knee replacement procedures, respectively, in 2021–2022 than in 2020–2021; about 58,635 hip and 58,443 knee. There were also more female patients requiring surgeries (with 57% and 58% hip and knee replacements, respectively) than male. There were more hip replacement patients above age 75 (44% female and 31.6% male), while the age of knee patients stood predominantly between 65 to 74 (41.2% female and 42.3% male). Fig. 1(a) depicts the number of hip and knee replacements for osteoarthritis by type of care, Canada, 2018–2019 to 2021–2022. The CJRR report also recorded an estimated cost of $9,387 for patients requiring day surgeries compared to inpatient surgeries ($12,402). There also were 91,600 fewer surgeries post-pandemic compared to 3 years prior while 15.6% replacement procedures (as day surgeries) were performed to treat both hip and knee osteoarthritis in 2021–2022 compared with 2020–2021 (8.2%), 2019–2020 (1.9%) and 2018–2019 (0.7%); more details are depicted in Fig 1 (b). More patients from Ontario, Manitoba, and Alberta, expressed satisfaction with improved quality of life 12 months after these procedures (Hip and Knee Replacements in Canada: CJRR Annual Report, 2021–2022 2023).

It is worthy of note to mention that the need for revision surgeries arises from infection and prosthetic loosening. Prosthetic loosening may be aseptic and septic; while aseptic loosening is linked with chronic inflammation caused by the activation of resident immune cells in contact with implant wear debris, chronic infections at implant sites define septic loosening. These scenarios are intricate and costly to fix as they require surgical and medical interventions with a team of surgeons, microbiologists, infectious disease physicians, allied health clinicians, and nursing staff (Sires, et al. 2022). The financial burden on the patients and the healthcare system is high. According to Okafor et al. (Okafor, et al. 2021), over US$25-82,000 (CAD$34-112,000) may be the combined financial cost of healthcare facilities in high-income countries like Canada, Italy, New Zealand, and Germany. Patient factors are some of the factors affecting complications due to infection. Most of these factors include morbid obesity, active smoking, and diabetes (Helito, et al. 2020, Rothfusz, et al. 2021).

As stated by the Canadian Institute for Health Information (CIHI) and CJRR in 2016-2017, a total of 2012 patients had an early revision (within 2 years) (Early Revisions of Hip and Knee Replacement in Canada 2020). It is stated that the average hospital stay cost for knee and hip revision (excluding those due to infection) is 1.4 and 1.6 times more than primary surgery, respectively ($15,647 versus $10,031 for primary for hip and $12,973 versus $9,184 for primary for knee). Also, it is assumed that the annual direct inpatient expenses associated with early revisions reach more than $42.1 million.

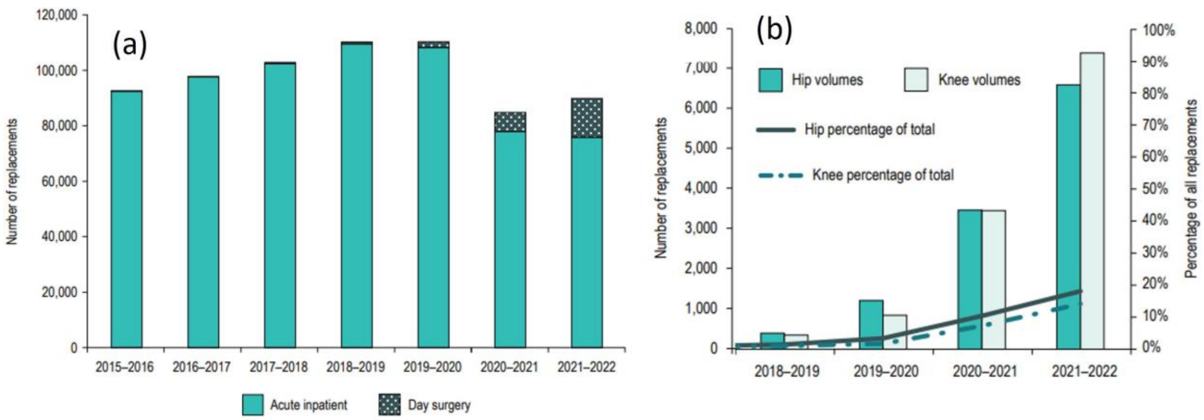

Figure 5. (a) Number of hip and knee replacements for osteoarthritis by type of care, Canada, 2015–2016 to 2021–2022; (b) Number and percentage of hip and knee replacements for osteoarthritis performed as day surgeries, Canada, 2018–2019 to 2021–2022. Source: Canadian Joint Replacement Registry (CJRR) annual report of the Canadian Institute for Health Information (CIHI) for hip and knee replacements in Canada (Hip and Knee Replacements in Canada: CJRR Annual Report, 2021–2022 2023). © 2023 Canadian Institute for Health Information

The Stryker case: Class actions and product recall due to implant failure (wear and corrosion particles)

Implants are designed to make life easier for patients, but some deficient implants caused patients' suffering to worsen based on the severity of implant deficiency. Stryker Corporation has been chosen as an implant manufacturer that received numerous class actions and recalled many of its products in North America. Stryker Corporation was founded as a medical devices and equipment manufacturing company in 1941 by Dr. Homer Stryker to provide products and services in medical and surgical, neurotechnology, orthopedics, and spine. This American multinational corporation has a revenue of US $17.108 billion in 2021 and a net income of US $1.994 billion in 2021.

In 2012, the FDA issued a warning for Stryker Rejuvenate hip replacement which caused the company to be fined US $1 and 2.5 billion, respectively, for their defective Rejuvenate and ABG II hip replacements (Stryker hip replacement lawsuits 2023). Stryker sent surgeons and hospital risk managers an urgent field safety notice outlining the above-mentioned implants' possible health risks, including corrosion and fretting; thus, all implants were recalled, and component production and sales were stopped worldwide. Stryker knee and hip implants use a metal-on-metal (MoM) design in which metal ball and metal socket rub together and become corroded through combined mechanical and chemical processes, which can release metal fragments to the patient's bones, tissues, and bloodstream, and cause joint dislocation, necrosis, and metallosis (Stryker Hip Replacement Recalls 2023). Moreover, if high concentrations of potentially toxic metals like cobalt and chromium enter the bloodstream, it would lead to cardiac and neurological issues (Defective Stryker Knee Replacement Lawsuits: An Overview 2019).

Summary

It can be challenging to diagnose implant failure since it is a complex problem that might include wear, loosening, fracture, instability, infection, and stiffness. Failures related to corrosion should be investigated from several perspectives. It is important to highlight the significance of continued research and collaboration between materials scientists, biomedical engineers, and medical professionals to improve implant design, minimize corrosion-related complications, and enhance patient outcomes. Understanding and addressing implant corrosion is pivotal in the pursuit of safer and more effective medical implants, ultimately improving the quality of life for countless patients.

Acknowledgment

I would like to express my sincere gratitude to my tutor, Prof. Yolanda Hedberg, and extend my heartfelt appreciation for the invaluable guidance, support, and also the creators of Corrosion, Equity, Diversity, Environment, and Society (CEDES) course for their dedication, expertise, and commitment to education. It has been an incredible journey, and I am looking forward to applying the knowledge and skills acquired here in my future endeavors.

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