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Hip Arthroplasty Biomaterials – A Technical Update

(A review paper)

Abstract

Background: Total Hip prosthesis replacement is one of successful invasive procedures in medical history. Hip joint replacement started by Sir John charnley by using of low friction artificial joint on 1960s. Subsequently bearing material, fixation methods and new designs were defined and modified. The main concerns about THA are biological response due to particles produced by bearing surfaces that lead to Osteolysis and prosthesis loosening. Modern THA biomaterials were developed to remedy this problem.

Methods: A journal research strategy was performed using different terms. The highest quality technical articles and reports were selected that included the best and newest related contents. Key search words were hip, biomaterial, wear, titanium, zirconia, alumina, UHMWPE and CO-Cr. Finally 69 sources were chosen and used in this review.

Results: Recent advances in hip prostheses have focused on mechanical strength, biocompatibility, bioactivity, increasing wear resistance and reliability using new technologies, as well as structure modification and nanotechnology hybridization. A hybrid design in nano-ceramics has increased resistance up to four times that of alumina, allowing for a smaller femoral head. The prosthesis stability, longer life, and reliability are needed due to the increase in young patients who need hip arthroplasty with higher activity levels, which can be achieved with scientific methods and newly improved materials.

Conclusion: This study introduces the biomaterials used in hip joint prostheses and discussed them from different aspects. In addition, more advanced biomaterials for THA have also been investigated to further reduce wear and increase the life of the prosthesis in the future.

Keywords: Alumina, Hip prosthesis, Biomaterials, Total hip arthroplasty, Ceramics

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Introduction

THA is one of the most common surgeries performed worldwide, and more than 200,000 THA procedures have been performed annually in the United States since 2003. About 2.5 million people worldwide live with hip arthroplasty, and this number is expected to increase by 572,000 by 2030. Recent developments in the field of artificial hip joints have focused on mechanical strength, biocompatibility, bioactivity, and materials with better wear resistance and mechanical reliability [(1)]. An infection caused by particles from sliding materials wear in THA initiates per prosthetic osteolysis. The activity of macrophages and the presence of wear particles may cause the release of Cytokines. As a result of inflammation, osteoclasts' activities increase and eventually lead to the loosening of the implant [(2)]. The functional goal of joint arthroplasty is to return the patient to daily life activities and range of motion without pain. Therefore, various biomaterials are used, which are constantly being developed. This study aimed to review the hip prosthesis and update the development of various biomaterials in THA [(3)].

History of hip joint prosthesis development

The metal-on-metal (MoM) sliding system was developed using a large diameter ball in 1965-1955. The use of this system declined in the 1970s

after Sir John Charnley introduced a metal-on-polyethylene (MoP)-based THA device in the 1960s. Long-term survival of these early implants was good, with a success rate of about 77-81% after 25 years post implantation [4]. The failure rate rose with the increase in hip arthroplasty in younger and more active patients, and there were concerns about the role of polyethylene abrasive particles in osteolysis and implant loosening. Accordingly, new materials were introduced to prevent wear and osteolysis. Pierre Boutin was a French surgeon who solved the design problem of polyethylene by using alumina ceramic in hip implants in the 1970s. Ceramic-on-ceramic (CoC) implants were used in THA, and these developments also suggested the ceramic on polyethylene (CoP) composite as an alternative to the sliding surfaces of competing MoM and CoC couplers in 1963-1973. Artificial hip joints consist of an Acetabular cap, liner, head, and stem. The main biomaterials of THAs include titanium alloy, cobalt-chromium alloy, Ultra-High Molecular Weight Polyethylene, and alumina and zirconia ceramics [5].

Methods

Anatomy and biomechanics of the hip joint

The hip joint is a synovial ball-and-socket joint, created by placing the head of the femur inside the Acetabular cavity of the hip bone. This joint is the largest joint in the body after the knee joint, and one of its important features is stability and mobility. The hip joint plays a role in transferring body weight from the pelvic girdle to the lower limbs. The stability and strength of the hip joint are necessary to bear body weight in daily activities. The hip joint has three degrees of motion freedom, which means having motion in sagittal, frontal, and transverse planes. Factors affecting the stability and strength of this joint include the depth of the Acetabular cavity, strong ligaments around the hip joint, size and strength of the joint capsule, and natural angle of the neck of the femur with the femur, which is about 120-130 degrees in an adult. An important factor in matching the downward direction of the acetabulum is the inclination of the neck of the femur [5,6] (figure 1).

