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"Computer assisted knee arthroplasty: state of the art and development of a multi-body model for ligament balancing"

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ABSTRACT

Background: Musculoskeletal disorders such as osteoarthritis, arthrosis and osteoporosis represent the main causes for disability and pain in the modern society. When the non-surgical treatments fail, the implant of joint prothesis after bone resection is usually suggested. Surgical technique contributes to the success of the operation, but it is influenced by surgeon's experience. In order to increase the accuracy of the implant and to achieve an optimal ligament balancing, in the last decades new techniques based on computer-aided systems have been introduced. Computer-assisted orthopedic surgery systems (CAOS) are modular systems that use a virtual model of the operative target to carry out the intervention planning and obtain real-time information on the surgical actions. In this study, a review of the current computer assisted systems for knee surgery was performed. Then, a multibody prosthetic knee model has been developed with the aim to calculate ligament balancing based on the estimation of the ligament force.

Methods: A multibody model of the prosthetic knee including contacts between femoral component and bearing was implemented. Furthermore, the collateral ligaments were defined as vector forces derived by a proper force-strain relationship and acting along the line that connect origin and insertion points of each ligament. A flexion movement of the knee was simulated. A first balanced knee condition was obtained by adjustments of the ligament parameters. Then, the balanced condition was modified by changing three model variables: (1) bearing thickness; (2) varus/valgus angle of the tibial component; (3) anterior/posterior angle of the tibial component. In addition, to easily examine the different implant configurations, a customized user-friendly interface was created.

Results: From each simulation both the contact forces between the femoral component and the bearing and the collateral ligaments forces were measured. In the balanced knee, contact forces agree with values found in literature. In fact, the contact forces difference between the medial and lateral compartments do not exceeds 67N. Ligaments forces are always less than the reported threshold of 50N. All considered model configurations have been compared to the balanced condition. Results show as changes in bearing thickness or tibial component orientation can significantly affect the ligament balancing.

CONTENTS

GENERAL OVERVIEW

Musculoskeletal disorders represent one of the main causes for disability and pain in the modern society. The impact and importance of these issues are critical not only for health and individual mobility, but also in terms of social productivity and large-scale economic growth [1].

The problem of musculoskeletal disorders is very serious: for example, according to some studies it is expected that the spread of *osteoarthritis* (OA) may grow approximately by 2030 up to 40% in North America and Europe [5]. *Arthrosis* is certainly the disease that affects most the joints: it involves the phenomena of alteration of the cartilage that covers the bones such as wear, thinning and osteophyte formation; as a consequence, it is responsible for limiting motor activities, disability in the workplace, the reduced people quality of life and finally the increase in health care costs [2]. Similarly, *osteoporosis*, *osteonecrosis* and *dysplasia* contribute to the list of those factors that suggest the implant of joint prothesis after bone resection, where the non-surgical treatments fail.

In particular, the implant of a joint prothesis must be carried out respecting in the most precise possible way principles based on the control of anatomy and function, recreating ligament balances and spaces that the implant occupies. The technique involves bone resection for degenerate surfaces and creating the prosthesis housing [3].

The surgical prosthetic knee substitution operation is called *knee arthroplasty* and it can be classified in 2 categories:

- **Total knee arthroplasty (TKA),** in which both the joint compartments (medial and lateral) are replaced
- **Uni compartmental knee arthroplasty (UKA),** in which instead one works only on one side of the knee, trying to respect the integrity of the healthy joint portion.

In this context it is possible to define a set of variables that contribute to the success of this operation:

- **Patient-related factors** - bone quality, weight, activity level
- **Factors associated with design -** contact area, compliance with anatomy
- **Surgical technique**

The last factor is often the most difficult to evaluate quantitatively because it is more subjective and closely related to the experience of the surgeon [4]. The operations must be carried out as precisely as possible to increase the post-operative outcome and reduce the risk factors of intra and post-operative complications. It is advisable for the doctor to manage the intraoperative variables not only to better restore the condition of the patient, but also to ensure a good implant survival.

Actually, surgical operations for the implant of knee prostheses can be grouped in:

a) **Conventional techniques**, in which the surgeon uses purely mechanical guides which in most cases do not respect the patient's anatomy. In addition, manual control of such intramedullary or extramedullary guidance does not ensure the correct alignment of the components [1]

b) **Computer-assisted and robot-assisted techniques (CAOS - Computer Assisted Orthopedic Surgery)**: techniques that allow the surgeon to manage different variables in the operative phase, such as leg alignment, ligamentous balancing, joint line maintenance and the components alignment [2]. These are minimally invasive and more conservative methods for treating musculoskeletal pathologies.
Among the CAOS systems it is possible to find robotic systems which work automatically, semi - active systems that require surgeon intervention and finally passive systems, divided into navigation systems and mechanical sensorized guides.

A first objective of this study is to classify, revise and critically analyze the new technologies available for the development of TKA and UKA, highlighting the advantages and disadvantages in relation to traditional instruments.

Soft tissue balancing is a kind of problem that is not particularly considered when traditional instrumentation is used and which many other assisted surgery systems overlook.
The stability of the knee is strongly influenced by the degree of muscles and ligaments tension, both in flexion and in extension condition: if during a prothesis replacement such

tension is not properly restored in the range of motion (**ROM**), then premature failure of the implant could occur.
Conventionally soft tissue balancing is performed by the surgeon intraoperatively and based on qualitative assessment, which may not always determine satisfactory results. Among the factors that contribute to the accuracy of the balancing of soft tissue tensions there are the inability to identify particular anatomical points, the impossibility of some ligaments to perform their function due to damage, or the need to sacrifice some joint portions to allow the insertion of the implant.
Ligamentous tension must be estimated on both the medial and the lateral side of the joint and the values should be very similar.
In traditional procedures, the doctor perceives these tensions through palpation and eventually loosens the ligaments if he becomes aware of an imbalance. As far as computer assisted systems concerns, on the other hand, the evaluation is based on geometrical aspects and on the measurement of forces and pressures acting on the trial tibial insert.

From these concepts comes the idea of developing a method that can provide quantitative information about the tension of the ligaments. The second aim of this study is to create an interface that allows the surgeon to obtain direct and indirect measures of ligamentous balancing in real time.
Working with a multi - body model of the prosthetic knee and supposing to have a sensorized bearing, the soft tissue balancing has been evaluated by measuring both the contact force between the femoral component and the bearing and the actual force exercised by some modeled ligaments (medial collateral ligament - MCL, lateral collateral ligament - LCL) throughout the flexion movement.
Thanks to the interface it is possible to adjust some parameters such as the thickness of the insert and the inclination on the frontal and the sagittal planes of the tibial plate in order to correctly place the implant and obtain a balanced model.

1. INTRODUCTION

1.1 KNEE ANATOMY

The knee joint is localized between the femur and the tibia. It transmits the loads, participates in the movement, helps in the preservation of the moment and provides a couple of forces for the activities involving the leg [6].

Figure 1.1: The human knee joint

1.1.1 FEMUR

The femur is a long bone defined by a body, called diaphysis, and by two extremities, the epiphyses. The proximal part is linked to the hip while the other distal portion articulates with the patella and the tibia, creating the knee joint.

In the proximal area, the femur has a round and prominent head that fits into the acetabulum and a well-defined anatomical neck.

The distal part, on the other hand, presents two large convex bone surfaces, the *femoral condyles*, distinct in *medial* and *lateral*. They are not symmetrical: in fact, the lateral condyle is wider and flat while the medial is more rounded. Furthermore, the curvatures of both condyles are not constant. The condyles are covered by articular cartilage and take part in the complex knee joint; among them there is the intercondylar fossa.

Anteriorly the two condyles converge in forming the patellar surface forming the articulation of the patella or kneecap. The two cruciate ligaments (anterior and posterior) and the two menisci (medial and lateral) are inserted into the condyles.

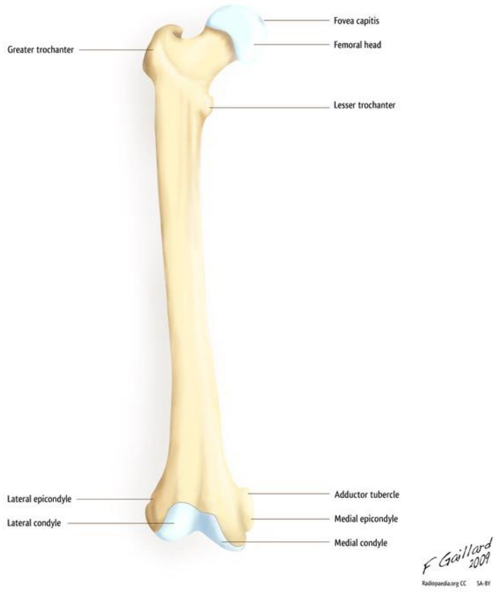


Figure 1.2: Human femur, frontal view

1.1.2 PATELLA

The patella, or kneecap, is a sesamoid bone located within the quadriceps femoris muscle tendon, which is the largest muscle group of the thigh. As previously stated, it is linked to the femur through the patellar notch, a smooth surface on the anterior distal end.

The patella has the function of moving the tendon from the distal end of the femur, thus modifying its angle of inclination respect to the tibia. This modification increases the force that can be applied from the femoral quadriceps to the tibia. Finally, the patella can enhance the main action and compact the joint.

1.1.3 TIBIA

The tibia is the largest bone of the leg: it articulates superiorly with the femur and the patella, supra - medially and inferior - medially with the fibula, and inferiorly with the talus. The proximal epiphysis of the tibia presents *the medial and lateral condyles* that are linked to the condyles of the femur. The lateral condyle has a large convex surface while the medial is concave. Between the two condyles is located the intercondylar eminence, a ridge between the two articular surfaces of the bone. The distal end of the tibia widens to form the medial malleolus, which concurs to form the medial part of the ankle joint [7].

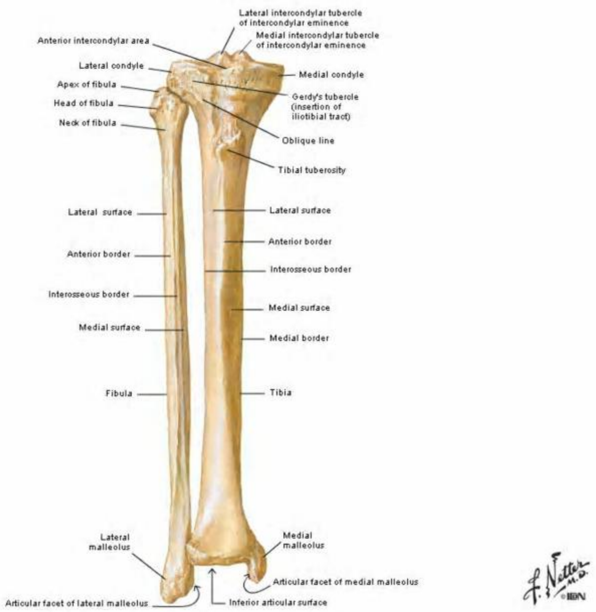


Figure 1.3: Human Tibia and Fibula, anterior view

1.1.4 THE KNEE JOINT

The knee joint is actually made by two articulations, the tibio - femoral one and the femoro - patellar one.

The **tibio - femoral articulation** is traditionally classified as a *modified hinge joint* or a complex ellipsoid that allows flexion and extension movements and a small rotation of the leg.

As already described above, the distal end of the femur has two ellipsoidal condyles separated by a deep trench: they articulate with the proximal end of the tibia, which is flattened and characterized by the ridge known as the intercondylar eminence.
The tibia margins are covered by thick fibrocartilaginous disks called menisci, which deepen the articular surface [7]. The menisci are very resistant because they are rich in collagen fibers arranged in such a way as to support all types of loads, including compression and cutting loads. They have anisotropic properties.

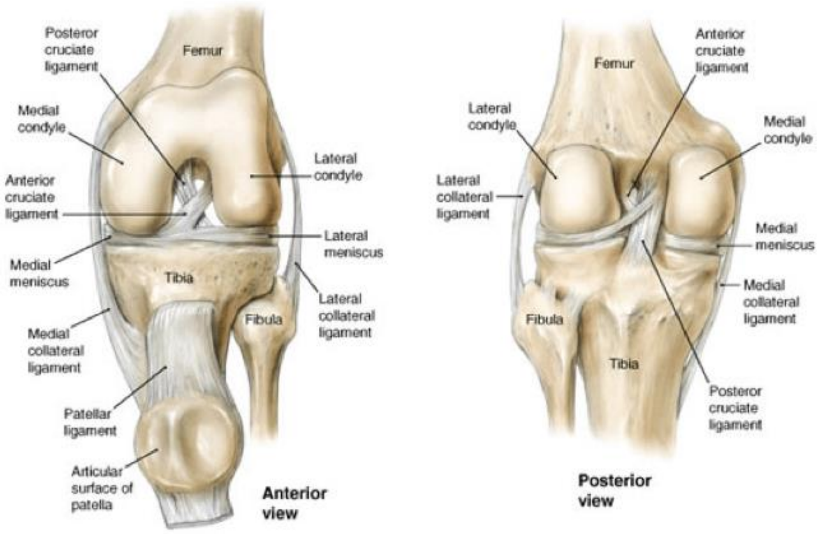


Figure 1.4: Knee joint anatomy, anterior and posterior views

Two cruciate ligaments extend between the intercondylar eminence of the tibia and the femoral trench. They take their name from the position they have in relation to the tibia, they are never lax and their task is to avoid antero - posterior movements.
In particular, the **anterior cruciate ligament** (**ACL**) prevents anterior displacement of the tibia in relation to the femur, while the **posterior cruciate ligament** (**PCL**) avoids the posterior displacement of the tibia. These ligaments cross each other in both antero - posterior and lateral - medial directions. The anterior cruciate ligament is linked to the tibia and the lateral condyle passing from an anterior to a posterior position; the posterior cruciate ligament, on the other hand, is still on the tibia and medial condyle, passing from a posterior to an anterior position.

The joint is also reinforced by the **collateral and popliteal ligaments** and by the tendons of the thigh muscles that extend around the knee [7].
The collateral ligaments are lax when the knee is flexed: in extension they go to avoid lateral-medial movements. One of the ligaments is lateral (fibular collateral ligament) and the other is medial (tibial collateral ligament).

The stability of the joint is also maintained by the joint capsule which assures good resistance. Although it does not provide a large contribution during the flexion, the capsule limits hyperextension.

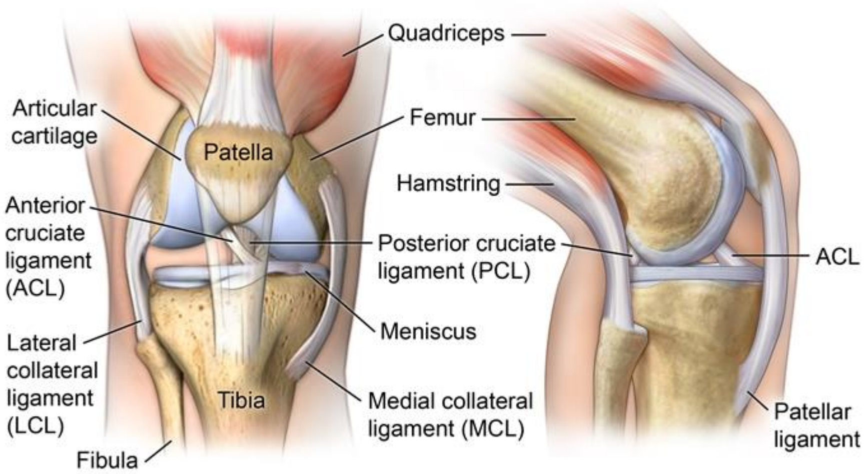


Figure 1.5: Knee joint ligaments, frontal and lateral views

1.2 BIOMECHANICAL HINTS

1.2.1 LOWER LIMB MECHANICAL AXIS

The success of a knee arthroplasty relies very much on the correct restoration of the lower limb mechanical axis. In the first surgical operations it was considered sufficient that the limb was apparently straight; today we know that alignment is fundamental for the success of the intervention and for the duration of the prosthesis [8].

It is possible to study 3 different types of axis for the lower limb:

- The **vertical axis**, used as a reference from which the other lines are computed
- The **anatomical axis**, which is drawn along the intramedullary canal of the bones
- The **mechanical axis**, defined by the straight line connecting the center of the hip to the center of the ankle.

In particular, the anatomical or diaphysis axis has an inclination of 9° in relation to the vertical axis, while the mechanical axis of the lower limb forms an angle of 3° with the vertical axis.

The restoration of the mechanical axis of the lower limb is ideal in knee arthroplasty, because an anatomical joint alignment seems to influence a medial plateau fixation failure, due to the increased forces [9].

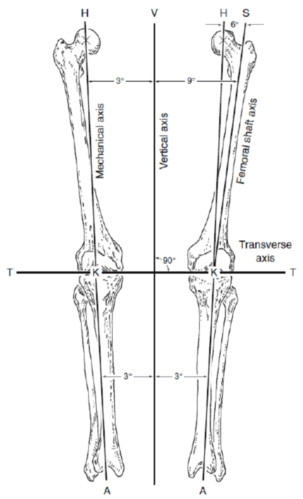


Figure 1.6: Anatomical and Mechanical axis of the lower limb

1.2.2 MOVEMENTS OF THE KNEE

The knee joint can perform movements on three planes, although the principal is that of flexion - extension on the sagittal plane. For this reason, it is usual to associate the knee joint with a hinge.

- **Flexion – Extension Movement**:

  It occurs on the sagittal plane and admits an excursion variable between 0 ° and 140 °

- **Internal – External Rotation**:
  The rotation of the knee around an axis orthogonal to the transverse plane is allowed by the presence of the tibial spine, which acts as a pivot.
  The amplitude of the movement is influenced by the knee position on the sagittal plane, specifically by the flexion - extension angle. When the knee is extended, the rotation is almost completely blocked by the joint between the femoral condyles and the tibia; the internal - external rotation amplitude tends to grow when the knee is flexed, reaching the maximum value when the flexion is 90°. In fact, the external rotation goes from 0° to 45° while the internal one goes from 0° to 30°.
  Over 90° of flexion, the internal - external rotation range decreases mainly due to the restricted rotation of the surrounding soft tissues.

- **Ab - adduction Movement**:
  The abduction and adduction movements on the frontal plane are influenced by the degree of knee flexion similarly to that seen for the internal - external rotation. The complete extension of the knee almost completely precludes movement on the frontal plane. When knee flexion does not exceed 30 degrees, ab - adduction movements increase, although both reach a maximum of a few degrees. Beyond the 30 degrees of flexion the movements on the frontal plane are limited by the action of the soft tissues [6].

There is also the possibility for the knee to translate along the anterior – posterior direction (2 or 3 mm on average), but this kind of movement is restricted by the action of the cruciate ligaments, which prevent anterior and/or posterior dislocation.

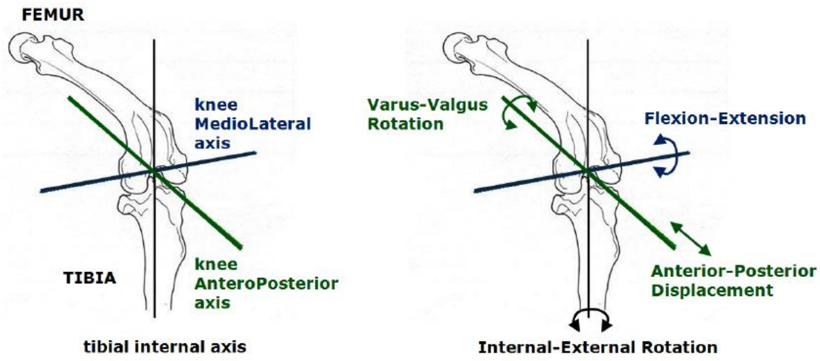


Figure 1.7: Schematic representation of the principal movements of the knee

POSTERIOR ROLLBACK

The articular surfaces movement can be described by the moving centrode, which represents the sequence of the instant centers of rotation. It is known that any motion can be considered as the sum of many partial motions, each of which is a rotation around a point (center of instantaneous rotation). The instant center of rotation is the point of the rigid body that has zero velocity in an instant of motion. If the instant center of rotation is on the contact surfaces of the joint there is a rolling movement, otherwise there is pure translation along the direction orthogonal to the segment that links the contact point and the instant center of rotation [10].

