IOP Conference Series: Materials
Science and Engineering

PAPER • **OPEN ACCESS**

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To cite this article: N F Cofaru *et al* 2018 *IOP Conf. Ser.: Mater. Sci. Eng.* **393** 012130

Modular device used in the surgery of the human tibia

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Abstract. The presented article is an original contribution which implies the design of a specialized modular device used at the different surgical procedures applied at the human knee. The increasing of the precision and quality of the surgical procedures using specialized devices is an important goal both for the engineers and for the doctors. In the paper are presented some diseases which affect the human knee and also the possibilities of surgical treatment of those. The main knee pathology which was researched, regards the axial deviations of the human lower member and correction using HIGH TIBIAL OSTEOTOMY (HTO) in all possibilities: with opening wedge or closing wedge, medial or lateral, uniplanar or biplanar. The complexity of these surgical procedures from geometrical point of view opens up the possibility to increase the quality of the medical act through using specialized devices. In this regard, in the present article it is approached the design and the modelling of the modular device destined for the knee surgery using HTO techniques. The main objectives are: establishing the needs and requirements that the device should accomplish, the identification of the primary functions, the development of the implementation solutions, the synthesis of these solutions and finally the 3D design of the device using Catia V5R20.

1. Introduction

In order to understand from a biomechanical and geometrical point of view the axial deviations existing in the lower limb, several considerations about the correct alignment of the leg bones in the case of the healthy patient are important. The correct alignment test is given by the collinearity of the straight segments connecting the center of the femoral head, the center of the knee joint and the center of the ankle. Any deviation from this axis becomes an axial deviation (Figure 1). Unfortunately, these deviations are quite common nowadays, the main cause being osteoarthritis characterized by the wear of the articular cartilage and the knee joint degradation [4, 9]. Osteoarthritis at the knee level is also called gonarthrosis, and it is predominant in female patients, and can occur at people aged between 40 and 70 [4, 1].

These deviations cause an abnormal strain of the knee with a displacement of the mechanical axis from the center to the medial or lateral, the worn-out cartilage will be overstrained, which further causes its wear and therefore further increase the deviation. The two effects potentiate each other thus entering a vicious circle which will lead to generalized arthrosis changes in the knee joint.

As shown in Figure 2, the mechanical axis of the leg passes through the center of the femoral head and the ankle but in the knee area it is displaced to the medial as a result of an intraarticular cartilage wear in that area.

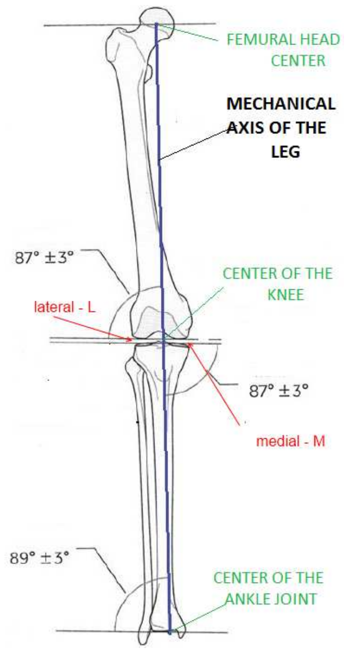

Figure 1. Mechanical axis of the human leg.

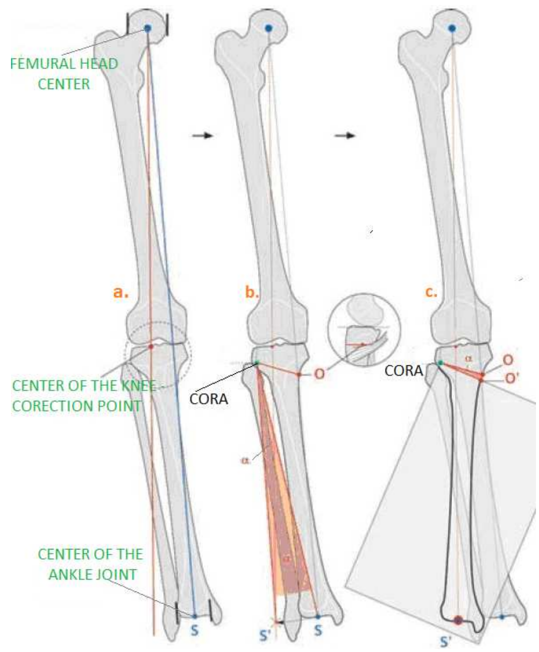

Figure 2. Axial deviations and correction from a geometrical point of view.

