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ORTHOPAEDIC IMPLANT: A COMPREHENSIVE STUDY OF ASSOCIATED RISK FACTORS

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ABSTRACT

Introduction: Orthopaedic technology plays a significant role, including anything from entirely spinal systems to joint restoration. These devices are often composed of metal, ceramic, or polymer. Orthopaedic surgery has helped millions of patients by restoring their mobility, relieving their pain, and ultimately improving their quality of life. But their high risk of adverse effects such as device breakage, surgical site infections, discomfort, edema, and so forth limited their utilization. So, the primary objective of the current study is to estimate the prevalence of adverse events after orthopaedic implantation.
Methodology: A meta-analysis was conducted on adverse effects of orthopaedic implantation, examining 151 case studies started from year 2000 to 2022, using the Medline, Embace, and Google Scholar databases. The review focused on factors like implant type, patient age, gender, reaction start time, adverse events, clinical presentation, and results.
Result and Discussion: Research verified that male patients experience more adverse effects from orthopaedic implants due to increased BMI, which strains the implants. Lower limb surgery is more common due to weight-bearing implants. Common adverse reactions include metallosis, fracture, and infection. An accumulation of metal ions in the bloodstream causes the implant to become loose, induce inflammatory responses, and cause chronic pain around the implant site.
Conclusion: Factors like implant quality, selection, fixation, fracture geometry, and postoperative care can lead to implant failure. Age and gender should be considered during preoperative planning and postoperative care. Traditional Polyethylene bearing surfaces are suitable for older patients. Patients should receive counselling, informed about implant options, and given weight bearing instructions.

Keywords: Adverse Event, Metallosis, Meta-Analysis, Medical Device, Orthopaedic Implant, Surgical Site Infection

1. INTRODUCTION
1.1. BACKGROUND

Orthopaedic technology is an important aspect of the medical device industry, encompassing everything from joint reconstruction to whole spinal systems or orthoses following traumatic events [1]. A domain that is gradually expanding as a result of the aging population, increasing obesity rates, degeneration, orthopaedic ailments, and sports-related injuries [2]. The orthopaedic profession not only has a rapidly developing market, but it also experiences continuous innovation. New biomaterials, intelligent implants, and 3D printing techniques are all helping to generate ever-better clinical orthopaedic devices that can satisfy a wide range of patient needs. Robotics and automation technology are now essential to the production of these excellent healthcare products [3,4]. The Orthopaedic Devices market is predicted to develop at a compound annual growth rate (CAGR) of 4.06% from 2024 to 2029, reaching a projected revenue of US$46.74 billion by that time. By that time, the market is likely to reach a volume of US$57.02 billion [5].

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Over the world, millions of people suffer from inflammatory and degenerative issues related to the bones/joints and frequently need surgery, such as total joint replacement. In addition, a variety of biodegradable, temporary, or permanent devices must be used to treat musculoskeletal issues such as scoliosis, osteoporosis, low back discomfort, and multiple bone fractures [6,7]. Thus, orthopaedic biomaterials are intended for implantation within the human body as components of devices intended to carry out specific biological functions by replacing or healing various tissues, including bone, cartilage, ligaments, and tendon, as well as by directing bone repair when required [8].

Initially, the marketing of medical devices in India was governed by the Drugs and Cosmetics Act of 1940 and the regulations of 1945. The 2017 Medical Devices Rules (MDR), which control the use of medical devices throughout the country, were released by the Indian government in 2017 [9]. Medical device risk is categorized by MDR into four classes: minimal risk (Class A), low to moderate risk (Class B), moderate to high risk (Class C), and high risk (Class D). Class B, C, and D orthopaedic implants are categorized as low, moderate, to high-risk [10]. An orthopaedic implant (OI) is a synthetic device intended to replace a bone, cartilage, or joint that has been damaged or deformed, possibly as a result of a congenital condition, a broken leg, or another accident [11].

