Tibio-femoral joint replacement for pediatric patient (development of an implantable titanium (Ti6Al4V-ELI) tumor prosthesis to completely replace a knee joint in a pediatric patient)

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ABSTRACT
Osteosarcoma is a malignant osseous neoplasm that represents 55% of malignant bone tumors in children and adolescents in the U.S (Savage & Mirabello, 2011). Of all the cases, 19% develop in the tibia, of which 80% are located in the proximal part of the bone. After several imaging techniques, it is required to perform a resection of the affected bone part (Prater & McKeon, 2022). The case of a 12 year old girl who suffered from proximal tibia osteosarcoma was presented. A femorotibial expandable prosthesis was designed taking into consideration the patient's current anthropometric measures as well as her adult measurements and weight. This design followed the ISO standards as well as some considerations regarding the patient, the material and the daily activities she will be able to perform. A stress, fatigue and a factor of safety analysis was employed taking the patient's weight when they are an adult with a multiplier of 3.46 times her bodyweight. The study considered the forces completely vertical and when the prosthesis is at a 45° angle. The analysis showed promising results, since all of the components had a factor of safety above 3, relatively low stress and a high life cycle and, reducing the risk of creating debris. It can be concluded that the prosthesis is adequate for the patient previously presented.

I. Introduction

Osteosarcoma can be described as a malignant osseous neoplasm, and is categorized as the most common primary bone cancer of childhood. Osteosarcoma represents 55% of malignant bone tumors in children and adolescents in the U.S. (Savage & Mirabello, 2011). Patients between the ages of 10 and 20 are the most affected, there is a slight incidence in males in relation to females of 1.3 to 1. Osteosarcoma occurs in any bony structure of the body, but it is more frequent in the appendicular skeleton and in 50% of patients it is located in the metaphyseal areas close to the knee (Mirabello et al., 2009).

The second most common place for an osteosarcoma to develop is the tibia with a total of 19% of all the cases, in which 80% of the tumors occur in the proximal part of this bone. The main symptom that the patient may experience is bone pain, which is often confused and seen as just a sprain, arthritis or growing pains. This may cause the patient to endure this tumor for weeks or months. Pathological fractures, fevers, fatigue, night sweats, shortness of breath, weight loss, itchy skin and respiratory symptoms, are not common but may present in some cases. The pain resulting from this tumor may present itself as a limp, and it might also cause swelling or a lump (Prater & McKeon, 2022).

When the doctor executes the physical exam, they will check if there is a decreased range of motion, a local or regional lymphadenopathy, respiratory issues with metastatic forms or a palpable mass. Afterwards, a lactate dehydrogenase and alkaline phosphatase analysis will be created to act as biomarkers and check for an increased osteoblastic activity. The next step is to create a diagnosis utilizing a radiograph and if the test shows any indication of osteosarcoma, a magnetic resonance imaging will be required. A computed tomography can then be used to plan the biopsy and state the stage of the disease. A PET can then be used to determine the extent of the tumor and identify the suspicious mass. To check for a bony metastasis, a radionuclide bone scan can be performed. Finally, another MRI or CT scan will be required as well as a fertility consultation with the patient to start the biopsy of the osteosarcoma (Prater & McKeon, 2022). For this report, an expandable prosthesis is designed to solve a clinical case related to the mentioned pathology.

II. Clinical Case Report

Clinical case report describes a 12-year-old female infant diagnosed with proximal tibia osteosarcoma. The pediatric patient has not achieved full skeletal maturity and requires a proximal tibial resection and replacement.

III. Prosthesis Design

A) Use of CT scan for prosthesis modeling/design

Prior to resection, routine examinations are evaluated to determine the extent of local disease and to distinguish the presence of metastases. This includes clinical evaluation, plain radiography, SPECT, chest radiography, and computed tomography (CT) scans as well. MRI is used to define the grade of the tumor, the involvement of the soft tissues, particularly the neurovascular bundle.

CT scan shows a cut or cross section of the body. The image shows bones, organs, and soft tissues more clearly than conventional X-rays. Also, a CT scan can show the shape, size, and location of a tumor. This study can even show the blood vessels that feed the osteosarcoma (all without having to operate on the patient).(Computed Tomography (CT) Scan, 2021)

A CT uses a thinner to create a series of images taken from different angles. The information from each angle is sent to a computer that creates a black and white image that shows a section of a certain area of the body (Computer Tomography and Cancer, 2014). By placing the CT image slices one on top of the other. The machine can create a three-dimensional (3-D) image.

Having a three-dimensional image allows knowing the geometry of the tibia, femur and fibula, as well as the location and distribution of osteosarcoma. With this information, the tibial, femoral and fibula area that will be exposed to osteotomy and that the prosthesis should replace is defined. Using the CT Scan, anthropometric data relevant to the design of the prosthesis can be acquired, such as the distance between the lateral and medial condyle, anterior edge, posterior surface, soleus line, and lateral edge.

A diagnostic CT scan is also vital for accurate, precise and safe placement of the implant with the fewest possible complications. Essentially, a CT scan prior to a tibiofemoral implant procedure will significantly improve the likelihood of a successful, trouble-free procedure and trouble-free recovery thereafter. (Bonnin et al., 2016)

3D tomography helps map the target bone for removal and replacement. It also pinpoints the location and spatial shape of other vital structures, such as blood vessels, bones, and major arteries. Nerves and arteries can be avoided, while the bone can be examined for areas of potential weakness.

B) Prosthesis design considerations

Important considerations for the prosthesis design include:

- The prosthesis must be designed to be extensible since it is a pediatric patient and he still has to grow. The extensibility can be through some internal mechanism or performing some revision surgery to manually extend the prosthesis.
- The prosthesis must be designed according to the selected materials, analyzing the internal structural mechanics through finite element analysis, complying with a minimum safety factor of 2 according to the Von Mises failure criterion. Similarly, the design of the prosthesis must be flexible enough to avoid the effect of bone degradation due to Wolff's Law or Stress Shielding effect.
- The prosthesis should be designed based on the patient's specific surgical planning.
- The prosthesis should be designed based on the correct manufacturability of the design.
- The prosthesis should be designed according to the feedback from medical personnel.
- Potential adverse effects should be considered in the design of the prosthesis such as abrasive wear of the parts, corrosion, metallosis, potential galvanic effects, rejection due to biocompatibility, etc.
- The prosthesis must be designed so that it complies with the normal biomechanical function of the person according to age, considering geometric characteristics that facilitate the re-insertion of some tendons or ligaments

C) Applied regulations/normative

The standards with which the prosthesis complies and the standards that must be applied during the manufacturing and testing process are shown in Table 1.