In order to perform the axial correction from a geometric point of view, the following steps are taken: the mechanical axis of the lower limb (Figure 2.a) is drawn by joining the center of the femoral head with the center of the ankle joint (the blue axis), another axis (the red axis) is drawn starting from the center of the femoral head and passing through the center of the knee joint which will obviously be projected outside the center of the ankle joint. Many times, an over-correction is made, taking into account the predisposition of the patient in question to the continuous wear of the intraarticular cartilage. The third step will be the establishment of the hinge point or CORA (Center of Rotation of the Angulation) (Figure 2b). The literature recommends a distance of 20 millimeters from the articular plane and 10 millimeters from the lateral surface. The second point O is established (Figure 2b) located on the cortical opposite to point B in the area where the blue axis intersects the tibia in the front view. The thus determined BO line will represent the trace of the cutting plane in front plane. To determine the rotation angle **α**, a line is drawn from the CORA point to point S, the center of the ankle joint. An arc is drawn, with the center in the CORA point, and having a radius equal to the distance between CORA and S until it intersects the line initially drawn (the red axis). The S' point is obtained. The angle α, between the two lines: CORA-S and CORA-S', is the correction angle and the line joining the center of the femoral head and the S' point is the new corrected mechanical axis. In order to effectively obtain the correction, a rotation of the CORA-O segment is performed around the same hinge point CORA with the angle **α** up to the CORA-O' position. The visible materialization of this geometric correction is made by the High Tibial Osteotomy surgical procedure (HTO).

2. High tibial osteotomy (HTO)

One of the common procedures in the surgical practice of correcting the axial deviations of the inferior limb is HIGH TIBIAL OSTEOTOMY (HTO). This is a surgical technique involving the creation of a bone wedge in the proximal tibia in order to eliminate the axial deviations suffered in the lower limb. The main purpose of the intervention is to realign the mechanical axis of the lower limb and, consequently, to redistribute the forces in the joint by unloading the affected section [5, 6, 10, 11, 16]. The main limitation of the correction is an angular one, not being allowed to exceed 18-20°, for larger values it is necessary to perform total prosthesis.

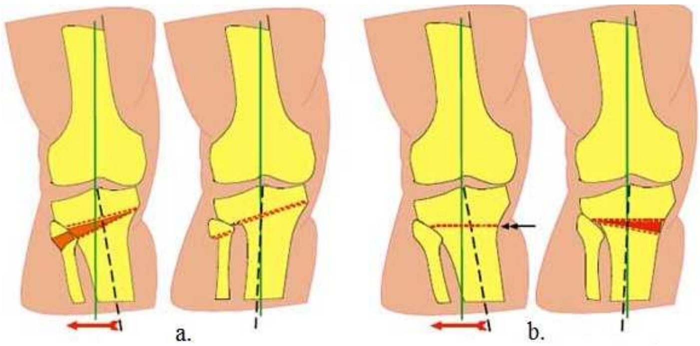

Figure 3. High tibial osteotomy (a – closing, b – opening).

Figure 4. Biplanar opening medial osteotomy [11].

HIGH TIBIAL OSTEOTOMIES (HTO) performed in the lower limb area can be classified according to several criteria such as: depending on the type of osteotomy wedge, there can be opening wedge or closing wedge osteotomies, when the incision (incisions) is initiated from the medial area the osteotomy is medial, and when it starts from the lateral area, the osteotomy is lateral and depending on the number of the cutting planes, there are uniplanar or biplanar osteotomies.