General requirements for biomaterials used in hip prostheses

Biomaterials used for the arthroplasty of the joint surfaces should have several characteristics (Table 1). The applied conditions to joint biomaterial in the human body are very difficult and complex. For example, stress is applied to the joint about three times the body weight during normal walking and about eight times the body weight when running [8]. Biomaterials used in joint arthroplasty should remain stable in vivo for more than ten years [9]. These biomaterials withstand more than two million loading cycles per year [10].

Biomaterials used in hip prosthesis

The biomaterials used in making hip prostheses are very diverse with different properties and are improving day by day. These biomaterials include many of metals, polymers, ceramics, and composites. The stem should be made of biocompatible metals with sufficient mechanical strength, and bioceramics and polymers are used in the sliding part. In the following, the mentioned biomaterials have been examined in detail.

Alumina

The wear components of hip arthroplasty prostheses are the main application of polycrystalline alumina bioceramics. Bioceramics, especially alumina, have been introduced and used clinically as a competitor to metal-polymer joint pairs over the past few decades. Until the 1970s, the standard articular surface was the Co-Cr/UHMWPE (Ultrahigh molecular weight polyethylene) pair, meaning that the femoral head of the prosthesis was made of a cobalt-chromium alloy, and the Acetabular part was made of UHMWPE. The reason for using this joint coupling system was its low price. The wear rate of this pair is high and depends on the patients' mobility and prosthesis head diameter. The lifespan of such a system is about ten years. For this reason, the mentioned system is often recommended for elderly and sedentary patients [12].

The high hardness of alumina is associated with its low friction and wear, which is limited by the low toughness of alumina. The results of the fatigue tests have shown that alumina implants should be produced with the highest possible standards to guarantee the quality, especially in young patients. Each bioceramic is distinguished from the other by inserting codes for tracking the product at the time of failure. Some alumina-alumina joint couplers have shown signs of damage or wear, known as stripe wear, after being removed from the patient's body. This type of wear appears as a long narrow area of damage on the femoral surface and an area on the edge of the Acetabular ceramic part. Studies on polycrystalline alumina bioceramics have indicated that the tribological properties of alumina are better than other biomaterials.

Failure of the ceramic articular surface in vivo is rare and is considered a serious matter. Such a situation has severe and acute consequences for the patient, surgeon, and orthopaedic implants industry. The clinical results indicate that most of the in vivo failures of the aluminum femoral head occur early after surgery (60% of all failures up to 12 months after surgery) [13].

Generally, failure of ceramic components of articular surfaces in vivo is caused by slow crack growth under static or repeated loading in the body, ultimately leading failure. The failure of ceramic articular surfaces comes from defects created during the bioceramic manufacturing or treatment stage and defects caused by corrosion and destruction in vivo.

Using bioceramics on joint surfaces does not affect the rapid failure behaviour of the material due to the applied load being lower than the tensile strength of the bioceramic. Although bioceramic has sufficient resistance to wear, it may break, and the joint is noisy during motion due to its low toughness and manufacturing process. The incidence of femoral head fracture decreased with the advent of the Morse taper design for bioceramic articular surfaces. The Morse taper's shape, dimensions, and dimensional tolerance are very important for ceramic articular surfaces [13].

Zirconia

Zirconia is a new bioceramic used primarily in making femoral head or acetabulum of the hip prosthesis and not the stem due to its unique properties [14]. The surface destruction of the zirconia head of the hip joint prosthesis can be considered a combination of aging and wear. The failure of zirconia femoral head implants confirms the importance of controlling the composition and microstructure in sensitivity to the Low Thermal Degradation (LTD) phenomenon [15]. The grain size and the amount of yttria affect the destruction of zirconia. Yttrium oxide (Y2O3) or yttria is used to stabilize zirconia, and zirconia containing ceria is less sensitive than the type containing yttria. Very high fracture toughness has been reported for ceria-stabilized zirconia [16]. Currently, 12Ce-TZP ceramics are proposed as ceramic implants for orthopaedic applications (joint surfaces) [17]. Micro-nano composites are alumina-rich nanocomposites in which zirconia nanoparticles are dispersed in micron alumina grains. The increase in crack resistance is due to two mechanisms of toughness increase due to phase transformation and, to a lesser extent, due to crack bridging in the composite in which alumina and zirconia are in the micron range [18]. Nano-nano composites are zirconia-rich nanocomposites in which the size of both phases is less than 500 nm. This type of composite is developed based on zirconia containing ceria-alumina [19]. Nanocomposite based on ZrO_2-10 CeO_2 with a small percentage of TiO_2 along with 30% by volume of alumina is one of the new systems that promises the presence of a new generation of joint wear bioceramics [20, 21]. The fracture toughness of this nanocomposite is four to five times that of alumina, and its bending strength is about two times that of alumina. The wear rate of this nanocomposite is four times lower than that of alumina. The use of this bioceramic allows the design of a smaller femoral head [22, 23].