In the tibio - femoral joint, during the movement in the sagittal plane and in condition of complete extension/flexion, the moving centrode has a semicircular shape and moves backwards.

Between the articular surfaces there is a combination of **rolling** and **sliding**. The mechanism that prevents the femur from rolling down from the tibial plate as flexion increases is due to the cruciate ligaments activity and to the bone geometry of the femoral condyles.

If the knee is extended or flexed by a different polar curve, the tibio - femoral joint surfaces do not slip tangentially on each other during movement, but undergo compression or traction, interfering with the tibia rotation movement.

The instant center of rotation can be considered as the surface contact point of the two rigid bodies and its position depends on the degree of flexion of the knee:

- In *complete extension* the instant center of rotation is located in the mid part of the joint surface;

- In *early flexion* the posterior rolling contact continuously moves posteriorly;
- In *deep flexion* the contact point is located posteriorly, as consequence of the femoral sliding [11].

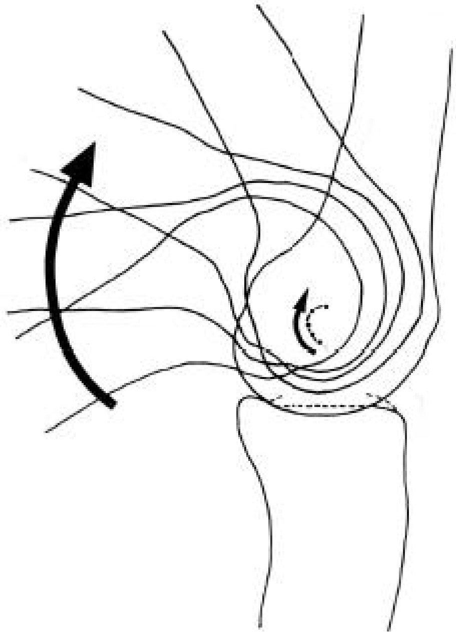


Figure 1.8: Moving centrode of the tibio-femoral joint

SCREW - HOME MECHANISM

The spiral movement of the tibial axis relative to the femur during the last degree of extension is due to the anatomical configuration of the medial femoral condyle: this movement ensures greater stability of the knee in each position compared to a simple hinge configuration. The rotational axis remains approximately in the area between the cruciate ligaments [6]. Therefore, the “screw – home” mechanism helps to decrease the work of quadriceps while standing [11].

1.3 KNEE ARTHROPLASTY: STATE OF THE ART

In general, arthroplasty can be defined as a surgical operation that aims to replace an articulation, more precisely the articular heads that form it, with a structure made of various materials. The goal of the implant, from the performance point of view, is to obtain a joint able to do effectively a work similar to the real one and also that is characterized by the absence of pain and durability in time [8].
It is possible to talk about a "coating" procedure for the knee joint, because the surgeon replaces only the damaged bone surfaces with appropriate prosthetic components.

As already mentioned above, the accuracy in positioning the knee prosthetic components depends on some variables such as the characteristics of the patient, the properties of the implant and the surgical technique. Main concepts related to the first two aspects will be explained below and, finally, basic information on the conventional technique of knee arthroplasty will be provided for introducing computer-assisted orthopedic surgery.

1.3.1 RECRUITMENT OF PATIENTS

When diagnosing knee osteoarthritis, many factors related to the patient must be considered and different kinds of assessments must be performed:

- *Physical evaluation*, which defines the point of greatest perception of pain with respect to the joint line (medial or lateral area), the range of motion (ROM), the leg deformity, the anterior cruciate ligament (ACL - Anterior Cruciate Ligament) and discomfort at the patellofemoral level (PF)

- *Radiographic evaluation*, because thanks to the radiographs it is possible to highlight the state of the articular surfaces. One limitation associated with this imaging modality lies in the fact that it is able to detect joint degeneration only at an advanced stage of the disease. Therefore, carrying out a further *MRI examination*, it is possible to observe small changes in the state of the subchondral bone, cartilage and anomalies of the bones, ligaments and meniscus [2].

The knee replacement can be recommended by the doctor in different situations:

- Severe knee *pain* or *stiffness* that limits daily activities, including walking, climbing stairs, getting up or sitting on the chair
- *Chronic inflammation* and *swelling* in the knee that does not improve with rest, ice, infiltrations or drugs
- *Deformities* of the knee: an arthritic knee become flexed and no longer extending, or a deformed knee (**varus** - deformed inward, **valgus** - deformed outwards)

Figure 1.9: Example of an arthritic medial compartment of a right human knee

It is also important to consider more general factors that characterize the patient. For example, in the case of uni compartmental knee arthroplasty, recruitment criteria have been defined and they include age, body weight (particularly BMI), level of physical activity, knee flexion amplitude and joint deformities [2].

1.3.2 PROSTHETIC IMPLANT CHARACTERISTICS

The knee prothesis is a coating joint: in other words, its aim is to cover damaged joint surfaces that must be properly prepared. Furthermore, it is a modular prothesis, made up of different parts:

- **Femoral component** - is a fairly thin rigid shell whose spherical curvature reproduces the condyles geometry. It is equipped with a fixing system to the bone and in some cases also with a central mechanical stabilizer. The femoral component is typically made of metallic materials that are rigid, with a high mechanical strength and with good resistance to abrasion. For the construction of these elements steels, titanium or cobalt alloys are used; no ceramic materials are used because the required design would accentuate their fragility in relation to physiological loads;

- **Tibial component** – it consists of a large plate that can completely cover the surface of the tibia. Also in this case, resistance to abrasion and stiffness need to be guaranteed: for this reason, the materials used are similar to those previously described;

- **Bearing** – this part can be fixed to the plate or movable. From a design point of view, the upper face of the bearing has the two concavities necessary to house the femoral condyles; the lower surface is flat conforming to the tibial plate. The bearing reproduces the physiological menisci and it is made of polymeric material, generally of high-density polyethylene (HDPE), because the coupling with the metal surfaces is characterized by a low friction and a good level of load damping.

Knee prothesis of different sizes exist on the market, in relation to the characteristics of the knee on which they should be implanted. Thanks to the patient-specific technologies it is also possible to create customized implants starting from radiographic examinations. As regards for the bearing, it can be made in different thicknesses that typically change with 1 mm steps. The choice of the right thickness of the bearing is essential for maintaining the balance of the surrounding the joint soft tissues. Finally, the patellar component is sometimes restored.

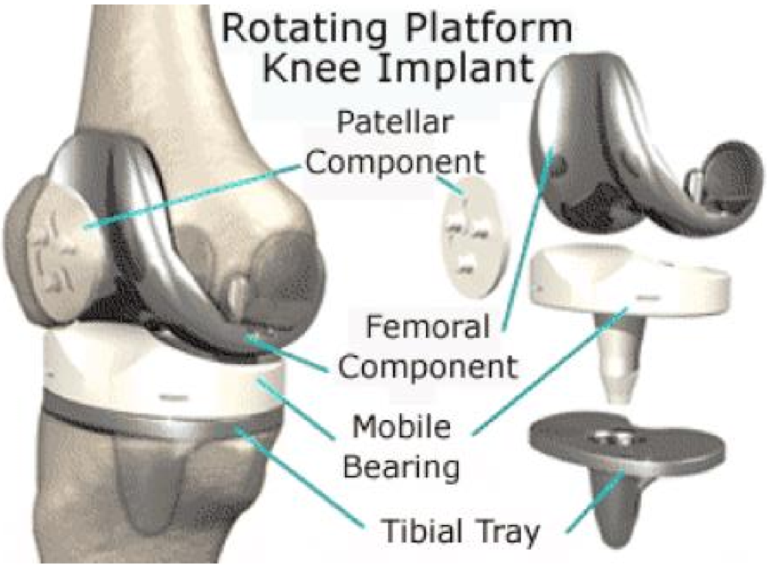


Figure 1.10: Main elements of total knee prothesis

The knee prostheses are further characterized by some very important properties that can provide durability and good recovery of the physiological movement:

- *Cemented protheses vs. uncemented protheses*: initially the uncemented prothesis were not particularly widespread and then surgeons proceeded to the placement of the various components fixing them with a cement based on PMMA. Cementation errors, thermal necrosis and the generation of an inflammatory state of fibrocartilage led to the experimentation of uncemented prothesis. These are made of porous titanium and hydroxyapatite coatings and their application is based on bone regrowth and / or on the press fit technique.

- *Fixed bearing vs. mobile bearing*: the first examples of prothesis had a fixed bearing on the surface of the tibial plate. However, they were poorly compliant, especially during flexion, and for this reason high stress points were generated with the consequent risk of polyethylene element loosening and wear. Over time, new models containing a mobile insert in direct contact with metal surfaces have been developed: this new structure guarantees congruence for the whole ROM, good stability and lower contact stress [2].

- *Symmetrical prostheses vs. asymmetric prostheses*: another subdivision concerns the shape of the implant. In the case of TKA, the polyethylene bearing houses both condyles belonging to the femoral component, but the two concavities may be the same or not. In the asymmetric protheses, in fact, the medial surface of the bearing is wider and deeper than the lateral one due to the anatomical differences of the two femoral condyles: the medial condyle is typically larger and more subject to loads.

  The purpose of the symmetrical models is to avoid a bad slipping of the patella in the intercondylar fossa and less pain in the post-operative phase: the femoral component design is realized in such a way that the trochlear groove is parallel to the flexion-extension axis and deeper, so to improve the congruence between the patella and the prothesis. In the asymmetric models, however, the intercondylar fossa is aligned with the longitudinal axis of the femur. The patella slope and the prevention of sub-dislocation allow less wear and lower risks of the fracture of the bone [12].

1.3.3 CONVENTIONAL KNEE ARTHROPLASTY

The knee arthroplasty involves the use of purely mechanical guides, cutting blocks and long oscillating blades, but not of computerized systems or robots.

PRE - OPERATIVE PHASE

The pre-operative phase, which was discussed earlier, is very important for determining those parameters that must be reestablished during surgery, such as lower limb alignment, the joint line and soft tissue balancing. Another fundamental aspect is the limb mechanical axis restoration: the surgeon must try to make a femoral valgus cut of 5 ° / 7 ° and a neutral tibial cut [15]. Furthermore, the pre - operative phase is necessary to plan the actions to be performed and therefore to determine the type of alignment, the size and the fixation of the tibial and femoral components of the implant.

All these aspects are treated during physical and radiological examinations.

INTRA – OPERATIVE PHASE

In the intra-operative phase, the patient is anesthetized and parameters such as blood pressure, blood oxygen level, heart rate and body temperature are continuously monitored for the duration of the intervention (which is about 2 hours) [14].

The knee is placed in a position of 90° of flexion and the surgeon performs the incision: in the case of total arthroplasty, it can be up to 25cm wide, while in a uni compartmental procedure the incision length can also be 5 cm.

At first, all damaged soft tissues are removed and balanced. Subsequently, the patella is moved to the side and the bone resection is carried out, using easily palpable bone anatomical points as a reference.

The first cut that is performed is the femoral one: the surgeon makes measurements with an intra or extra medullary mechanical guide to determine the right amount of bone to eliminate. Generally, for the preparation of the femoral surface, 5 cuts are made: the first one is made on the distal part of the femur, then the surgeon realizes the anterior and posterior cuts and finally smooths them both [14]. With this procedure the housing for the upper component of the implant is correctly shaped, and it is applied to the bone by means of an acrylic cement based on PMMA.

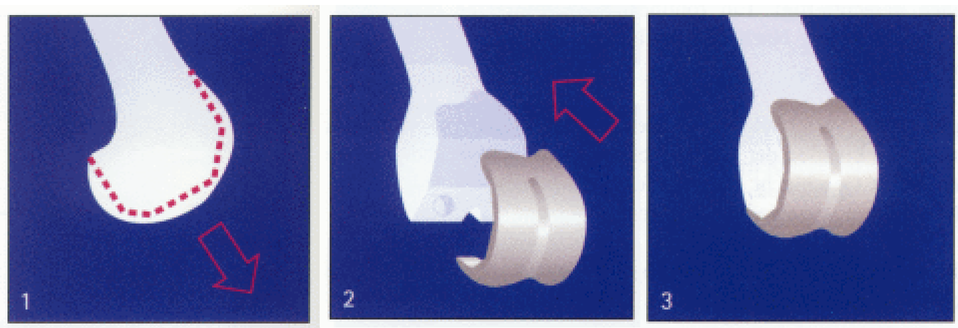


Figure 1.11: Example of femoral cuts and positioning of the prosthesis

As regards the tibial component, the cut performed in this case is much simpler: the doctor removes the damaged portion of the bone and then uses an extra medullary guide along the tibial axis that helps to make a cut perfectly parallel to the proximal surface [14]. The tibial plate is then applied to the bone and fixed with acrylic cement; the mobile insert is manually inserted between the two prosthetic components like a spacer.

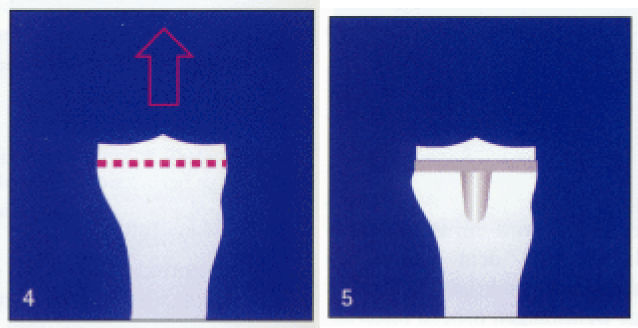


Figure 1.12: Example of tibial cut and prosthesis housing

Before repositioning the patella correctly, the surgeon may eventually cut on it and apply a plastic component that ensures congruence with all the other elements of the implant.

In the intra-operative phase, another fundamental aspect is also taken care of, the **soft tissue balancing**. This is a very important procedure because the prothesis stability in the ROM and its durability over time are strongly dependent on the balance of the tissues surrounding the joint.

During the balancing of soft tissues two measures are introduced, the **flexion gap** and the **extension gap**, which correspond to the distance between the femoral resection and the tibial cut respectively at 90 ° of flexion and in full extension. It has been shown that if these two intervals both have a rectangular shape and the same size, then the surrounding joint tissues are in tension balancing. In other words, the gaps between the two bones must be parallel and for this to happen it may be necessary to rotate the femoral component externally [16].

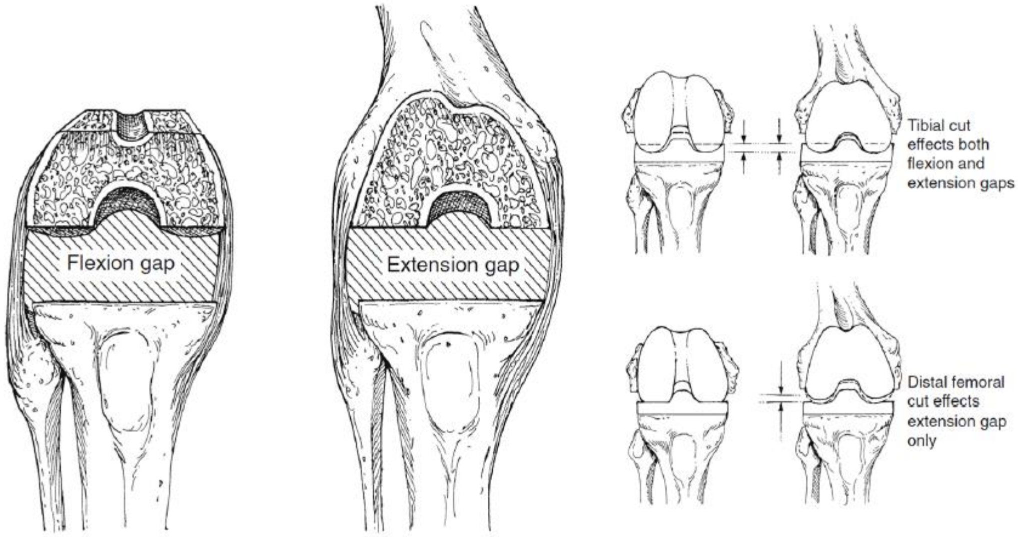


Figure 1.13: Flexion and Extension gaps

The conventional methods for achieving ligamentous balancing are based on qualitative information:

- **Method of measured resections**: in this first method the surgeon performs all the bone cuts, independently of the soft tissue balancing, using anatomical reference points [17] such as the trans-epicondylar axis, the antero-posterior axis and the posterior condylar axis. Then, through the use of trial prosthetic components, he ensures that the tissues are balanced and he determines how much the femoral component must be externally rotated. Usually the required value is 3°.

  However, relying on anatomical landmarks does not always lead to correct results due to anatomical variability between patient and patient, and for this reason one can easily fall into error [18]. Furthermore, it has been estimated that with this technique, asymmetric flexion gaps are obtained and there is a greater incidence of condyles lift – off.

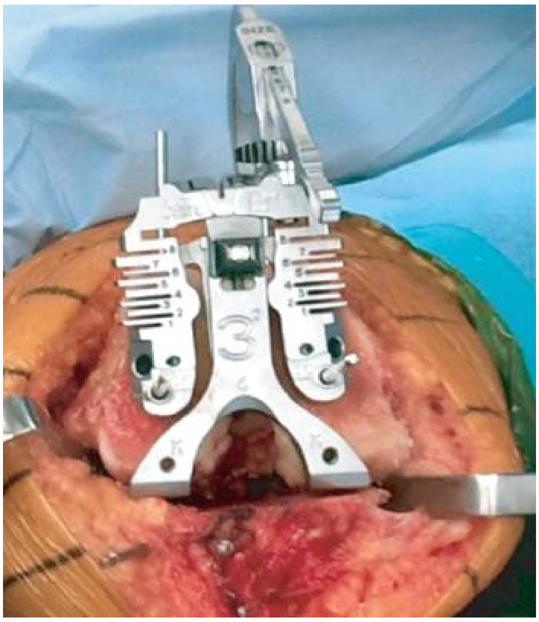


Figure 1.14: An example of guide for aligning the rotation of the femoral component with respect to the posterior epicondylar axis

- **Gap balancing method**: this second technique involves an initial soft tissue release and the resection of the femur and tibia surfaces is carried out in extension. Through a spacer block, the surgeon evaluates the gap symmetry, the ligamentous balancing and the alignment with respect to the mechanical axis: if there is no equilibrium condition then the ligaments are loosened until the alignment becomes neutral and the extension gap is symmetrical [18]. The next step involves flexing the knee and balancing the gap making it symmetrical to the extension one. Even in this case the ligamentous balancing is useful to address the correct external femoral rotation. To verify the rightness of the procedure, secondary determinants can be used: for example, it can be seen that in the flexion condition the tibial resection is parallel to the trans epicondylar axis and perpendicular to the antero - posterior axis [18].

  The gap balancing method is preferred to the measured resections and it seems to be more reliable because it is less dependent on bone anatomy; the technique is therefore effective in reproducing good stability of the bending gap.