Norm	Explanation
ISO 10328	It establishes that the factor of safety of a lower limb prosthesis must be 3-5 times the body weight of the patient. The prosthesis designed contemplates a multiplier of 3.46 times the body weight of an adult instead of the child and has a factor of safety above 2,
ISO/AWI 7207-2	It specifies surface finish necessities for articulating surfaces of total and partial knee joint prosthesis. It provides a guide for the periodic validation of production processes.
ISO 14243-5:2019	It establishes the relative angular movement between articulating patellofemoral joint components, the pattern of the applied force, sample configuration, speed and duration of testing and test environment. These are used to test the durability of the total knee joint prostheses in wear-testing machines with a controlled load and displacement. It must endure more than 50,000 cycles with the load being 3 times the body weight of the patient.
ISO 10993-1	It categorizes the devices based on the duration and nature with the contact of the body. It is the assessment of the biological safety of the medical device.
ISO 5832-2	In this norm, it establishes the manufacturing process the titanium alloy must go through. In this case it is for Ti6Al4V and this alloy is included in the ISO.
ISO 5834-2	It specifies the requirements and testing methods for moulded forms such as sheets and rods of ultra-high-molecular-weight polyethylene.
ISO 10993	It is the biological evaluation of sterile and non sterile objects that come into direct or indirect contact with the patient's body. This mostly consists on biocompatibility and the effects that it might have, such as cytotoxicity, sensitization, hemocompatibility, pyrogenicity, implantation, genotoxicity, carcinogenicity, reproductive and developmental toxicity, and degradation.
ISO 14243-1	This norm specifies the optimal flexion-extension angular movement between articulating components in a total knee joint prostheses. It also specifies the pattern in which the applied forces must be to be tested in a wear-testing machine. Environmental conditions for the wear-testing machine are also specified.
ISO 14243-2	Assessment method related to the wear of the tibial component in the total knee joint prosthesis using a gravimetric technique. This technique is specified in ISO 14243-1 and ISO 14243-3 and it consists of soaking the design in a lubricant repeatedly and measuring the weight loss to calculate how much it wears down.
ISO 14879-1	It specifies the test method to determine the endurance properties of the tibial tray used in the knee-joint prostheses to support and secure the articulating surface. This tibial tray is placed so that one condyle of it extends as a cantilever. Afterwards, a cyclic force is applied to the unsupported condyle with a spacer. The force is

	applied until it fails or it surpasses the number of cycles.
ISO WD N1202:2020	It is for implants for surgery. It is a measuring method to detect antibacterial ability of the implant surface.
ISO 12891-2:2020	This document demonstrates the methods of analysis after the retrieval of a surgical implant. The analysis is divided in three stages, with each stage getting more destructive than the previous.
ISO 14971:2019	It provides manufacturers a framework that gives insight and judgment systematically to manage the risks associated with the medical device. It helps manufacturers by establishing principles of risk management that have evolved over time.
ISO/FDIS 14155:2020	It states good clinical practice for the design, conduct, recording and reporting of the clinical investigations carried out in human subjects.
ISO 14243-3	It specifies the relative movement between the articulating components, the pattern of the applied force, sample configuration, speed and duration of the test to be used for wear testing of total knee-joint prosthesis in wear-testing machines, with an axial load control, flexion/extension angular motion control, AP displacement control and tibial rotation control. It is tested by placing the prosthesis in an apparatus that employs cyclic variations of all of the previously described movements and an axial force to the interface between the tibial and femoral components, all of this is needed to simulate a normal human walking.
ASTM F2003	It accelerates the aging of ultra high-molecular-weight polyethylene to evaluate the material's mechanical and chemical stability in an extended aged condition. It verifies if the experimental conditions are within tolerance through aging in a temperature and pressure regulated oxygen chamber.
ISO 7207-1	It classifies the femoral, tibial and patellar components of the knee joint prosthesis, where at least one compartment of the patient's knee is replaced. It also establishes the dimensions these components must have
ISO 21536	It provides specific requirements for knee joint replacement implants. It describes the requirements intended for performance, materials, design attributes, manufacture, design evaluation, sterilization, packaging information according to the manufacturer and methods of testing.

Table 1. *Standards with which the prosthesis complies and standards that must be applied during the manufacturing and testing process.*

D) <u>Biomechanics of the designed prosthesis</u>

Once the leg is flexed, the semitendinosus and semimembranosus muscles allow for internal rotation, while the biceps femoris, because it is located on the lateral side, causes external rotation after flexion.The knee has both internal and external rotation, the first one brings the toe inward

during foot adduction, this rotation is 30°, while the second does the opposite,

sending the toe out more than normal and this occurs during foot abduction, the amplitude of this rotation varies by about 30°. The knee naturally rotates depending on the angle of knee flexion. (Affatato, 2015).

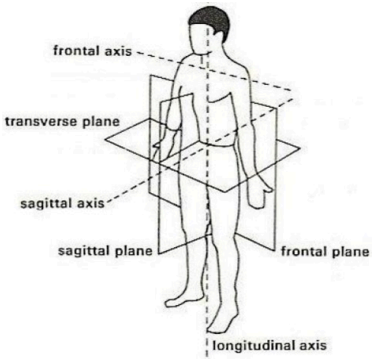


Fig 1. *Planes and axes of movement of the body (Planes and Axes of Movement - Movement Analysis in Sport - Eduqas - GCSE Physical Education Revision - Eduqas - BBC Bitesize, 2022)*

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Flexión de 120 a 140°	**Extension 2-8°**
Semimembranosus Semitendinosus Biceps Femoris Gracilis Sartorius Popliteus Gastrocnemius	Quadriceps
External rotation 30°	**Internal rotation 30°**
Biceps femoris	Semimembranosus Semitendinosus
	Biceps Femoris Gracilis Sartorius Popliteus

Table 2*. Degrees of freedom and muscles involved in knee movement (General Anatomy and Musculoskeletal System (THIEME Atlas of Anatomy), 2014)*

The mechanical axis of the lower limb is composed of the straight line that joins the centers of 3 joints, hip, knee and ankle. This axis joins with the axis of the leg, on the other hand the mechanical axis forms an angle of 6° with respect to the axis of the femur. (CHAPTER 2 BIOMECHANICS of the KNEE Introduction, n.d.). The valgus angle can present pathological variations, in addition to sexual variations, in which this angle is greater in women because the separation of the hips is greater in them. This separation forms an angle of 3° between the mechanical axis and the vertical.

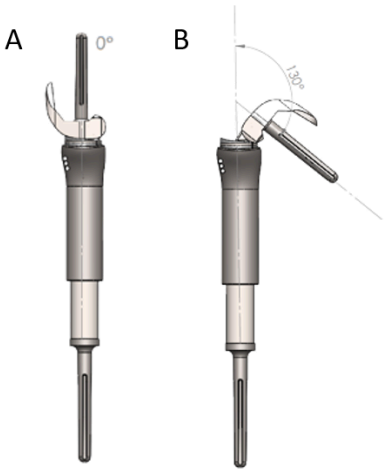


Fig 2. *Maximum extension and flexion of the prosthesis*

The varus angle of the prosthesis can be adjusted to the needs of the patient, this through the implementation of a hinge-type mechanism in which the angle of the hole where the screw that assembles the femoral and tibial component is inserted can be modified. The prosthesis allows flexion and extension mobility from 0° to 130° (Figure 2), as well as 30° of internal and external rotation (Figure 3), this through the implementation of the hinge-type mechanism and some rails that guide the rotation of the prosthesis. By allowing the knee to rotate, it simulates a better performance of the biomechanics than if it only had flexion and extension. This also provides comfort and reduces stress on the screw that joins the femoral and tibial component.