Hybrid design of ceramic layer on Oxiniumtm (zirconium layer on zirconium with the help of surface modification process)

The behaviour of ceramic coatings is unpredictable on joint surfaces. In this

method, the worked zirconium alloy (Zr-2.5Nb) is oxidized by a thermal penetration mechanism to form a surface layer of oxidized zirconium with a thickness of 5 micrometers on the surface of the alloy. The oxidized surface is then polished to the standard CoCr alloy size. The metal surface turns into ZrO_2 ceramic with excellent adhesion and cohesion properties due to surface oxidation. This ceramic layer has the advantages of zirconia, such as low friction, non-adhesive wear resistance, and roughness regardless of problems related to the brittleness of all-ceramic components. The surface hardness of this layer is lower than alumina, but it has provided better results than CoCr alloy in terms of wear rate. In a simulation, oxiniumtm heads showed 45% less wear than smooth Co-Cr heads. In addition, this difference increased when the heads were roughened, and the wear was 61% less for oxiniumtm[24].

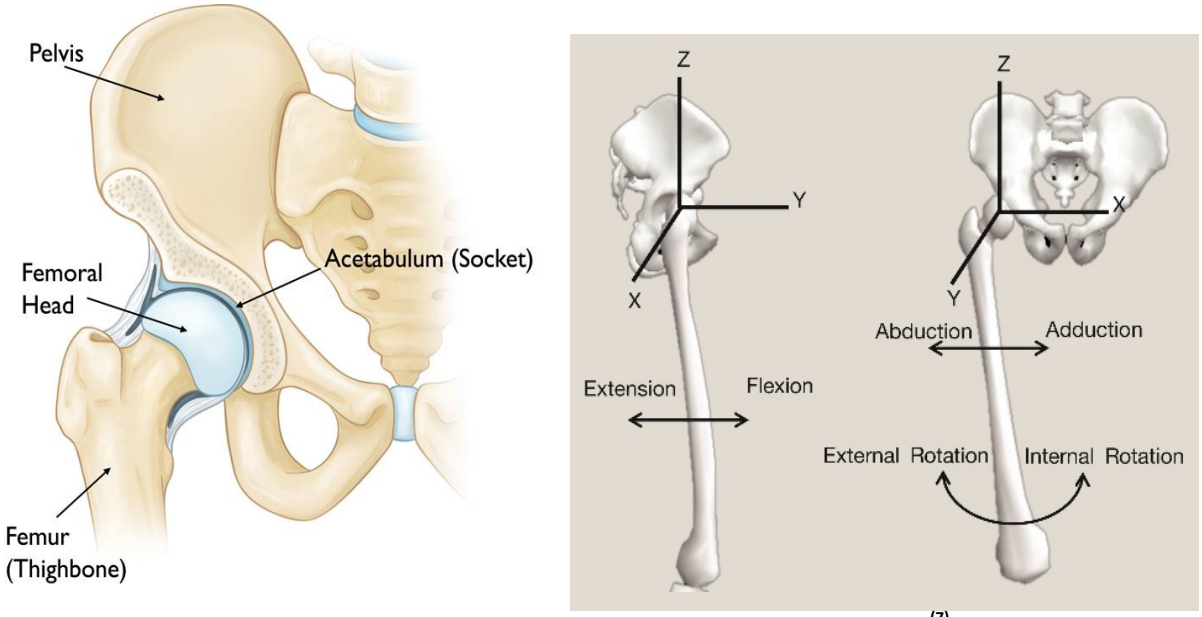

Figure 1: a) Hip joint, b) Biomechanical sketch of the hip joint [7]