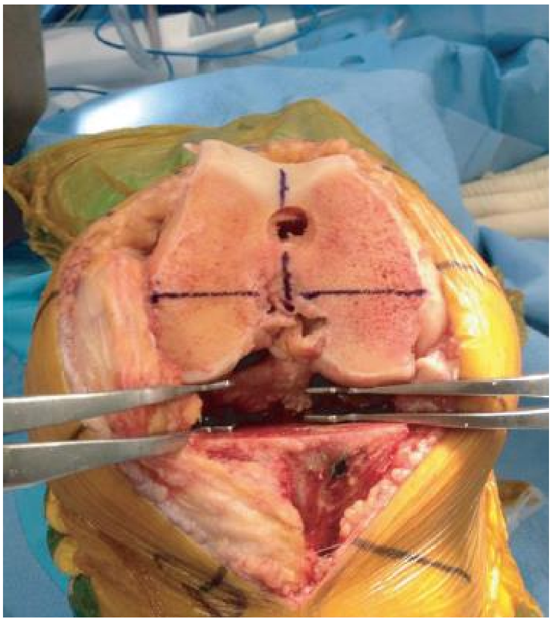


Figure 1.15: Bending gap and verification of the correct balance of the ligaments using reference axes

Both conventional techniques are dependent on the surgeon's experience and sensitivity. In fact, he must be able to recognize tensioned and / or loose ligaments simply by palpating them. The tension measurement is an indirect measurement.

2. COMPUTER AND ROBOTIC ASSISTED KNEE SURGERY

The accuracy of performing an operation such as knee arthroplasty is critical and for this reason surgeons continuously try to develop the operative techniques in order to achieve better performance.

In general, conventional knee arthroplasty techniques attain excellent results, with the exception of 5% of cases, due to failure of the prosthesis, infection, instability or dislocation of the fracture [19]. Among the other problems that can be found, there are:

- Error greater than 3 ° in the alignment between the femur and the tibia;
- Errors related to the use of pre-operative models obtained with x-ray imaging techniques;
- Difficulty in determining anatomical landmarks on the femoral head and on the heel;
- Use of conventional instrumentation based on standard bone models and not on specific patient characteristics;
- Little reliability of visual inspection for control of implant placement accuracy [19].

In order to increase the accuracy of the implant placement and thanks to the development of many new technologies, in the last decades new techniques based on the use of computer-aided systems have been introduced.

2.1 ELEMENTS OF CAOS SYSTEMS

2.1.1 DEFINITION AND CLASSIFICATION

CAOS (Computer Assisted Orthopedic Surgery) systems allowed the development of a new approach for orthopedic surgery, in which traditional mechanical instrumentation is no longer used, but instead of computers and robotic technologies [20]. In general, they can be defined as *modular systems* that use a virtual model of the operative target to carry out the *intervention planning* and obtain real-time information on the surgical actions [1]. From this point of view, the introduction of the CAOS systems has brought improvements in intraoperative visibility and has also ensured good accuracy not only in the area of knee arthroplasty, but also for other operations such as prosthetic replacement of the hip or spinal and shoulder surgery [1].

CAOS technologies can be classified into:

- **Active systems**: they are nothing more than robots capable of performing the surgical operations autonomously, without the doctor intervention. Examples of commercial active robots are OMNIbotics, ROBODOC, CASPAR and Acrobot;

- **Semi - active systems**: they require partial intervention by the surgeon to carry out the operation, but generally they provide real - time feedback so that the doctor can work in safe conditions. In fact, these systems allow to operate only within a predefined zone and can oppose resistance if the surgeon approach foresees the overcoming of the edges of this area. In this way it is possible to prevent excessive bone resection or malpositioning of the implant. Among the most widespread semi - active systems there are MAKO Robotic - Arm System and Navio Surgical System;

- **Passive systems**: they support the doctor's work by providing information in real time, but do not perform any kind of practical function. The main passive systems are navigation systems (Blu IGS, Orthopilot), but the sensorized cutting guides can also be included in this class. Some commercial examples are Perseus, OrthAlign and Iassist [1, 13, 21, 22].

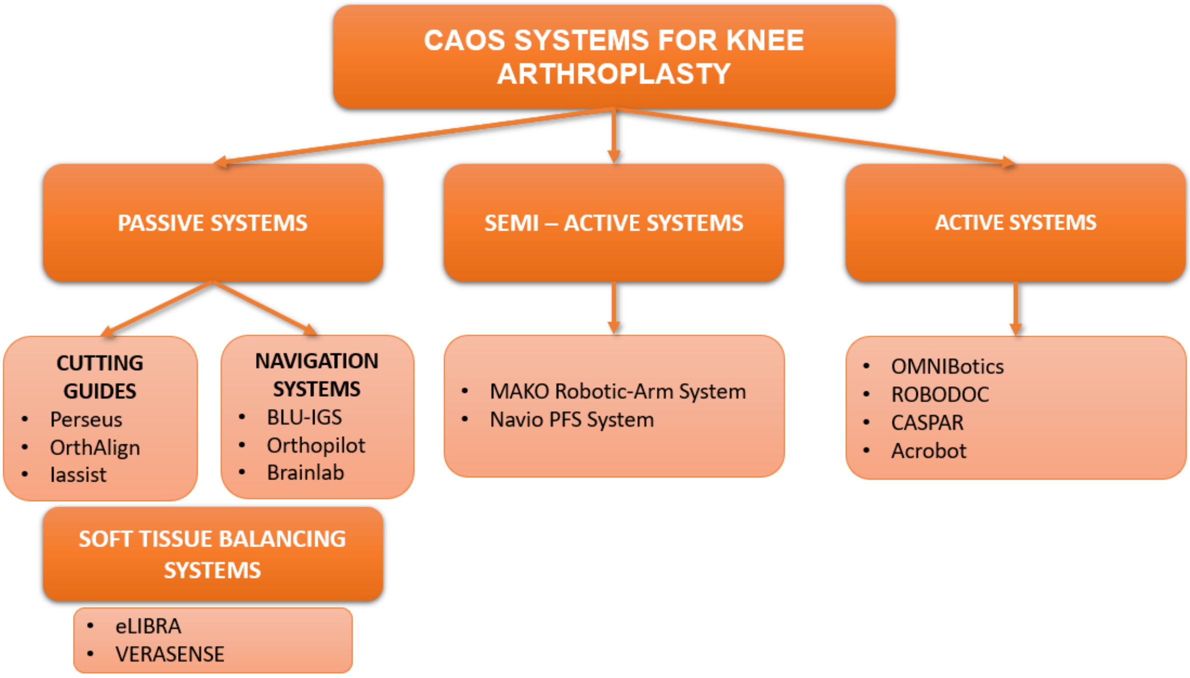


Figure 2.10: Classification of CAOS systems and commercial examples

2.1.2 BUILDING BLOCKS

Although there are many different types of CAOS systems, the concepts on which they are based are very similar.

THERAPEUTIC OBJECT (TO)

The therapeutic object is the target of the operation, the knee joint to be treated [1].

VIRTUAL OBJECT (VO)

The virtual object is a realistic representation of the patient's anatomy (TO) necessary to plan and / or monitor the progress of the intervention. During the operation, the VO also allows the surgeon to view the position and orientation of the instrumentation used.

The VO can be recorded in the preoperative phase from medical images, or during the operation, making use of particular tracking systems. The most common methodologies for creating the anatomical digital model are listed below:

- **CT / MR images**: the use of CT scanners in the orthopedic field is very convenient because the obtained images are characterized by an excellent contrast between the bone and the soft tissue. Moreover, they do not present geometrical distortion. Despite this, the use of CT scanners is associated with patient exposure to radiation and additional costs for examinations.

  Generally, models obtained from CT images are associated with the preoperative phase and this may be a problem due to the variability of bone morphology: in case of an intraoperative mismatch between the virtual model and the therapeutic target, there could be errors. For this reason, some systems are made up of an O-shaped arm for the acquisition of 3D images even during the surgical procedure. However, particularly costly instrumentation is required, which implies changes in hospital facilities [1];

- **Fluoroscopic images**: this approach requires that a set of markers, placed on specific anatomical reference points, are recorded by a series of fluoroscopic images. Subsequently, a software can combine these images to create a virtual model that represents the anatomy of interest and the position of the surgical and implant objects. The acquisition of many images from different points in the space allows the realization of VOs that do not rely on the intraoperative changes associated with the patient's movements [23].

  Since the fluoroscopic images are 2D, models are subject to distortion, because the information related to a dimension is lost during the projection phase [1];

- **Imageless navigation or SDA (Surgeon Defined Anatomy)**: virtual models obtained with these techniques do not derive from medical images acquired in the preoperative phase, but they are implemented directly during the surgical procedure. Imageless systems consist of a tracking equipment, such as an infrared camera and markers: in order to obtain the VO it is necessary to slide a tracking instrument on the articular surface, so that its position is continuously recorded by the camera [1]. The information acquired by the tracking device is processed by software that makes further use of a large number of CT scans to build a model that perfectly suits to the points plotted.

Imageless navigation has the advantage of not requiring the patient's exposure to radiation, but the accuracy of the virtual model is strictly dependent on the precision and experience of the surgeon [23].

NAVIGATOR

The navigator is the CAOS system component that connects the VO to the TO and to the End Effectors (EEs), providing a spatial transformation of coordinates.

For the active systems, the navigator coincides with the robot and it is necessary that the EEs are registered, in addition to the VO. As for passive systems, however, the navigator is a simple tracking system that determines the location and orientation of the TO with 3D coordinates. In most cases, the tracking is **optical**: the device is located in an operating room compatible with infrared light and is equipped with a camera and some markers. Markers can be placed in specific anatomical points or on surgical instruments and they are divided into:

- Active, they emit infrared light
- Passive, they only need to reflect the light emitted by the camera.

However, the visual field between the camera and the markers must not be obstructed and this can be a problem [1]. It can be solved by using tracking methods based on **electromagnetic fields** or **inertial sensors** (IMU - Inertial Measurement Unit).

The navigator allows the correspondence between the preoperative plan (VO) and the intraoperative plan (TO) through registration. The articulation instruments geometry is typically represented in a different coordinate system (COS) compared to the one used by the navigator for the representation of the VO: the recording operation allows a matching between the two coordinate systems using a geometric transformation [1, 24]. Among the methods used for matching, there are:

- *Paired - point matching*, in which pairs of points belonging to the TO and to the VO are matched by means of a probe and checkpoints. The technique is however not very accurate [1];

- *Surface matching*, more convenient than the previous one because it does not require the application of instruments and checkpoints, but it is based only on the surfaces of the VO;

- *Fluoroscopic images*, using fluoroscopy technology it is possible to record many images from different positions and refer them to a common coordinate system placed on the target;

- *Customized models*, the matching between TO and VO can be realized using 3D patient specific bone models segmented based on preoperative data.

During the surgical operation it is possible a relative movement between the TO and the navigator: this movement is precisely balanced with the **reference**. In some cases, such as for robots, the joint is directly connected to the system by a physical bond, like a bone clamp or a second robotic arm; in many other cases, instead, the surgeon proceeds with the installation of a DRB (Dynamic Reference Base) containing the reflective markers that can be tracked.

2.2 ACTIVE SYSTEMS

The active robotic systems do not need any assistance from the surgeon during the operation: once the intervention planning has been carried out, the doctor has only access to an emergency button if something goes wrong [25]. According to some studies, robotic systems have better performance than navigation systems, since they involve shorter times for bone resection, small deviation errors in coronal and sagittal and a better restoration of the lower limb mechanical axis [20]. Here are some commercial examples of active systems.

OMNIBotics

The system, originally called PRAXIM, uses the automatic and active technology iBlock for bone cutting and has it been approved by the Food and Drug Administration for TKA operations in 2010.

The virtual knee model is implemented with an "image free" technique based on optical tracking: all the information necessary for the surgical procedure is obtained in the intra-operative phase. The iBlock platform is an accurate motorized femoral guide that is mounted on the bone which ensures a reduction in systematic errors due to surgical instruments malpositioning.

However, this system does not provide consistent feedback to the surgeon and is a closed platform that is limited to the implant of specific design prothesis [20, 26].

Figure 11.2: OMNIBOTIC model

ROBODOC

ROBODOC is the first active robot for orthopedic surgery introduced in Germany in 1994. It is a workstation which can create the virtual model of the joint from CT images and plan the intervention; moreover, it completely controls a 5-axis robotic arm equipped with a milling device [20]. The ROBODOC system is very accurate, allows the surgeon to follow the status of the operation and it is also an open platform, which works with different types of prosthesis.

Compared to conventional surgery and some navigation systems, ROBODOC needs a longer time to perform the operation and this means a greater risk of infection for the patient.

Moreover, the optical tracking apparatus, although quite accurate, requires the installation of pins which do not have to loosen during operation [22].

Figure 2.12: ROBODOC system

CASPAR E Acrobot

CASPAR (Computer Assisted Surgical Planning and Robotics) is another active system that uses imaging techniques to build the virtual model of the knee. It has been made in Germany and marketed for THA and TKA interventions in 2000 [20, 13].

Instead, Acrobot has been developed for interventions by UKA and TKA; it is the first to introduce a feedback system for the surgeon, paving the way for the semi - active MAKO and Navio platforms [20].

2.3 SEMI – ACTIVE SYSTEMS

2.3.1 MAKO

The MAKO Robotic - Arm System is an example of a semi - active system created by Stryker and marketed since 2005 for uni-compartmental and total knee arthroplasty (UKA, TKA) and total hip arthroplasty (THA) [20].

Figure 2.13: MAKO Robotic - Arm System

The 3D model of the patient's knee is implemented from preoperative **CT images** and it is used by the doctor for intervention planning. Once the VO has been registered to the current anatomy, it is possible to make considerations regarding the implant size and positioning, to determine the flexion and extension gaps during a passive flexion and to establish the exact cutting area within which the robot must operate [25]. The main characteristic of MAKO, or more generally of semi - active systems, is that the robotic arm is freely manipulated by the doctor in a region defined during the preoperative phase: if the cutting tools were to end up beyond the pre-established area, the system would provide visual and/or auditory feedback and it would resist movements until stopping [27]. In other words, during the bone resection, the doctor can observe on the monitor the exact point where he is applying the drill and when the tip of the instrument overcomes the boundaries defined in the model, the systems provides a signal and it stops.

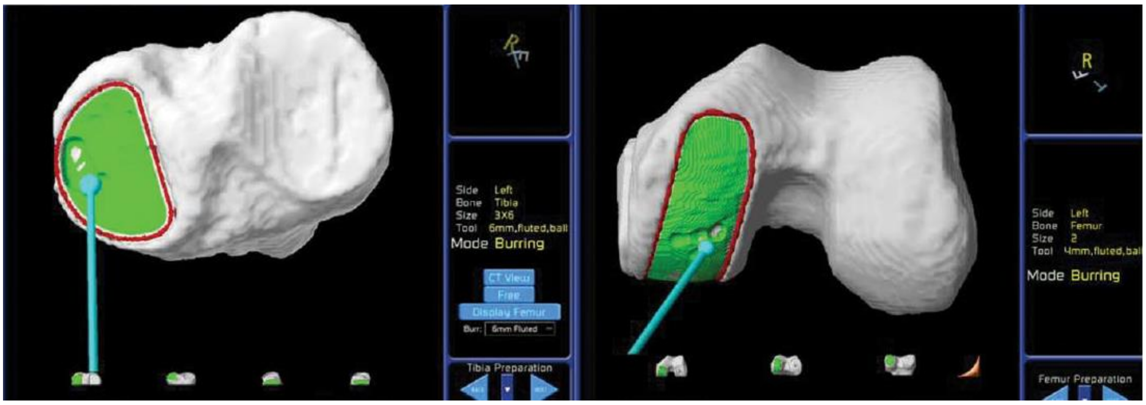


Figure 2.14: Virtual representation of the operation carried out with the MAKO robot

UNI COMPARTMENTAL ARTROPLASTY SURGICAL TECHNIQUE

Preoperative planning is performed with a 3D patient-specific virtual model, obtained from hip, knee, ankle and subsequent image segmentation of CT scans. The main aspects that are treated at this stage of the procedure are:

- Alignment metrics;
- Virtual positioning of the system;
- Cinematic gaps for ligament balancing;
- Dynamic alignment of the limb.

In particular, the system allows an accurate control of the inclination of the tibial cut on the sagittal and coronal planes; in the case of uni compartmental arthroplasty it suggests increase varus angle of the implant if the patient suffers from osteoarthritis in the medial compartment [27].

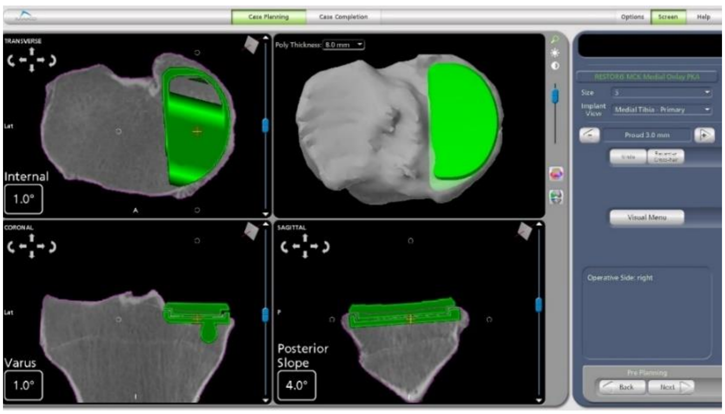


Figure 2.15: Graphical interface of the MAKO system for intervention planning

The **intraoperative phase** of a knee arthroplasty performed with the MAKO system is quite different from the one associated with conventional techniques. The following steps can be summarized:

a) **Definition of the intraoperative setup**: Application of the arrays necessary for the optical tracking of the femur and tibia. The patient's knee is flexed by approximately 90° to position the markers: the tibial markers are placed about 4 fingers below the tubercle and on the tibial ridge, while the femoral markers are placed about 4 fingers above the patella, along the central axis of the femur.

Figure 2.7: Femoral and tibial markers for optical tracking

b) **Registration and verification**: After making the incision, the surface points of the joint and the anatomical reference points are captured with a probe to record the operating target position on the virtual model.

c) **Capture of the poses**: Other data are acquired by repositioning the knee according to different degrees of flexion, under stressed and non-stressed conditions.

d) **Intraoperative planning**: The virtual model allows for real-time changes on the components to balance flexion movements. Appropriate loads are applied to stress collateral ligaments and then the femur and tibia positions are recorded during a passive knee movement (0, 30, 60, 90, 120 ° flexion). The system also evaluates the flexion and extension gaps, indicating them on the monitor, and it suggests how to modify them to achieve ligament balancing. Regarding to this last aspect, positions and inclinations of the femoral and tibial components are modified to have at all the flexion angles (abscissa axis) a laxity between 1 and 2 mm, maintaining a greater laxity (up to 3 mm) between 30 ° and 60 ° of flexion.

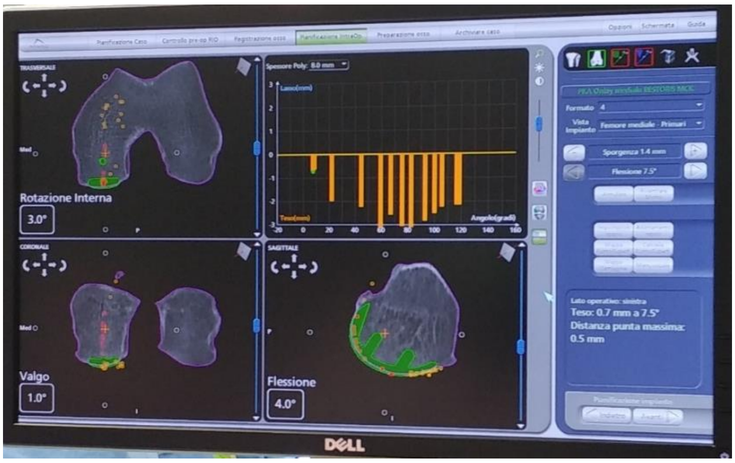


Figure 2.8: Visualization of joint gaps for different degrees of flexion for ligament balancing

e) **RIO registration and verification**: The surgeon moves the robotic arm describing a three-dimensional movement to perform the calibration and to determine the coordinates of the point corresponding to the center of the cutting tools.

f) **Bone resection**: The bone resection is guided by a drill able to provide feedback to the surgeon. The operation is carried out within a specific volume (depth is also considered) and the robotic arm can oppose resistance to movement at the limits of the predefined cutting zone. The surgeon can observe from the screen the portion of bone that he is resecting in real time.