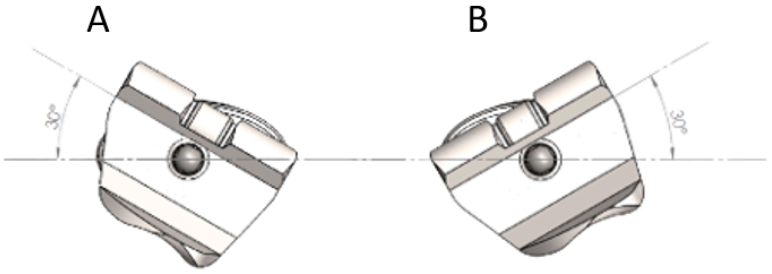


Fig 3. *Maximum internal and external rotation of the prosthesis*

Since the designed prosthesis has the specifications of a 12-year-old infant who requires a tibiofemoral prosthesis that could have a long-term life cycle. The implant will be subjected to high loading and unloading cycling due to the normal activities of the patient. To ensure the structural integrity of the prosthesis, the maximum load on the prosthesis was taken into account.The external load applied to the prosthesis depends on the patient's mass as well as the load multiplier on the knee joint as a function of body weight (table 3)

Activity	Multiplier of load at the knee joint depending on body weight (L)
Stair descending	346%
Stair ascending	316%
Level walking	261%
One legged stance	259%

Knee bending	253%
Standing up	246%
Sitting down	225%
Two legged stance	107%

Table 3. *Forces at knee joint as percentage of body weight (Kutzner et al., 2010)*

Force loads applied on the prosthesis

$$Patient\ mass \rightarrow m$$
$$Body\ weight \quad \rightarrow W = (m)\ x\ (g) \quad \ldots\ldots\ldots\ldots\ldots\ldots \mathbf{1}$$
$$Load\ on\ the\ prosthesis \rightarrow W_P = W.L \quad \ldots\ldots\ldots \mathbf{2}$$

The estimated mass for the patient when she reaches adulthood is 65kg subjected to a load multiplier of 346% when descending stairs.

$$Patient\ mass \rightarrow m = 65\ kg$$
$$Body\ weight \quad \rightarrow W = (65\ kg)\ x\ (9.81\ m/s^2) = 637.65\ N \quad \ldots\ldots\ldots\ldots\ldots\ldots \mathbf{1}$$
$$Load\ on\ the\ prosthesis \rightarrow W_P = 637.65\ (3.46) = \ 2206.269\ N \quad \ldots\ldots\ldots \mathbf{2}$$

The physical activity that most demands the prosthesis is descending stairs, considering its load multiplier and the weight of the patient, the prosthesis was designed to safely support, without presenting elastic deformation or fracture, a load of 2206N.

E) Prosthesis design for reinsertion of soft tissue and replacement for ligaments

The designed prosthesis considered the addition of three openings in the anterior side of the tibial component (figure 4) for sewing the patellar soft tissue and evaluating patellar positioning. Additionally, the prosthesis includes the femoral and tibial stems for them to be inserted to the tibial and femoral medullary canals respectively. On the other hand, the four main ligaments of the knee are the anterior and posterior cruciate ligaments and medial and lateral collateral ligaments. For this prosthesis design, ligaments are considered to be removed and replaced by the hinge mechanism that allows the flexion and extension of the knee.

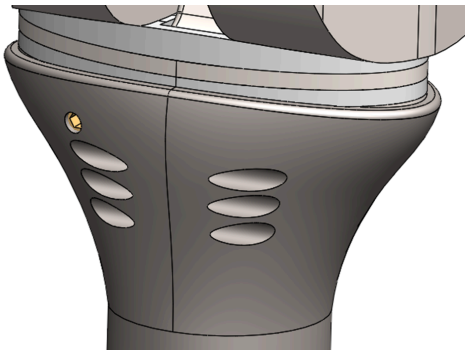


Fig 4. *Anterior openings for patellar soft tissue sewing.*

F) Prosthesis extension mechanism design for pediatric patient

Patients suffering from bone cancer undergo traditional treatments including chemotherapy, radiation therapy and

surgery. Surgery, until very recently, consisted of the amputation of the cancerous limb. However, the advances achieved thanks to the associated treatment pointed to a new role for oncological surgery and led to the development of so-called conservative surgical techniques. Surgeons have begun performing less mutilating amputations and, where possible, resection of the tumor along with a portion of the bone. This contributed to the development of new reconstruction techniques. The objective of these techniques is to replace large bone losses by applying not only oncological prostheses but also bone grafts and other reconstruction methods. The fact that bone cancer mainly affects children, who are in the process of growing, makes the problem even more difficult, since the limb with a prosthesis implanted in place of the diseased bone will be shorter after a certain time. Having said this, the designed prosthesis contains an extensible mechanism as a solution to this problem.

The extensible mechanism works through a worm and crown system made of Ti6Al4V ELI. The crown has an extrusion with a thread, which simulates a screw, this is connected to the tibial stem, which has an internal thread like a nut. When the crown turns clockwise, the thread is introduced into the tibial stem, causing the prosthesis to decrease its length. Conversely, if the crown rotates counterclockwise, the screw will push the tibial stem allowing extension of the prosthesis. The extension mechanism has a fixture screw that prevents the prosthesis from extending or shrinking when not desired.

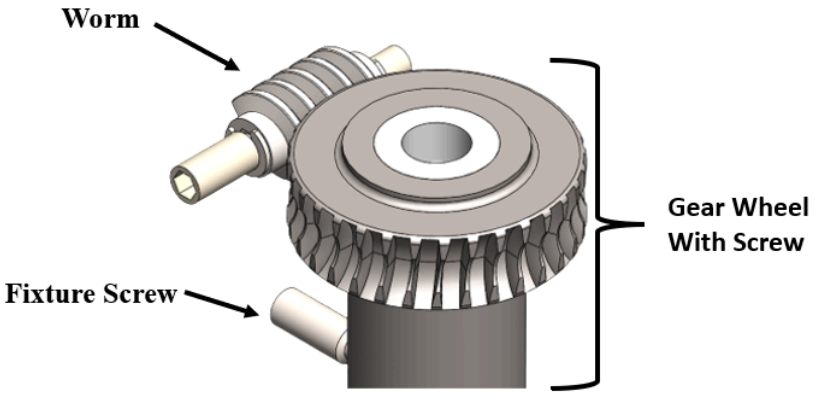


Fig 5. *Extensible mechanism*

The crown has a power transmission ratio of 32 to 1 with respect to the worm, and the screw thread has a pitch of 1.9304mm, this means that for every 32 turns of the worm the crown makes one turn, causing a 1.9304mm extension or contraction. A power screw is implemented mainly for three characteristics; gain a great mechanical advantage (move large loads with minimal stress), generate large forces without sweeping, and obtain precise axial movements. The screw thread is of the ACME type, it is easier to manufacture compared to a square thread. It has superior root strength characteristics compared to a square thread. The wire has an optimum efficiency of around 70% for helix angles between 25° and 65° outside of this range, the efficiency drops. (Power Screws - Roy Mech, 2013) The helix angle of the prosthesis screw is 60°

