Towards a Dynamic Tibial Component for Postoperative Fine-tuning Adjustment of Knee Ligament Imbalance

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Abstract: During TKA surgery, a correct tibiofemoral alignment of the installed prosthesis can be effectively achieved by means of Computer-Assisted techniques. Unfortunately, the achievement of perfect ligament balance conditions still remains as unsolved problem. Any inaccuracy during the operation may degenerate and lead to prosthesis failure. Our aim is to develop an adaptive knee prosthesis, able to follow the physiological evolution of the body and, potentially, to modify its shape to fit the patient's morphological changes. In this paper, we focus on the actuation of the tibial component in order to compensate for collateral ligament imbalances. We face with severe constraints concerning the available volume, the high-accuracy level and system's solidity and biocompatibility. We discuss a model that we proposed in a previous work and we highlight its drawbacks. We consider then three possible approaches to realise the actuation: the use of a micromotor, the action of a magnetic field and the use of an external tool. After evaluating the pros and cons of each case, the micromotor approach is selected. We conclude by introducing an original design of adaptive tibial implant that we are currently developing.

1 INTRODUCTION

Total Knee Arthroplasty (TKA) consists in the complete replacement of the knee joint by means of a prosthesis. This operation is quite risky and complicated, since the surgeon must be able to restore the perfect mobility of the knee joint while ensuring, at the same time, a long-lasting stability of the installed implant. The outcome of TKA surgery is thus greatly dependent on the surgeon's experience and perception (Scuderi and Tria, 2006).

The two key achievements of TKA surgery are the correct alignment of the prosthesis with respect to the mechanical axis of the lower limb and the set up of a proper tension for medial and lateral ligaments (Vail and Lang, 2006). While a correct tibiofemoral alignment can be effectively achieved by means of Computer-Assisted Orthopaedic Surgery (CAOS) techniques, the inaccuracy in ligament balance still remains as unsolved problem (Winemaker, 2002).

Concerning medial and lateral ligaments, the tensioning conditions that are set up during the surgery will not fit the predictable changes in patient's weight, physiology and lifestyle. Thus, throughout the first decade after the intervention, knee balance conditions could become suboptimal, leading to postoperative complications.

In this context, even the slightest inaccuracy in the bone cutting process during the surgery may be amplified and create serious complications, such as component loosening and polyethylene early wear (Almouahed, 2011). Undesired distances between the prosthetic components can be generated and collateral ligament tension values might change in an uncontrolled way. As a consequence, the lifespan of the installed implant risks being considerably reduced and the patient may start suffering severe pain already a few years after the surgery. In such a case, the only solution is represented by revision surgery. The patient undergoes a second operation during which the prosthesis that has become suboptimal is replaced by another one.

If primary TKA is a very complex operation, revision surgery is even more delicate. The

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prosthetic knee articulation undergoing a postoperative complication is less strong than before and the second rehabilitation period is normally more stressful than the first one. The development of an autoadaptive knee prosthesis, able to follow the physiological evolution of the body and, potentially, to modify its shape to fit the patient's morphological changes would represent a great innovation in the field of orthopaedic surgery.

Our project falls within this framework. Our objective is to develop an instrumented tibial component to be employed in both the intraoperative and postoperative periods. It is meant to be able to check knee balance conditions immediately after the rehabilitation stage and correct potential ligament imbalances. In this sense, the active implant we are developing necessarily embeds custom-designed mechatronical components and a telemetry system, in order to interact with the surgeon via a computer interface.

The main constraints we face with are of different nature. First, considering the small dimensions of prosthetic parts, we need very compact components. Secondly, the entire system needs to be really robust, in order to face with the whole set of efforts acting on the knee joint. Thirdly, we must choose the optimal power supply and control techniques in order to ensure a high accuracy level. All these considerations have to be made by keeping the biocompatibility issue as a basic criterion for the selection of proper components.

1.1 State of the Art

Marmignon et al., (2004) proposed two models of instrumented knee distractor for intraoperative use. The first one consisted of a tibial baseplate and two separated femoral plates. Two scissor jack mechanisms, each one controlling the position of a single femoral plate, allowed to raise or lower the two moving trays independently, by keeping them parallel to the surface of the tibial baseplate (Figure 1). The upper surfaces of the two femoral components, in contact with the femoral condyles, were equipped with force-sensing resistances and height sensors. By making use of a navigation system, tibiofemoral gaps, ligament lengths and distraction forces could be intraoperatively measured and monitored with high accuracy.

