Investigation of Bio-materials Used in Knee İmplant

Bahadır Birecikli*
Batman University, Technical Sciences Vocational School
Batman

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*Sorumlu Yazar: Bahadır Birecikli
E-mail: bahadir.birecikli@batman.edu.tr

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Knee joint is formed one of the most serious parts of his body for human beings throughout history. An increase in young people, traffic accidents, walking, running, and other similar movements have led to increased proliferation of the knee orthopedic disorders. Rapid growth and diversification of knee diseases as well an accurate recognition of this region has created a need for treatment. Human knee in case of encountered pain, functional limitation and wear, in total knee arthroplasty due to knee replacement surgery performed on the initiative of medically normal and comfortable walking recovered.

In our country is like all over the world, degradation of the knee joint against deficiencies that adversely affect the daily life applications are made with increasing frequency. With the advancement of technological development, researches on this area have been continuing today as a result of producing implants more suitable for bone structure and connective tissue.

Anahtar Kelimeler: Knee Arthroplasty, Prosthesis, Implants, Biomechanics

1. INTRODUCTION

A knee joint is a joint that we use the most to maintain our daily lives and that is open to degenerative changes and also has very important functions. The knee joint, which is the largest joint in the human body, has been one of the most important parts of the human body throughout history [1].

Especially in the last century, the increase and diversification of sports activities have increased knee traumas. In falls, the knees are usually the first to touch the ground. The knee joint is the joint most frequently damaged by trauma in people sitting in passenger cars. The increase in the young population, traffic accidents, frequent participation of women in sports activities, and the increase in walking, running and similar movements have led to an increase in orthopedic disorders in the knee [2].

243,919 primary total knee arthroplasties were performed in the United States in 1995 [3]. The annual number of total knee arthroplasty performed in the United States is expected to double by 2030, reaching an estimated 454,000 procedures. Also, 19,138 revision total knee arthroplasties were performed in the United States in 1995 [4]. Using hospital discharge data in Ontario from 1989 to 1994, Coyte estimated an annual increase of 14.1% for primary total knee arthroplasty and 19.3% for revision total knee arthroplasty [5].

The rapid increase and diversification of knee diseases has necessitated the need to know this region very well for a correct treatment. This can be achieved through anatomy. The anatomy examines not only macroscopic of the knee joint, but also its biomechanics, function, cross-section and many more aspects.

In cases of pain, wear and limitation of function in the human knee, mechanical limitation is relieved with the implants used with the surgical intervention of total knee arthroplasty and gait is made medically normal and comfortable [6].

Orthopedic implants are divided into two types as permanent and temporary. Permanent implants are designed for damaged joints. The duration of use is as long as the remaining life of the patients after the implant. Temporary implants are generally used for fracture fixation. Their job is to build a bridge between the broken bones until full union is achieved. The service period is usually up to several months.

The prostheses currently used are mostly of western origin and designed according to the needs of this society. However, the knee joint produced for today's Turkish people has some differences compared to the western people. In our country, knee sections suitable for prosthesis are being tried to be made. However, it is necessary to choose a prosthesis compatible with the knee. As a result, the durability of the implant and the longevity of the implant decrease, and thus the desired success rate in TKA (total knee arthroplasty) decreases by almost %50. Between 37% and 55% of patients who underwent TKA surgery reported that there was no significant functional improvement even 6 months after surgery, and 50% reported that they were not satisfied with the results [7]. Total knee arthroplasty applications in our country started in 1987 [8].

The most needed types of prostheses in the world today are knee prostheses and hip prostheses. [9]. Particularly orthopedically, the places where human movements are most affected are the body parts that encounter stress concentration. It is to consider the reproducibility and repair conditions by creating custom designs for high precision design criteria. For this, studies should be carried out by determining the criteria that take into account the orthopedic material design and material production that ensure possible long-term use.