1.2. TYPES OF ORTHOPAEDIC IMPLANT

1) **Screws:** An orthopedic implant that resembles the screws you can buy at any hardware store is called a screw. The head of an orthopedic screw might be cross headed or flat. Compression is the main action of the screws used in orthopaedic implants, aiding in the healing of the broken bone. The rotator cuff or a torn labrum are examples of injured areas that are tightened using a screw. Screws can also be used by an orthopaedic surgeon to fix a broken bone or strengthen a weak spot. It is possible to insert the screws permanently. They are available in several shapes and sizes [12,13].
2) **Plate:** In 1886, orthopedic plates were initially utilized to treat lengthy bone fractures. Plates were and are still the most effective treatment for stability, reconstruction, and fractures. There exist five major categories of plates: Buttress plates, Neutralization Plates, Bridging plates, Tension Plates, Compression plates
3) **Prostheses:** An additionally type of orthopedic implant called a prosthesis is used to replace damaged joints or bones. Additionally, it can be utilized to provide broken bones the support they need. Patients can regain their physical strength and activity in a reasonable amount of time with this implant, which is usually utilized for the knees and hips [14,15]

Furthermore, because of their mechanical qualities, which provide the necessary stabilization, metals are the most frequently utilized class of biomaterials for fracture fixation; nevertheless, ceramics and polymers have also been used [16]. Still the most desired qualities are provided by metals [17]. Biomaterials utilized to make orthopaedic implants are shown in Figure 1.

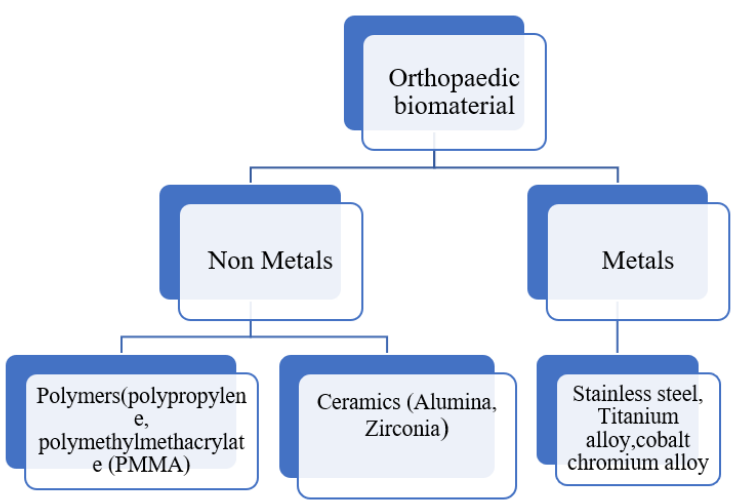


Fig. (1). Types of Orthopaedic Biomaterial

Millions of patients have benefited greatly from orthopaedic surgery by having their mobility restored, experiencing pain alleviation, and eventually enjoying a higher quality of life. Orthopaedic implants include devices for repairing fractures and supporting the spine, as well as prosthetics for rheumatic joints. Investment, research, and clinical outcomes in joint replacement, particularly knee and hip replacement, have undoubtedly advanced most significantly. Long-term results have shown that prosthetic joint replacement is an extremely dependable treatment [18].

Nevertheless, the adverse consequences of introducing metals typically iron, copper, and bronze into living tissues have long been recognized. Their medical applications were limited due to their high vulnerability to corrosion, tissue irritation, and suppuration [19]. Despite their good manufacturability for complicated configurations, their use was limited by the high rate of negative side effects (tendency to corrosion, low biocompatibility, and consequent tissue irritation) [20]. A retrospective case study that examined more than 1900 adverse events connected to different medical devices came to the conclusion that orthopaedic implants, posed a higher percentage of adverse events. However, there are a few things to keep in mind when choosing orthopaedic implants. Evaluation should be done of patient-specific variables as age, general health, and lifestyle. A patient's bodily compatibility, strength, and longevity should all be carefully examined when selecting an implant material, such as titanium or stainless steel [21].

The Medical Devices Rules (MDR) mandate that the Government of India regulate medical devices, including OI. Additionally, manufacturers and importers are required by law to report any adverse events that may occur from the use of medical devices. Healthcare practitioners are required to report suspected adverse events at the Materiovigilance Programme of India (MvPI), while manufacturers and importers are required to do the same [22,23]. Adverse events related to the use of OIs, including broken devices, surgical site infections, swelling, and pain, were reported to MvPI. These events included femur plates, femoral nails, orthopaedic nails, orthopaedic plates, knee implants, hip implants, spinal rod and screws, tibia plates and nails, bone cement and so on. [24]. Nevertheless, despite the success of this kind of surgery, more research is still required because average life expectancy is increasing, requiring longer-lasting implants, and complications and negative effects are common [25]. which often indicate for replacing the prosthesis. Furthermore, it is generally accepted that aseptic loosening of the implants is nearly a given 15–20 years following surgery. When all other factors are taken into consideration, the most common joint replacement problem is the degradation of the prosthetic components and the body's subsequent biological reaction to the substance released by the implant [26]. Therefore, the goal of the current study is to perform a thorough review and meta-analysis of adverse events related to orthopaedic implants.