Table 1: Desirable properties for biomaterials of articular surfaces

Characteristics	Features
Mechanical properties	High strength, high Young's modulus, high fracture toughness, and high resistance to fatigue and deformation during loading in the body (The femoral part must be able to withstand large and variable stresses in the human body environment and withstand many stress cycles)[11]
Behaviour in the biological environment	High corrosion resistance in the human body, biocompatibility, and inertness in biological and non-magnetic environment
Tribological properties	High hardness and good surface finish (low surface roughness) for long-term wear resistance and low friction
Surface properties	Appropriate wet ability (low contact angle) between the articular surfaces and the inter-articular fluid to achieve good fluidity in the body
Production and commercial considerations	Accessibility, justifiable balance between quality, durability, and price

Titanium alloys

Ti+βα alloys such as Ti-6Al-4V have been most widely used for STEM, THA components, and uncemented Acetabular because of their comparable low density, biocompatibility with bone, high mechanical strength, and good corrosion resistance [25,26]. Titanium alloys are not used for femoral head construction due to low wear resistance. During the last two decades, vanadium-free titanium alloys such as Ti-6Al-7Nb+βα alloy have been developed with improved biocompatibility by accompanying biocompatible elements such as niobium [27, 28].

Cobalt-chromium alloys

Co-Cr alloys are one of the main materials used for the hip prosthesis. Favourable strength, corrosion resistance, and wear properties make Co-Cr alloys one of the main choices for implant materials and joint heads due to their wear resistance. These alloys are mainly used as cement-stabilized femoral stem materials due to their higher Young's modulus than titanium alloys. Cobalt-chromium alloys are resistant to pitting corrosion and crevice corrosion in the human body. The three cobalt alloys used for hip implants are listed below:

- ASTM F562, (Co-20Cr-35Ni-10Mo) wrought alloy
- ASTM F1058, (Co-20Cr-5Ni-7Mo-Fe) wrought alloy
- MP 35N, (35Co-35Ni-20Cr-10Mo) thermo mechanically processed

CoNiCrMo alloy is relatively new, whose fatigue and high tensile strength make this material suitable for use in places or long-term service periods without causing stress, fatigue or failure. CoNiCrMo is suitable for use in the main body of hip prostheses, which is especially essential in cases where the implant must be replaced because it is difficult to remove the destroyed part of the implant inside the femoral canal. In addition, new arthroplasty rejects secondary surgeries due to poor stabilization and inefficiency of implants [29, 8].

Bioactivated surfaces and alloy surface modifications

Metals and porous coatings were developed to achieve a good bone-to-implant connection, reduce the risk of loosening, and produce and effectively bridge bone cells to the implant surface. Titanium and some of its alloys and tantalum in porous metal materials are suitable for orthopaedic applications [30, 31]. Hydroxyapatite coating is also used to achieve stable mechanical stabilization of an implant in the bone bed [32] (figure 2).

UHMWPE and UHMWPE cross-linked polymer (XLPE)

UHMWPE is one of the subsets of polyethylene [34], in which longer chains help to transfer the charge to the main body of the polymer more effectively by strengthening intermolecular reactions. Finally, very strong material is created with a very high strength against wear and impact, which is the highest compared to other types of thermoplastics. Polyethylene with ultra-high molecular mass has a low friction coefficient and is very resistant to wear (in some cases, this amount is 15 times more than carbon steel) [35]. The friction coefficient of UHMWPE is much lower than that of nylon and acetyl, which can be compared with the friction coefficient of polytetrafluoroethylene (PTFE) [36, 37]. UHMWPE was introduced in 1962 as a sliding surface (BEARING) in the Charnley hip prosthesis. UHMWPE abrasive particles are known as the main cause of osteolysis and are a serious challenge in hip joint arthroplasty [38,39].

The new XLPE was developed to improve UHMWPE in both cemented and uncemented implants. Studies have been conducted to improve the wear resistance, maintain the mechanical properties, and prevent the oxidation process [40, 41]. Cross-linking is performed using gamma rays or electro beam to break molecular bonds and a higher crosslink density is obtained to increase wear resistance using irradiation with gamma or electron beams. Heat treatment is performed to remove free radicals, which appear after cross-linking. In vivo studies have reported a 95% reduction in wear rates. In addition, a 42% to 50% reduction in wear rate using XLPE compared to conventional PE was reported [42,43]. In addition, the biological activity of abrasive particles and osteolysis decreased significantly [44].