Figure 2.9: Real time view of the bone cutting

g) **Placement of the trial prosthetic components**: The trial prosthetic components are implanted to determine if the dimension and positioning defined in the preoperative phase are correct. The check is performed using a pointer belonging to the optical tracking system.

h) **Cementation of the components of the prothesis**: Once the test components have been removed, the final prothesis is implanted by means of a layer of cement. Before concluding the operation, stability tests are performed by moving the leg and dynamic alignment of the lower limb occurs.

i) Cutting suture and removal of markers and pins

Pre operative planning	• Patient specific virtual model of the knee from CT images • Implant positioning and choice of sizes on 3D model • Editable planning
Intra operative procedure	• Alignment of the prosthetic surfaces with the real thickness of the cartilage • Femoral and tibial tracking • Ligament balancing during the entire ROM • Robotic assisted bone milling
Post operative control	• Excellent precision in the alignment of the components

Figure 2.10: Summary features of the MAKO system

2.3.1 NAVIO

Another semi-active system for knee arthroplasty is the Navio PFS (Precision Free – Hand Sculptor), a newer and more useful technology for the assistance of unicompartmental arthroplasty of knee and patellofemoral arthroplasty. It received the CE mark and had approval from the Food and Drug Administration in February and December 2012 respectively [28].

Figure 2.11: Navio system

The main difference in relation to the MAKO system is the 3D virtual model directly obtained in the intra-operative phase. The Navio system is defined as **'image free'**, it does not require the acquisition of clinical images before the operation by CT scan, MRI or fluoroscopy, but uses an **optical probe** that allows to continuously trace the position of the operative target. This aspect is certainly an advantage because it limits the patient exposure to radiation and eliminates the costs associated with radiographic examinations.

The **robotic arm** can be manipulated by the surgeon thus allowing an intra-operative information recording, intervention planning, anatomy navigation, proper bone preparation and ligamentous balancing.

The Navio system does **not** provide **feedback** to the surgeon when it operates beyond the borders defined in the preoperative phase. However, it can prevent unwanted bone removal by modulating exposure and speed of the motorized drill [28].

2.4 PASSIVE SYSTEMS

2.4.1 NAVIGATION SYSTEMS

Navigation systems allow to **plan** and accurately **assist** the execution of the bone cuts, avoiding the use of traditional instruments, and to accurately place the implant to ensure a **good balance of the articular ligaments**.

They are distincted by:

- **Monitor**, which allows visualization of the virtual model of the articulation and intra-operative parameters;
- **Tracking system**, with which it is possible to determine the position and orientation of objects and the articulation in 3D space, but also of joint centers of hip, knee and ankle.

The different types of navigation systems can be classified according to the method of acquisition of morphological data:

- Computerized tomography / Magnetic resonance;
- Fluoroscopy;
- Imageless techniques

But also, according to the tracking method:

- Infrared light;
- Electromagnetic fields.

The tibial cut is performed following the indications given by the monitor:

- Varus/valgus angle (VV)
- Anterior - posterior tibial inclination (AP)
- Medial and lateral height of resection

It occurs for femoral resection similarly. Even in this case, the surgeon looks at the extension and flexion gaps to perform the ligament balancing [29].

BLU – IGS

The BLU - IGS platform is a CAOS system developed by OrthoKey. In a few steps it allows to plan the optimal resections of the femur and tibia, basing on bone morphology. Furthermore, BLU - IGS realizes a good balance of articular ligaments in flexion and extension.

It does not require pre-operative images to create the anatomical model of the joint, but it is sufficient to record some anatomical landmarks that are combined with the set of data stored in memory by the control system.

The software that monitors the total knee arthroplasty is MIRO '- TKA. The main goals are proper limb alignment and ligamentous balancing.

Figura 2.12: Ligament balancing by software: planning in extension and flexion

2.4.2 CUTTING GUIDES

Cutting guides are used in total knee arthroplasty operations (**TKA**) to precisely align the femoral and tibial cut sections. In some cases, they allow the doctor to carry out a validation of the resections in real time.

General characteristics:

- They consist of a mechanical guide to which **inertial sensors** (**accelerometers** and **gyroscopes**) are applied. Thanks to these instruments it is possible to reconstruct the mechanical axis of the femur and tibia, and then define the positioning and orientation of the guide. The software is able to define the position and orientation of the mechanical guide and the AP and VV angles to optimize the resections. Adjustments are possible by adjusting the mechanical knobs. Finally, the surgeon can proceed with the application of the cutting block and then cut the surface according to what is planned;

- Cutting guides are designed to maintain the **accuracy** of navigation, but they are much faster and easier to use;

- The use of cutting guides does not change the workflow of the surgical operation because in most cases they are compatible with traditional mechanical instrumentation. **No extra time** is required;

- Compared to navigation systems, the cutting guides have the advantage of not providing for the insertion of large pins, on which to place the markers, and the use of specific optical techniques. They do not obstruct the intra-operative view [31].

Computer-assisted cutting guides do not account for ligamentous balancing.

PERSEUS

Perseus is a cutting guide developed by OrthoKey to perform TKA interventions. This is a single-use device provided sterile, capable of communicating via Bluetooth with an application that can be installed on iPad and iPad mini. The software provides intra-operative information in real time. It is an open system, compatible with different types of implants.

Figura 2.13: Perseus system applied to a mechanical guide and graphic interface of the software

The main steps of the surgical procedure are:

a) **Preparation of the system**: switch the device on, wait for it to connect to the software and hook it on the instrument;

b) **Distal femoral cut**: To *mount* the cutting guide on the femur, flex the knee by 90 ° and make a hole between the two femoral condyles on what is called the "knee center". The pin is inserted inside the bone and it must be rotated in such a way that it is aligned with the Whiteside line and has two points of contact with the femoral surface;

The next step is the *acquisition* of intra operative information: the surgeon must make the knee perform short and rapid movements in a lateral – medial arch and in a flexion - extension arch. In this way, it is possible to virtually define a surface whose normal passing through the center of the knee intersects the center of rotation of the hip, reconstructing the **femoral mechanical axis**.

The monitor indicates the guide position relatively to the femur mechanical axis. The values show how far the sliders of the guide move to reach the desired goal. The values at the top of the screen allow to change the objective on the front plane (VV) or on the lateral plane (AP).

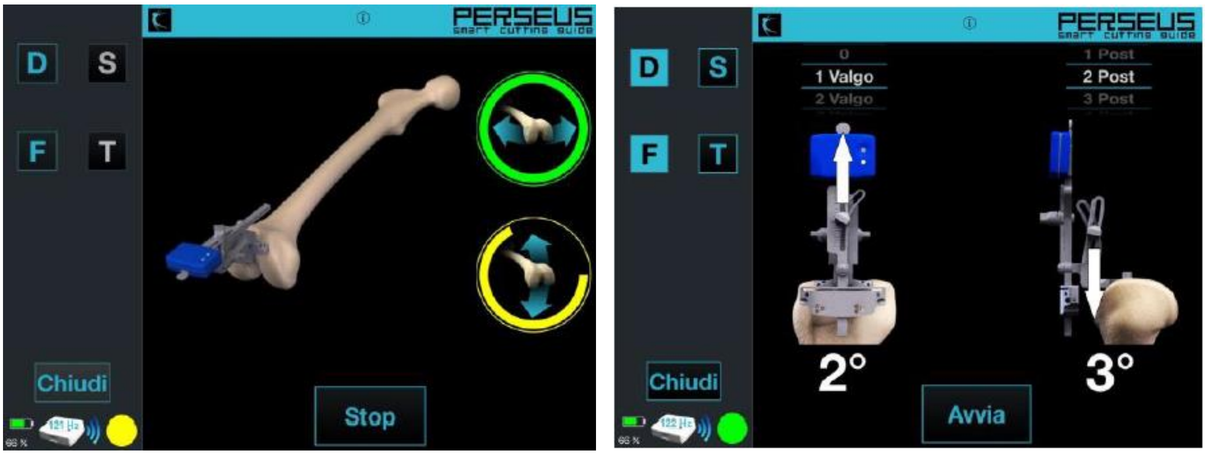


Figure 2.14: Indication on the movements to be performed during registration; Values of VV and AP angles calculated using the inertial sensor

The doctor can refine the positioning as suggested on the screen by moving the guide sliders. Then he can insert the cutting block on the front rail and place the spacer sickle to determine the thickness of the distal resection. Once the cutting block has been fixed in the definitive position, the resection can be carried out;

c) **Proximal Tibial Cutting**: To mount the cutting guide, the surgeon flexes the knee and attach the castle to the tibia at the level of the tibial insertion of the anterior cruciate ligament. Furthermore, the tibial support is placed on the distal part of the tibia, 1-2cm proximal to the malleoli, using the silicone strap. In this way it is possible to virtually define a surface whose normal loop through the center of the ankle intersects the knee center, the tibial mechanical axis.

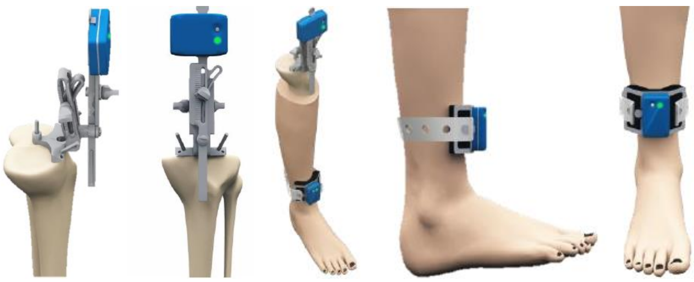


Figure 2.15: Instruments for proximal tibial resection

Even in this case the surgeon must perform tight and rapid movements describing an arch of intra-extra rotation of the femur and an extension and flexion arch of the tibia.

The monitor shows the position of the guide with respect to the mechanical axis of the tibia and how to move the sliders to reach the desired target.

In the positioning and assembly of the cutting block, one can think of adjusting according to what the software suggests, by moving the mechanical cursors. Then the cutting block is applied, and the tibial resection is performed [32].

KNEEALIGN AND IASSIST

KneeAlign is another inertial sensor for cutting guide in TKA. It is an open system, equipped with a palmtop directly mounted on the mechanical guide, which allows to analyze some femoral and tibial parameters (VV angles and AP inclination of the components).

iASSIST is a model developed by Zimmer for TKA consisting of 2 units:

- Cutting guide unit, which provides analog values of the varus / valgus and flexion angles. Once the registration has been made, the values of these angles are indicated by luminous LEDs;
- Reference unit, which drives the movements to perform the registration. It emits audio signals whenever the acquisition of a position is terminated.

The intraoperative validation operation requires the use of an appropriate mechanical instrument on which to apply the cutting unit.

2.4.3 SYSTEMS FOR LIGAMENT BALANCING

Among the most used methods for ligaments balancing, there are the measured resection or gap balancing techinques: both of them provide qualitative and inaccurate information. Furthermore, this phase of the surgical technique depends a lot on the experience and sensitivity of the doctor, because he must be able to recognize if a ligament is sufficiently tense or lax by palpation.

To solve this problem, tibial inserts were instrumented with load cells to dynamically evaluate the balance of the knee and provide the doctor with quantitative information. These sensorized systems allow to measure the forces acting in the two compartments and therefore to choose the most appropriate thickness for the definitive bearing [16].

eLIBRA

It is a ligament balancing system that can be of 2 dimensions (large or small) depending on the implant. eLIBRA contains force sensors in both the lateral and medial portions and the values that are measured during flexion are shown on the display. The values measured can vary from 1 to 20 and 15N are associated to each of them.

Figure 2.16: eLIBRA system

The use of eLIBRA in the intra-operative phase involves 3 steps:

a) **Balancing in extension**: it is necessary to apply eLIBRA on the spacer and insert the system in the articular space, keeping the leg in extension. The load values are indicated on the display;

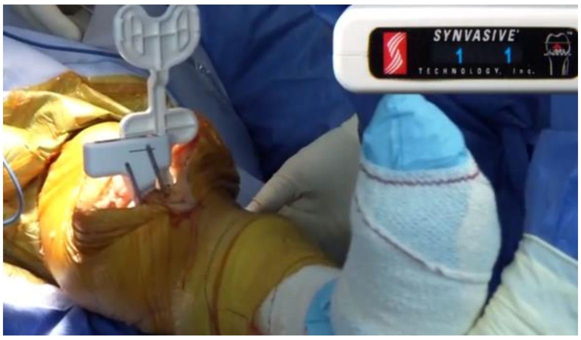


Figure 2.17: Balancing in extension with eLIBRA system

b) **Balancing in flexion**: The surgeon inserts the femoral component LIBRA, he flexes the knee at about 60 ° and applies the instrumented tibial insert. In this phase it is attempted to settle the rotation of the femoral component in order to obtain a flexion gap symmetrical to that of extension.

From the *indications* reported by the manufacturer, the readings observed on the medial compartment should range from 4 to 8, showing that the MCL responds well [33].

Lettura Mediale X med	< 4	< **60N**	Utilizzare un inserto tibiale più spesso
	> X lat		Ruotare la comp. Femorale per ottenere valori identici
	> 9	> **135N**	Ridurre lo spessore dell'inserto
	> 9	> **135N**	Per inserto più sottile: release, resezione tibiale
	< X lat		Verificare MCL funzionale, angoli varo valgo tibia

Figure 2.18: Indicative values of loads on the medial compartment

VERASENSE

VERASENSE is a single use device of different sizes designed by Orthosensor. It is an **open wireless** system, which sends information to a control system with monitor (LinkStation).

The distinctive trait of VERASENSE lies in the fact that it allows to measure the loads in the medial and lateral compartments for the whole ROM, with the closed capsule and the reduced patella. As in the previous case, there are force sensors whose range can vary from 5 to 40lbf.

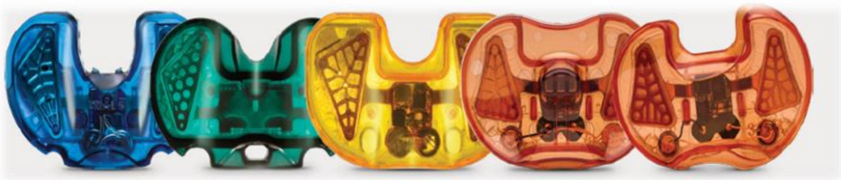


Figure 2.19: Examples of VERASENSE models for different types of implants

In order to use VERASENSE it is necessary to apply it on a trial bearing and insert it into the articulation:

a) **Control of the tibio femoral congruence through the contact points**: it is a very delicate problem, because a wrong orientation of the femoral component can lead to pain, loss of the kinematic functionality, errors in patellar tracking and short life of the implant.
In this regard, the surgeon must check the *points of origin of the medial and lateral contact forces between the insert and the femoral component* on the LinkStation's monitor. Each position is derived from the center of load on the articular surface of the tibia, calculated by the sensors of each compartment. In this phase the angle of inclination formed by the line linking the two points and the middle - lateral axis of the insert is analyzed. According to some studies [17], when the femoral condyles are restored to the center of the tibial plateau and the rotation of the femoral contact points is below 5 °, the tensions of the articular ligaments are sufficiently balanced;

b) **Interpretation of the coronal balance**: If the lateral or medial ligaments are under tension a valgus or varus deformed knee is observed, and the implanted prothesis is not stable. In general, the range of load recommended by producers is between 5 and 40lbf (between 22 and 178N). The range from 41 to 70lbf (182 - 311N) is at the limit;

above it the sensor is overloaded [34]. According to clinical research [17], a difference in load between the medial and lateral compartments of less than or equal to 15lbf in the range of motion is indicative of soft tissue balance in the coronal plane;

Figure 2.20: VERASENSE interface and indication of loads for balance analysis on the coronal plane

c) **Interpretation of sagittal balance**: when the knee is passively flexed, if the femoral component makes a symmetrical rollback and the tibial insert does not lift off, then a condition of equilibrium can be defined. When the rotation of the femoral component rotates, moving the contact beyond the third central where the insert can be divided, then the contact forces increase and the ligaments are not balanced [17].

2.5 COMPARISON BETWEEN COMPUTER OR ROBOT ASSISTED SURGERY AND CONVENTIONAL SURGERY

The discussed technologies are recent and still not widespread. The main advantage that these systems can provide to orthopedic surgery is the acquisition of **intra-operative information** that would not be available with conventional techniques. Thanks to them, the surgeon can achieve much more precise results.

Several studies have shown that robot-assisted surgery is very **accurate** in the control of some variables such as mechanical alignment of the lower limb, maintenance of the joint line, implant placement and finally ligament balancing. The improvement of these issues can have positive implications on the life of the prothesis and on a functional point of view.

Among the main advantages of computer assisted techniques and robots there are [19]:

- Dynamic evaluation of the deformity for any flexion angle and with the patella in situ (in the conventional TKA the operation can be carried out only for precise angles of 0° and 90 °);
- Calculation of the the soft tissues tension to obtain a perfect balance of the knee;
- Accurate restoration of the limb mechanical axis;
- Reduction of blood losses;
- Decreased phenomena of embolism caused by extramedullary instrumentation;
- Accuracy of data related to soft tissue tensions of 1 mm and 1°;

Among the disadvantages [19]:

- Greater time required for the operation;
- Learning curve to perform the procedure;
- High costs for maintaining the system;

The actual benefits of using CAOS systems to perform a knee arthroplasty operation are not perfectly defined because most of the studies make short-term conclusions.

For example, Lonner et al. [35, 20] analyzed the alignment of the tibial component implanted with the MAKO system in the case of UKA: after 3 months, despite the error made on the tibial plateau posterior slope was greater than the one achieved with traditional techniques, on the coronal plane there was a good result. In fact, if with traditional surgical techniques the tibial component is oriented about 2.7 ° in relation to the mechanical axis, in robot assisted UKA an angle of 0.2 ° has been observed.

Another group of researchers tried to document the better durability of the implant positioned via robotic systems and patient satisfaction [36]. Specifically, patients were asked if they had removed, re-operated or had their implant reviewed and to quantify the level of satisfaction associated with the success of the operation. Considering a relatively short follow-up period (minimum of 2 years), it has been shown that uni compartment knee prosthesis implants placed by robotic technology had a survival rate of 98.8% and that approximately 92% of patients were satisfied or very satisfied of prosthetic knee functionality.

In the study conducted by Ponzio et al. [37] the size distribution of the polyethylene bearing during traditional and robot assisted UKA interventions was evaluated. If a tibial resection amplitude of 8 - 9mm can be considered conservative, the authors observed that these values were respected in 93.6% of robot assisted UKA cases and in 84.5% of traditional UKA cases. In addition, a high percentage (15.5%) of subjects operated with the traditional technique has undergone a cut of width greater than 10mm, showing that with robot assisted systems it is possible to obtain more precise, accurate and conservative bone resections.

The results obtained from these studies and many others seem to be promising but they need to be confirmed and deepened. In the literature, the authors focus more on the advantages derived from the use of this technology in the short term and lack, instead, data on the state of the patient and of the prothesis after a long period of time from the implant.
An aspect that is certainly very important is related to costs: the use of such technologies requires substantial investments by healthcare companies. The knowledge of the potentials and possible advantages / disadvantages of these surgical assistance systems is essential to achieve a correct cost-effectiveness analysis.

3. MATERIALS AND METHODS

The problem of conventional techniques for ligament balancing is associated to the fact that they provide indirect and / or qualitative measures of tensions; moreover, the success of the operation only depends on the surgeon's experience. In this study a multibody (rigid body dynamics) model of the prosthetic knee that allows simulating a passive flexion and to predict both the contact forces in the two compartments and the tensions of some ligaments is introduced.

Furthermore, in order to observe how some intra-operative parameters may affect the balancing of ligament tensions, a graphic interface that can modify some properties of the implant is developed.