2. METHODOLOGY

Using the Medline, Embace, and Google Scholar databases, a systematic evaluation of published publications was conducted starting from year 2000 to 2022 to identify cases of orthopaedic implant failure that had been reported. "Orthopaedic implant failure," "Adverse event orthopaedic implant," "metallosis," and "orthopaedic implant fracture" were among the terms found in medical subject headings (MeSH). All identified studies were thoroughly examined in terms of implant type, patient gender, age, reaction start period, adverse event, clinical presentation, outcome, and treatment in the abstracts and titles. The reactions caused by orthopaedic implants, such as fracture, aseptic loosening, metal hypersensitivity, etc., were the main focus of the study. Due to the limited presentation of findings in abstract format, conference proceedings and conference abstracts were excluded from the search. Languages other than English were not accepted for manuscripts. Deduplicated results were obtained. Studies that were deemed ineligible were eliminated, while those that might be included were investigated.

2.1. INCLUSION CRITERIA

- Studies comparing the result and frequency of OI reactions, implant breakage, or any other periprosthetic reaction following implantation met the inclusion criteria.
- All patients, regardless of age, will be included, regardless of gender.
- All clinical empirical investigations, whether experimental or observational, have revealed adverse responses in relation to orthopaedic devices.
- The case should be valid and include a suspected medical device, an adverse reaction, an identifiable patient, and an identifiable reporter.

2.2. EXCLUSION CRITERIA

- Patients who intentionally or unintentionally break or respond negatively to OI will not be accepted.
- Studies with pregnant women will not be included.
- Studies on non-orthopedic implants.

3. RESULTS

According to the inclusion criteria, 151 case studies in total were chosen. Three age groups comprised the patient population: younger (less than 40 years old), middle-aged (40–60 years old), and elderly (more than 60 years old). The gender distribution of patients experiencing orthopedic implant failure is displayed in Table 1. The included patient's mean age was 54. Particularly, 46% of the patients were women and 55% were men. Compared to women, men experienced more OI adverse responses at baseline. Their increased body mass index may be the cause of this, placing more strain on the implants.

Table 1. Male Vs Female Orthopaedic Implant Reaction

	Age Range						
Gender	**0-40**		**41-60**		**60+**		**Not available**
Female	9	47%	28	55%	29	43%	3
Male	10	53%	23	45%	39	68%	10
Total	19		51		68		**151**

The frequency of OI adverse responses is seen in Table 2. Metallosis (61%) accounted for the majority of adverse events, along with fracture/breakage (19%), infection (9%), osteosarcoma (8%), and dislocation (3%). Orthopaedic implants include a variety of metal alloys, such as cobalt, chromium, nickel, titanium, etc., in an effort to combine maximum biocompatibility with long-term endurance. The implant could malfunction, though, if the metal alloys cause harmful responses or inappropriate activation of the innate or adaptive immune system. The adverse reaction of each metal to OI is graphically represented in Figure 1. The most often occurring metal allergies are nickel, cobalt, and chromium-based alloys, as well as bone cement. Likewise, a surgical site infection (SSI) can develop in 30 days or less after surgery, it is considered a microbial contamination of the surgical wound [27]. In the field of orthopedics, surgical site infections following implant procedures are hazardous for the patient and the physician [28]. Figure 2 depicts a graphical representation of the microorganism linked to the development of adverse responses.

Table 2. Incidence of Adverse Reaction

Reaction Type	**Male**	**Female**	**Total**
Dislocation	5	0	5
Fracture/Breakage	19	9	28
Infection	11	3	14
Metallosis	38	54	92
Osteosarcoma	9	3	12
Total	82	69	151