Arthroplasty attempts aimed at regulating the function of the knee joint started in the 19th century, and in the last 20 years, a successful point has been reached with the understanding of the anatomical and biomechanical properties of the knee joint. Studies on knee surface replacement have a history of 130 years [10].

In order to gain a functional knee, first Barton in 1827 and Rodgers in 1840 tried to bring motion to the knee joint. In 1863, Verneuil proposed the first application of "interposition arthroplasty" by placing a joint capsule between the two resected surfaces of the joint. Due to infections in this period, this study was performed on developed knees and was unsuccessful [11].

Waldius produced hinged type prosthesis in 1950 that can replace both knee joint surfaces. In addition, these prostheses contain an intramedullary handle. In later times, he dealt with works like Guepar and Shiers. This type of prosthesis has been used in patients with deformities and severe joint disorders. Afterwards, it was observed that it caused limitation of movement and created inadequacy [12].

In the 1960s, McIntosh used two basic systems in knee arthroplasty. These are the non-mechanically assisted (non-limiting) “surface replacement” arthroplasties of which it is the predecessor. Afterwards, Waldius, Shiers and Guepar applied the fully mechanical supported (full limiter) "hinge type" they developed. Shiers and Gunston took the foundations laid by McIntosh one step further and ushered in the modern era of knee arthroplasty in 1971 [13].

Gunston applied the first cemented knee "surface arthroplasty" by adapting Charnley's experience from low-friction total hip arthroplasty to McIntosh's design. In Gunston's thesis, the movement in the knee joint is not on a single axis; it is revealed that it takes place on variable rotation centers over time. In this design, Gunston aimed to identify metal components by applying bone cement and to minimize friction by placing high-density polyethylene between these components. Gunston and Freeman-Swanson developed total knee prostheses related to the use of titanium alloys and the use of metal insoles. They also contributed significantly to prosthesis design and surgical technique [14].

The modern era in knee arthroplasty began in 1971. In 1972, coventry produced a geometric prosthesis in which the cruciate ligament in both knees was preserved, based on the biomechanical principles of the knee joint. Freeman then produced an I.C.L.H (Imperial Collage/London Hospital) type prosthesis that was used partially cementless. Subsequently, press-fit and cementless TKA prostheses were developed. Freeman, Swanson and Samuelson have developed prostheses that are known by their own names by eliminating the deficiencies in I.C.L.H type prostheses. These prostheses have recently found widespread use [15].

In the golden age of TKA history, in the early 1980s, Hungerford et al. developed the precision instrumentation system. This system aims to minimize errors. With alloys such as ceramic, chromium-cobalt mixture and titanium to overcome wear problems in prostheses; they have developed prosthetic types in which UHMWPE (Ultra height molecular weight polyethylene) components are used together. In parallel with the new developments that emerged with the use of these new types of prosthetic materials, the distances covered by prosthesis designs as a result of clinical trials have led to the production of today's modern prostheses in which all three parts of the knee are replaced in arthroplasty [16].

By the 2000s, TKA has now found a wide range of applications as total hip prostheses. Prof. Dr. Orhan Aslanoğlu implemented the first hinged type total knee prosthesis application in our country. Hinge type total knee prosthesis was applied to a patient with rheumatoid arthritis at Ege University.

Total knee replacement now has a widespread application area all over the world and has achieved high success rates [17].

2. MECHANICAL AND BIOLOGICAL STRUCTURE OF THE KNEE JOINT

2.1. Anatomical Planes and Axes

The standing position with the heels together, head and shoulders upright, face and palms forward, arms at the sides, eyes facing forward is called the anatomical position. The human posture seen in Figure 1 is called anatomical posture and all plane and axis definitions are made according to this posture [18].

