

# An Active Tibial Component for Postoperative Fine-Tuning Adjustment of Knee Ligament Imbalance

A. Collo, P. Poignet, C. Hamitouche, S. Almouahed, and E. Stindel

**Abstract**— Ligament tensioning is a key step in Total Knee Arthroplasty surgery. The surgeon has to manually set proper tension conditions for the two lateral ligaments of the knee. Inaccuracies may lead to severe postoperative complications and, in the worst-case scenario, to revision surgery. Unfortunately, suboptimal balance conditions are unavoidable and no assistance tool has been developed up to now to help the surgeon during the surgery. The goal of this work is to propose an instrumented tibial component able to evaluate ligament balance conditions after surgery and to monitor their evolution in the postoperative period. Thanks to an embedded actuation system, optimal ligament tension values can be restored so as to improve the prosthesis lifespan and avoid the need for revision surgery.

## I. INTRODUCTION

Nowadays, a set of computer-assisted techniques can be employed during Total Knee Arthroplasty (TKA) surgery in order to assist surgeons. The correct positioning of the prosthetic components can be precisely planned in the preoperative period and effectively achieved during surgery [1]. However, in some cases the proper alignment of the prosthesis with respect to the mechanical axis of the lower limb may not be sufficient to ensure a long-lasting stability of the installed implant. To this end, a key achievement of TKA surgery consists in setting up a proper tension for medial and lateral ligaments [2]. In order not to give rise to any postoperative joint instability, none of these two ligaments should be looser (or tighter) than the other. Ligament tensions are manually set by the surgeon intraoperatively, according to the outcome of both the bone cuts and the component positioning stages. As it will be presented in the following, different instruments have been proposed in order to set up perfect balance conditions during TKA. Unfortunately, despite the assistance provided by such tools, ligament balance still majorly depends on the surgeon's experience and perception, thus remaining an unsolved problem [3, 4].

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The prosthetic components are passive components which are not able to fit the morpho-functional changes that the patient normally undergoes during and after the rehabilitation period. Even the slightest inaccuracy in the ligament tensioning process risks being amplified throughout the first years after primary TKA. Thus, knee balance conditions could become suboptimal and lead to postoperative complications, such as misalignments, component loosening and polyethylene early wear [5].

Consequently, the implant lifespan (usually 15 to 20 years) might be severely reduced. In the worst-case scenario, revision surgery is necessary to install a new knee prosthesis and restore perfect balance conditions. In this context, over the last decade the orthopaedic community has started developing the idea of active knee implants, which could adapt to the physiological evolution of the body and fit the patient's morphological changes. This project falls within this framework. The goal of this work is to design an instrumented tibial component, part of a fixed-bearing knee prosthesis, able to monitor ligament balance conditions in the postoperative period. An embedded actuation system should allow to correct any detected ligament imbalance right after the rehabilitation period, thus compensating for the unavoidable inaccuracies of TKA surgery.

This manuscript is organised as follows. Section II presents the State of the Art in instrumented knee implants. Section III gives a detailed description of the proposed model. Section IV shows the results of static analysis simulations and presents a first full-scale prototype of the proposed tibial component. Section V is about conclusions and perspectives on future work.

## II. STATE OF THE ART

In order to set up proper ligament balance conditions, the surgeon must carefully check tibiofemoral gaps, distraction forces and ligament lengths during the surgery [1]. In the literature it is possible to find a host of instrumented knee implants that the surgeon can employ intraoperatively. However, the assistance provided by such devices is not enough to guarantee optimal postoperative balance conditions.

An instrumented knee distractor was proposed by [6] for TKA surgery. This device, composed of a tibial baseplate and two mobile femoral plates, made use of two scissor jack mechanisms to raise or lower the two mobile trays independently. Thanks to the presence of embedded force-sensing resistances and height sensors, the surgeon could continuously measure tibiofemoral gaps and forces during the surgery. Despite offering a remarkable distraction range

(15 mm), the two scissor jack mechanisms could only provide up to 100 N distraction force, a too low value with respect to knee joint normal operating conditions [7]. In a second model [8], two fluid inflatable rubber bladders replaced the scissor jack mechanisms. Unfortunately, the orientation of the mobile femoral plates turned out to be uncontrollable, thus also this version was set aside.