Fig. (1). Metal-Wise Orthopaedic Implant Reaction Cases

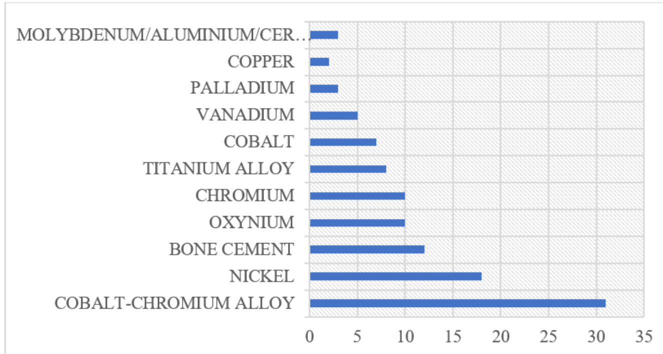
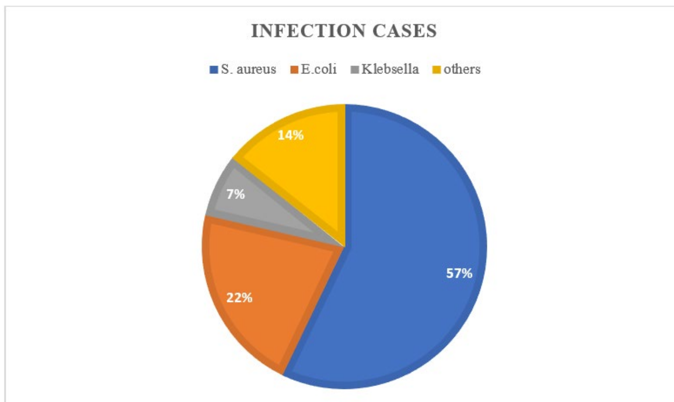


Fig. (2). Micro-Organisms Implicated



The association between implant type and the type of reaction that failed during the study period appears in frequency table 3 below. The majority of the implants were found in the lower limbs, which may be explained by the implant sharing the weight of the lower limb which bears the body weight [29]. It is observed that the incidence of reaction was higher for screws and plates as well. This could be explained by the fact that, in contrast to nails, which are load-bearing devices, plates and screws share a load. Implants in the spine, ankles, and feet, as well as implants in the shoulder and tibia, were not common. However, there is a dearth of information about the types of implants that frequently malfunction; instead, the contents of the implant are more important [30].

Table 3. Relationship B/W Nature of Reaction and Implant Type

Implant Type	**Dislocation**	**Fracture/ Breakage**	**Infection**	**Metallosis**	**Osteo-carcinoma**	**Total**
Hip Implant	0	9	2	34	8	53
Knee Implant	3	6	1	27	0	37
Nail/Plate/Screw/Joints	1	8	10	16	4	39
Spinal Implant	1	1	0	6	0	8
Tibiofibular Implant	0	0	0	3	0	3
Foot & Ankle Implant	0	0	0	5	0	5
Shoulder Implant	0	4	1	1	0	6
Total	5	28	14	92	12	151
% to Total Reaction	3%	19%	9%	61%	8%	100%

In contrast to late implant failure, which starts to occur after a year following surgery, early implant failure refers to cases that happen within the first few months to a year following surgery. The percentage distribution of early versus late implant failure is shown in Figure 3, and the relationship between early versus late implant failure and the type of adverse event is shown in Table 4. Whereas 52% of instances involve late implant failure, only 40% of cases involve early implant failure.

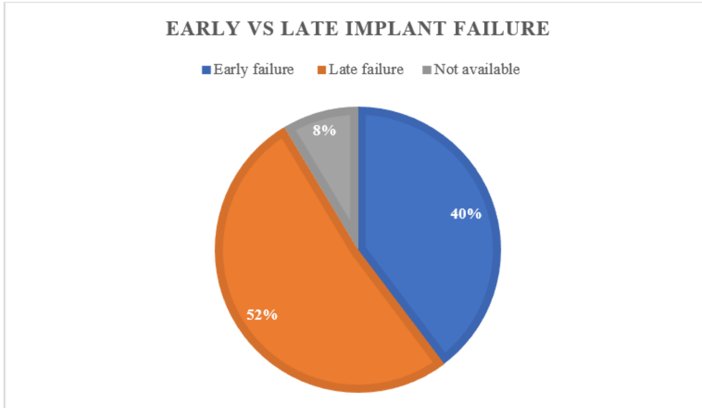


Fig. (3). Percentage of Early Vs Late Implant Failure

Table 4. Early Versus Late Implant Failure

Reaction type	Early failure	Late failure	Not available
Metallosis	37	47	8
Fracture/Breakage	15	13	0
Infection	7	3	4
Osteosarcoma	0	12	0
Dislocation	1	3	1
Total	60	78	13