3.1 MULTI BODY KNEE MODEL

The multibody model of a **prosthetic left knee** is derived from CAD models of bones and total prothesis. The rigid body geometries were imported into the MD Adams program (MSC Software Corporation, Santa Ana, CA, USA) and properly assembled.

CAD models of standard bones from Sawbones, already cut and prepared for the implant procedure, have been adopted for the femur and tibia.

For the prosthesis modeling, geometries of the femoral component, of the tibial component and of a symmetrical mobile insert were used. To facilitate the analysis of the contact forces acting in the two compartments, the bearing was divided in two equal parts. The lateral compartment is highlighted in red, the medial in green.

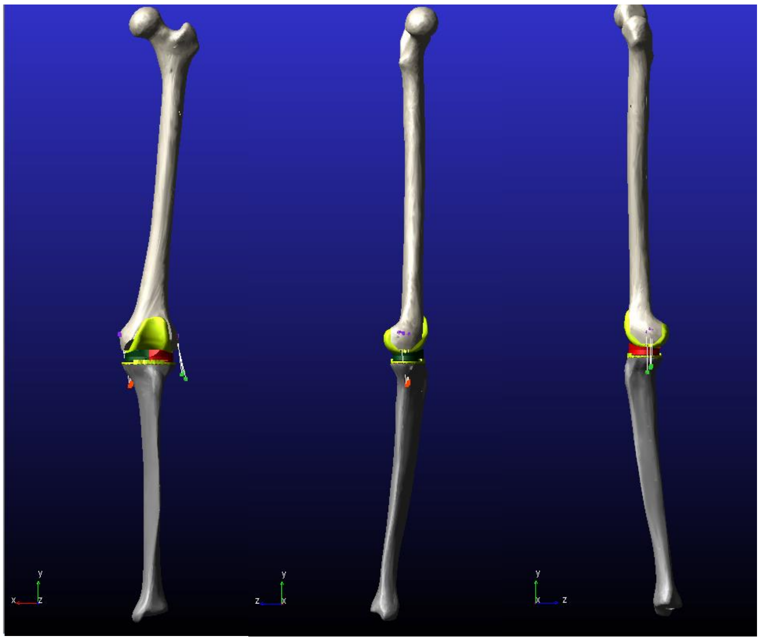


Figure 3.1: Total multibody model. Anterior and lateral (right and left) views

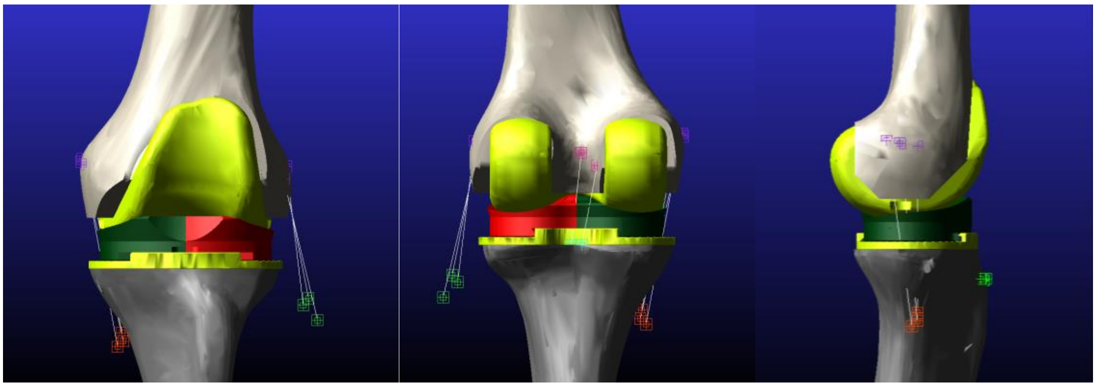


Figure 3.2: Detail of the prosthetic knee. Anterior, posterior and lateral (right) views

The medial collateral ligament (MCL) and lateral ligament (LCL) are shown in the figures, modeled using 3 bundles associated to 3 forces, with attachment points on the femur and tibia. In particular, the distal attachment sites of the lateral collateral ligament are ideally applied to the fibula, not represented in the model.

3.1.1 RIGID BODIES AND CONNECTORS

The knee is modeled as a *hinge*, made of the following rigid bodies:

- **Femur**: it is bound to the ground in the proximal part through a *fixed joint*, so that it does not move during passive flexion. A density of $1 \cdot 10^{-6}$ kg / m^3 has been defined;

- **Femoral component**: it is tied to the distal part of the femur at the cuts level. The femoral component is in *titanium*, characterized by a density equal to $4{,}85 \cdot 10^{-6}$ kg / m^3, a Young's modulus of $1024 \cdot 10^5$ MPa and finally a Poisson coefficient equal to 0,3;

- **Mobile bearing**: it is placed between the femoral component and the tibial plate. The insert is made of UHMWPE (Ultra High Molecular Weight Polyethylene), with a density of $9{,}6 \cdot 10^{-7}$ kg / m^3, a Young's module equal to 800 N / mm^2 and a Poisson coefficient of 0,13;

- **Tibial plate**: the tibial plate, connected to a fixed joint to the proximal end of the tibia, is in titanium and has the same characteristics as the femoral component;

- **Tibia**: it rotates around the joint center. The tibia makes a 5 ° excursion, starting from a situation of almost complete extension up to 85° flexion. The tibial density is $2{,}74 \cdot 10^{-6}$.

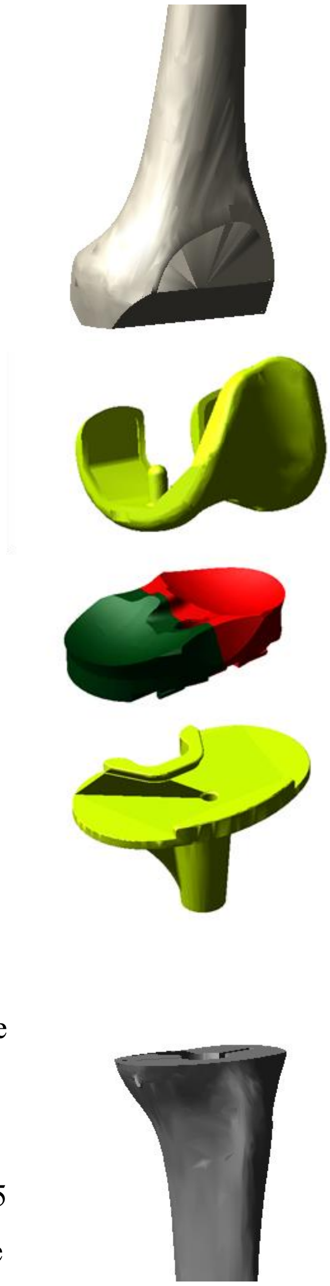


Figure 3.3: Rigid bodies of the knee model

For each part of the model, the corresponding material was created and assigned. Table 3.1 summarizes the characteristics of each of them.

	Material	Density [kg/mm³]	Young Modulus [MPa]	Poisson Coefficient
Femoral Component	Titanium	$4{,}85\cdot10^{-6}$	$1024\cdot10^{5}$	0,3
Tibial Plateau	UHMWPE	$4{,}85\cdot10^{-6}$	$1024\cdot10^{5}$	0,3
Bearing	Titanium	$9{,}6\cdot10^{-7}$	800	0,13

Table 3.1: Materials parameters

3.1.2 CONTACT FORCES

According to other models [38, 39, 40], the femoral component and the mobile bearing interface is modeled with a deformable contact (F_{cont}).

During flexion, the two prosthetic components are subjected to compression and tend to deform along the normal direction to the contact surface: the two deformations will be different because of materials' characteristics.

The algorithm used by MD Adams to describe the contact properties is called "Impact" and, in addition to determining the value of the F_{cont} force for each simulation step, it allows to observe the movement of the contact points during the collision. If during the movement there is no interpenetration between the two bodies, then there is no contact and F_{cont} is null. Instead, if there is an interpenetration between the femoral component and the mobile bearing, this information can be used to evaluate the local deformation. Although the bodies are assumed to be rigid, the contact forces correspond to those evaluated if the interpenetration is associated with local elastic deformations [41].

The mathematical law that describes the contact is inspired by the Hertzian model of behavior of a nonlinear spring, but it also has a term that includes dissipative phenomena, useful for explaining the physical nature of the energy transferred during the impact.

$$F_{cont} = k_c\, \delta_{int}^{exp} + C_c \dot{\delta}_{int}$$

In which:

- F_{cont} is the contact force;
- k_c is the spring stiffness associated with the contact, which depends on the properties of the materials and the geometry of the surfaces;
- δ indicates the interpenetration between the two geometries;
- exp depends on the shape of the surfaces;
- $\dot{\delta}_{int}$ is the interpenetration speed.

The contact parameters values are taken from the literature [40] and in some cases adapted on the basis of a sensitivity analysis, observing the contact forces trend, the interpenetration depth in the two compartments and the computational time.

Moreover, the presence of a **coulomb frictional force** is hypothesized, for which the values of the static and dynamic friction coefficients are inserted.

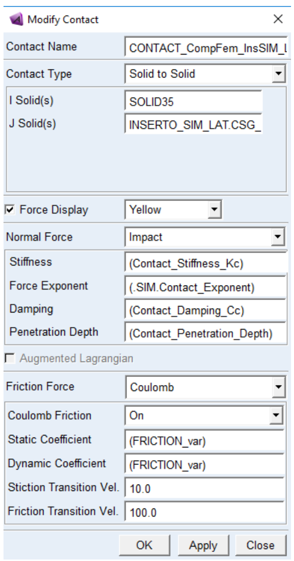


Figure 3.4: Contact Force Dialog Box

Contact Parameters	Values
Contact stiffness k_c	$1 \cdot 10^5$
Contact exponent exp	2,2
Contact damping C_c	1000
Penetration depth	$1 \cdot 10^{-3}$
Static coefficient	$2 \cdot 10^{-2}$
Dynamic coefficient	$2 \cdot 10^{-2}$

Table 3.2: Contact parameters

3.1.3 LIGAMENTS FORCES

In the multibody model presented in this study the medial collateral ligament (**MCL**), the lateral ligament (**LCL**) and the posterior cruciate ligament (**PCL**) are represented, but the last one is not studied.

Since the provided bone models do not come from human subjects but are standards for experimentation, the ligaments attachment sites on the femur and tibia have been deduced from literature information [44] and appropriately adapted for the specific model.

According to previous studies [38, 39, 40], each of the collateral ligaments is divided into 3 bundles (anterior, middle and posterior) modeled as one-dimensional springs [39].

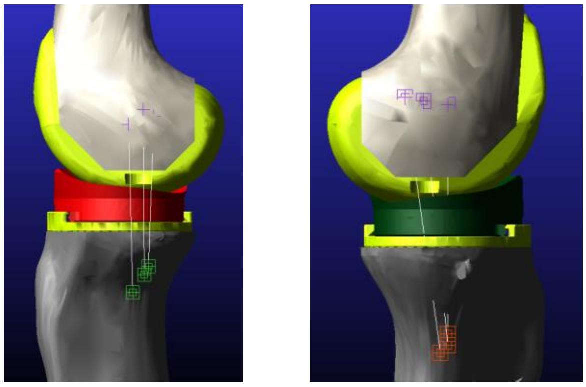


Figure 3.5: Modeling of the collateral ligaments with 3 bundles of fibers: anterior, middle and posterior. Left: LCL, right: MCL

The force f_{lig} of each fiber is described by a mathematical law introduced Blankevoort [42], according to which the trend is non-linear for low deformation values, less than the quantity $2\varepsilon_l$:

$$f_{lig} = \begin{cases} \frac{1}{4} k \frac{\varepsilon^2}{\varepsilon_l} & 0 \leq \varepsilon \leq 2\varepsilon_l \\ k\,(\varepsilon - \varepsilon_l) & \varepsilon < 2\varepsilon_l \\ 0 & \varepsilon < 0 \end{cases}$$

- f_{lig} is the force of a single bundle;
- k is the ligament stiffness;

- ε is the deformation of the single fiber, calculated from its current length L and the zero-load length L_0, the ligament length when it begins to be taut:

$$\varepsilon = \frac{(L - L_0)}{L_0}$$

- L_0 is obtained from strain (ε_r) and length (L_r) values evaluated in a reference condition, which usually corresponds to the extension:

$$L_0 = \frac{L_r}{(\varepsilon_r + 1)}$$

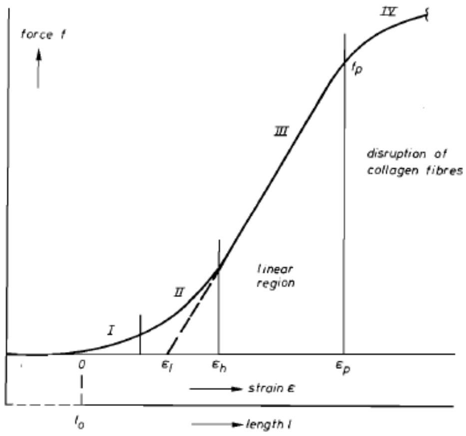


Figure 3.6: Ligament tension curve

In the present model, the Blankevoort law is modified by introducing a term that explains the ligaments viscoelastic behavior, which depends on the damping coefficient c_r and the speed of ligament lengthening $v_{curr} = \left(\frac{d}{dt}\right)L$. In conclusion, the mathematical law that describes each ligamentous fiber force is given by:

$$f_{lig} = \begin{cases} \frac{1}{4}k\frac{\varepsilon^2}{\varepsilon_l} - c_r v_{curr} & 0 \leq \varepsilon \leq 2\varepsilon_l \\ k\,(\varepsilon - \varepsilon_l) - c_r v_{curr} & \varepsilon < 2\varepsilon_l \\ -c_r v_{curr} & \varepsilon < 0 \end{cases}$$

A subroutine that considers the material characteristics (k, c_r) and measures carried out in real time of L and v_{curr} is implemented to obtain the force trend of each bundle.

The following table shows the parameters used in the model. The zero-load length L_0 was initially calculated from values of ε_r and L_r of literature [43] and as described by the formula, but subsequently percentage changes were made for the specific model. For each bundle, L0 values have been modified according to the following information:

a) Recruitment intervals [45];
b) The force produced from each ligament fiber has to be less than 50N. This threshold has been adopted to f_{lig} trend remaining in the nonlinear "toe region" [46].

Ligament	Ligament Bundle	Stiffness k [N]	ε_r	L_0
LCL	aLCL	2000	-0,25	60,99
	sLCL	2000	-0,05	48
	pLCL	2000	-0,08	41,9
MCL	aMCL	2750	0,04	61,2
	iMCL	2750	0,04	62,4
	PMCL	2750	0,03	65,4
PCL	aPCL	9000	-0,24	41,91
	pPCL	9000	-0,03	28,42

Table 3.3: Single ligament bundles characteristics

3.1.4 PASSIVE FLEXION

When the surgeon has to assess the ligaments tensions in the intra-operative phase, he usually places the knee in extension and flexes it up to 90 °, holding the limb at the heel or ankle level and without applying compression loads.

To simulate this type of movement with the virtual model, a **bushing** has been inserted in the distal area of the tibia to flex the knee without exerting compression load. It models spring and damper forces acting between two parts. In MD Adams, it is possible to define the force and torque magnitudes using six Cartesian components (Fx, Fy, Fz, Tx, Ty, and Tz), which are a linear function of the translational and rotational displacement between two coordinate systems moving with the two parts. Bushing acts on the tibia and reacts on a moving part (red cylinder), translating the bone along the z axis thanks to the high stiffness of the z component in translational properties.

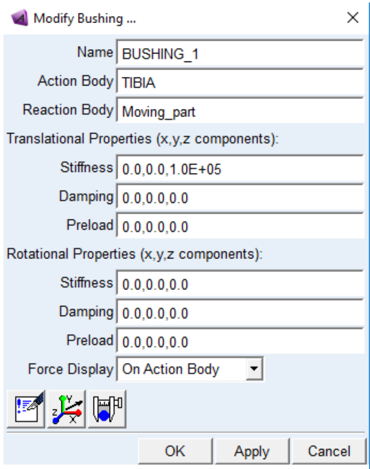


Figure 3.7: Bushing dialog box

A **revolute joint** applied to the joint center allows the rotation of the mobile cylinder and therefore of the tibia.

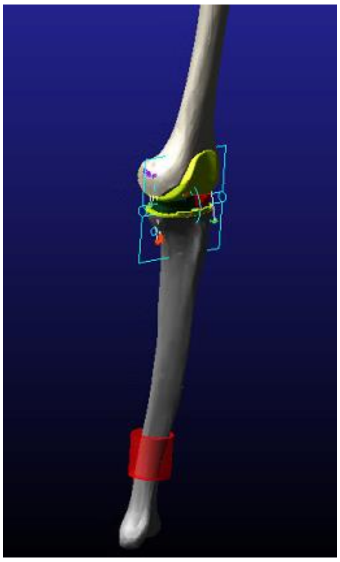


Figure 3.8: Revolute joint for passive flexion

Initially, the knee is not completely extended, but flexed by 5 °, so it starts from a condition of extension of 175 °. During the flexion, which lasts **9.5s**, the joint settles to an equilibrium condition and then makes an arc moving 10 °/s by means of a **motion** applied at the hinge level that models the knee joint. At the end of the passive flexion, the knee will be in a condition of flexion of 85 °.

In order to dynamically evaluate the degree of flexion, the measurement of the angle formed by 3 markers was inserted: the first one on the femur, the second one at the center of the joint and finally the third marker on the mobile cylinder. The last one has not been chosen on the center of mass of the tibia because it tends to move when the orientation of the prosthetic implant is changed, causing measurement errors.

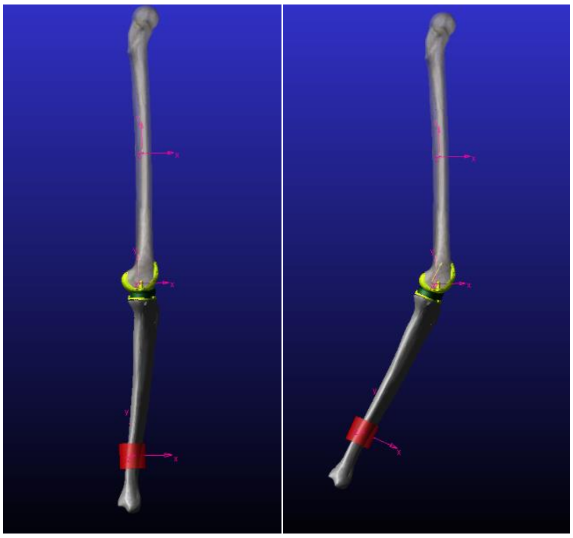


Figure 3.9: Passive deflection guided by bushing and markers for the measurement of the angle

3.2 GRAPHICAL INTERFACE AND MODEL CHANGES

Although in the planning phase of knee arthroplasty surgery it is possible to define the desired position and orientation for the prosthetic implant, the doctor may no longer respect the starting indications if he realizes that the joint ligaments are not balanced. In some cases, he can simply proceed with fibers loosening, in other cases, when the errors are important, it may be necessary to change the size of the mobile insert or to intervene again on the bony cuts.

A custom graphical interface was developed with MD Adams to modify the position and orientation of some components of the total knee prosthesis and to evaluate how the contact forces and the ligaments forces change.

It is assumed that the described multi body model is in a condition of **equilibrium**, both as regards the loads acting in the two compartments, and at the level of tensions produced by the ligaments. In fact, from a morphological point of view, the bone geometries used are perfectly congruent to the components of the implant and the ligaments modeling sufficiently reflects already validated examples in other studies.