Another instrumented tibial baseplate for the intraoperative estimation of knee ligament balance was proposed by [9]. Six strain gauges embedded in its upper surface allowed the measurement of the net tibiofemoral loads applied by the surgeon, who could intraoperatively improve the planning of bone cuts and components positioning. Unfortunately, all these fine-tuning adjustments revealed to be suboptimal once the actual prosthetic components had to replace the force-sensing device.

Other instrumented knee implants have been developed as intraoperative assistance tools [4, 10], but none of them gives the possibility to compensate for the inaccuracies of TKA surgery in the postoperative period. To cope with this lack, our research team has developed the first smart knee implant able to postoperatively monitor and assess ligament balance conditions [11]. It consists of an instrumented tibial component that exploits the presence of four piezoelectric elements embedded in the tibial baseplate. An approach based on the center of pressure of the net tibiofemoral forces acting on the platform allows to detect any imbalance condition [12] (Fig. 1).

The piezos are meant to serve also as energy harvesters, thus dispensing with the need for an external power supply. An embedded telemetry system allows the wireless control of the prosthesis and data communication to the clinician's computer. Upon achievement of such diagnostic capabilities, the next step consists in the actuation of the proposed device. The idea is to end up with an active knee implant, able to slightly modify the relative position of its components according to the detected ligament imbalance. Restoring optimal balance conditions right after the rehabilitation period should, in the long term, reduce the need for revision surgery.

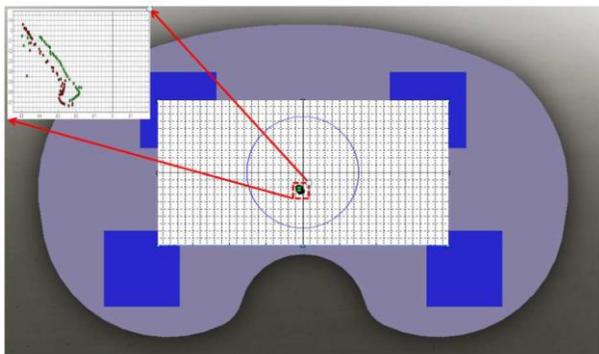


Figure 1. The four piezoelectric elements are embedded in the tibial baseplate and the trajectory of the net tibiofemoral force can be measured [12].

### III. MODEL DESCRIPTION

#### A. Clinical Needs

This project focuses on the postoperative need for re-tightening a loose lateral ligament. In primary TKA [13] and tibial osteotomy [14], spacer blocks are commonly employed to increase the tibial platform thickness (up to 17.5 mm) on the side corresponding to the considered ligament. The smart knee implant proposed in this work is able to reproduce the correcting action of spacer blocks, but in the postoperative period and autonomously, that means without resorting to a surgical operation. This is achieved by laterally lifting the tibial tray up to 3 mm on the side corresponding to the loose ligament, in order to properly re-tighten it (Fig. 2) without substantially modifying the prosthesis alignment to the lower limb mechanical axis [1, 2].

Postoperative ligament balance conditions must be evaluated as soon as the patient is able to walk autonomously again. To this aim, a follow-up visit is planned right after the rehabilitation period. The patient is asked to walk a few steps. The trajectory of the center of pressure of the net tibiofemoral forces acting on the tibial platform is recorded and wirelessly transmitted to the computer of the clinician [12]. With such information, the surgeon is able to detect any imbalance condition and to define the appropriate correcting action in terms of ligament re-tensioning. The idea is to gradually proceed by successive stages: a first actuation is carried out and, right after, ligament tensions are checked again. Further refinement corrections can be made until optimal balance conditions are restored.