Figure 3 shows the osteotomy in the proximal tibia and both the opening wedge osteotomy and the closing wedge osteotomy are presented [7, 8]. It can be seen that in the case of closing wedge osteotomy (Figure 3a) two cuts are performed, the resulting wedge is eliminated, the cuts are placed one over the other with the axial correction of the tibia. In the case of the opening wedge osteotomy, a single cut is made, and the wedge is dome by the angular opening of the two resulting surfaces. In terms of the area where the cuts are made, Figure 3a shows a lateral osteotomy, and Figure 3b shows a medial one. It should be mentioned that the medial approach, both in the case of the closing wedge and the opening wedge, does not involve cutting the fibula, which can be an important advantage.

Figure 4 shows a biplanar osteotomy in the sense that there are two sectioning planes, one in which the osteotomy wedge is performed and one that makes an angle of about 110° with the first and divides the tibial tuberosity. The degree of success of the intervention depends on good geometric planning.

3. Designing and modeling of the modular device used at the high tibial osteotomy (HTO)

Increasing precision in performing this surgical technique is a very important goal in order to achieve good long-term results. That is why we want to suggest designing a specialized device for performing these techniques.The purpose of designing this device is to increase the dimensional and geometric precision of the surgical technique, in particular by conducting the strain relief hole in the CORA hinge point both in position and diameter and in the exact angular positioning of the cutting plane or planes. It is mandatory to proceed in designing the device from the requirements and needs that it must meet. This implies first of all the quality and the precision of the surgical procedure. Without a specialized device, the cuts intended to achieve the osteotomy wedge are made only based on the skill of the surgeon by means of the radiological control providing only 2D images. Because the approach needs to be spatial, the requirement for a specialized device is obvious. An important starting point for doing this is the models and the inventions in the European and American literature [2, 3, 12-15] which, however, appear to solve punctual problems, do not provide an overview of the requirement specific to the operation and neither a large degree of generality. Under the given conditions, the main objectives of conceiving and designing this device are the following:

- establishing the requirements and the needs that the device has to meet;
- identifying the primary functions;
- developing the implementation solutions;
- 3D modeling and designing the device;
- assembling the device on the tibia.

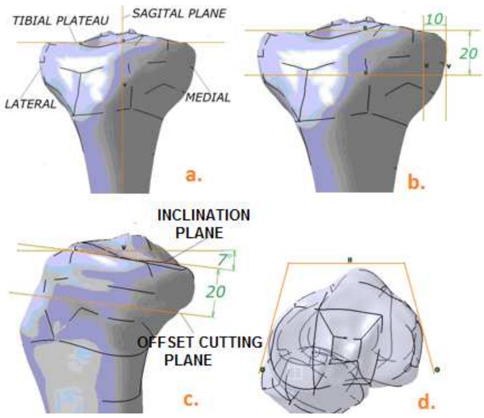

Figure 5. Geometrical references for HTO.

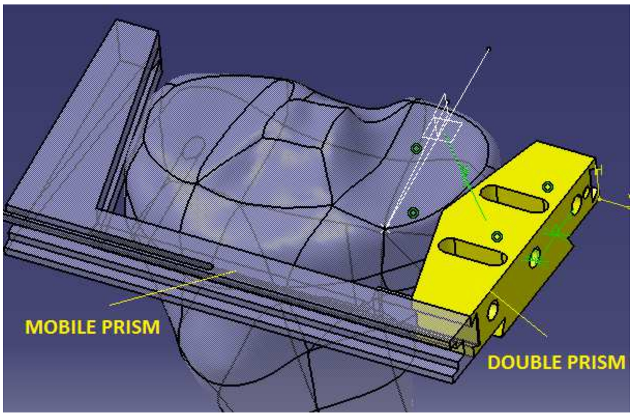

Figure 6. Fixation prisms elements.

A first requirement would be that the device approaches both the opening wedge and the closing wedge osteotomies, both the medial and the lateral ones, both the uniplanar and the biplanar, which involves a generalized, parameterized and modularized approach.

To summarize, in both situations (closing-opening) it is necessary to create a wedge having a peak angle equal to the angle of the axial deviation of the lower limb. For the closing osteotomy, two cuts are made, the resulting bone wedge being removed and the bone fragments of the tibia realigned by closing the wedge. In the case of the opening osteotomy, a single cut is made, and the fragments are realigned, resulting in a gap through the opening of the wedge.