Figure 2: Porous and bioactivated surfaces of hip prosthesis [33]

Table 2: The wear rate of the sliding surfaces of the hip joint in the simulation test in the in vivo environment		
Joint pair	**Linear wear rate (µm per year)**	**Resource**
Co-Cr/ UHMWPE	200	47
Alumina/ UHMWPE	Less than 100	48
Zirconia (Y-TZP)/ UHMWPE	Less than 100	53
Alumina/ Alumina	Less than 5	52
Zirconia (Y-TZP)/ Zirconia (Y-TZP) (tetragonal zirconia stabilized with yttria)	Failed	52

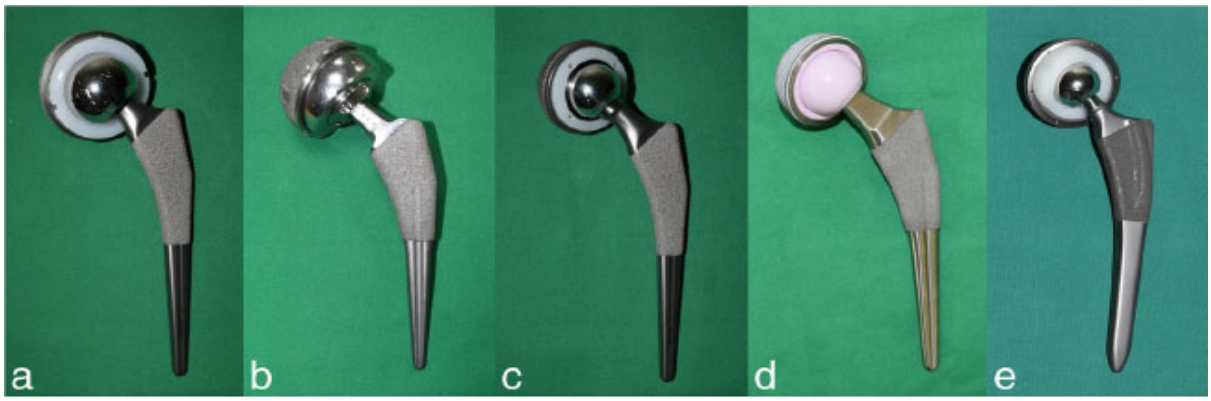

Figure 3: Sliding materials used in THA; a) Sliding MoP [47, 48] b) Sliding MoM with a large head [49] c) Sliding MoM with a small head [50, 51] d) Articulating CoC [52, 53] e) Articulating CoP5 [54, 55]

Articulated sliding couplers

Several bearing surfaces and their wear rates are used in clinical applications (Table 2). Joint sliding couplings should have a low friction coefficient, high surface hardness with low ductility and scratch resistance with little wear particles. In addition, the surfaces concerning the tissue should be non-toxic, biocompatible, and bioneutral [45, 46].

Wear in hip prostheses

Biotribology is the effect of friction and wear in biological systems [56]. Wear is one of the significant issues in joint surfaces, and the relative movement of two surfaces under mechanical load against each other can produce wear particles. The entry of large amounts of these particles into the biological environment may lead to losing the implant [57]. Several simulators have been developed over the past 31 years to simulate thigh and knee joints. Different loading cycles can be applied to the desired prosthesis with the help of this equipment, just like what happens in the body [58]. Abrasion is an essential category due to disrupting the device function such as bone resorption caused by loosening joint prostheses (due to the presence of particles resulting from wear). Wear is often unpredictable and occurs based on different mechanisms, which cannot be removed and are considered a critical factor in determining the lifespan of the device [59].

Four different types of wear behaviour can be observed in a prosthetic joint. Type 1 wear occurs between the desired joint surfaces, like the femoral head with Acetabular liner in the hip prosthesis. Type 2 wear takes place between a primary articular surface and a surface not intended as an articular surface, like the femoral head and the piece behind the metal strap (cup) of an Acetabular liner. Type 3 wear appears between articular surfaces in the presence of a third object, like the femoral head and Acetabular liner, along with polymer cement fragments (polymethyl methacrylate), metal fragments, hydroxyapatite particles (in uncemented prosthesis), bone particles, or articular ceramic particles. Type 4 wear happens between secondary surfaces, which have not been mentioned as joint levels [60].