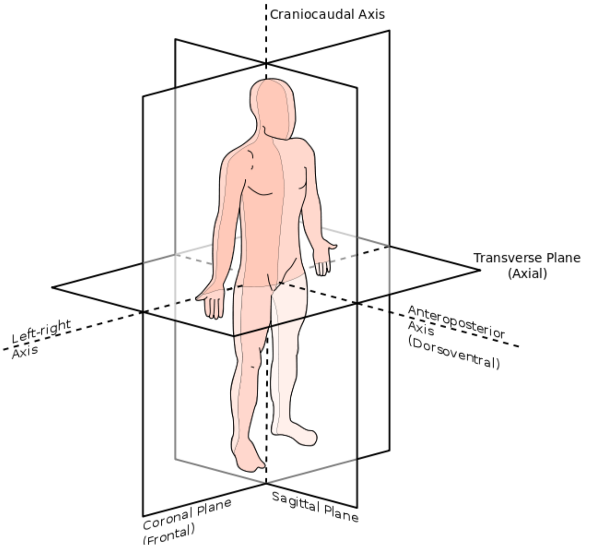

Figure 1. Anatomical planes and axis [18]

The parts and movements of the human body are studied and described in three axes and planes in space. Anatomical planes; consists of sagittal plane, transverse plane (horizontal) and frontal (coronal) planes. The plane perpendicular to the ground running from front to back and from top to bottom is the sagittal plane. It divides the body into two parts, right and left. If this plane crosses the midline and divides the body into two equal parts, it is called the midsagittal plane. The plane running parallel to the ground is defined by the transverse (horizontal) plane. The frontal (coronal) plane is the plane that runs perpendicular to the ground from right to left and from top to bottom. According to these planes, external for the part close to the body surface, internal for the deep part, intermediatus for the middle and extremities (represents the part of the body outside the head and trunk, that is, the arms and legs), proximal for the part close to the body, distal for the far part The terms medial for the inner side and lateral for the outer side are used [19].

2.2. Knee Joint and Biomechanics

The knee joint, which is the biggest joint in our body, is a type of ginglimus, that is, a hinge type joint. The knee joint has the widest range of motion in the body in terms of range of motion. The major task of the knee joint is to carry the weight of our body and to provide walking shown in Figure 2 [20].

During the daily activities of human beings, an average of 4 MPa stretching occurs in bones and approximately 40-80 MPa tension in tendons. While a healthy knee carries a load of 2 to 5 times the body weight during walking, this load can be up to 8 times the weight during running. The amount of load on the human knee during walking is between 1300-3500 N (Newton) shown in Figure 3 [21].

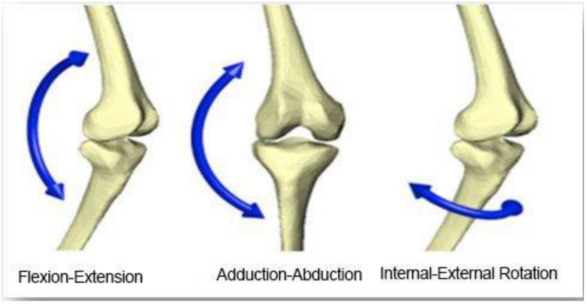

Figure 2. Joint movements of the knee in three planes [20]

We can list the movements of the knee joint as follows:

- In the sagittal plane----- extension – flexion
- In the transverse plane---- external rotation - internal rotation
- In the coronal plane-----abduction-adduction

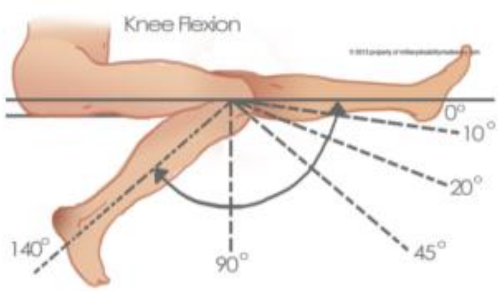

Figure 3. Flexion and rotation of the knee [21]

The average range of motion of the knee joint is between 0-140°. However, not all of this range of motion is used for everyday activities. It may vary according to the phase of walking. When the human knee is upright on the feet, the knee joints support the body above the knees. This event accounts for 86% of the total body weight on average. If a person stands on one leg; a load of 93% of the body weight is placed on the knee joint. The plane in which the knee joint performs internal-external rotations is the transverse plane. While there is no sliding motion in the first 20° of flexion, sliding motion is added to the rolling motion after 20°. During this sliding and rolling motion, the contact point slides back approximately 14 mm until it reaches 90° of flexion.