It is also necessary to establish specific requirements based on the geometric configuration of the tibia, the bone on which the device will be assembled. For this purpose, the orientation and the fastening surfaces must be studied in relation to the adapted surface. These will be on the tibia and the reference planes required are (Figure 5a):

- the sagittal plane medially crossing the anterior-posterior knee;
- the plane tangential to the tibial plateau located between the medial and lateral condyles of the tibia;
- the vertical planes, tangential to the medial and lateral surfaces of the tibia.

Using the same projection, we can define the minimum execution area of the CORA that the projected device will be able to mark through a bore hole. This area is bounded by two offset planes located 20 mm from the tibial plateau and 10 mm from a plane parallel to the sagittal plane and tangential to the lateral surface of the tibia (Figure 5b). Even though there is no consensus on the two dimensions in the literature, however, most sources recommend these minimal dimensions. The position of the hole was established only in the frontal plane but the bore hole will not be perpendicular to this plane as, viewed from the sagittal plane, the tibial plateau is not horizontal but has an inclination towards the rear by about 7-10 degrees (Figure 5c) and therefore it is necessary to incline all the cutting planes that should take this aspect into account.

Considering the geometrical configuration of the tibia, we believe a short prism orientation surface is suitable. (Figure 5d).

Starting from the above-mentioned requirements, the main functions that the device must perform are the following:

- positioning, guiding and fixing the short prism orientation element on the tibia in accordance with the previously described planes;
- the existence of a system for positioning the CORA in relation to the reference elements;
- the possibility to drill a hole in the CORA with the ability to change the hole diameter; the possibility to displace the CORA on two perpendicular axes in a controlled manner; the possibility to perform the cut or cuts needed to make the osteotomy wedge;
- the possibility to control the angles of the osteotomy wedge;
- the ability to guide the cuts mandatorily in the CORA hole (the convergence of the cuts).

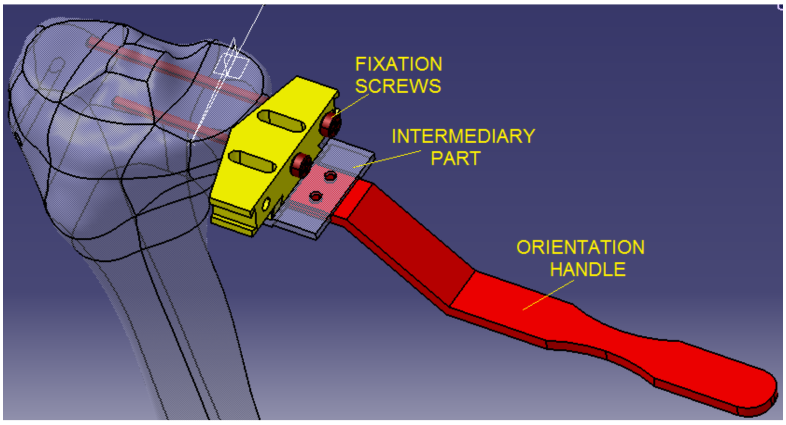

Figure 7. Fixation prisms elements.

Starting from these functions, technical and constructive solutions were sought for their implementation. Using creative design-modeling methods, we reached a number of proposals which are described below.

For the orientation of the tibia two constructive elements are suggested: a double prism in which a movable prism can be guided (Figure 6). Care should be taken to ensure that the upper surface of the double prism is tangential to the tibial plateau and thus to achieve that posterior inclination of 7-10 degrees. From the point of view of the anterior posterior positioning, it will be placed in such a way as to ensure the mounting of the mobile prism and good access to the osteotomy area.

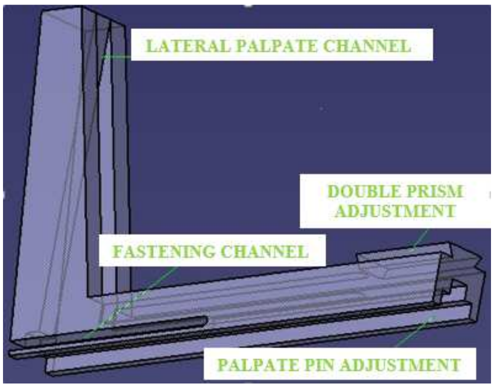

Figure 8. Mobile prism – constructive elements.