Ceramic-ceramic joint prostheses indicate a very low wear rate (about one micron per year), while Ceramic-UHMWPE coupling is reported at about 100 microns per year [61] (figure 3) (table 2).

Hip arthroplasty

The prosthesis for total hip arthroplasty consists of the femoral and Acetabular parts. The femoral stem or body also consists of three parts of head, neck, and handle made of titanium alloy or cobalt-chromium alloy and is placed inside the bone canal through cementation or pressure placement. Zirconia, cobalt-chrome alloy, or alumina makes up the femoral head. The Acetabular part is made of ultra-high molecular weight polyethylene or ceramic [62, 63].

Hip prostheses are available in integrated and modular types. Integrated prostheses are often cheaper and less prone to corrosion or loosening. However, multi-part prostheses allow the implant to be adjusted according to the patient's anatomy. In multi-part implants, the femoral head is connected to the femoral neck with a Morse Taper to apply changes in the size and type of femoral head and neck length [64].

Upon hip arthroplasty, the old liner can be replaced with the metal shell. Many studies have developed an effective retention system for positioning and increasing the fit between the metal shell and other prosthesis parts. When the prosthesis does not fit well in the desired location, the hip joint will be displaced, and the femoral head will be damaged because the hip joint is in direct contact with the metal shell. The micron movement between the implanted prosthesis and the shell produces polyethylene particles that eventually destroy the bone. The design characteristics should allow the implant to support more than eight times the body weight. The appropriate length of the femoral neck, correction of the motion center, and femoral balance reduce the bending stress on the bone-prosthesis interface [65] (figure 4).

Stabilization of hip prostheses

Stabilizing a stable interface between the device and the host tissue at the cellular and organ levels is one of the basic problems of orthopaedic implants with an articulated state. Stabilization can be divided into

different groups. Most of the common problems of fixing such implants are infection, wear and related particles, and motion, displacement, and failure of implants, and loosening of the implant in the long term. These problems appear as osteolysis in the bone bed, which is the main reason for the loosening of the femoral body in the long term. Other reasons for implant loosening are incompatibility of the mechanical properties of the tissues with the implant, low biocompatibility of the implant, decreasing the quality of implant materials, surgical methods, implant design, patient selection, and care after surgery.

Each prosthesis is stabilized particularly, and the efficiency of THR depends on the characteristics of the bone cement used in some cases. Some of these characteristics are high or low viscosity of cement, using antibiotics, and heat generated during cement polymerization[66].

Other critical factors affecting the stabilization of non-cemented caps in the short term are rapid stability and the possibility of tissue growth. Studies have examined the abnormal loosening of cemented caps and concluded that the loosening mechanism due to osteolysis is biological and not mechanical [66]. Femoral bodies have an articular surface connection with the Acetabular caps, which can play an important role in the longevity and performance of the body. Stabilization of the body is performed using cemented and uncemented methods. The uncemented method can be considered in mechanical fixation methods and a porous coating to increase the possibility of tissue growth. A coating of hydroxyapatite is may used to conduct tissue growth in the solution of using a porous coating. Any hard material in contact with the bone surface can change the bone density due to the changed stress pattern, and bone destruction is accelerated due to particles in the joint surfaces between the Acetabular cap and femoral head. Osteolysis often occurs in the distal and proximal part of the prosthesis, which is accelerated by the abnormal loosening of the implant and increases the wear rate of the UHMWPE cap. The primary failure mode of the femoral prosthesis occurs following osteolysis in the distal part of the stem or body of the prosthesis due to the interface separation between the bone cement and prosthesis body. In addition, the particles created due to gravity gather [65, 66] (figure 5).

Stabilization with cement

Bone cement is the weakest part between the bone and the prosthesis. Bone cement failure and loosening of the interface between cement and body is considered the essential factor in the failure of prosthesis fixation (Figure 6). Two junctions are created by the stabilization of bone cement. The first is the bone-cement interface, and the second is the prosthesis-cement interface. According to studies, the amount of loosening of femoral prostheses is 10% and 11%, respectively, due to the weakness of cement bone and prosthesis-cement junctions. Reports have shown that the loosening of cemented femoral components from the cement-prosthetic interface is due to their trapped porosity.