#### B. Components Description

Three different approaches were discussed [15] to realise the tibial component actuation. The miniaturised actuation system proposed here is based on two main subparts: a customised screw-nut mechanism and a gear train. For sake of clarity, they are described here separately.

*The screw-nut mechanism* – Fig. 3 shows how the customised screw-nut mechanism is assembled in the tibial

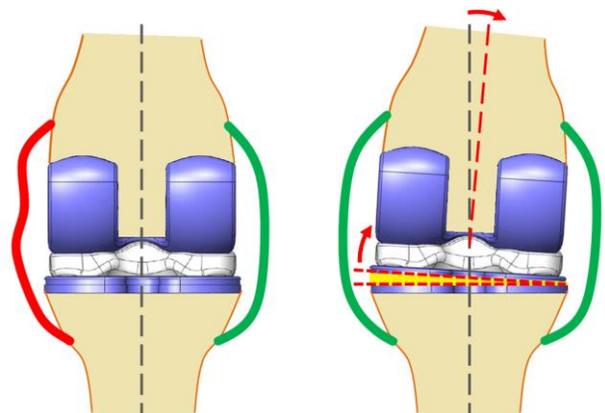


Figure 2. Simplified representation of knee lateral ligaments after TKA surgery. A too loose lateral ligament (left) can be properly re-tightened by lifting the tibial tray up on the corresponding side (right).

baseplate. The screw body is 16 mm long and is positioned perpendicularly to the baseplate surface. The screw head, on the lower side of the baseplate, is a geared wheel that can only rotate without translating. The nut has a total thickness of 5 mm: 3 mm with a square section (10 mm side length) and 2 mm with a rounded profile, as shown in Fig. 3. The square section part of the nut is contained in the baseplate

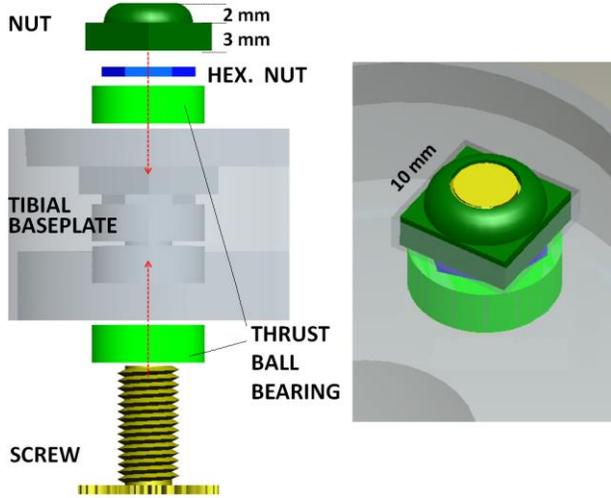


Figure 3. The customized screw-nut mechanism is embedded in the tibial baseplate. The screw rotation (on the bottom) controls the nut translation (on the top), perpendicularly to the baseplate.

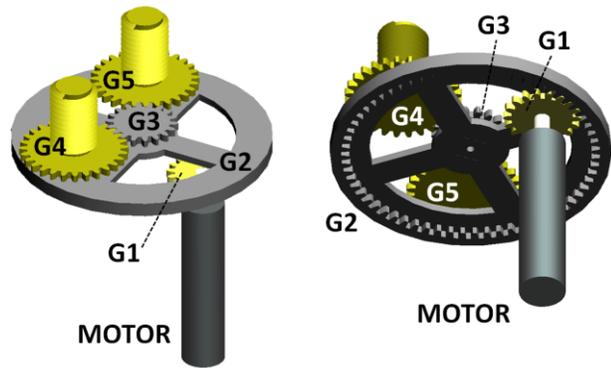


Figure 4. 3D-views of the gear train. The input gear G1 is fixed on the micromotor shaft. The two output gears, G4 and G5, are the heads of the screws of two screw-nuts mechanisms. The motor is positioned laterally so as to be embedded in the hollow tibial stem.