Table 5. Symptoms Associated with Adverse Event

Symptoms	Pain (Acute/Chronic)	Dermatitis (Rash/eczema)	Breakage	Swelling	Others	Total
Metallosis	55	26	3	1	7	92
Fracture/Breakage	12	1	4	0	11	28
Infection	2	1	0	1	10	14
Osteosarcoma	12	0	0	0	0	12
Dislocation	1	0	0	1	3	5
Total	82	28	7	3	31	151
% to Total Reaction	54%	19%	5%	2%	21%	100%

The relationship between symptoms and orthopedic implant reaction is shown in Table 5. One or more cutaneous reactions, such as a rash, hives, edema, or pruritus, are usually the main symptoms. Additionally, joint stiffness and chronic discomfort are present in some patients. Results show that metallosis is the primary adverse consequence of orthopedic implants. Even if the quality of materials and production techniques that reduce the number of contaminants in metal alloys have improved significantly, certain patients may still be allergic. As a result, the skin, tissues, and bones in the vicinity of the implants sustain significant harm. The sole remedy for this is reconstructive or revision surgery.

4. DISCUSSION

The planning and delivery of healthcare has been significantly impacted by medical implants, both in terms of patient outcomes and business viability. Surgery using orthopaedic implants is regarded as "one of the most successful operations of the 20th century." For most beneficiaries, it's a beneficial, transformative intervention that results in better mobility and less pain [31,32] One of the biggest developments in orthopedics is the use of metal devices for immobilization.

Orthopaedic implant failure rates and explanations vary depending on age and gender. Bone density decreases with age, affecting implant stability and increasing the risk of fractures and implant loosening. Moreover, immune systems and healing rates are often reduced in the elderly, which increases the risk of implant infection and inadequate integration. Male and female anatomical differences also affect the alignment and longevity of implants. The success of implants overall and bone density can be impacted by variations in women's osteoporosis and hormone levels.

Orthopaedic implants [33,34] function as weight-bearing or weight-sharing devices. As a portion of the body's weight is supported by the own bone, weight bearing implants have a higher risk of implant failure than weight sharing devices [35]. Implant failure is more frequent in lower limb surgery because knee and hip joints bear a lot of weight and experience a lot of stress and motion, which increases the likelihood of wear and tear on implants. Furthermore, precise implant design and alignment are required due to the intricate anatomy of these joints; deviations may cause aberrant wear, misalignment, or loosening. Additionally, obesity puts more strain on the joints and hastens implant deterioration [36,37,38]. Numerous studies show that metallosis or hypersensitivity reactions are highly common. Issues regarding potential hypersensitivity reactions, carcinogenic consequences, and foetal toxicity in expectant mothers have been raised by the introduction of metal ions into the blood. Patients with metal-on-metal (MoM) joint replacements need to exercise cautiousness in regards to this worry. When an implant's metal surfaces come into contact with one another, small pieces of metal are released. The metal components of an implant may corrode over time and release ions into the surrounding tissues. In addition to causing inflammation and other problems, the body's immune response to these metal particles may exacerbate the illness.