Bond failure begins in the area between the cement and the prosthesis, followed by a gradual loosening of the cement-bone interface. Severe osteolysis occurs in many hip joints after a fracture of the ligaments. The average time for the first signs of failure after surgery is nine months. Scholars believe that progressive loosening depends on the geometry of the prosthesis stem and its final surface. The cylindrical shape allows prosthesis rotation, as well as scraping the bone cement by the final untreated surface. These cases are caused by the loosening and decomposition of the bone [67]. The shear strength of PMMA bone cement is about one-third of its tensile strength. Bone cement cannot withstand shear forces caused by the body rotation when considered bearing the shear force. The prosthesis stem should have a square section with a smooth final surface. In addition, the final untreated surface may hold the implants better due to the larger surface area, but such a surface causes the bone cement to scratch when the prosthesis loosens[66,67]. The problems in the bone-cement interface are caused by the inherent

properties of bone cement and external factors such as the cementing method and the state of the bone surface. The toxicity of the monomer and poor properties of the cement due to the inevitable presence of voids can cause the prosthesis to loosen from the bone-cement interface. The strength of the bone-cement interface is increased by bone growth within the cement after stabilization. Bone cement, used for quick stabilization, provides the necessary conditions for tissue growth by merging absorbable particles such as particles of inorganic bone materials. The number of particles added to cement should be controlled because an extensive number of particles increase viscosity and decreases strength. As the particles settle inside the bone cement, the amount of porosity in the cement decreases and the average size of the pores increases. Tensile strength decreases with the increasing amount of bone particles. Fatigue properties are improved by adding more particles, while the optimal amount of bone particles is 30% by weight. Sufficient porosity is provided for bone growth under these conditions [66, 67].

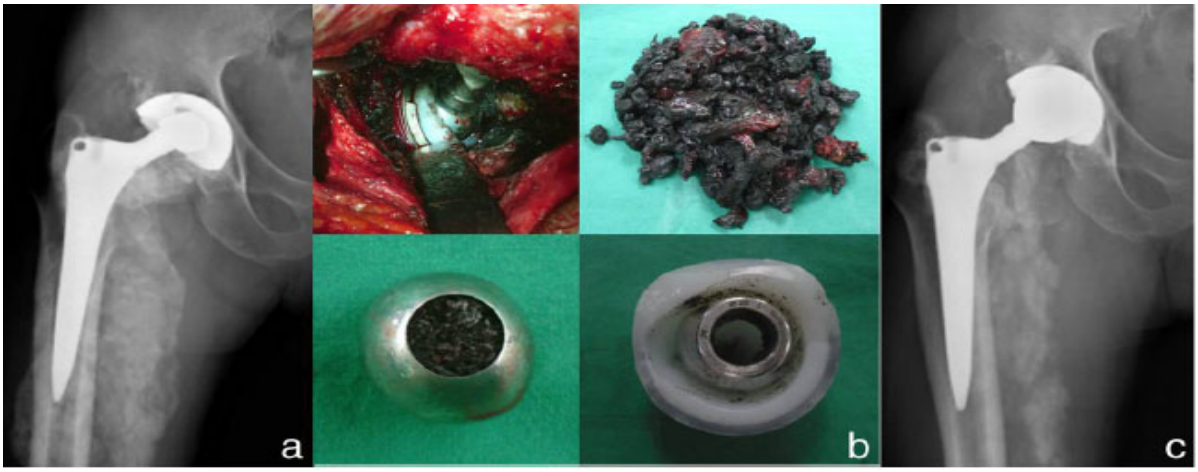

Figure 4: A 62-year-old male patient with right hip joint arthroplasty using MoP prosthesis a) radiograph shows liner wear and metallosis b) severe metallosis and osteolysis c) post corrective surgery radiograph including excision of mass, change in metasul liner and metal head after cementing [59,8]