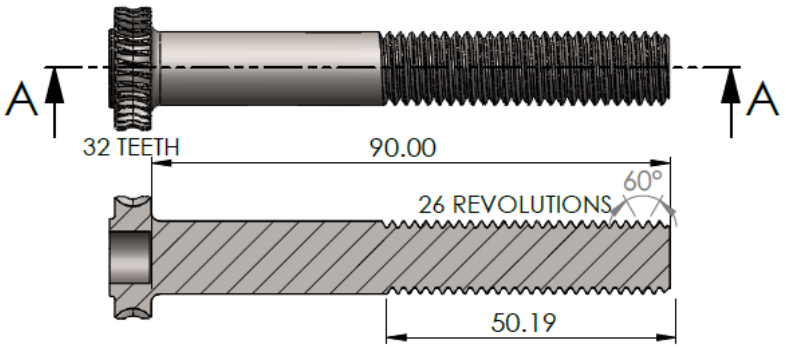


Fig 6. Main geometric characteristics of the extensible mechanism screw

The system is designed to be elongated depending on how the patient's other leg grows. Each time this screw is rotated, it increases by 1.9mm in length with a maximum length of 42mm more than the original size. According to (Belmonte et al., 2022) the length of a woman's tibia can be calculated from her height with the following formula; T=(H-61.53)/2.9, where "T" is Tibia Length and "H" is patient Height. The height of the patient is 140cm and according to (A Century of Trends in Adult Human Height, 2016) in Mexico it is estimated that the average height of the woman is between 158 cm and 164 cm.

Substituting such heights, the current and final length of the tibia was calculated, 27.05mm and 35.33mm respectively. As the prosthesis must replace a third of the tibia, the initial length of the tibial component is 103mm, and the final length is 145mm (This length excludes the stem which is 80mm long). The prosthesis has extra 24mm in the extension mechanism in case the patient grows more than expected.

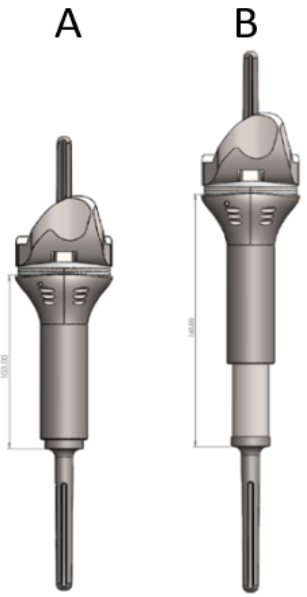


Fig 7. Tibial component length A) Initial length, B) Maximum length

The main advantage of a minimally invasive prosthesis is the possibility of its extension without major surgical intervention. This makes it easier to control the implant lengthening process and perform it more frequently. This consequently makes it possible to reduce the rehabilitation time after arthroplasty.

After the prosthesis is implanted, the patients will have to be checked every 3 months for 1 year, then 6 months for the next 4 years and after that it will be annually. The studies will have a complete physical examination, an X-ray of both legs to compare the growth of the healthy

leg with the other leg, a CT scan for the chest, and a bone scan if there is suspicion of bone metastasis. The lengthening procedure must be done after the completion of chemotherapy and after the limb length discrepancy (LLD) exceeds 2 cm. The extending mechanism is exposed with a small incision of 2 cm. There are 2 nails in the prosthesis, one will block the lengthening system and the other will be used to extend the prosthesis.

Both of these nails must be extended using Allen keys. The nail used to extend the prosthesis will have a 1 engraved in it while the other one will have a 2. When using the Allen key it must be inserted until the engraved line in the design is no longer visible, meaning it was inserted correctly. If the design is visible it means that it was not properly inserted and it will damage the prosthesis.

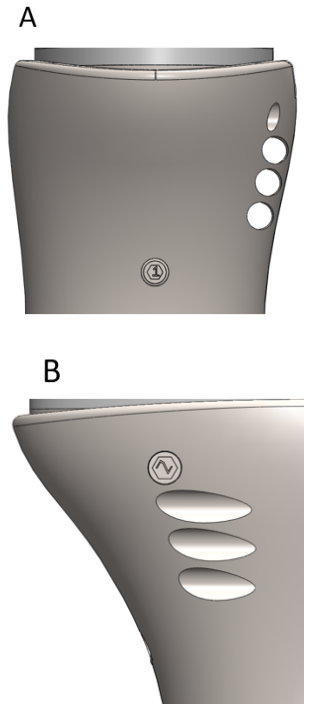


Fig 8. *Extendable mechanism screws A)Expansion screw B)Fixture screw*

The length of the tibia and the growth of the proximal and distal epiphysis is calculated with periodical X-ray films. Radiographs can be utilized if there is a suspicion of aseptic loosening. Septic loosening can be detected and diagnosed through fludeoxyglucose positron emission tomography, triple phase bone, and indium-111 leukocyte scans. Aseptic loosening is measured through a progressive zone of radiolucency surrounding the components,radiographs and calculating the position of the components.

G) Prosthesis design in relation to the patient-specific surgical planning

The proximal tibial of the pediatric patient is resected through an anterior medial 15 cm incision using as a reference the medial patellar incision procedure. The incision begins at the top medial corner of the patella, continues down along the patellar tendon, and ends down at the anterior medial aspect of the leg (around the proximal diaphysis of the tibia).

The prosthesis was designed according to the anthropometric measurements of the patient and so that it could be able to be inserted and fitted through the performed incision. From the overall dimensions of the prosthesis, 103 mm belong to the implant tibial area, 3 mm are from the polyethylene insert, and 12 mm belong to the femoral component.

As mentioned before, for the postoperative phase, the prosthesis was also strategically designed so that it can be expanded. The incorporation of two nails in the anterior and lateral sides of the prosthesis makes it possible for surgeons to perform a 2 cm incision and expose the nails to manipulate the extendable mechanism.

H) Prosthesis design in relation to its adequate manufacturability

For an accessible and proper manufacturability of the prosthesis, it was divided into 20 different parts. However, To facilitate assembly during surgery, the prosthesis is pre-assembled in 3 subassemblies, the femoral subassembly, tibial subassembly and screw for joining the femoral and tibial components. Overall, the prosthesis consists of a femoral component, a femoral component stem, an articulating surface, the extension mechanism screws, a tibial component and a tibial component stem.