TABLE I. GEARS PARAMETERS

	$G1 = G3$	$G2$	$G4 = G5$
Pitch Diameter (mm)	9	32	14
Number of Teeth	18	64	28
All spur gears:	module = 0.5		pressure angle = 20 degrees

and prevents the nut from rotating with the screw body. As a consequence, due to the presence of the thread, the screw rotation produces the nut translation along a direction that is perpendicular to the tibial baseplate. The customised screw-nut mechanism just described has a standard M5x0.8 thread (5 mm pitch diameter, 0.8 mm pitch).

The tibial baseplate embeds a total of four screw-nut mechanisms of this kind, two per each side (medial and lateral). The free rotation of each screw head with respect to the baseplate is allowed by two thrust ball bearings, tightened between them by means of a thin hexagonal nut.

*The Gear Train* – The lower part of the tibial baseplate partially embeds two gear trains, one per side. Each single train (Fig. 4) has one input gear (named G1) and two output gears (G4 and G5). The latter are the geared wheels that, as previously mentioned, form the screw heads of the screw-nut mechanisms. G2 is a large internal gear, on whose upper surface a smaller gear (G3 = G1) is rigidly fixed. When G1 is driven by a rotary stepper micromotor, the train transmits the rotation to G4 and G5, thus making the two screws turn together at the same speed. Table I summarizes the gear parameters, that have been selected so as to maximize the overall gear ratio in compliance with the tibial tray dimensions.

### C. Working Principle

The actuation of one side of the proposed tibial component is illustrated in Fig. 5. The clinician wirelessly activates the micromotor on the side corresponding to the detected loose ligament. Via the gear train, the two screws on that side start rotating together. This produces the translation of the nuts, which get unscrewed out of the baseplate. A mobile tibial tray, initially contained in the baseplate but not constrained inside it, gets laterally pushed upwards by the two nuts. During all this, the corresponding profiles of the baseplate and the mobile tray make the latter pivot on the non-actuated side without changing its orientation. Once completed the actuation, the mobile tray is still partially contained in the baseplate with which it shares three contact points: the actuated nuts and the pivot point on the other side.

### D. Design and Actuation Considerations

*Dimensions* – A detailed 3D CAD model of the proposed implant was realised. As previously explained, in the starting position the tibial baseplate fully contains the mobile tray and partially embeds the gear train (Fig. 5). The overall thickness of the instrumented tibial component gets to 18 mm. This value is almost three times that of classical tibial platforms, but it is imposed by the presence of embedded components. Consequently, a more significant amount of bone should be removed in the bone cut stage, during TKA surgery. A common solution consists in employing a thinner polyethylene insert, as proposed in [16]. Moreover, the actuation system presented here can easily integrate the first model developed by our research team for the detection of knee ligament imbalance [11].

The position of the four actuated nuts in the tibial baseplate was determined so as to guarantee the desired tray

uplifting and ensure stability. Simulations showed that a 2 mm unscrewing of the actuated nuts laterally lifts the tibial tray up of 3 mm. This is in line with the primary goal of our work and confirms the effectiveness of the selected design.

**Materials** – All the prosthetic components and the actuation system mechanical parts are assumed to be made in titanium alloy (Ti-6Al-4V Grade 5), a biocompatible material that is commonly chosen for knee implants [2].

**Balance fine-tuning** – As previously mentioned, the trajectory of the net tibiofemoral forces is recorded during a follow-up visit [12]. By comparing such data with specific reference trajectories, which describe the situation of optimal balance conditions, the clinician is able to identify the loose ligament and to quantify the corresponding lateral tibial tray raise. The gear ratio between each output gear and the input gear is 5.55 (Table I), so at least six motor revolutions (G1) are needed to produce one complete revolution of the two actuated screws (G4 and G5). One full screw revolution produces a nut translation of exactly 0.8 mm (pitch) and lifts the mobile tray up of 1.2 mm. With such information, intermediate adjustments can be planned by controlling the number of motor steps.