2.3. The Bone Structure of the Knee

The knee joint consists of three bones namely the femur, patella (knee cap) and tibia shown in Figure 4 [22].

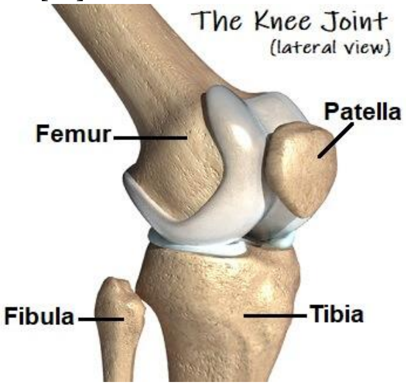

Figure 4. Bone structure in the knee joint [22]

1) FEMUR: It is the thickest and longest bone type in our body. In the anatomical position, the orientation of the femur bone is from bottom to top and from outside to inside. The femoral bone is the strongest and longest bone in the body, narrowing in the middle, expanding upwards and downwards, thus consisting of a long body with proximal and distal ends. The anterior surface is flat and convex in all directions.

2) TIBIA: It is located on the anterior inner side of the leg skeleton. The upper end of the bone is thick. It consists of two condyles (condyle medialis, condyle lateralis) projecting posteriorly and laterally. The tibia is the main body weight bearing bone and is on the anterior-inner side of the leg. It is the second largest bone in our skeleton.

3) FIBULA: It is a long and thin bone located on the outside and back of the leg. It is very thin compared to the tibia and has slipped a little lower.

4) PATELLA: The kneecap bone is the biggest sesamoid bone of the human body. It is a flat triangular bone in front of the knee joint.

Patella is the joint with the widest range of motion in the human body. This is ensured by joint stability and ligament integrity. In other words, it is provided by cruciate ligaments, internal-external lateral ligaments and surrounding muscle tissue. While the bone structure of the knee provides dynamic stability in muscles and tendons; the meniscus, capsule and ligaments provide static stability in the knee joint. This structure of the knee joint allows six different types of freedom of movement.

The cruciate ligaments are of great importance in the functional anatomy of the knee. Bone is a connective tissue that connects certain structural elements of the body. In addition, bone is a composite material consisting of many solid and liquid phases in the mechanical field. It consists of an organic mineral matrix of bone fibers and cells with a substrate surrounded by collagen (insoluble protein) fibers. In addition, inorganic substances such as mineral salts are also present in the bone. The organic component of the bone provides healing and flexibility, the inorganic component makes the bone hard and solid. The components of bone vary according to the type of bone tissue, type of bone, sex, age, species, and presence of bone disease.

The mechanical behavior of the bone depends on the magnitude of the applied load, the speed of application and the direction of application. Compressive strength of bone is much higher than tensile strength. Bone has the property of a viscoelastic (time dependent) material. Bone has a harder and stronger structure at high elongation rates. Since there are so many variables that determine the components of human bone, the modulus of elasticity ranges from 17 to 24 GPa.

2.4. The Prosthesis and Implants

Although the knee joint is actually a hinge joint that allows flexion and extension. It is a polycentric (multiaxial) joint in terms of the function of rotation, sliding and swinging movements. The knee joint is known as one of the most complex joints in the entire body. The knee joint has become more exposed over time, allowing for the production of different prosthesis designs. An ideal prosthesis should provide anatomical integrity and allow normal range of motion by providing knee kinematics but should not alter joint stability.

Today, one of the most vital issues with prosthetics is loosening. As a result, independent components have been designed and friction between the designed components has been minimized.

Historical development of knee implants, from the late 1960s to the late 1970s, approximately 10 anatomical and 13 functional models were developed in Figure 5 [23].