I) Surface Finish

The expandable tibial femoral replacement prosthesis presents a joint made up of two metal parts, femoral and tibial, including a polyethylene insert that serves as a support surface for the screw that joins the femoral and tibial components. The surface finish of metal components is a very important factor in minimizing the wear rate of polyethylene and, subsequently, the gradual production of metal and plastic waste.

The prosthesis must undergo grinding and polishing, it is a common process in medical implants, such as knees, hip stems, ankles (Rosler, 2016). After casting, these parts are machined and then undergo a multi-stage drag finishing process for aggressive surface grinding, resulting in a high gloss polished and smooth surface. The roughness of the functional surface should be reduced from about Ra=1.0 µm to less than Ra=0.5 µm.

J) Bone-implant interaction

The interaction between the prosthesis and the bone is achieved by means of a bone cement. Bone cement allows a surgeon to affix prosthetic joint components to bone that is slightly porous due to osteoporosis; Bone cement dries within 10 minutes of application. The main compound in cement is polymethyl methacrylate (PMMA). It consists of two parts: one powder and one liquid in a 2/1 ratio.

The powder part is composed of 87% PMMA, 10% radiopaque agent (barium sulfate or zirconium dioxide) and 2-5% benzoyl peroxide. The second liquid component is made up of 97% methyl methacrylate, an oxidizing agent (hydroquinone methyl ester, topanol or hydroquinone) and a tertiary amine that acts as a polymerization accelerator catalyst (3% DMP-toluidine).

- The union is produced by mechanical interdigitation, not by adhesiveness.
- Bone-cement resistance: by surface area and degree of bone penetration (up to 5 mm). Improvement is achieved by the introduction of low-viscosity cement, careful cleaning and by pressurization

Manual cement mixing techniques are not uniform, frequently producing a high porosity of this material (with the negative effects that this entails). The degree of porosity can be reduced by centrifugation and vacuum mixing. The optimum thickness is about 2-4 millimeters (mm). With a thickness less than 2 mm there is a risk of breaking the cement layer. (Rubén et al., n.d.) To improve interdigitation prosthesis Stem has no sharp edges or corners.

K) *Use of medical staff feedback for prosthesis design*

Medical staff feedback was an important part of the prosthesis design process. Essential information was obtained from it such as the six degrees of freedom of the knee joint. For the prosthesis design, a hinge mechanism was developed that allows the prosthesis to make flexion and extension movements in a range from 0º to 130º. Additionally, prosthesis also allows a 30° internal and external rotation of the knee. Another medical staff feedback advice was needed to determine the cement procedure of prosthesis. For the prosthesis design, bone.implant interaction was accomplished by cementing the tibial and femoral stems to the tibial and femoral medullary canals respectively. The correct cement mixing techniques to improve its properties can prevent the prosthesis loosening and an increase in the materials porosity. Improvement techniques of cement properties include: the slow shake of it for only 90 seconds (maximizes the resistance to the compression), mixing it under vacuum (reduces porosity and microcracks), use a low viscosity cement plus injection device, pressurize it (increases interfingering), and clean the bone bed of blood and debris.

L) *Prosthesis potential adverse effects*

There are some potential adverse effects surrounding the prosthesis that need to be considered. Biocompatibility, corrosion, and metallosis are the most common effects related to the material selection of the prosthesis. Metallosis is generally defined as the corrosion caused by the natural erosion of metal components in a prosthesis or implant. For this report's prosthesis design, a titanium alloy is used as the material of the main components because of its excellent corrosion resistance and good hard-tissue compatibility. However, there are reported cases of pathologies related to titanium rejection.

Other adverse effects include infection, material sensitivity reactions, reduced life expectancy of prosthesis components, prosthesis loosening, instability, dislocation between prosthesis components and septic or aseptic failure. For these effects, it is recommended to verify if the patient has a clinical history with other physiotherapeutic problems (this includes metabolic disorders that impair bone formation like osteoporosis) or mental/neuromuscular disorders.
The presence of these effects involves a high risk of implant failure and can cause other complications such as skin pathologies, gastrointestinal problems, and even cardiovascular diseases.

IV. Prosthesis material selection

Prosthesis material selection to avoid Wolff's Law effect or and stress shielding

Stainless “surgical” steel is one of the most frequently applied alloys to manufacture surgical implants and instruments. These alloys serve for the fabrication of at least half of all orthopedic implants used in the USA (Szczęsny et al., 2022), This material is durable, ductile, and, thus, relatively simple to process. It is also non-toxic and biocompatible, as it does not evoke an adverse reaction from adjacent tissues.

Nowadays titanium alloys are implemented for implantable prosthesis, the most popular titanium alloy used for implants is aluminum vanadium doped alloy (Ti6Al4V). Currently, practically every type of orthopedic implant has a titanium ‘variant’, including screws, plates, intramedullary nails and rods, external fixators, and joint prostheses. Since titanium is non dielectric and does not increase in temperature when exposed to alternating magnetic fields, it is ideal as an implant as it also does not interfere with magnetic resonance imaging. This significant advantage of titanium has dominated the materials’ application in traumatology and joint replacements, and practically monopolized the market of implants used in spine surgery.

Besides CoCr alloys, have been applied in prostheses manufacture, often produced with some content of Mo and other metals including nickel, tungsten, and titanium. Specifically, the most common orthopedic implant alloys contain between 62–68% Co, 27–30% Cr, 5–7% Mo, and <2.5% nickel, with an example alloy classification used for medical purposes being ASTM F75 CoCr alloy [36–38]. CoCr alloys were introduced in early 1900’s and have been characterized by good biocompatibility, high wear, and corrosion resistance, which result from high cobalt, molybdenum, and chromium content (almost twice that of steel). (Szczęsny et al., 2022) Moreover, these materials are simple to cast, and, thus, complex shaped implants could be produced at relatively low cost.

	Implant Type	Yield Point [MPa]	Ultimate Tensile Strength [MPa]	Young's Modulus [GPa]	Elongation [%]
Bone	bone		130–205 MPa	17.9–18.2	
Steel	316 L	170–750	465–950	205–210	30–70
Ti and alloys	CP-titanium	170–480	240–550	105	15–24
	Ti6Al4V	795–875	895–965	100–114	10
	Ti6Al7Nb	795	860	105	10
	Ti5Al2.5Fe	820	900	110	6
	Ti3Al2.5V	585	690	100	15
	Ti13Nb13Zr	836–908	937–1037	79–84	42–44
	Ti12Mo6Zr2Fe	1000–1060	1060–1100	14–85	18–22
	Ti24Nb4Zr8Sn	570–700	755–830	46–55	13–15
CoCrMo alloys	Cast 28Co6CrMo	450	655	210–250	8
	Wrought Co28Cr6Mo	517–827	897–1192	220	12–20
	Co28Cr6Mo Forging	827	1172	220–230	12

Table 4. *Physical characteristics of bone and most extensively used orthopedic surgery alloys. [Szczęsny et al., 2022]*

The three materials have mechanical and physical properties suitable for the manufacture of the tibiofemoral prosthesis; however, the material that prevents bone resorption due to Wolff's law is needed. Since bone is an anisotropic and viscoelastic material, it forms and reabsorbs according to the mechanical stresses it undergoes, bone adapts depending on the level of stress it receives. If the load on a particular bone is increased, it will remodel itself over time to become stronger to withstand that type of load. The internal architecture of the trabeculae undergoes adaptive changes, followed by secondary changes in the outer cortical portion of the bone, resulting in thicker bone. Conversely, if the load on a bone is decreased, the bone will become less dense and weaker due to lack of the necessary stimulus to continue remodeling.