The device's overall thickness measured 6.1 mm and it could provide a remarkable distraction range of 15 mm. A great weakness of this distractor was the maximum overall distracting force that could be produced, only 100 N. This value, too far from the normal operating conditions of the knee joint (ISO 14243-3, 2004), led to the proposal of an alternative design.

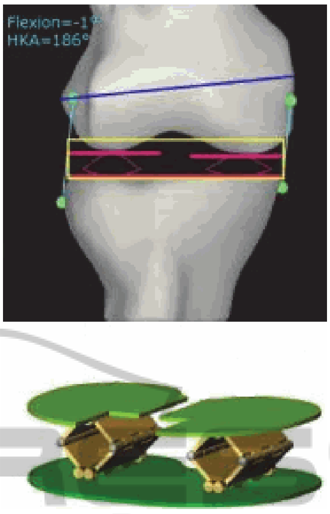

Figure 1: Example of use of the knee distractor instrumented with two scissor jack mechanisms (Marmignon et al., 2004).

The scissor jack mechanisms were thus replaced with two rubber bladders (Marmignon et al., 2005), to be inflated with a fluid (air or physiological serum). The volume changes induced by the fluid were manually controlled and led to the displacement of the femoral plates with respect to the tibial baseplate. This design offered better performances, since each femoral plate could develop a force of 100 N. Unfortunately, the distraction range was reduced to 11 mm and the parallelism of the system was no longer guaranteed, leading to suboptimal working conditions.

Crottet et al. (2005) proposed a small force-sensing device to estimate knee ligament imbalance intraoperatively. It consisted of a tibial baseplate of 6 mm thickness whose upper surface was equipped with two sensitive plates, to be put in contact with the two femoral condyles. Each plate had three deformable bridges instrumented with strain gauges (thick-film piezoresistive sensors). When a load was applied to the articulation, it developed reaction forces which caused proportional deformations of the instrumented bridges (Figure 2).

The knowledge of sensors positions and their measured data allowed to estimate the location of the applied net tibiofemoral loads acting on the medial and lateral compartments of the tibial baseplate. With this information, ligament balance conditions could intraoperatively be evaluated throughout the whole knee kinematics.

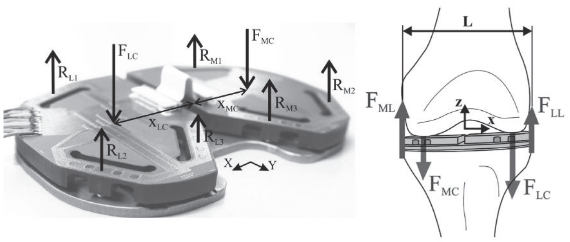

Figure 2: The forces measured by the tibial force-sensing device (Crottet et al., 2005).

This flexibility of usage allowed a better bone cuts planning, a more accurate components positioning and gave the possibility to carry out fine-tuning balance corrections with a high level of precision. However, a major limitation stood in the way ligaments were modelled for the computations: they were reproduced by means of springs, a clearly too strong approximation (Marmignon, 2004).

1.2 Description of the First proposed Model

In the literature we can find many other instrumented implants that actually own diagnostic capabilities, but could only exploit them in the intraoperative period. This means that they are used as measurement tools before the pose of the actual knee prosthesis, which will be installed once the optimal conditions are set up. On the other hand, what we want to develop is an adjustable prosthetic component to be employed not only during TKA surgery, but also postoperatively. Given that tibiofemoral alignment conditions can be perfectly obtained thanks to well-developed Computer-Assisted Total Knee Arthroplasty (CATKA) techniques, we focus on the problem of monitoring and assessing collateral ligament tension values.

We refer to the smart knee implant proposed by Almouahed et al. (2010). An instrumented tibial component, part of a total knee prosthesis, was equipped with four piezoelectric elements, intended to be used as both force sensors and energy harvesters. The total thickness of the tibial component was 4.5 mm, in line with usual dimensions. A first-version prototype of the entire implant was developed and studied in laboratory by direct wiring.