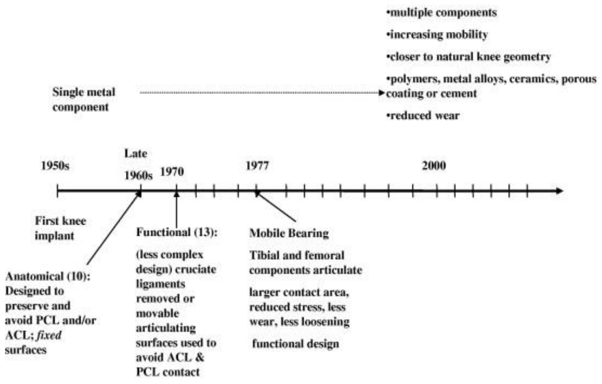

Figure 5. Implant development stages [23]

Implants and biomedical prosthetic devices are artificial devices that are used in biological systems and are intended to function as the original part. These artificial devices are made of metal, ceramic and polymer materials or combinations of these. Metals are primarily used in the human body for orthopedic purposes as surgical implants. These implant materials must meet chemical, biological and mechanical properties in order to fulfill the desired task.

A. Chemical resistance: It is the resistance of the biomaterial to corrosion.

B. Biocompatibility: It is the effect of the biomaterial on the body.

C. Mechanical compatibility: It is related to the material from which the prosthesis is manufactured. In addition, mechanical properties are measured by shear, uniaxial tensile and uniaxial compression tests.

A successful knee joint implant should not restrict mobility. The knee joint also includes the compatibility of the implant with the host tissue and removal of the implant with low wear rate and low friction torque as shown in Figure 6. Knee implants have many problems such as infection and loosening due to the area where they are placed as shown in Figure 7 [24].

Figure 6. Knee implant [24]

Figure 7. Knee radiography with total knee prosthesis [24]

2.5. Bio-Materials, Properties and Used in Making Implants

Implants are given the desired shapes without deteriorating their mechanical properties. Implants should not corrode in body fluids. Bio-materials should not poison the patient; therefore, they should not contain toxic substances. It should be easily purified from germs with pressurized steam and radiation. Implant material due to fatigue caused by loads should not break. To keep stresses within safe limits, strength and fatigue properties should be used together with the shape of the implant where stress concentrations cannot be avoided. This means that implants should be made of materials that can be replaced if damage occurs. Materials with which the body reacts may also make it difficult for the surgeon to remove the implant from its location.

Bio-materials must be placed in the tissue, taking into account the body's natural tendency, the immune system. It is not the right method to do this by removing the body's defense (immune system). It is most reasonable not to render the implant invisible by the body's chemical receptors. This is very difficult to do as materials such as nylon and polyethylene can be easily recognized as "foreign" in the body was given in Table 1. The nylon is more prone to degradation by cells of the immune system than polyethylene [25].

Metals are the main group of materials used in the healing of fractures due to their superior properties in their strength and ductility. According to Venable, Stuck, and Beach's 1937 report, metals generate electrical potential when deposited in the saline environment of soft tissue; this leads to local tissue death, corrosion of the metal and ultimately loosening of the implants.

All metals and their alloys corrode in a salty environment. This corrosion is greatly enhanced by fretting wear from movement between metal components (plates or nails and screws). Most knee implants are passivized for corrosion resistance. To minimize the effect of corrosion, the use of dissimilar materials should be avoided, and care should be taken not to scratch the implant during placement.