The reduction in bone density (osteopenia) makes the bone more susceptible to fracture, this is known as protection against stress and can occur as a result of the implantation of a prosthesis (Säämänen et al., 2010). The selection of the cross section and the material must be carried out with the aim of keeping the stress on the bone as close to the stresses suffered by a bone that has not been subjected to the implantation of a prosthesis. For this reason, a comparison was made of the stresses to which the tibia is subjected when the material and diameter of the stem of the prosthesis varies.

The stress received by the prosthesis and by the bone is compared as an effect of an axial load and a moment calculated from the weight of the patient and the load multiplier in the knee joint, the load was applied at 45 degrees since it is when the greatest stresses are generated. Total stress can be calculated by combining the axial and bending stresses. The formulas

are obtained from the stress formulation marked with the number 3.

$$\sigma = \frac{F}{A} + \frac{Mc}{I} \text{.....3}$$

$$A = \pi(r_0^2 - r_i^2) \text{ ....4}$$

$$I = \frac{\pi}{4}(r_0^4 - r_i^4) \text{.....5}$$

Equations 4 and 5 are for a circular cross section (hollow), Equation 4 calculates the section area, in this case the bone, and Equation 5 is to obtain the moment of inertia of the bone as well.

Equation number 6 is to calculate the stress in the bone effect of an axial load from the cross sections of the stem, the bone and the modulus of elasticity (E) of the materials. Equation 7 is used to calculate the stress caused by an axial load on the stem.

$$\sigma_{bone} = \frac{E_{bone}F}{E_{bone}A_{bone}+E_{stem}A_{stem}} \text{.....6}$$

$$\sigma_{stem} = \frac{E_{stem}F}{E_{bone}A_{bone}+E_{stem}A_{stem}} \text{ .....7}$$

Equation number 8 is to calculate the stress in the bone effect of a moment from the cross sections of the stem, the bone and the modulus of elasticity (E) of the materials. Equation 9 is used to calculate the stress in the stem caused by a moment.

$$\sigma_{bone} = \frac{E_{bone}M(d_{out}/2)}{E_{bone}I_{bone}+E_{stem}I_{stem}} \text{.....8}$$

$$\sigma_{stem} = \frac{E_{stem}M(d_{stem}/2)}{E_{bone}I_{bone}+E_{stem}I_{stem}} \text{....9}$$

Prosthesis length [mm]	Bone area [mm^2]	8mm Steam area [mm^2]	I Bone [mm^4]	I Stem [mm^4]	E Ti6Al4V [Mpa]
145	290.7444	50.1056	6006.46046	3216.9984	107000
E Steel [Mpa]	**E Co28Cr6Mo [Mpa]**	**E hueso [Mpa]**	**Axial Loading [N]**	**Moment [Nmm]**	**Bone relative ratio [mm]**
207000	220000	18050	1560	226200	10.41

Table 5.*Data used in the stress calculation when an 8mm stem is implemented*

8mm diameter stem						
	Axial loading		Pure Bending Moment		Stress Magnitude	
Material	Bone Stress	Stem Stress	Bone Stress	Stem Stress	Total Bone Stress	Total Stem Stress
Ti6Al4V	2.654	15.733	46.951	213.889	49.605	229.622
Steel	1.803	20.674	27.445	241.877	29.248	262.550
Co28Cr6Mo	1.731	21.093	26.039	243.894	27.769	264.987

Table 6. *Bone and stem stresses when 8mm stem is implemented*

Prosthesis length [mm]	Bone area [mm^2]	9mm Steam area [mm^2]	I Bone [mm^4]	I Stem [mm^4]	E Ti6Al4V [Mpa]
145	277.4351	63.4149	4070.44946	5153.0094	107000
E Steel [Mpa]	**E Co28Cr6Mo [Mpa]**	**E hueso [Mpa]**	**Axial Loading [N]**	**Moment [Nmm]**	**Bone relative ratio [mm]**
207000	220000	18050	1560	226200	10.41

Table 7. *Data used in the stress calculation when an 9mm stem is implemented*

9mm diameter stem						
	Axial loading		Pure Bending Moment		Stress Magnitude	
Material	Bone Stress	Stem Stress	Bone Stress	Stem Stress	Total Bone Stress	Total Stem Stress
Ti6Al4V	2.388	14.154	34.011	154.941	36.399	169.095
Steel	1.553	17.807	18.639	164.272	20.192	182.079
Co28Cr6Mo	1.485	18.102	17.605	164.900	19.090	183.002

Table 8. *Bone and stem stresses when 8mm stem is implemented*

Prosthesis length [mm]	Bone area [$mm^{2]}$]	10mm Steam area [mm^2]	I Bone [mm^4]	I Stem [mm^4]	E Ti6Al4V [Mpa]
145	262.56	78.29	1369.45886	7854	107000
E Steel [Mpa]	**E Co28Cr6Mo [Mpa]**	**E hueso [Mpa]**	**Axial Loading [N]**	**Moment [Nmm]**	**Bone relative ratio [mm]**
207000	220000	18050	1560	226200	10.41

Table 9. *Data used in the stress calculation when an 10mm stem is implemented*

10mm diameter stem						
	Axial loading		Pure Bending Moment		Stress Magnitude	
Material	Bone Stress	Stem Stress	Bone Stress	Stem Stress	Total Bone Stress	Total Stem Stress
Ti6Al4V	2.147	12.726	24.566	111.911	26.712	124.637
Steel	1.344	15.417	12.876	113.477	14.220	128.894
Co28Cr6Mo	1.282	15.626	12.126	113.578	13.408	129.204

Table 10. *Bone and stem stresses when 8mm stem is implemented*

According to the results, the titanium alloy Ti6Al4V is the material that allows the bone to carry a greater stress, likewise the 8mm stem increases the stress on the bone. In other words, the prosthesis must have an 8mm stem and be machined in Ti6Al4V to avoid bone resorption due to Wolff's law.

V. Prosthesis Structural Analysis

For the determination of the stress analysis, safety factor and fatigue, the ANSYS software was used to carry out the analysis by means of the finite element method. Two analyzes were performed, the first with the prosthesis at zero degrees of flexion and the second with the prosthesis at 45 degrees of flexion, which is when the maximum stresses are produced. In both analyses, the 2206N load was normally applied to the surface contacting the distal femur. Some assembly components were removed to perform static analysis, in order to reduce the number of elements and nodes to reduce the computational capacity invested in the solution. The removed components are those that do not fulfill a structural function, such as those involved with the worm and spacers.