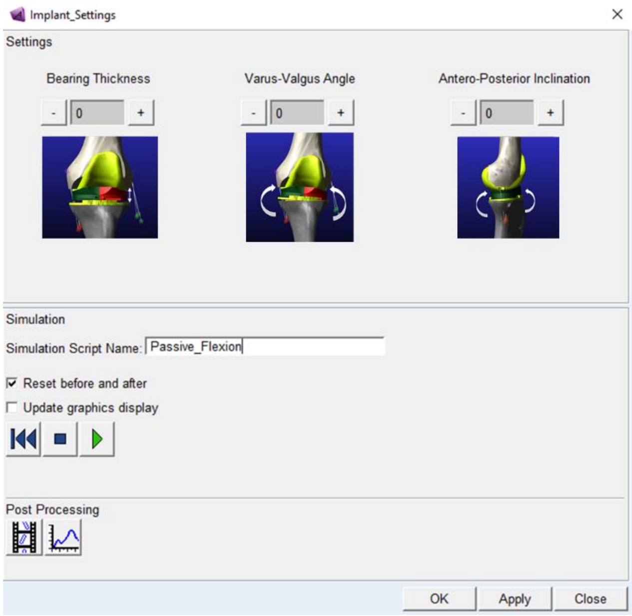


Figure 3.10: Custom graphical interface for the modification of intraoperative parameters

At the top, the graphical interface allows the modification of:

- **Bearing thickness**: in the intra-operative phase an insert size that allows a dynamic measurement of the contact forces within a range that can vary from about 20N to 180N [34] is usually chosen. If, for example, the measured contact forces are close to the lower limit of the range, it may be useful to choose a thicker insert that also guarantees a correct tensioning of the ligaments.

  From a computational point of view, to get this modification it is not necessary to change the bearing geometry, but it is possible to change its position along the vertical axis. In the interface, the user can enter the dimension [mm] corresponding to the increase or decrease of the insert thickness. Automatically, the calculation code associated with the field accesses the coordinates of the position markers of the two elements in which the bearing is divided and allows its translation in the vertical direction. Although the bearing may visually detach from one of the two prosthetic components, fixed joints have been retained;

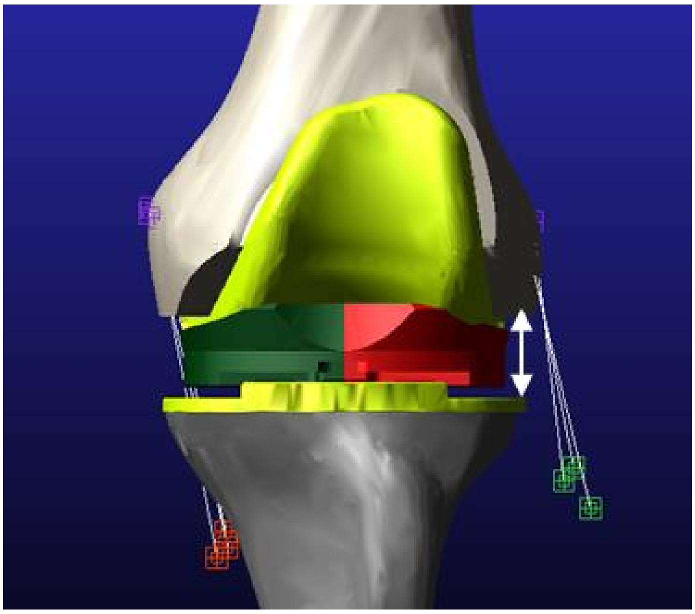


Figura 3.11: Height variation of the mobile bearing to simulate the change in thickness

- **Varus / Valgus angle**: the alignment of the prosthetic components on the coronal plane can be indicated with the angle formed by the mechanical axis of the bone and the medial to lateral axis. As the model is constructed, both the femoral and the tibial components are in a balanced condition on the coronal plane.

Sometimes the surgeon may need to tilt the prosthetic components medially or laterally, to minimize the difference between the contact forces in the two compartments, to obtain symmetrical extension and flexion gaps or to ensure ligament balancing.

The interface allows to change the orientation of the tibial plateau and the mobile insert in relation to the value digited into the field. In particular, for *positive angles* the tibial plate is laterally tilted, making the knee *varus*, for *negative angles* the component is rotated medially, adding degrees of *valgus*. The calculation code changes the orientation of the tibial plate position marker;

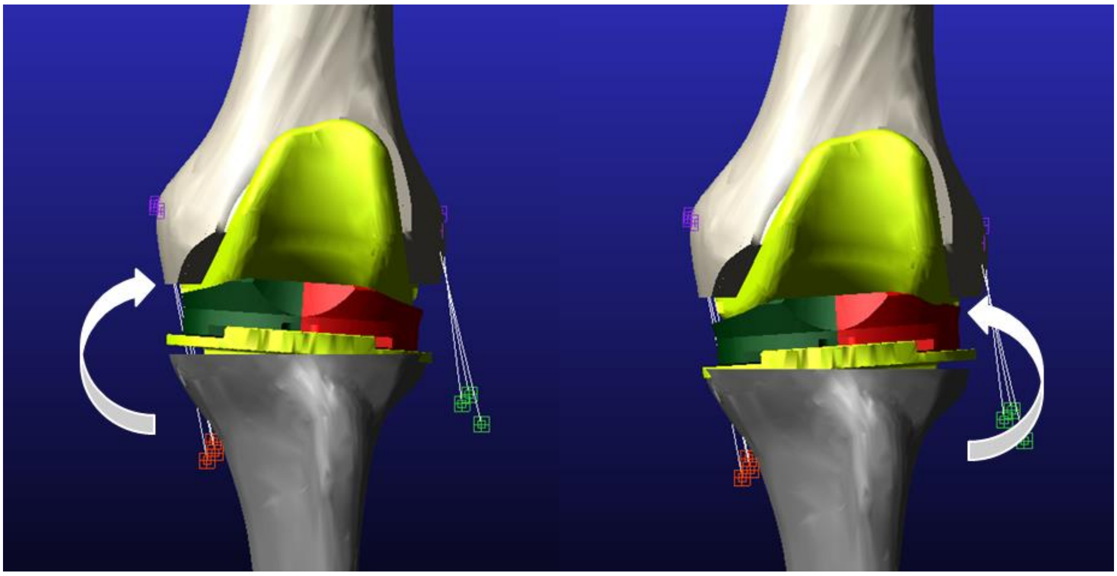


Figure 3.12: Inclination of the tibial plate on the coronal plane. Left: positive inclination, varus knee. Right: negative inclination, valgus knee

- **Antero/posterior inclination of the tibial plate**: the last modification that can be performed with the graphic interface is the inclination of the prosthetic tibial plate on the sagittal plane, for reasons similar to the previous case.

  By inserting *positive values* of angles, it is possible to incline the model *posteriorly*; for *negative values* the tibial position marker is *anteriorly* oriented.

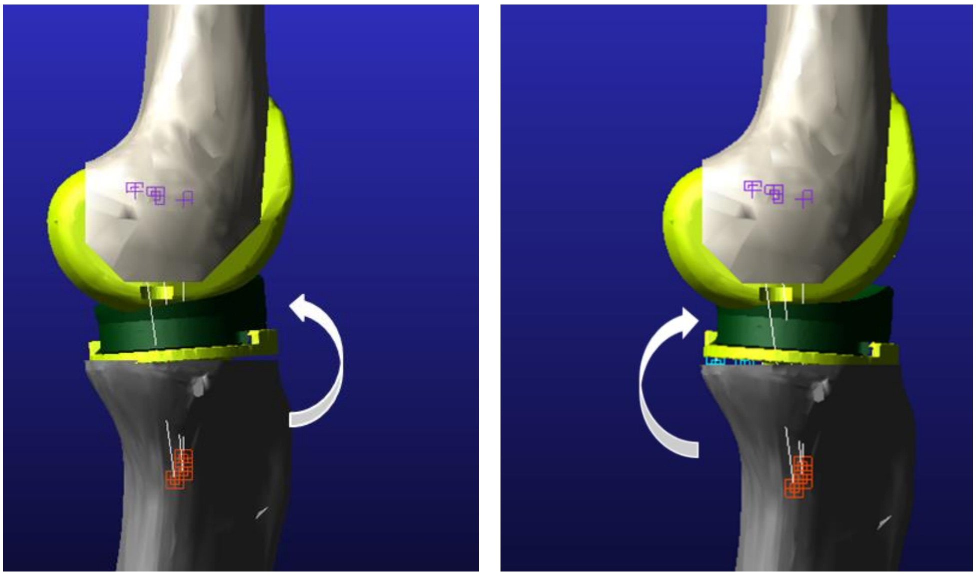


Figure 3.13: Inclination of the tibial plate on the sagittal plane. Left: positive angle, backward tilt. Right: negative angle, anterior inclination

Changes are applied when the knee is *extended* and can be performed individually or even all together. The codes used for the creation of the dialog box are shown in the appendix.

The graphic interface further includes a section dedicated to the simulation. It allows:

- Run the passive flexion script, with the possibility to display the simulation status
- Access the performed simulation video
- Open the post processor and view the contact and ligaments forces trends.

4. RESULTS AND DISCUSSION

Some passive flexion simulations were performed to evaluate contact forces acting in the two compartments and collateral ligaments forces under different model conditions.
In the first simulation the balanced knee model was considered and subsequently the following changes were made:

- Bearing thickness variation of ±1mm and ±2mm;
- Inclination of the tibial plate on the coronal plane of ±2 ° and ±4 °;
- Inclination of the tibial plate on the sagittal plane of ±2 ° and ±4 °.

Through the use of the MD Adams post processor it was possible to create two types of graphs:

- Representation of the contact forces between the femoral component of the prothesis and the mobile bearing in the two compartments;
- Representation of the forces produced by each fiber in which the collateral ligaments were divided.

The graphs must be read from right to left. On the abscissae axis the degrees of extension are indicated: with respect to the excursion performed during the simulation, 85° of flexion are represented, in which the collateral ligaments have a dominant role [15].

4.1 CONTACT FORCES

In general, for all the cases analyzed, the contact forces have a similar trend: they assume the maximum value at the extension phase and then decrease with growing flexion. Furthermore, according to literature [33, 34], the contact force acting on the lateral compartment is always less than that acting on the medial section, even in the unbalanced models.

The first simulation is performed with the **balanced knee model**: the values of the contact forces agree with what is reported in other studies [47] and in the indications of some commercial products [33, 34]. It can also be observed that the contact forces are rather balanced in the two compartments and their difference does not exceed the threshold value of 15lb (67N) indicated by Roche et al [17].

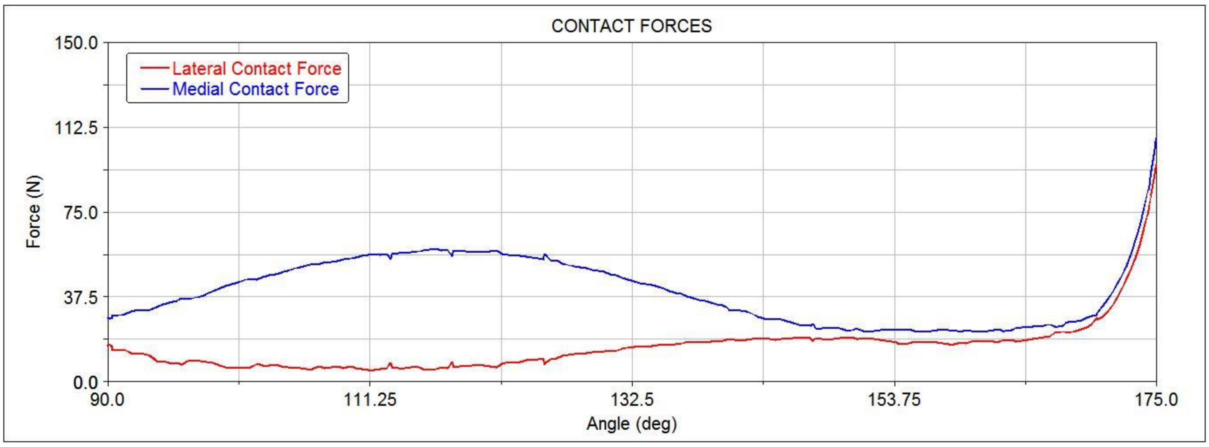


Figure 4.1: Contact forces during flexion of the balanced knee model

This condition can be taken as a **reference** to evaluate what happens when the model is subject to changes.

Assuming to use a bearing of *different thicknesses*, the following trends of the contact forces are obtained in the lateral compartment and in the medial compartment respectively:

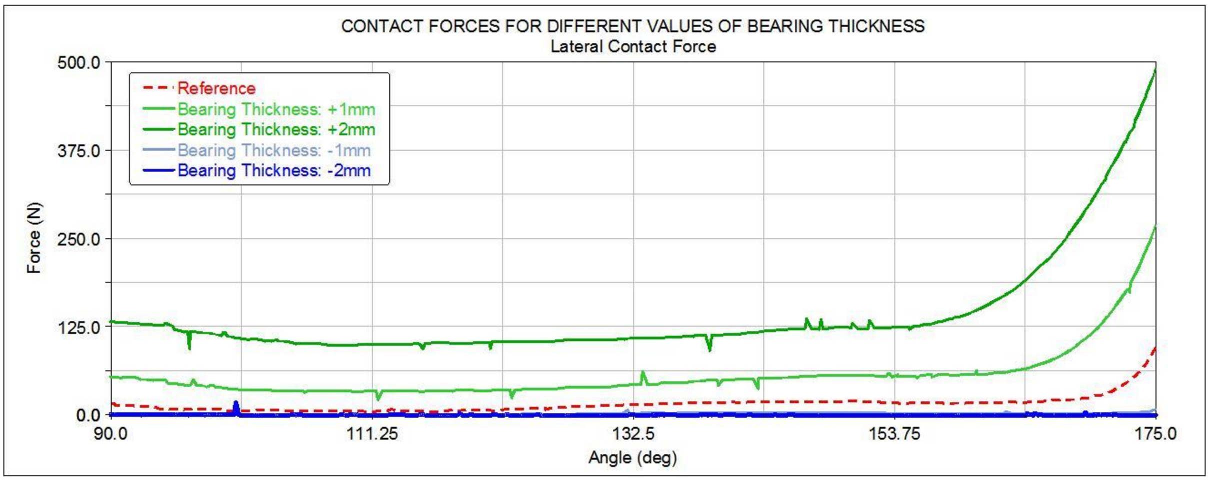


Figure 4.2: Lateral contact force for different bearing thicknesses

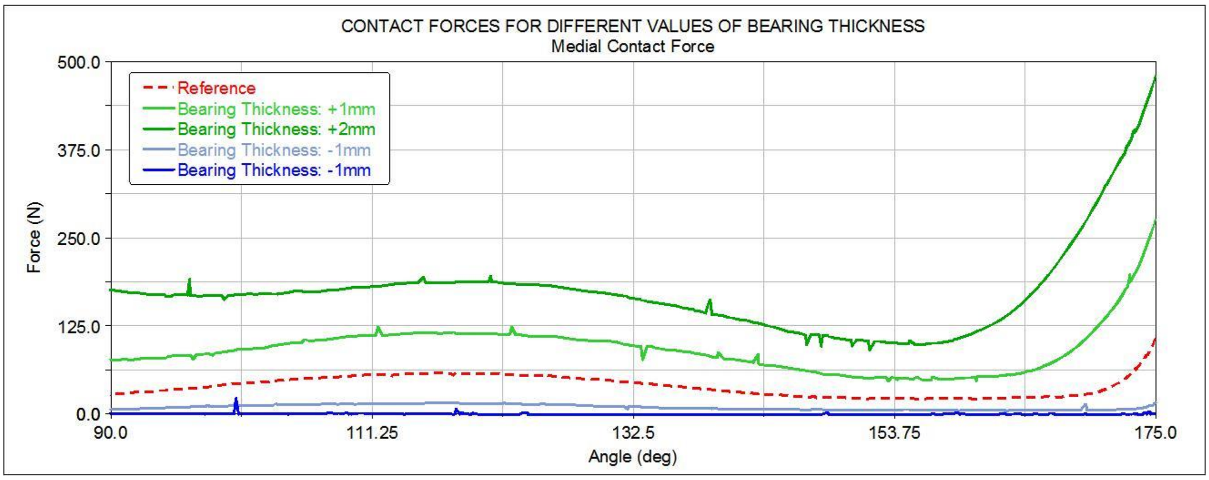


Figure 4.3: Medial contact force for different bearing thicknesses

The two graphs show the contact forces trends in a condition of equilibrium (dashed) and for various thicknesses of the bearing. The color scale is used to highlight different situations: thickness increases are indicated by green colored curves, while the use of thinner inserts is emphasized by blue colors. The obtained results agree with what is expected: using inserts of greater thickness (1mm, 2mm) there is a considerable increase in the contact force for both compartments. Considering thinner movable bearings, it can be observed that the contact is lost in both dimensional cases in the lateral compartment, while in the medial compartment the contact is maintained when the bearing is thinner than 1mm with respect to the original one.

Different considerations for the contact forces trends when the model is no longer in *equilibrium on the coronal plane* can be made:

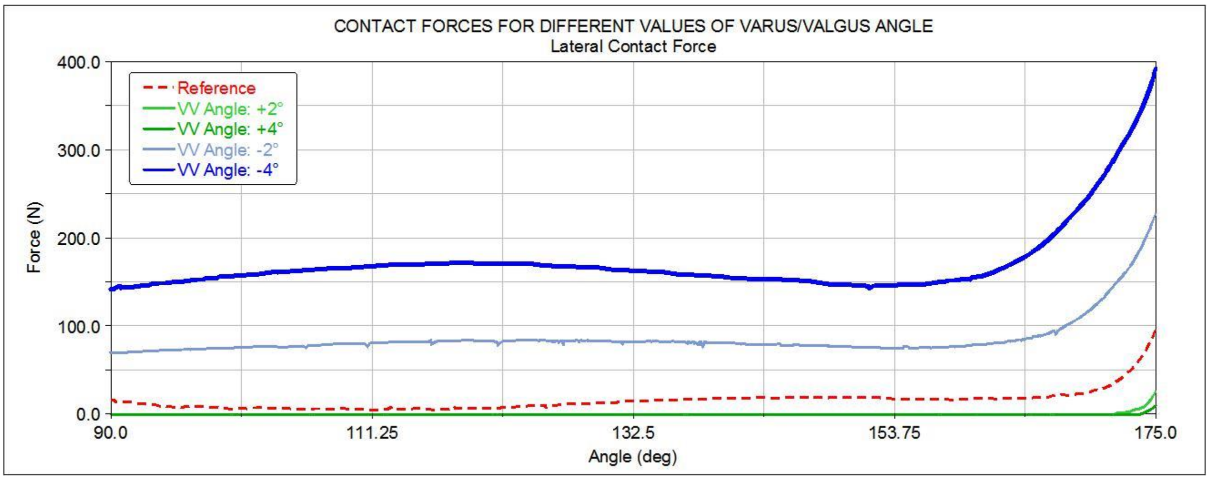


Figure 4.4: Lateral contact force for different tilt values in the coronal plane

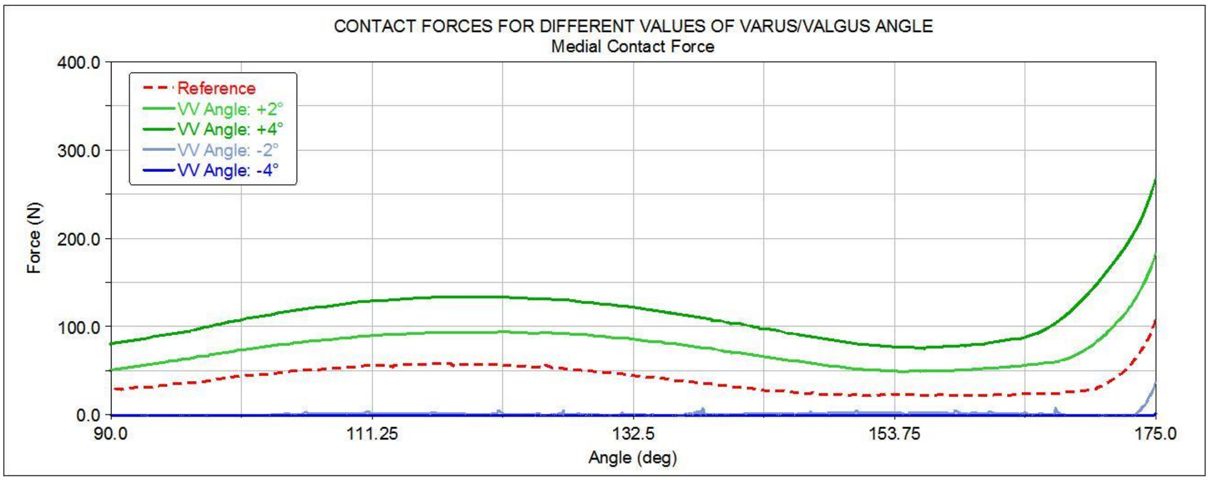


Figure 4.5: Medial contact force for different tilt values in the coronal plane

To evaluate how the contact forces change in relation to the tibial plateau orientation in the coronal plane, reference can be made to the equilibrium condition indicated by the red dashed curve. The adopted color scale includes green color to indicate positive angles (lateral inclination, varus angle) and blue color to represent negative angles (medial inclination, valgus angle).