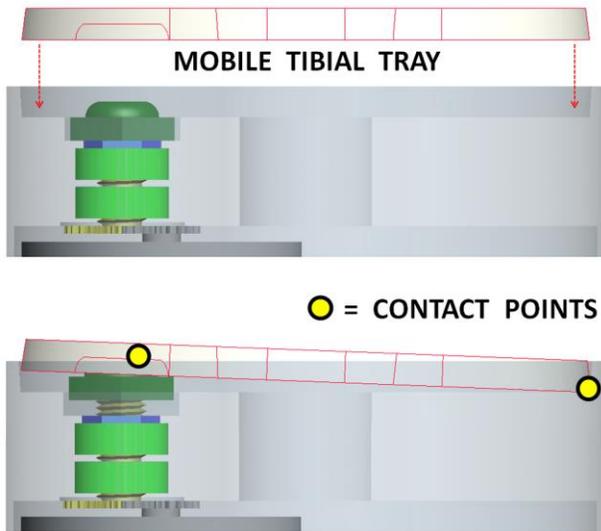


Figure 5. Example of actuation of the proposed tibial component (front view). On the side corresponding to the detected loose ligament, the mobile tibial tray gets laterally lifted up by the two actuated nuts.

**Actuation force** – The system actuation is performed with the patient in lying position, so that the only force acting inside the knee joint is the passive force of the two lateral ligaments. This force is uniformly distributed on the mobile tibial tray and acts perpendicularly to its surface, as a compression of the femur onto the tibia. The value of such force has been estimated [17] as 150 N on each side. The total force produced by the actuation system must be able to overcome this passive force in order to lift the tibial tray up as desired. The system mechanical model was accurately studied by means of static force analysis. Each actuated nut, while unscrewed out of the baseplate, produces the force  $F$  described by (1) [18]:

$$F = \kappa \cdot T / r, \quad (1)$$

where  $r$  is the screw thread mean radius (2.24 mm for M5x0.8 screw) and  $T$  is the torque applied on the screw-nut system. The term  $\kappa = a / b$  depends on the thread parameters and is defined by (2) and (3):

$$a = 1 - f \cdot \tan(\alpha) \cdot (1 + \tan^2(\theta/2) \cdot \cos^2(\alpha))^{1/2} \quad (2)$$

$$b = \tan(\alpha) + f \cdot (1 + \tan^2(\theta/2) \cdot \cos^2(\alpha))^{1/2} \quad (3)$$

where  $\alpha$  is the thread helix angle (3.25 deg for M5x0.8 screws),  $\theta$  is the thread angle (60 deg for standard metric profiles) and  $f$  is the friction coefficient in the thread (the worst-case scenario is considered:  $f = 0.36$  for titanium alloy on titanium alloy).

**Microelectronics** – The hollow tibial stem offers a volume of about 50 cm<sup>3</sup> to host both microactuators and all the microelectronics for power supply and data transmission. The chosen rotary stepper micromotor (Faulhaber ADM0620-2R-V2-05) occupies a cylindrical space of 30 mm height and 6 mm diameter. Combined to its integrated planetary gearhead (06/1 K 1024:1), it is able to provide up to 35 mNm intermittent torque to G1. Inductive coupling is meant to be employed to provide wireless power supply or to recharge a specific microbattery embedded at the bottom of the tibial stem and properly connected to a miniaturised telemetry system for motor control. The microelectronic components can be assembled all together in order to fit the available space.

**Efficiency** – According to the aforementioned numerical values, each actuated screw should produce an actuation force  $F = 90.4$  N. Thus, the total force pushing the tibial tray upwards would be of about 180 N. Even if friction effects are taken into account by (2) and (3), this result remains theoretical and needs to be proven in real working conditions. Nevertheless, the great efficiency guaranteed by the gear train (95-97 % estimated [19]) and the possibility of selecting other biocompatible materials to improve thread friction conditions should not lead to too much poorer actual results.