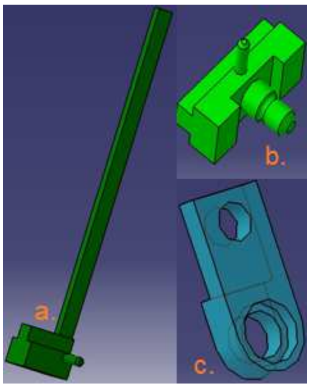

Figure 9. Palpate pin, slider part spigot, bush support plate.

From a constructive point of view, it can be noticed that the double prism (Figures 6, 7) has an absolutely symmetrical construction in the idea of being able to use it for both the medial and the lateral areas. In the lateral areas there are guiding channels in which the mobile prism will be adjusted. In the upper part, it has two elongated channels in which it is possible to adjust and fix a connecting part prior to fastening the double prism to the bone or the cutting elements after the fastening. These elements will be positioned axially along the channel at the bottom of the prism. On the front of the double prism there are also three holes through which the screws will be inserted for fastening the device on the tibia.

The movable prism (Figure 8) has a double prism adjustment area and a geometric configuration specific to its functional role. In the body of this part there are a series of channels whose functional role will be described below.

Thus, the lateral palpate pin (Figure 9a) responsible for the contact with the lateral cortical of the tibia will be adjusted in both the lateral palpate channel and in the palpate pin adjustment channel. Also the slider part spigot (Figure 9b) will be adjusted in this channel. The bush support plate is assembled on the cylindrical area of the slider.

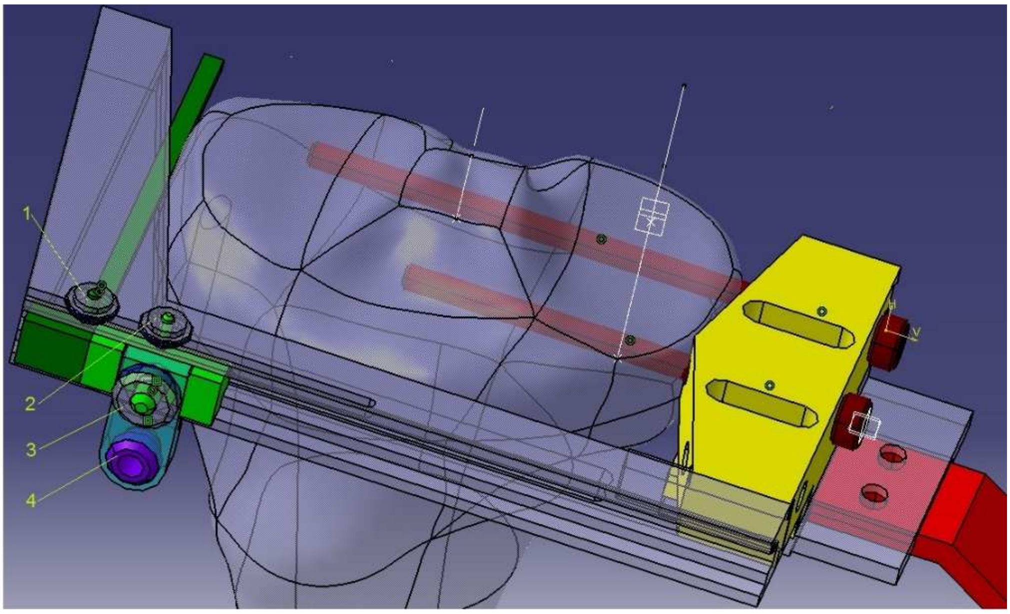

Figure 10. Device for achieving the CORA holes.

In order to position the double prism, it is fastened to an intermediate part fixed to an ergonomic handle (Figure 7). After evaluating the correct position of the double prism, it will be fastened in the tibia by means of the fixing screws. After the fastening, the intermediate part and the handle are removed, the double prism being in fact the control element according to which all the operations will be carried out.

The mobile prism will be adjusted on the double prism using the adjustment channel (Figure 8) until the inclined surface of the moving prism will be in contact with the lateral cortical surface of the tibia as in Figure 6. This position will be maintained by fastening the mobile prism to the fixed one by means of special screws.