Table 1. Natural and synthetic materials used in implants and devices [25]

FIELD OF APPLICATION	MATERIAL TYPE
Skeletal System Joints	Titanium, Titanium-Aluminum
Artificial tendons and ligaments	Teflon, poly (ethylene terephthalate)
Bone filler	Poly(methyl methacrylate) (PMMA)
Thin metal sheets used to fix broken bone ends	Stainless steel, cobalt-chromium alloys
Deformities in the bone	Hydroxyapatite
Dental implants	Titanium, alumina, calcium
Cardiovascular System	Poly(ethylene terephthalate), Teflon
Heart valves	Stainless steel, carbon
Blood vessel prosthesis	polyurethane
Catheters	Silicone rubber, Teflon, polyurethane
Sense Organs In the inner ear cannel	Platinum electrodes
Organs Artificial heart	Polyurethane
Corneal bandage	Collagen, hydrogels
Contact lenses	Silicon-acrylate, hydrogels
Intraocular lenses	PMMA,Silicone rubber, hydrogel

Most knee implants today are commercial grade titanium (Ti and oxygen). Titanium is a metal with high resistance to corrosion, biological compatible and non-magnetic. Titanium alloys are more durable and 60% lighter than steel.Even though, titanium has the strong anti corrosion properties, it can cause inflammation and biofilm occurrence corresponding to application inside the body.

2.6. Polymeric Composites

The modulus of elasticity of metals and ceramics is 10-20 times greater than the modulus of elasticity of hard tissues of the human body. The incompatibility of the modulus of elasticity of the bone with the modulus of elasticity of the metal or ceramic implant is one of the most serious problems faced by orthopedic surgery. Sharing the amount of load on the bone and the implant is related to the durability of the implant materials. Adapting the implant material so that its durability is the same in the tissues to which it is attached prevents deformations that may occur in the bone. This phenomenon is called the concept of stress shielding (SS). Stress shielding is known as the decrease in the strength of the bone in the areas where the bone comes into contact with the prosthesis. Because of this most knee implants today are manufactured from 316L stainless steel, Ti-6Al-4V alloy, or commercial grade titanium (Ti and oxygen).

As an alternative, fiber-reinforced polymeric materials, namely polymeric composites, have started to take place widely today in order to eliminate all these problems mentioned above. Polymeric composites can also be used as soft tissue implants in dentistry applications and orthopedics.

2.7. Polymeric Composites Knee Model and Custom Knee Prosthesis

The most important basic features of personalized knee prostheses are the shape and size characteristics that change depending on the age and gender of the patients. Considering that not all people have the same biological structure (height, weight, etc.), this result is quite natural. As a result of this diversity, the criterion in the selection of the prosthesis to be applied is to find the most suitable one among the standard prostheses.

Before the personalized knee prosthesis treatment, the femur, tibia and patella bone joints are examined with the images obtained by CT (Computerized Tomography) of the patient's knee joint. After this examination, the minimum amount of bone to be removed is determined. . Since the personalized knee prosthesis is mounted on the patient's knee joint and will remain inside the body, the material must be selected carefully. The knee prosthesis must be compatible with the area where it will be used. In addition, it must also have the characteristics and capacity to fulfill the duties of the place where it is located. For this purpose, various types of composite materials have been used in knee prosthesis.

A new hybrid knee implant has been developed that combines a polymer composite (CF/PA12) with an existing commercial implant system made of stainless steel. This hybrid implant reduces bone loss and stress shielding by transferring much more load to the femur compared to conventional metallic implants. Thanks to the compatibility of the carbon fiber material reinforced with polyamide 12 to the spongy structure of the bone, the load on the metal alloy component is prevented from being absorbed by the metal component and transferred to the bone. Thus, the deterioration of the bone by taking normal loads is prevented. Another feature of CF/PA-12 is that it shows better biologicalcompatibility than titanium alloy materials.

In addition, the life of CF/PA-12 for fatigue loads, which are very effective under normal life conditions, has been proven to be much better in studies shown in Figure 8. With this result, the hybrid implant has been found to provide significantly better osseoinduction and longer implant life than conventional metallic implants. [26].