**Locking issue** – In most everyday life activities, knee prostheses ceaselessly undergo very strong efforts. Uncontrollable vibrations and shear forces generate inside the knee joint and act mainly on the mobile tibial tray. Cyclic efforts are transmitted to the two actuated nuts that, constrained inside their square holes, cannot produce any screw rotation. Thus, the nuts keep their lifted position and this ensures the lateral uplifting of the tray. Moreover, the nuts transmit axial efforts to the screw bodies via their common threaded profiles. For each screw, the presence of the thin hexagonal nut and the two miniature thrust ball bearings is necessary to prevent force transmission to the gear train. The peak net tibiofemoral force that can be generated inside the knee joint during normal gait cycle is 2600 N [7]. Such force is uniformly distributed on the tibial tray, so 1300 N act directly on the actuated side. Each thrust ball bearing (Shenzhen, F5-10m, 5x10x4 mm) can absorb axial loads up to 950 N, which are transmitted to the baseplate that is rigidly fixed on the tibial bone. In addition

to all these considerations, the motor stall torque, amplified by the gear train, contributes to blocking the rotation of the output gears.

*Sealing* – The design must guarantee the sealing of the embedded actuation system. The lateral uplifting of the tibial tray creates a thin spacing between the baseplate and the tray itself. In order to prevent fluids from filling this slot, an elastic micro-membrane attached between the upper tray bottom surface and the internal surface of the baseplate could create a sort of sealed volume for the embedded components. Additionally, the microactuators and their related electronics could be properly arranged in specific casings treated with a biocompatible coating material.

#### IV. SIMULATIONS AND PROTOTYPING

##### A. Static and Dynamic Analysis

Forces distribution and component deformations were evaluated by means of static and dynamic analysis simulations performed on the 3D CAD model. The tibial tray was blocked in 2 mm-raised lateral position and subjected to a cyclic distributed force of 2600 N [7]. As predicted, high Von Mises stress concentration was located around the three contact points (two actuated nuts and the pivot point on the opposite side), as shown in Fig. 6. Neither relevant deformation nor uncontrolled movements were detected.

Concerning the efforts that the screw-nut mechanism faces with, titanium screw threads offer great performances in terms of yield tensile and compressive strength limits. By way of illustration, a standard steel M5x0.8 screw of the lowest class withstands more than 4500 N ultimate tensile load. Titanium alloy screws are lighter and more resistant than steel ones. Furthermore, considering the average tensile strength of the selected titanium alloy (950 MPa), it can be concluded that no mechanical failure of the actuation system components is likely to take place.

##### B. Fabrication

A full-scale prototype of the proposed tibial component was realised in order to evaluate the actuation system working principle on one side of the prosthesis. The tibial baseplate and mobile tray, as well as the nuts, were fabricated as plastic components by means of a 3D printer. In order to facilitate parts assembly and handling, a thicker baseplate was employed. Standard steel screws and spur gears were used for the realisation of the gear train. The

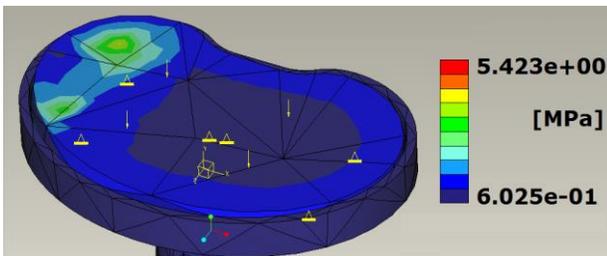


Figure 6. Static analysis showed no relevant component deformation.

forementioned miniature thrust ball bearings were properly embedded in the baseplate, so as to allow screw rotation.

The assembled prototype and some components details are shown in Fig. 7. With respect to the design presented in this work, the prototype is much thicker (41 mm from the mobile tray upper surface to the bottom side of the gear train) and must be manually actuated (G1 and the micromotor are not taken into account). Hence, it has to be considered as a simple proof-of-concept of the proposed novel mechanism for further development.