The above described parts are assembled resulting in a first modular device used to position the system and making the CORA bore hole (Figure 10). The operation of the device largely results from the previous constructive description. Thus, after aligning and fastening the bone relative to the two prisms, the lateral palpate pin is moved laterally through the palpate adjustment channel until it comes into contact with the lateral surface of the bone. It is fastened in this position with the help of the notched nut 1 (Figure 10). The slider can move within the same channel as the palpate pin, independent of it. When the side surfaces of the slider and the palpate pin are in contact in this position, the slider bush has an axis positioned 8 millimeters to the side of the bone (Figure 10). To achieve positions greater than 8 millimeters, a controlled (graduated) displacement of the slider relative to the mobile prism is achieved. On the cylindrical area of the slider, the bush support plate is fastened to it by means of the nut 3.

The bush support plate (Figure 11b) has a drill hole on its surface in which the drill bushes 4 of different interior dimensions (Figure 11a) can be mounted. This ensures the possibility of executing boreholes of different sizes only by changing the bushing. In this position the axis of the guiding bush 4 is 2 cm from the upper surface of the double prism, determining the position of the CORA relative to the tibial plateau. For larger distances, a set of bush support plates (Figure 11b) of different sizes can be used to control the CORA position in this direction. The CORA bore will be done by drilling through the guide bush 4.

After the bore is completed, the movable prism is removed with the parts mounted on it, the assembly remaining as in Figure 12.

Figure 13 shows the device for making closing osteotomies. The new constructive elements are: the notched pin 1 which has the role of performing the CORA bore, and by the made notch even its axis, the control rod 2, the fastening screws 3, the adjusting screw 4 and the cutting body 5.

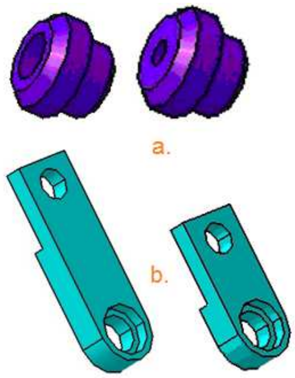

Figure 11. a. Bush guide, different diameters; **b.** Bush support plates.

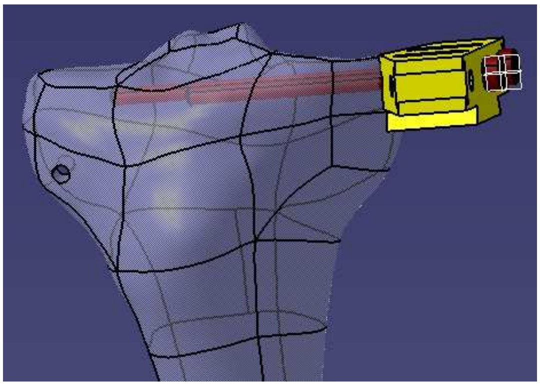

Figure 12. Tibia after drilling CORA hole.

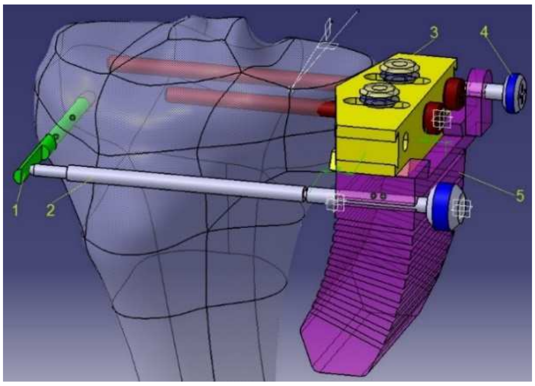

Figure 13. Device for closing High Tibial Osteotomy – geometrical positioning.

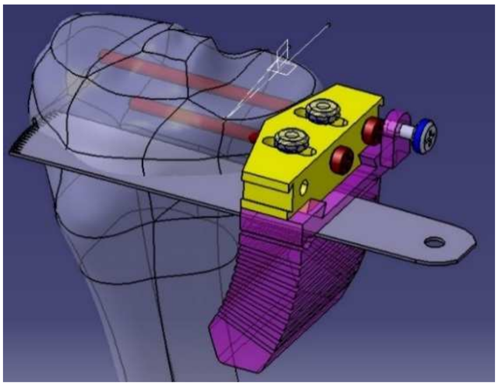

Figure 14. Device for closing High Tibial Osteotomy – manufacturing of the cuts.