It can be observed how the contact forces between the lateral and medial compartment vary in a specular way. For example, assuming to tilt the tibial plate laterally by a 4 ° angle, the contact force acting on the medial compartment is in the superior region to that of the reference. In the same condition, the contact force acting on the lateral compartment, instead, will be lower than the reference value. The argument is analogous considering the negative angles (medial inclination, valgus angle).

Finally, the graphics below show how the contact force change in the two compartments when there is no more *balance on the sagittal plane*:

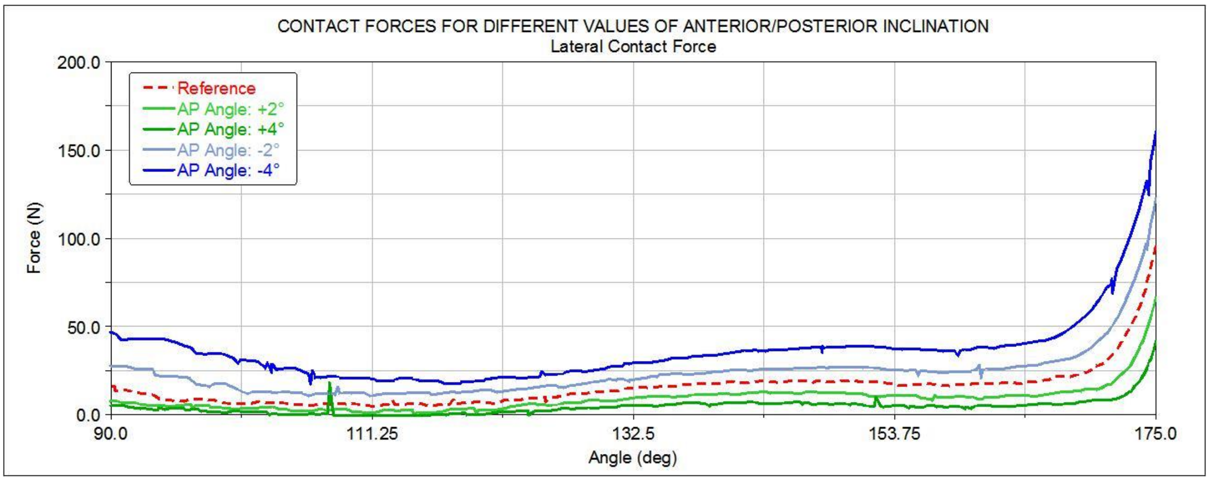


Figure 4.6: Lateral contact force for different tilt values in the sagittal plane

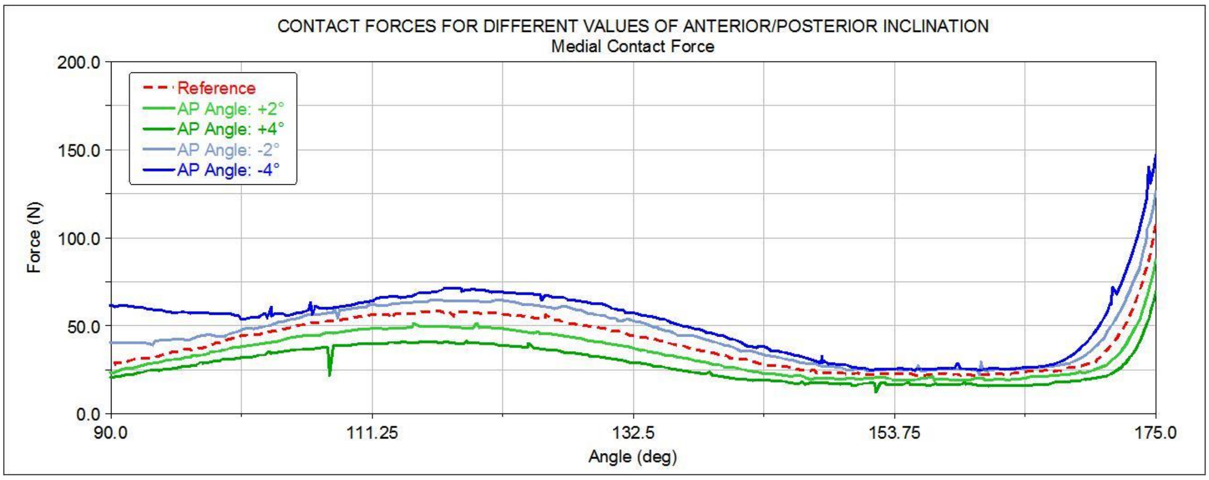


Figure 4.7: Medial contact force for different tilt values in the sagittal plane

On the sagittal plane, positive angles indicate a posterior tilt of the tibial plateau, while negative angles demonstrate an anterior inclination. The trends of the contact forces in the two compartments vary symmetrically: for positive angles of inclination, the curves occupy

the region below the reference curve, because of a lower compression of the components; for negative angles, the contact forces are wider and position above the reference curve.
However, changes in contact forces are rather limited compared to what happens by modifying the tibial plate inclination on the coronal plane.

4.2 LIGAMENTS FORCES

This model is able to directly supply the values of the forces exerted by the ligaments throughout the passive flexion. In particular, the contributions associated to the 3 fibers in which the collateral ligaments are divided are highlighted: the forces associated with the anterior fibers are shown in red, the forces of the intermediate bundles in blue and the forces of the posteriors are shown in green.
Following the approach used for contact forces, the results obtained in the simulation with the reference model can be used to make considerations on what happens in unbalanced cases.

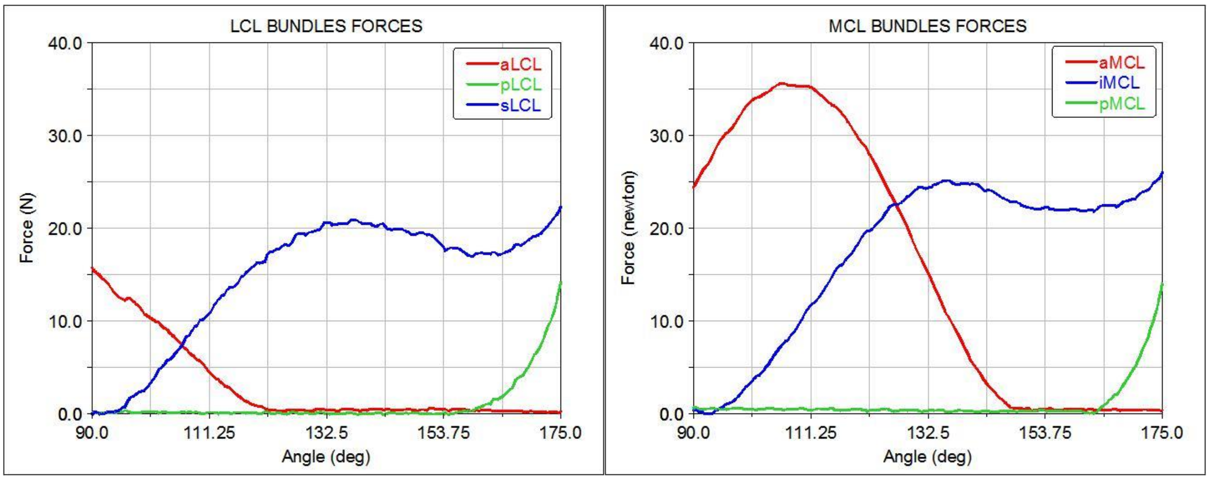


Figure 4.8: Ligament bundles forces. Left: LCL, Right: MCL

During passive flexion, since the model is properly balanced, ligament forces remain within the 50N threshold [46]. The anterior bundle is recruited mainly in the flexion phase, the intermediate fibers are active for almost the entire duration of the movement and finally the posterior fibers tend to activate in extension.

Considering the previous variations in the **thickness** of the mobile bearing, the corresponding trends of the ligament forces are reported. As mentioned previously, green colors are associated with greater bearing thicknesses and blue colors associated with thinner bearings.

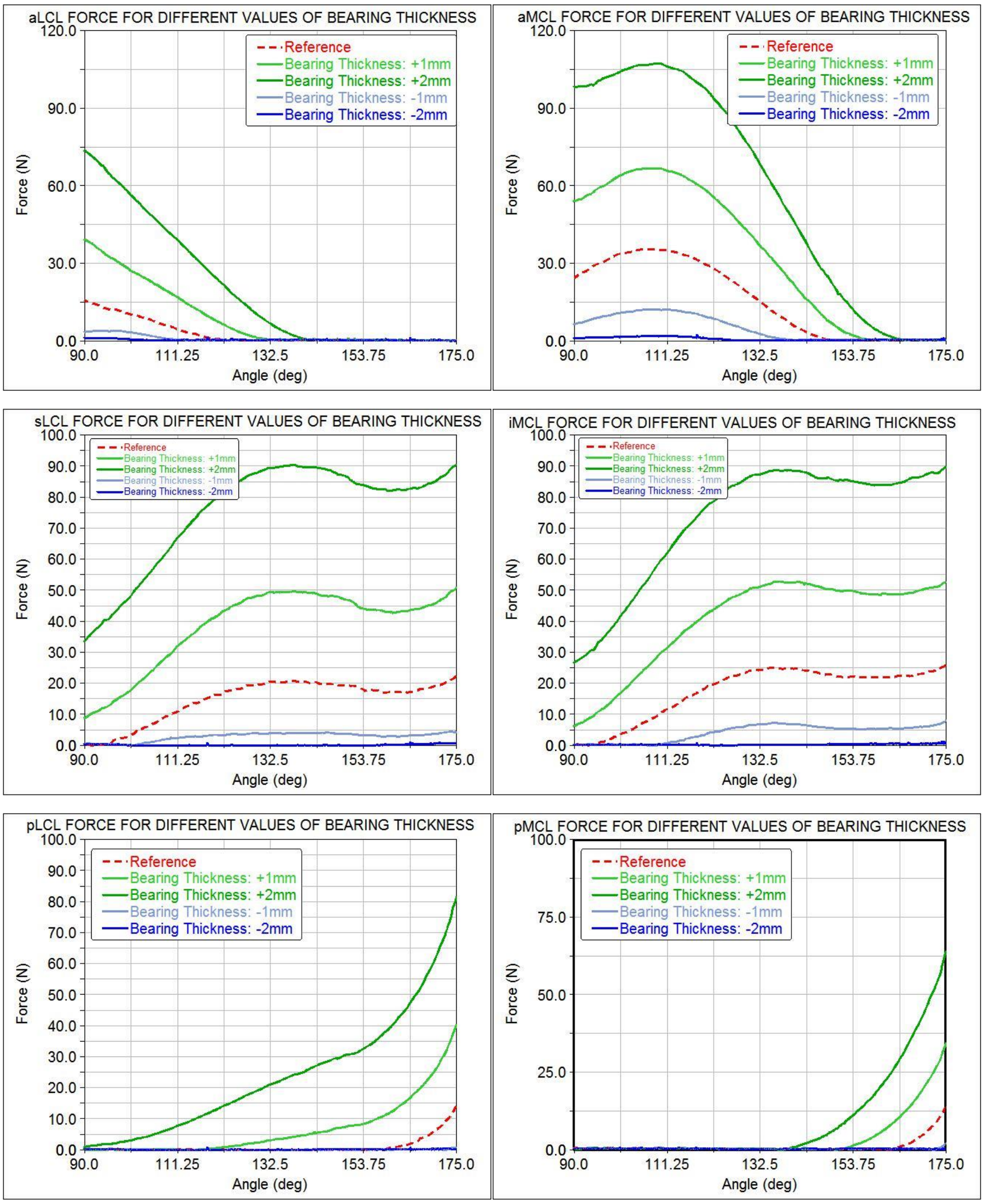


Figure 4.9: Ligament fibers forces as for different bearing thicknesses. In the left column are shown the LCL fibers forces, in the right column those of the MCL

The variation in the thickness of the bearing only influences the amplitude of the ligament forces, similarly to what is seen for the contact forces: when thicker inserts are used, the ligaments are tauter and consequently they produce greater forces; for thinner inserts the fibers are lasse and exert forces lower than the reference ones.

When making changes to the orientation of the tibial plateau in the **coronal plane**, the following force curves for the ligaments are obtained:

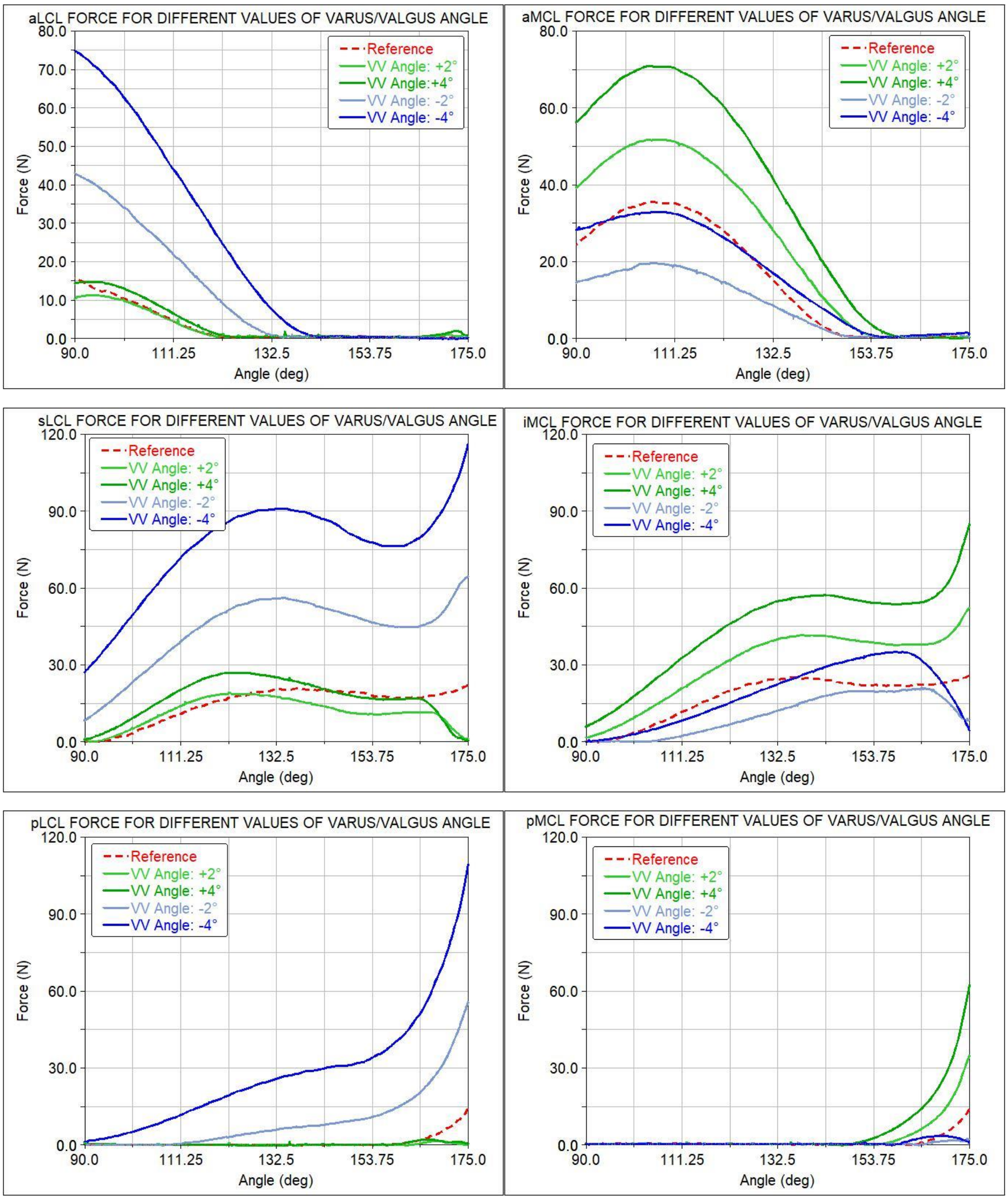
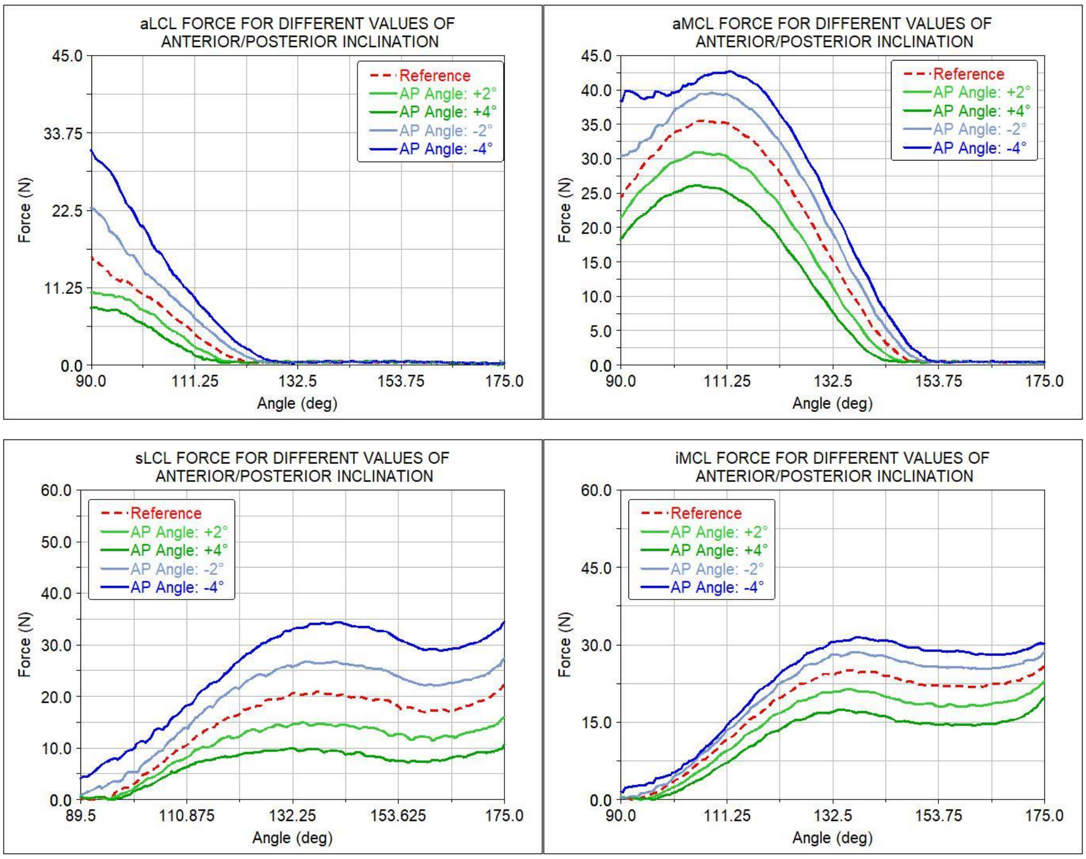


Figure 4.10: Ligament fibers forces for different tibial plateau tilts in the coronal plane. In the left column are shown the LCL fibers forces, in the right column those of the MCL

The colors used to represent the of the ligamentous fibers forces are the same used for the contact forces. It is possible to complete the previous discourse by with considerations on the soft tissue balancing. Taking again the case of the positive inclination of 4°, in addition to increasing the contact force on the medial compartment, there is an increase in the force exerted by the MCL because in this configuration the ligament is stretched. The same phenomenon occurs for the LCL when the tibial plate is tilted laterally by -4 °. The intermediate fibers of the collateral ligaments take on a different trend from the reference one when they are loose.