By manually turning G2 in counterclockwise direction, the two nuts embedded in the baseplate translate along the screw axis direction. Their simultaneous movements lift the mobile tibial tray up without changing its orientation. The stability of the mobile tibial tray was assessed both during and after the actuation process. No uncontrolled rotation of the tray took place with respect to the baseplate. It was also confirmed that a 2 mm nut translation produces a 3 mm lateral uplifting of the mobile tray. As expected, thanks to the thrust ball bearings, compressive forces manually applied onto the tray surface do not get transmitted to the gear train.

This first prototype was meant to assess the effectiveness of the working principle and of the locking system. The fabrication of customised metal parts will give the possibility to assemble a fully functional prototype. In the very near future, it is planned to make use of the aforementioned rotary stepper micromotor to drive the actuation system by controlling the rotation of G1. In addition to this, experimental tests with a force sensor will be carried out in order to measure the total actuation force actually developed by the system and compare it to the computed theoretical value.

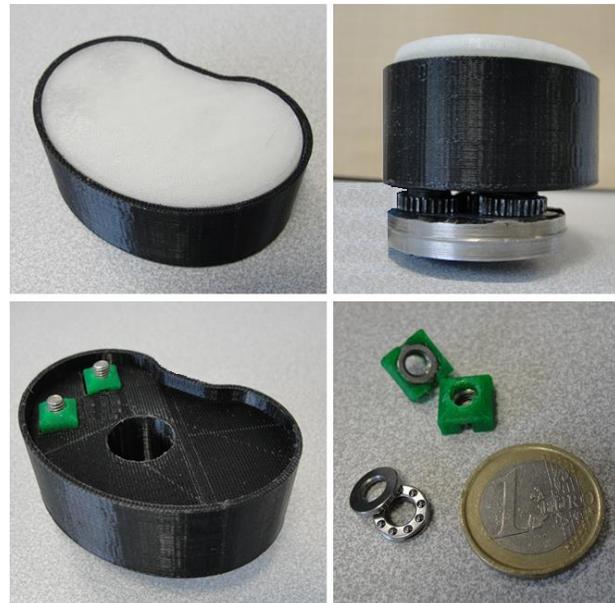


Figure 7. The first full-scale prototype of the proposed instrumented tibial implant, with detail of the miniature thrust ball bearing and the customised nut (bottom right picture).

## V. CONCLUSIONS AND PERSPECTIVES

This work presents a novel instrumented tibial component for a fixed-bearing total knee prosthesis. The originality of such model consists in providing the surgeon with the possibility to monitor and, if necessary, correct knee ligament balance conditions in the postoperative period. To this aim, the tibial component already proposed by our research team was further developed by adding a miniaturised actuation system embedded in its baseplate. By controlling this system wirelessly, the surgeon can adjust the relative position of the prosthetic components and compensate for the unavoidable inaccuracies of TKA surgery. Upon further refinements, this active knee implant might represent a great innovation in the field of orthopaedics and could strongly reduce the need for revision surgery.

The proposed model satisfies the set of constraints imposed by biocompatible environments. The embedment of miniature electronic components faces with the strong tibiofemoral efforts that cyclically act inside the articulation during daily life activities. The passive mechanical irreversibility offered by the actuation system provides a reliable locking system to keep the tibial tray in the actuated position without any motor participation. Also, the components design ensures a proper and uniform distribution of tibiofemoral forces inside the tibial baseplate, aspect which should guarantee a long lifespan of the whole actuation system. In these terms, the instrumented tibial component presented here should offer great robustness and high durability.

Theoretical mechanical studies were carried out along with simulations on a detailed 3D CAD model, in order to prove the system feasibility and evaluate its performances. The realisation of a first full-scale prototype by means of a 3D printer and standard steel components allowed to test the actuation system working principle and to perform some initial design optimisations. The next stage will be the fabrication of a full-scale steel prototype, with the purpose of carrying out experimental studies on a knee simulator. This will allow to reproduce normal knee kinematics conditions and practically evaluate components resistance, as well as to estimate the actuation system lifespan.

The power supply and wireless control issues will be further discussed and achieved in collaboration with partner research teams. Results will be presented in a future work.

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