From a functional point of view, the notched pin 1 is inserted into the CORA bore. After inserting the pin for performing the cuts, the cutting body 5 is mounted on the double prism. It is designed to perform the closing osteotomy which requires the execution of two cuts, the correction angle being the angular measure between the two cutting planes.

The cutting body 5 has radial channels arranged angularly from 2 to 2 degrees. The constructive design is made in such a way so that the first channel is parallel to the superior side and its plane of symmetry will pass through the axis of the CORA bore (Figure 13). In order for the cuts to be convergent, the position of the cutting body relative to the double prism is very important in the CORA bore. The positioning of the body (Figure 13) is achieved using the control rod 2, which is mounted in the notch parallel to the tibial plateau having the axis contained therein. As soon as the tip of the rod 2 reaches the notched area of the pin 1, it is necessary to bring the cutting body into the channel on the rod. Then CORA becomes the center of the circular area where the radial channels are. This can be done by means of the positioning screw 4 that moves the body and brings it to the desired position. After this convergence, the position is maintained by means of the screws 3.

After the fastening, the notched pin 1 and the control rod 2 are extracted and the first cut can be made parallel to the tibial plateau, by means of the oscillating saw. (Figure14). After this, the second cut is made at an angle equal to the correction angle. Correction angles of 4 to 20 degrees with a two-degree increment are allowed.

Regarding the opening osteotomies, a more frequently used procedure, both uniplanar and biplanar osteotomies have been approached. The modular constructive element that differentiates the device variant is the cutting body (Figure 15). Its geometric configuration results from the surgical technique. As previously mentioned, a single cut is made for the opening osteotomy which has a certain inclination

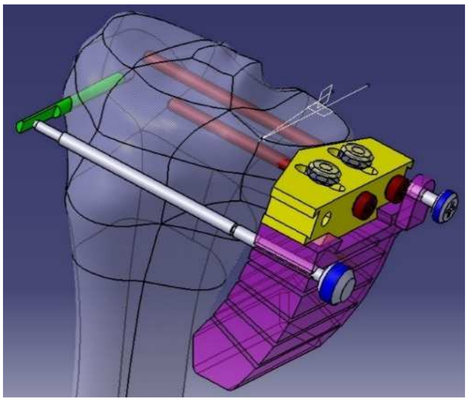

Figure 15. Device for uniplanar opening High Tibial Osteotomy.

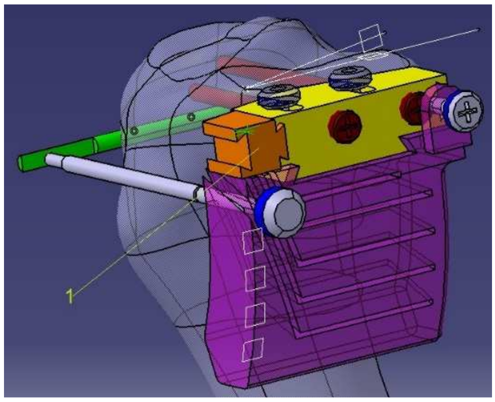

Figure 16. Device for biplanar opening High Tibial Osteotomy.

towards the tibial plateau and which obviously has to reach the CORA. Consequently, the cutting body will have the same shape (Figure 15), with the difference in the radial channel spacing, which will be rarer, 3-4 positions corresponding to the inclination of the sectioning plane. In this case the correction angle is given by the angular distance that creates the osteotomy wedge. The channel parallel to the superior surface of the body was maintained as a position control element.