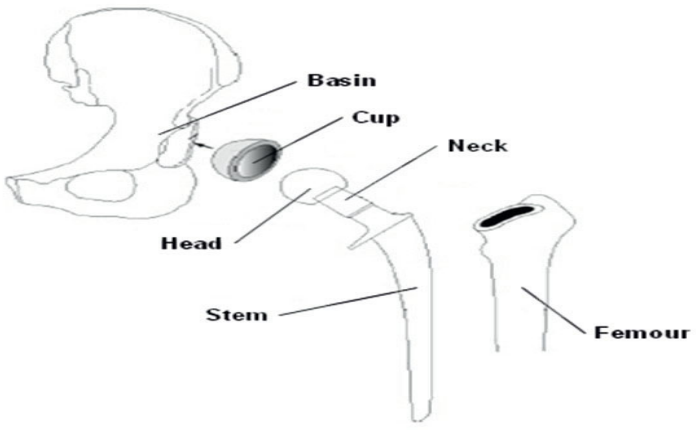

Figure 5: Hip joint arthroplasty

Uncemented stabilization

Efforts to develop a durable and biocompatible interface between tissue and prosthesis led to Moore's design of the femoral prosthesis. This prosthesis has large apertures with holes in the proximal area, and stabilization is conducted mechanically. Generally, any biocompatible material with enough space to accommodate osteons (the basic unit of dense bone structure) allows the growth of bone tissues into its space.

The problems of biological stabilization are the harsh and invasive nature of the surgery, the need for a long period of immobilization of the limb to create the right conditions for tissue growth, the unpredictability of when a person will be able to walk, difficulties of eliminating infection, and the impossibility of its re-growth when the created interface is accidentally destroyed due to additional loading. In addition, the porous coating may weaken the prosthesis, and there is a high risk of corrosion due to fatigue, especially in the case of metals, due to the increase in implantable areas [66, 67].

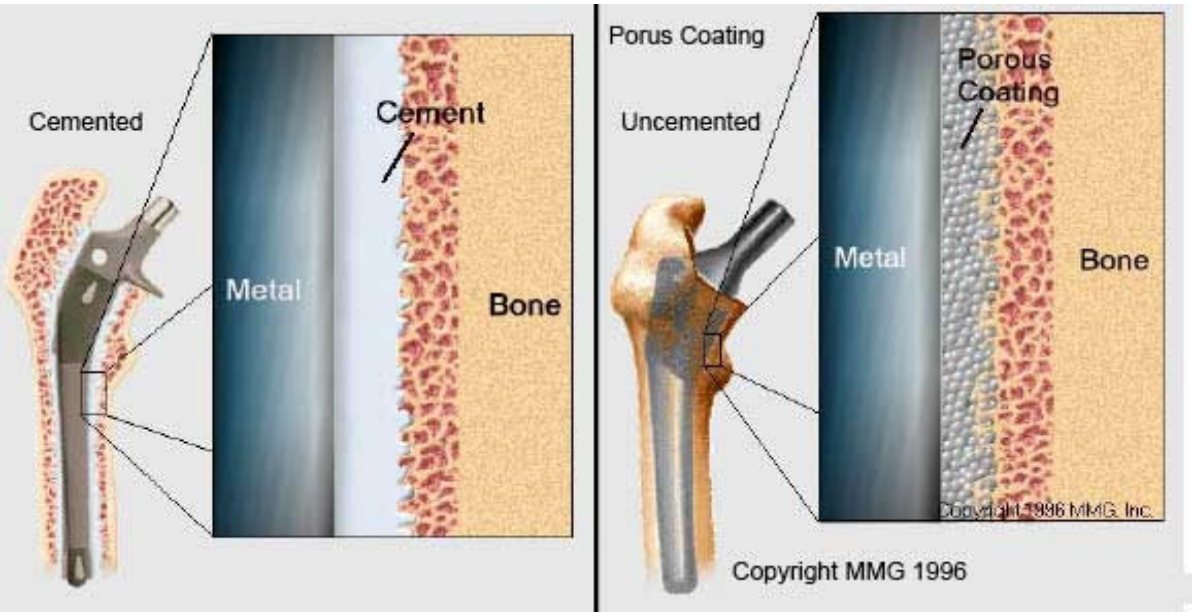

Figure 6: Stabilization of hip prosthesis a) cemented b) uncement

Conclusion

A THA procedure relieves pain and leads to greater activity in patients. The stability and longer life of the prosthesis are needed due to its increase in young patients requiring hip arthroplasty despite the success of this method. Appropriate surgical technique and sliding surfaces are decisive in the lifetime of hip prostheses and are the most important, along with the stabilization method of the prosthesis. The new sliding surfaces reduce wear and have shown promising results in clinical tests. Therefore, scientific communities should focus more on reducing erosive wear, proper stress shielding, and better design. Continuous research on future biomaterials for use in the hip prosthesis is necessary, and all researchers should continue their studies until reaching the desired and reliable data for each type of implant. This article is intended to be used by surgeons, students, designers, and internal manufacturers of orthopaedic implants to make the country progress in this field.

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