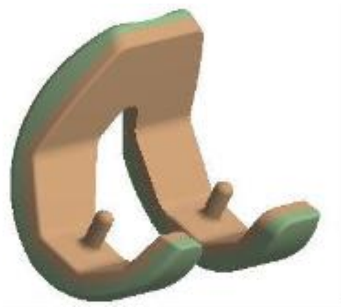

Figure 8. Hybrid femur component with CF/PA-12 inner surface [26]

Improvements that can be made in personalized prostheses can be listed as follows:

- Contact surfaces can be increased in order to reduce the stress values.
- Stress concentrations in sharp corners can be reduced by preparing circular transitional surfaces.
- The properties of bone structures (spongy and cortical) can be determined by cadaver studies and more precise results can be obtained.
- After the appropriate model is created, it may be possible to make a personalized implant.

3. DISCUSSION AND CONCLUSION

Estimated life expectancy for human beings is increasing day by day. In addition, the number of people in the older age group is increasing. As a result of the contribution of technology to modern life, the need for people to perform their daily activities without pain has arisen. Therefore, it is inevitable that they want to perform their physical activities without pain. This should only be achieved by providing sufficient range of motion in the knee joint without pain. The fact that the knee joint is in a mobile structure causes it to be exposed to the most wear over time as age progresses. Therefore, joint arthroplasty emerges as a solution for the treatment of knee joint damage in diseases that increase with joint degeneration, which is frequently encountered in advanced ages.

The parts referred to as orthopedic implants, developed to prevent the loss of mechanical properties of the human body, are manufactured from materials that are as biocompatible with the body as possible, even if they are foreign bodies to the organism.

The human body; it is seen that various implant types and functions such as plates, nails, screws, joints used in various parts of the shoulder, spine, hip, knee, ankle, and their functions are increasing day by day. Total knee arthroplasty is one of the most frequently used methods and it is applied to regain the functions of the worn knee joint; it is a surgical intervention in which an artificial knee joint is inserted. Prosthesis designs and operative techniques are undergoing many changes with technological developments.

In the literature, basic criteria such as mechanical strength, fatigue life and most importantly biocompatibility should be considered in order to produce suitable prostheses. In order to design and develop orthopedic implants, vital and important criteria such as biocompatibility, elasticity close to bone elasticity, simple connectivity to bone tissue, susceptibility to specific design, corrosion resistance, lightness and cost should be considered.

Providing these basic criteria can be achieved with an excellent material choice. Along with experimental tests in the field of tissue engineering and materials engineering, rapid advances and positive developments in laboratory studies will also contribute to this process. However, if the right design factors are not formed, unexpected damage can be caused. For this reason, there is a need for an optimum design that will not impair the use of the structural properties of the material.

The following factors should be taken into account when designing implants:

- Properties of implant material
- General anatomy and deviations
- Effect of bone on implant
- Local bone amount
- Dynamic strain and weight bearing conditions
- Physiological and biomechanical conditions
- Local healing rates in bones
- Adequate space at the fracture site
- Variety of fracture types
- Surgical technique
- Possible complications

While 243.919 total knee prostheses were made in 1995 in the developed country of the world, USA, it is predicted that this number will be around 454,000 in 2030. As a natural consequence of this, the number of knee replacement complications has increased, and the number of knee replacement revisions has increased accordingly. Again, in the USA, the number of knee arthroplasty has increased by 14.1% in the last 5 years. In addition, the number of revision knee arthroplasty increased by 19.3%.

In the Biomechanics Meeting held by the European Union in 1990, 250,000 femoral head implants are used in a year in Europe and 500,000 in a year in the world. In Turkey, according to unofficial statistics, the use of femoral head implants reaches 20,000 in a year.

While the total market for orthopedic implants in the United States was $2,098 million in 1991, it is reported that by 1998, 11 million Americans (5.1% of the total population) had at least one implant in each. The use of implants is not only in the knee joint, but also in areas other than orthopedics. It is also used in maxillofacial surgery, screws, skull plates and cardiovascular surgery.

The rapid development of technology, accordingly, the widespread use of composite materials in knee implants and ensuring their long-term use, making patient-specific designs, being renewable, that is, considering reproducibility or repair conditions, are the criteria to be considered in the design and production of orthopedic materials allows research to continue [27].

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