On the **sagittal plane**:



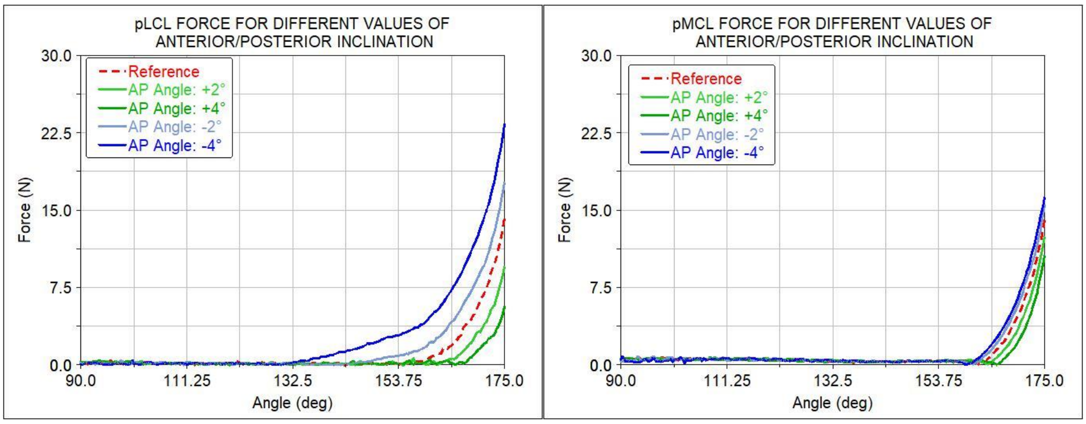


Figura 4.11: Ligament fibers forces for different tibial plateau tilts in the sagittal plane. In the left column are shown the LCL fibers forces, in the right column those of the MCL

The trends of the forces exerted by the bundles for different orientations of the tibial plateau on the sagittal plane are very similar to those of reference. It can be noted that for negative angles values, the ligaments become more lassi, for positive inclination values, instead, the ligaments become looser.

4.3 CONCLUSIONS

The goal of this study is to develop an application that fills some gaps shown by CAOS systems for knee surgery. Although they are able to realize operational planning in a few steps and to perform bone resections very precisely, they are not able to provide direct measures on ligamentous balancing. The only information that can be obtained in real time are:

a) Measurement of extension and flexion gaps, useful for balancing techniques such as measured resection or gap balancing;
b) Measurement of intercompartmental contact forces between the femoral component and an instrumented mobile bearing.

A multi-body knee model with features already validated in other studies [38, 39, 40, 42, 43] was developed to simulate what happens during the intra-operative phase and to provide more precise information on ligaments tension state.

In particular, a passive knee flexion was simulated from an extension condition and the contact forces in the two compartments and collateral ligament forces were dynamically measured (Medial - MCL, Lateral - LCL).
The results obtained in a condition of knee balance were initially evaluated and then considerations of what happens when the prosthetic implant has a different orientation in space were made.

In conditions of equilibrium, the **contact forces** reach the maximum value in the extension phase and tend to decrease with an increase in the degree of flexion, according to what has been evaluated by Verstraete M. A.et al. (2017). The range of values in which the contact forces fall also respects the information reported by some manufacturers of instrumented inserts [33, 34], which carry out similar measurements. The same goes for the difference in load in the two compartments, which overall remains within 67N [17] for the entire duration of the simulation.
The implementation of a customized dialog box made it possible to quickly and easily make some changes to the features of the system:

- Variation of the thickness of the mobile insert;
- Varus / valgus inclination on the coronal plane;
- Anterior / posterior inclination on the sagittal plane.

The variation in the amplitude of the contact forces is directly proportional to the change imposed on the insert **thickness**: for thicker inserts greater forces were obtained in both compartments vice versa for thinner inserts.
The tibial component has been rotated both on the coronal and on the sagittal plane to observe how contact forces change. On the **coronal plane**, positive angles of inclination determine a varus knee, while negative values correspond to a valgus knee. The measured contact forces respect the deformation conditions: for varus knees the contact forces are greater on the medial compartment than on the lateral side and for valgus knees, on the other hand, the contact forces have greater amplitude on the lateral section of the joint. Depending on the coronal rotation degrees imposed, the trend of the contact force does not change, but only the amplitude.

On the **sagittal plane**, positive angles correspond to a posterior inclination of the tibial plateau and negative angles are associated with an anterior inclination of the component. The graphs show that as the tibial plateau front inclination increases (negative angles), the contact forces on both compartments are greater. The vice versa occurs due to a posterior inclination of the tibial plate (positive angles).

The indications on the forces amplitude variation depending on how the components of the implant are oriented are very useful in the intra operative phase, because the surgeon can realize how much he can tilt the bone cut to stay within the allowed load limits.

The strength of this model concerns the prediction of the **collateral ligaments tensions**, which can be useful to the surgeon to improve the orientation of the bone cuts.

From the results it is evident that by increasing the **thickness** of the insert, the collateral ligaments are tauter and exert greater force during flexion; vice versa, when thinner mobile bearing thicknesses are chosen, the collateral ligaments are laxer.

On the **coronal plane**, when the tibial plate is tilted laterally like in a varus knee, the medial collateral ligament MCL tends to exert greater force on the joint throughout the duration of flexion, while the LCL lateral collateral ligament maintains a behavior similar to the equilibrium condition. This condition could suggest to the surgeon to reposition the implant in a different way to virtually realize a medial ligament bundle release, as recommended in the literature but through conventional techniques [15].

If instead the tibial component is medially inclined, the knee has a varus deformation and the LCL is tauter: starting from this condition the surgeon could modify the orientation of the bone cut to relax the LCL, according to what reported by Bottros J. et al. (2006).

Finally, the trends of the collateral ligament forces were evaluated in correspondence with changes of the implant on the **sagittal plane**: for posterior inclinations of the tibial plate, the ligaments are laxer in both compartments; for anterior inclination of the tibial plate, instead, they exert more intense forces and are more in tension.

The results obtained must however take into account the approximations adopted in the development of the model. The geometries of the femur and tibia have not been derived from medical images but are simply standards used in experiments. This issue also influences the ligaments modeling, because their attachment points on the femur and tibia are not perfectly congruent to the physiological cases, since bone anatomical landmarks cannot be identified. Another approximation concerns the mathematical law that describes the ligaments force: due to the variability of the connective tissue constitution, the model may not be suitable for all subjects.

The multi body application created is a development of an issue that is still not very well analyzed by CAOS systems: the soft tissues balancing. Future developments of this study to ensure more precise and reliable measures on ligament forces could include the implementation of bone geometries from CT images and reconstruction of ligaments with MR imaging.

5. APPENDIX

5.1 BEARING THICKNESS CHANGE CODE

```
if cond=( str_is_space( ".SIM.DV_2" ) )
   if cond=( ".SIM.DV_2" != ".SIM.DV_2" )
      ! user changed the name, need to update hidden field
      interface     field     set     field=.gui.design_variable_cremod.variable_name
strings=(eval(".SIM.DV_2"))
   end
   variable create variable_name=.SIM.DV_2 &
       &
      real=$_value &
       &
       &
      units=no_units &
       &
      delta_type=relative &
       &
       &
       &
      range=-1.0,1.0 &
       &
       &
      use_range=yes & ! Toggle has on/off upside down
       &
       &
       &  ! Toggle has on/off upside down
      comments=(eval( .gui.design_variable_cremod.entity_comments ))
end
! Update mode
if cond=( ! str_is_space( ".SIM.DV_2" ) )
   variable modify variable_name=.SIM.DV_2 &
       &
      real=$_value &
       &
       &
      units=no_units &
       &
      delta_type=relative &
       &
       &
       &
      range=-1.0,1.0 &
       &
       &
      use_range=yes & ! Toggle has on/off upside down
       &
       &
       &  ! Toggle has on/off upside down
      comments=""
end
```

```
if cond=( "off" == "off" )
   variable modify variable_name=.SIM.DV_2 &
      allowed_values=(none) &
      use_allowed_values=no
end
! Update field if requested
if cond=( ! str_is_space( "" ) )
   interface field set field_name= &
      strings=(eval(DB_DEFAULT_NAME_FOR_TYPE(.SIM.DV_2.self, "variable")))
end
! .gui.design_variable_cremod / Exe - end ===================
if cond=( str_is_space( ".SIM.DV_2" ) )
   interface dialog display dialog=.gui.design_variable_cremod par="", ""
end
```

5.2 VARUS/VALGUS ANGLE CHANGE CODE

```
mark mod mark=.SIM.ground.MARKER_711 adams_id=711 loc=0.0, (DV_2), 0.0
ori=$field_1_2_2, 0.0, $_value relative_to=ground
```

5.3 ANTERIOR/POSTERIOR ANGLE CHANGE CODE

```
mark mod mark=.SIM.ground.MARKER_711 adams_id=711 loc=0.0, (DV_2), 0.0 ori=$_value,
0.0, $field_1_2 relative_to=ground
```

5.4 START SIMULATION CODE

```
if cond=((.gui.sim_int_panel.c_interactive.displayed == 1))
if cond=((.gui.sim_int_panel.c_interactive.duration.displayed == 1) &&
(eval("$duration"))=="" )
  mdi gui_utl_alert_box_1 type = "Warning" text = "Enter Duration."
return
end
if cond=( (.gui.sim_int_panel.c_interactive.end_time.displayed == 1)
&&(eval("$end_time"))=="" )
  mdi gui_utl_alert_box_1 type = "Warning" text = "Enter End Time."
return
end
if cond=( (.gui.sim_int_panel.c_interactive.step_size.displayed == 1) &&
(eval("$step_size"))=="" )
  mdi gui_utl_alert_box_1 type = "Warning" text = "Enter Step Size."
return
end
```

```
if  cond=(  (.gui.sim_int_panel.c_interactive.number_of_steps.displayed  ==  1)     &&
(eval("$number_of_steps"))==""   )
  mdi gui_utl_alert_box_1 type = "Warning" text = "Enter Steps."
return
end
end
var set var = .mdi.errno int=0
if cond=("$control" == "interactive")
   if cond=($initial_reset)
      simulation single reset
   end
   if cond=("$end_time_duration_option" == "Forever")
      simulation single trans &
         type              = $simulation_type   &
         initial_static    = $initial_static    &
         forever           = true               &
         `step_size        = $step_size`
   else
      simulation single trans &
         type              = $simulation_type   &
         initial_static    = $initial_static    &
         `duration         = $duration`         &
         `end_time         = $end_time`         &
         `step_size        = $step_size`        &
         `number_of_steps = $number_of_steps`
      end
else
   simulation single scripted &
      sim_script_name = $f_script_name &
      reset_before_and_after = $reset_ba
end

mdi gui_utl_check_sim alert_done=no alert_stop=no
var set var = .mdi.errno int=0   ! in case a simulation is running
```

5.5 POST PROCESSOR OPENING

```
interface dialog undisplay dialog =.gui.sim_int_panel
interface plot window open
undo flush
```

6. BIBLIOGRAPHY E SITOGRAPHY

[1] Zheng G., Nolte L.P. (2015), *Computer-Assisted Orthopedic Surgery: Current State and Future Perspctive*. Front. Surg. 2:66

[2] Kleeblad L.J., Zuiderbaan H.A., Hooper G.J. et al (2017), *Uni compartmental Knee Arthroplasty: State of Art*. JISAKOS

[3] Gastoldi F. (2017), *L'adozione delle innovazioni robotiche in ambito health care: l'introduzione del robot in ambito ortopedico*.

[4] Wasielewski R.C., Galat D.D., Komistek R.D. (2004) *Computer-Assisted Ligament Balancing of the Femoral Tibial Joint Using Pressures Sensors*. Navigation and Robotics in Total Joint and Spine Surgery

[5] Deep K., Shankar S., Mahendra A. (2017) *Computer Assisted Navigation in Total Knee and Hip Arthroplasty*. SICOT J, 3, 50

[6] Nordin M., Frankel V.H. (1989) *Basic Biomechanics of the Musculoskeletal System*, Lippincott Williams & Wilkins

[7] Seeley, Sthepens, Tate (2005) *Anatomia (II edizione)*, Idelson Gnocchi

[8] *Enciclopedia Medica Italiana, Volume 1* (1985), USES

[9] Cherian J. J., Kapadia B. H., Banerjee S. (2014) *Mechanical, Anatomical, and Kinematic Axis in TKA: Concepts and Practical Applications*. Current Reviews in Musculoskeletal Medicine

[10] Bignardi C. (2016), Appunti del corso di *Bioingegneria Meccanica*, Politecnico di Torino

[11] https://boneandspine.com/normal-biomechanics-of-knee/

[12] Causero A., Di Benedetto P. et al. (2014), *Design Evolution in Total Knee Replacement: Which is the Future?* Acta Biomedica

[13] Van der List J.P, Chawla H., Pearle A.D (2016), *Robotic – Assisted Knee Arthroplasty: An Overview*. The American Journal of Orthopedics

[14] Andrea Collo. *Study, Design and Evaluation of an Actuated Knee Implant for Postoperative Ligament Imbalance Correction.* Mechanics [physics.med-ph]. Télécom Bretagne; Université de Bretagne Occidentale, 2014. English

[15] Bottros J., Gad B., Krebs V., Barsoum W. K. (2006), *Gap Balancing in Total Knee Arthroplasty*. The Journal of Arthroplasty

[16] Lee DH., Park JH., Song DI., Padhy D., Jeong WK., Han SB. (2010) *Accuracy of Soft Tissue Balancing in TKA: Comparison Between Navigation – Assisted Gap Balancing and Conventional Measured Resection*. Knee Surgery, Sports Traumatology, Arthroscopy

[17] Roche M., Elson L., Anderson C. (2014), *Dynamic Soft Tissue Balancing in Total Knee Arthroplasty*. Orthopedic Clinics of North America

[18] Daines B.K., Douglas D.A. (2014) *Gap Balancing vs. Measured Resection Technique in Total Knee Arthroplasty*. Clinics in Orthopedic Surgery, 6:1-8

[19] Desai A. S., Dramis A., Kendoff D., Board T. N. (2011) *Critical Review of the Current Practice for Computer – Assisted Navigation in Total Knee Replacement Surgery: Cost – Effectiveness and Clinical Outcome*. Current Review of Musculoskeletal Medicine

[20] Siddiqi A., Hardaker W. M., Eachempati K. K., Sheth N. P. (2017) *Advances in Computer – Aided Technology for Total Knee Arthroplasty*. Trending in Orthopedics

[21] Tamam C., Poehling G. G. (2014) *Robotic – Assisted Unicompartmental Knee Arthroplasty*. Sports Medicine and Arthroscopy Review

[22] Jacofsky D., Allen M. (2016) *Robotics in Arthroplasty: A Comprehensive Review*. The Journal of Arthroplasty

[23] Mavrogenis A. F., Savvidou O. D., Mimidis G. et al. (2013) *Computer – Assisted Navigation in Orthopedic Surgery*. Orthopedics

[24] Kowal J., Langlotz F., Nolte L. P., *Basics of Computer – Assisted Orthopaedic Surgery*

[25] Lang J. E., Mannava S., Floyd A. J. et al. (2011) *Robotic Systems in Orthopedic Surgery*. The Journal of Bone and Joint Surgery

[26] http://www.omnils.com/healthcare-professionals/OMNIBotics.cfm

[27] Roche M., O'Loughlin P. F., Kendoff D. et al. (2009) *Robotic Arm – Assisted Unicompartmental Knee Arthroplasty: Preoperative Planning and Surgical Technique*. The American Journal of Orthopedics

[28] Lonner J. H. (2015) *Robotically Assisted Unicompartmental Knee Arthroplasty with a Handheld Image – Free Sculpting Tool*. Operative Techniques in Orthopedics

[29] http://www.bbraun.com/en/products-and-therapies/orthopaedic-joint-replacement/orthopilot/kneesuite/tka-smart.html

[30] http://www.orthokey.com/index.php/cas-solutions/cas-sol-1

[31] http://www.orthalign.com/kneealign/

[32] *Perseus system*: https://www.smartperseus.com/en/

[33] *eLibra*: http://www.zimmerbiomet.com/medical-professionals/knee/product/elibra-dynamic-knee-balancing-system.html

[34] *VERASENSE*: https://www.orthosensor.com/resources/product-information-2/

[35] Lonner J.H., John T.K., Conditt M.A. (2010) *Robotic arm-assisted UKA improves tibial component alignment: a pilot study*. Clinical Orthopaedics and Related Research

[36] Pearle A.D., van der List J. P., Lee L. et al. (2016) *Survivorship and patient satisfaction of robotic-assisted medial unicompartmental knee arthroplasty at a minimum two-year follow-up*. Knee

[37] Ponzio D. Y., Lonner J. H. (2016) Robotic Technology Produces More Conservative Tibial Resection Than Conventional Techniques in UKA. The American Journal of Orthopedics

[38] Bloemker K. H., Guess T. M., Maletsky L., Dodd K. (2012) *Computational Knee Ligament Modeling Using Experimentally Determined Zero-Load Lenghts*. The Open Biomedical Engineering Journal (6, 33-41)

[39] Guess T. M., Liu H., Bhashyam S., Thiagarajan G. (2013) *A Multibody Knee Model with Discrete Cartilage Prediction of Tibio – Femoral Contact Mechanics*. Computer Methods in Biomechanics and Biomedical Engineering (Vol. 16, No. 3, 256 – 270)

[40] Muller J. H., Zakaria T., van der Merwe W., D'Angelo F. (2016) Computational Modelling of Mobile Bearing TKA Anterior – Posterior Dislocation. Computer Methods in Biomechanics and Biomedical Engineering (Vol. 19, No. 5, 549 – 562)

[41] Flores P., Ambrosio J., Claro J. C. P., Lankarani H. M. (2005) *Influence of the Contact – Impact Force Model on the Dynamic Response of Multi – Body Systems*. Journal of Multi – Body Dynamics, Proceedings of the Institution of Mechanical Engineers Vol. 220, part K

[42] Blankevoort L., Kuiper J. H., Huiskes R., Grootenboer H. J. (1991) *Articular Contact in a Three – Dimensional Model of the Knee*. The Journal of Biomecanichs (Vol. 24, No.11, 1019 – 1031)

[43] Chen Z., Zhang X., Ardestani M. M. et al. (2014) *Prediction of in Vivo Joint Mechanics of an Artficial Knee Implant Using Rigid Multi – Body Dynamics with Elastic Contacts*. Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine

[44] Liu F., Yue B., Gadikota H. R. et al. (2010) *Morphology of the Medial Lateral Collateral Ligament of the Knee*. Journal of Orthopaedic Surgery and Research, 5:69

[45] Blankevoort L., Huiskes R., de Lange A. (1991) *Recruitment of Knee Joint Ligaments*. Journal of Biomechanical Engineering, Vol. 113

[46] Guess T. M., Razu S. (2016) *Loading of the Medial Meniscus in the ACL Deficient Knee: a Multibody Computational Study*. Medical Engineering & Physics

[47] Verstraete M. A., Meere P. A., Salvadore G. et al. (2017) *Contact forces in the Tibiofemoral Joint from Soft Tissue Tensions: Implications to Soft Tissue Balancing in Total Knee Arthroplasty*.

LIST OF FIGURES