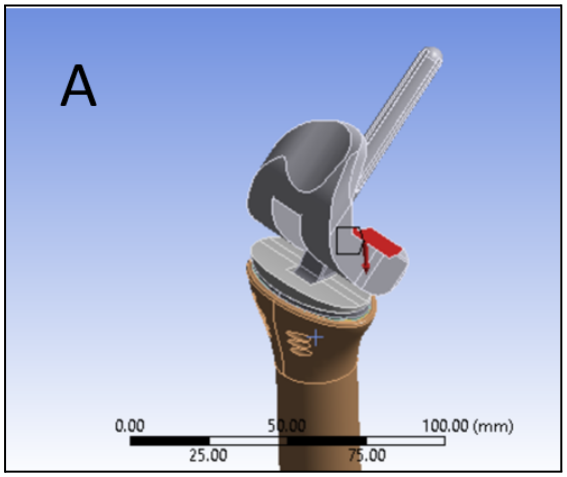


Fig 9. *Force applied on the prosthesis A) Flexión 45 degrees.*

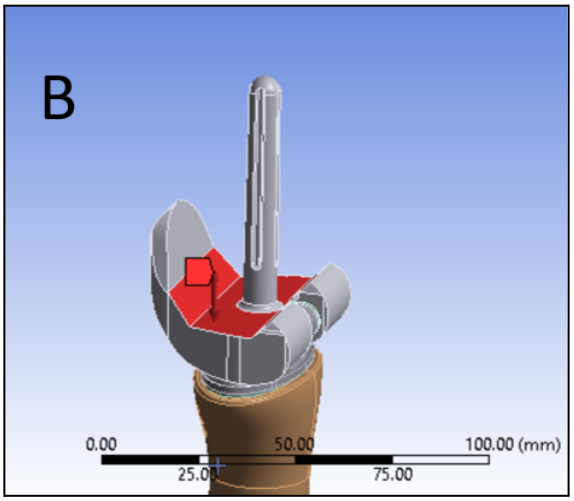


Fig 10. *Force applied on the prosthesis B) Full extension*

The geometry previously made in SOLIDWORKS was loaded, in the preprocessing the border conditions were defined, in both analyzes the stem of the tibial component was used as a fixed geometry (Figure 11), this to simulate the cementation of the prosthesis with bone.

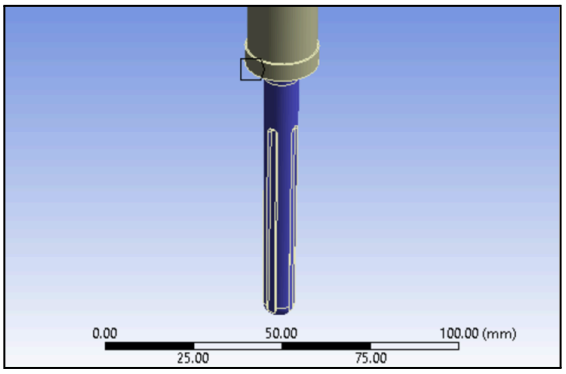


Fig 11. *Fixed geometry applied to the prosthesis*

The materials assigned to the components of the prosthesis were Ti6Al4V ELI and UHMWPE, the material assigned to each component is shown in table 11.

I.D	Component name	Material
1	Plate for components join	Ti6Al4V ELI
2	Seal plate	Ti6Al4V ELI
3	Tibial Component	Ti6Al4V ELI
4	Femoral component	Ti6Al4V ELI
5	Tibial stem	Ti6Al4V ELI
6	Gear wheel with screw	Ti6Al4V ELI
7	Screw for joining the femoral and tibial components	Ti6Al4V ELI
8	Polyethylene plate	UHMWPE
9	Ring gear bushing	UHMWPE
10	Screw top bushing	UHMWPE
11	Cushioned plate	UHMWPE

Table 11. *Prosthesis components implemented in static analysis*

A mechanical type mesh with a maximum element size of 1mm was applied to ensure the independence of the mesh and a good adaptation of the mesh to the geometry of the implant, the rapid transition condition was also applied.

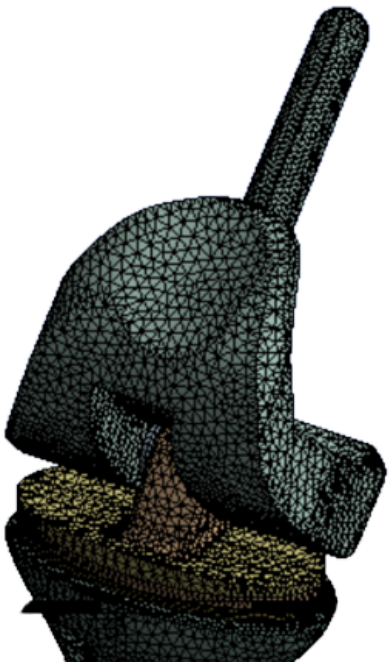


Fig 12. *Mesh applied to geometry*

Bonded contacts were established, these do not allow sliding or separation between faces or edges. This type of contact allows for a linear solution as the contact length/area will not change during load application. On contact is determined in the mathematical model, gaps are closed and any initial penetration is ignored. When running the simulations, the results shown in table 12 and 13 were obtained.

I.D	Component name	Stress [MPa]	Factor of safety
1	Plate for components join	62.66	13.49
2	Seal plate	71.62	11.8
3	Tibial Component	69.76	12.12
4	Femoral component	29.63	28.54
5	Tibial stem	42.28	20.02
6	Gear wheel with screw	16.75	50.48
7	Screw for joining the femoral and tibial components	17.04	49.63
8	Polyethylene plate	5.14	4.72
9	Ring gear bushing	0.35	69.42
10	Screw top bushing	2.28	10.65
11	Cushioned plate	5.53	4.39

Table 12. *Maximum stress and factor of safety during full extension*

I.D	Component name	Stress [MPa]	Factor of safety
1	Plate for components join	140.14	6.03
2	Seal plate	27.04	31.27
3	Tibial Component	37.73	22.41
4	Femoral component	252.98	3.34
5	Tibial stem	28.13	30.06
6	Gear wheel with screw	17.12	49.39
7	Screw for joining the femoral and tibial	128.57	6.57

	components		
8	Polyethylene plate	4.93	4.92
9	Ring gear bushing	2.36	10.29
10	Screw top bushing	1.51	16.09
11	Cushioned plate	0.28	86.78

Table 13. *Maximum stress and safety factor during prosthesis flexion at 45 degrees.*

In table 12 and 13 it is possible to identify the maximum stress and the safety factor for both analyses, in which it is identified that all the components comply with the safety factor of 2. As suggested when the prosthesis has 45 degrees of flexion it is when the maximum stresses occur, but given the geometric characteristics of the prosthesis and the mechanical properties of the selected materials, such stress does not present a risk to the structural integrity of the implant.