The cut is achieved through one of the radial channels. In the case of the biplanar osteotomies where two cuts are required, the cutting body (Figure 16) is designed as such, each radial channel being intersected by the second osteotomy plane placed 110° to the first. Planes perpendicular to the respective radial channels were built in order to draw these channels. The device for biplanar opening osteotomies is shown in Figure 16. In order to achieve the technique, the double prism had to undergo a constructive change. It had to be shortened (Figure 16) to allow the cutting blade to access the second plane. Since in the CORA achievement phase the double prism has to have the configuration of the uniplanar osteotomies, the connective part 1 has been created (Figure 16), which, after the CORA is completed, will be removed. As in the case first, the notched pin and the control rod are removed, and the two cuts are performed through one of the radial channels and the inclined channel belonging to it.

4. Conclusion

The design of such a generalized modular device allows the performance of all kinds of osteotomies: lateral, medial, closing or opening, uniplanar or biplanar, under high geometric and dimensional precision conditions. The presented article is characterized through a high degree of originality, practically the resulted device being in a proportion of 100% the contribution of the authors. Also, it results that using such a device facilitates the surgical procedure, making it a more precise and safe one. The patients have definite advantages because a correct and precise surgery is the best premises for a fast recovery and a fast resuming of the daily routine.

References

[1] Brockmeier P M 2008 *Effects of Articular Cartilage Defect Size and Shape on Subchondral Bone Contact: Implications for Surgical Cartilage Restoration*, The Ohio State University, Department of Mechanical Engineering, Honors Theses

[2] Cofaru I I, Oleksik M, Cofaru N, Roman M and Fleaca R 2010 Experimental Stand Used for Studies of the Knee’s Articulation Pathology, *Academic Journal of Manufacturing Engineering* **8**(3)

[3] Cofaru I I, Brindasu P D and Cofaru N 2013 Computer Simulation Paradigm Regarding the Structure and Mechanical Characteristics of Human Long Bones, *Advanced Materials Research* **814** 99-103

[4] Fleaca R 2010 *Transplantul Osteocondral Autolog în Tratamentul Leziunilor Cartilajului Articular*, Universitatea Lucian Blaga, PhD Thesis

[5] Getgood A, Brett C, Slynarski K, Kurowska E, Parker D and Engebretsen L 2013 Short-term

Safety and Efficacy of a Novel High Tibial Osteotomy System: A Case Controlled Study, *Knee Surg Sports Traumatol Arthroscopy* **21**(1) 260-269

[6] Keith M, Baumgarten M D, Fealy S, Lyman S and Wickiewicz T M 2007 The Coronal Plane High Tibial Osteotomy. Part 1: A Clinical and Radiographic Analysis of Intermediate Term Outcomes, *HSS Journal* **3**(2) 147-154

[7] Bae D K, Song S J, Kim H J and Seo J W 2013 Change in Limb Length after High Tibial Osteotomy using Computer-Assisted Surgery: A Comparative Study of Closed- and Open-Wedge Osteotomies, *Knee Surg Sports Traumatol Arthroscopy* **21**(1) 120-126

[8] Lustig S, Scholes C J, Costa A J, Coolican M J and Parker D A 2013 Different Changes in Slope Between the Medial and Lateral Tibial Plateau after Open-Wedge High Tibial Osteotomy, *Knee Surg Sports Traumatol Arthroscopy* **21**(1) 32-40

[9] Potter H G and Foo Li F 2006 Magnetic Resonance Imaging of Articular Cartilage: Trauma, Degeneration, and Repair, The American Journal of Sports Medicine **34**(4) 661-677

[10] Smith J O, Wilson A J and Thomas N P 2013 Osteotomy around the Knee: Evolution, Principles and Results, *Knee Surg Sports Traumatol Arthroscopy* 21(1) 3-22

[11] Modern High Tibial Osteotomy, http:/www.ilizarov.org/HTO1.pdf,

[12] Hofmann et al 1991 Patent No. 5053039

[13] Schreiber et al 1992 Patent No. 5078719

[14] Jenkins et al 1998 Patent No. 5722978

[15] Collazo et al 2012 Patent No 5613969, US 8192.441B2

[16] Reising K, Strohm P, Hauschild O, Schmal H, Khattab M, P. Sudkamp N and Niemeyer P 2013 Computer-Assisted Navigation for the Intraoperative Assessment of Lower Limb Alignment in High Tibial Osteotomy Can Avoid Outliers Compared with the Conventional Technique, *Knee Surg Sports Traumatol Arthroscopy* **21**(1) 181-189