Meta-analysis research confirmed that the primarily reaction occurs is metallosis, in metal-on-metal orthopaedic implants and most prevalent metal allergies are discover to be nickel, cobalt, and chromium-based implants [39]. Cobalt and chromium are typically used in orthopedic implant as metal alloys to increase strength and resistance to corrosion. But the body may experience oxidative stress as a result of these metals being released, which can harm cells and cause inflammatory responses. Nickel can also cause hypersensitivity reactions such dermatitis and systemic inflammatory reactions. Despite being thought of as nonallergenic materials, titanium alloys are frequently utilized for patients with suspected metal allergies since they have much less nickel than cobalt chromium or stainless steel. Even though there have been case reports of titanium allergies as well, the buildup of these metal ions in the bloodstream causes inflammatory responses, implant loosening, and persistent pain surrounding the implant site that may get worse over time [40]. It's crucial to keep in mind that materials used in orthopaedic implants may not completely safe. A small percentage of patients still be allergic, despite major advancements in material quality and production techniques that reduce impurities in metal alloys. Larger-scale research is required to investigate cost-effective and trustworthy methods for identifying allergies to metal implants [41]. Dislocation is another and rare consequence following complete knee replacement. Excessive soft tissue release, fexion extension gap mismatch, incompetent extendsor mechanism, implant malpositioning, and improper primary implant selection are the most commonly mentioned reasons of instability and dislocation [42]. After revision surgery, the most crucial element in preventing dislocation is precise flexion–extension gap balancing. According to our research, Staphylococcus aureus is the most common causative pathogen with orthopedic infections. Once again, surgical site infection following implant surgery is terrible for the patient and the physician. Eradication of the infection in fracture fixation devices is challenging because it comes from micro-organisms that proliferate in biofilm. This could result in higher rates of morbidity and death, extended hospital stays, recurrent debridement, and longer rehabilitation [43]. The length of the process directly affects the rate of infection; for example, cases lasting one hour or less had a wound infection rate of 1.3%, whereas cases lasting three hours or longer had a wound infection rate of 4%, which was rather significant and required control measures. [44]. Malignancy is by far the most dangerous side effect of orthopaedic devices and prosthetic materials. Prosthetics made of silicon, cobalt, chromium, nickel, iron, manganese, stainless steel, and cobalt have all been linked to cancer in humans. According to some authors, osteonecrosis, which increases the likelihood of developing a sarcoma, can be brought on by implant insertion. The occurrence of cancers in close proximity to metallic implants provides compelling evidence that there may be a significant association. Even if there is very less chance that an implant will cause a sarcoma, doctors should at least take this possibility into account if new symptoms or pain arise in connection with metallic orthopaedic gear [45]. The mean time for the sarcoma to manifest is nine years [46]. Late failures are typically the result of wear and fatigue that occurs naturally over the course of an implant's lifespan whereas early failures are more likely to be caused by avoidable causes such design defects or surgical errors.

The results of a meta-analysis show that orthopaedic implant failure can occur days or even years after implantation. It is most likely the quick wear particle production that occurs immediately after implantation that causes early metallosis. Inadequate implant design, poor material selection, or issues with coatings or material pairing during production can all lead to this. Due to inadequate design, substandard surgical technique, or material deficiencies that make it unable to endure the immediate mechanical demands placed on it, implants may rupture early [47].

Plastic, brittle, or fatigue failure can all contribute to mechanical implant failure or breakage. In contrast to brittle implant failure, which results in very little or no material deformation, plastic implant failure entails deformation of the implant material [48]. Inadequate technique, insufficient fixation, and/or insufficient postoperative immobilization have been implicated with fatigue failure. On the other hand, brittle and plastic failure typically accompany mechanical stress or subsequent severe damage [49,50,51,52]. Orthopedic implant surgery is a very effective intervention that offers advantages for long-term functionality. But as the world's population ages and life expectancies rise, more OI procedures will be performed, which will raise the rate of revision. In order to maximize the postoperative results for patients, surgeons must take into account a variety of factors that may have a negative impact on certain patient populations. Confounding variables for survival rates include things like body mass index, age, gender, implant bearing surface, and surgical method. Individuals who are admitted due to an implant failure encounter both financial and psychological strain. The scarred tissue and the difficulty of retrieving fractured implants make these revision treatments problematic for orthopedic surgeons. There is an increased risk of fixation failure and neurovascular damage infection. As a result, minimizing the number of failures is quite desired [53,54,55]. Therefore, orthopedic implants are current research topics that should be given consideration in the modern healthcare systems.

5. CONCLUSION

The majority of the issues facing orthopaedic surgery are essentially the same as those facing orthopaedics fifty years ago; however, the range of potential treatments has increased significantly due to the development of novel materials that enable the creation of inventive devices. A number of factors, including implant quality, implant selection, fixation quality, fracture geometry, and postoperative care, can lead to implant failure. To reduce hazards, age and gender should be taken into account during preoperative planning, implant selection, and postoperative care. While alternatives have arisen for younger, higher-demand patients, traditional Polyethylene bearing surfaces are still regarded as good options that work very well in older, low-demand patients with a life expectancy of less than 15 years. Prior to starting any kind of treatment, the patient must get extensive counselling. The surgeon bears the task of carrying out the intended postoperative care. Patients should be given the option to choose an orthopedic implant and should be informed about the benefits and drawbacks of both local and branded high-quality options. Patients should also be given precise instructions regarding weight bearing following surgery. Immunologists, orthopaedic surgeons, and materials scientists must work together to better understand the origins of adverse reactions and develop prevention and management techniques. The future of orthopaedic implants lies in the rapidly developing field of personalized medicine. Personalized implants are designed to match the biology of each patient, increasing the success rate of joint replacement surgery and lowering the risk of unfavourable reactions.

CONFLICT OF INTERESTS

None.

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