Gerber's mean stress theory was applied, where mean stress and alternating stress influence. Graphically (Figure 14) any point with a combination of mean and alternating stresses to the left of the line will resist, while one to the left of the line will resist. the right of the line will fail based on this criteria.

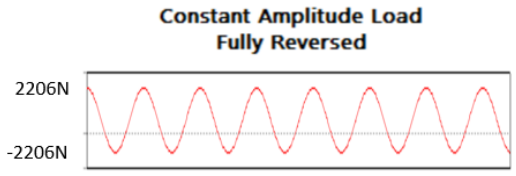


Fig 13. *Fully reversed load amplitude applied to fatigue analysis*

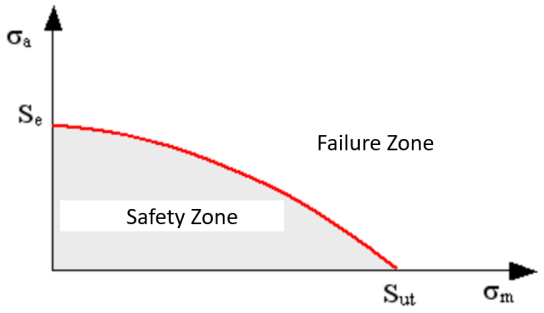


Fig 14. *Graphical representation of the failure and safe zones according to the Gerber criteria (Hindawi Publishing Corporation, 2015)*

Fatigue analysis was only performed for the prosthesis in 45 degree flexion,It was only possible to carry out the fatigue analysis for the titanium components since there are no graphs of stress against life cycles for polymers, a fully reversed loading was implemented.Through finite element analysis, the life cycles for each component were found, shown in table 3.

I.D	Component name	Life [Cycles]
1	Plate for components join	1e8
2	Seal plate	1e8
3	Tibial Component	1.4083e6
4	Femoral component	1e8
5	Tibial stem	1e8
6	Gear wheel with screw	1e8
7	Screw for joining the femoral and tibial components	1.339e5

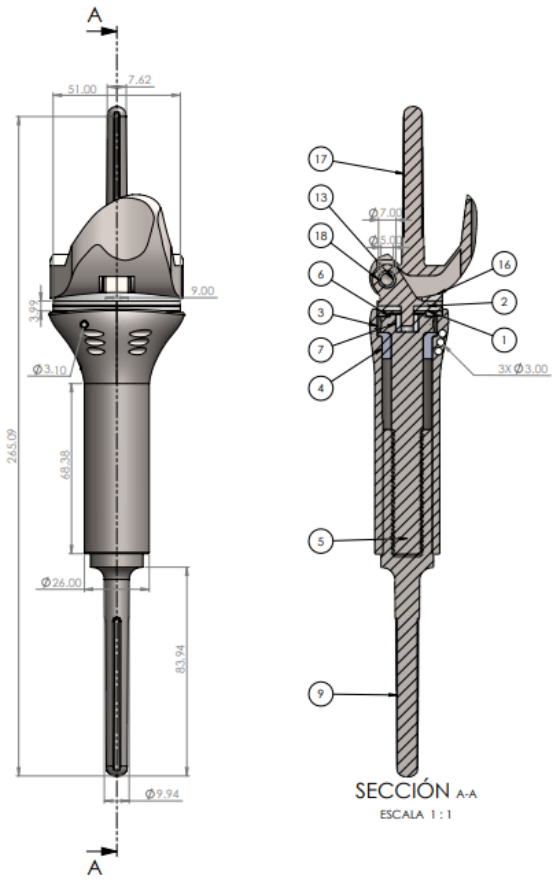
Table 14. *Life cycles for each Ti6Al4V component*

Table 14 indicates that all components except the tibial component and the screw will have an infinite life. The life of these 2 components is greater than 50,000 cycles, which indicates that they comply with the ISO 14243-5:2019 standard, which establishes that the lower limb factor prosthesis must be 3 times the patient's body weight for 50,000 cycles . The designed prosthesis contemplates a multiplier of 3.46 times the patient's body weight, has a safety factor greater than 2, and its component with less life resists 133,900 cycles of a fully reversible load of 2206N.

VI. Conclusion

The proposed design proved to be a viable option for the pediatric patient. The stress generated in each component turned out to be low due to its geometry and material. The stress analysis illustrates that the prosthesis can support at least 3 times the required weight established by ISO 14243-5:2019 and at the same time have a safety factor greater than 3. The fatigue analysis shows that most of the prosthetics have infinite life, except for the tibial component and the screw, however, since these components have a useful life of 133,900 cycles, they still pass the required parameters. The prosthesis complies with the stipulated design considerations. Additionally, the material selected for the prosthesis (Ti6Al4V ELI) avoids the reabsorption of the bone, which is the effect of Wolff's law. The extendable mechanism located in the tibial component has the capacity to extend from 103 mm to 145 mm through a minimally invasive surgery. The prosthesis provides the patient with normal mobility, complying with flexion from 0 degrees to 130 degrees and with internal and external rotation of 30 degrees. In addition, the varus or valgus angle can be adapted to the physical characteristics of the patient.

VII. Schematic drawing of prosthesis



N.° ELEMENT	NAME	DESCRIPTION	QUANTITY
1	Sealing Plate	Seals the tibial component and functions as a guide for the rotational movement of the prosthesis.	1
2	Polyethylene plate	Divides two titanium components avoiding wear and facilitating sliding between both pieces	1
3	Tibial Component	Functions as a housing for the extension mechanism, has holes to fix the patellar ligament, simulates the shape of the proximal part of the tibia	1
4	Center bushing	Allows wear-free rotation of the crown of the extendable mechanism	1
5	Gear wheel with screw	Part of the extendable mechanism. It has two main parts, crown gear and thread.	1
6	Screw top bushing	Reduces friction between the sprocket and the seal plate, allows for better alignment.	1
7	Ring gear bushing	Center all the pieces plates	1
8	Femoral Component Spacers	Allows alignment of the screw that joins the femoral and tibial component	2
9	Tibial stem	Composed with a section of the thread that allows extensibility and a stem which has channels that improve the prosthesis cementation	1
10	Worm Screw	When turning, the Gear wheel with screw moves, extending the prosthesis, it has a ratio of 32 to 1	1
11	Worm shaft	Allows the worm to be attached to the tibial component	1
12	C-Ring	Fixed the worm shaft	2
13	Bushing for joint between subassemblies	Reduces the friction generated during the flexion and extension movement, also provides a softer and more comfortable support for the patient	1
14	Screw for joining the femoral and tibial components	Joins the femoral and tibial component has a threaded area and a smooth area	1
15	Fixing screw	Prevents the prosthesis from stretching or shrinking when not required	1
16	Cushioned plate	Limits the maximum degree of flexion and extension and provides padded support.	1
17	Femoral component	Replaces the resected area of the femur, has a 60mm stem for cementation of the component	1
18	Plate for components join	Features a bore that allows alignment and bonding between the tibial subassembly and the femoral component	1

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