Collateral ligament balance conditions were evaluated by adopting a Center of Pressure (CoP)-based approach. Collected data were supposed to be transmitted to the outside of the prosthesis thanks to a wireless telemetry system (Lahuec et al., 2010). A microprocessor and an antenna could be hosted in the hollow stem of the tibial component. A very strong point of this transmission system was its characterisation as being totally self-powered. Its power-supply was completely ensured by the electric energy harvested by the four piezoelectric elements during gait cycle motions.

System feasibility was confirmed by theoretical studies (Almouahed et al., 2011) and a partner laboratory is currently working on the power issue in order to obtain definitive results.

This instrumented knee implant is the first one able to postoperatively monitor and assess collateral ligament balance, during an active range of motion and without the need to be powered by an external source of energy. Upon achievement of such diagnostic capabilities, our next objective was to actuate this knee implant, in order to have an active prosthesis able to compensate for the detected imbalance by autonomously correcting the position of its components.

In a recent study (Almouahed et al., 2012) we further developed this knee implant. We proposed to instrument it with two embedded microactuators. In this new design, the tibial component consisted of a fixed baseplate and a mobile tray, the latter connected to the former by means of two scissor lift mechanisms (a Medial and a Lateral one). The goal was to be able to move upwards and downwards the upper mobile plate (Figure 3).

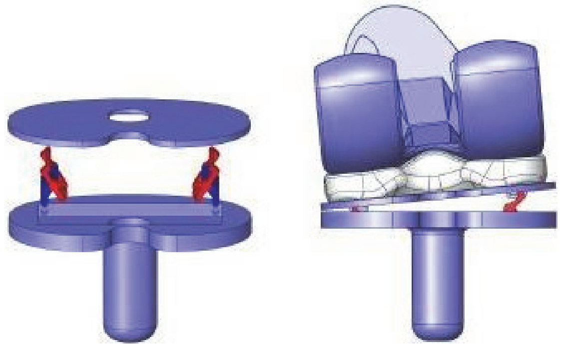

Figure 3: Location and example of use of the two scissor lift mechanisms embedded in the fixed tibial baseplate (Almouahed et al., 2012).

In this way, the relative position between the polyethylene insert (properly fixed on the upper surface of the mobile plate) and the fixed tibial part could be adjusted in order to meet correct balance conditions, both intraoperatively and postoperatively. Each scissor mechanism was supposed to be driven by a sliding pin, controlled by a miniature linear actuator positioned in the fixed tibial part.

A detailed 3D CAD model of the whole implant was realised and studied. Simulations led to the estimation of its minimum lifespan and of the points where peak Von Mises stresses occurred. More practical issues, like the choice of a suitable micromotor and its power supply, were not considered. In this current work, we approach such problems and propose a new design for the adjustable autoadaptive knee implant.

2 POSSIBLE APPROACHES

After consultation with orthopedic surgeons, we know that to restore a proper collateral ligament tension we need to be able to lift up one side of the mobile tibial plate, according to the detected loose ligament (medial or lateral). We should be able to compensate for up to 3 mm vertical distance, in order not to affect the tibiofemoral alignment of the prosthesis with respect to the lower limb mechanical axis. The level of accuracy is clearly submillimetric.

The peak tibiofemoral force acting on the tibial component during gait cycle is 2600 N (ISO 14243-3, 2004). Consequently, the actuation system that we are designing must be robust and resistant to strong cyclic efforts.

The lift up of the tibial plate is carried out with the patient in supine position. In such a condition, the only tibiofemoral forces acting inside the knee joint are due to collateral ligament tensions, which result in a total compressive force of 150 N on each side of the tibial plate (Marmignon, 2004). This is the reference value that we need to consider while looking for a good design.

A first consideration about the validity of the proposed scissor lift mechanism can already be made. Considering the entity of tibiofemoral efforts and the small dimensions of the scissor structure, in fact, a too high reaction force would be transmitted to the micromotor shaft (Figure 4).

Simulations showed that, for a 3 mm lift up, the peak tibiofemoral force of 2600 N acting on the tibial baseplate would transmit to the actuator a force higher than 4500 N. It does not exist any micromotor tiny enough so as to fit the available volume and, at the same time, able to oppose such an important passive force.

A normal linear micromotor of dimensions 3x3x6 mm typically offers a stall force of 0.3 N. These values are clearly too far from normal knee cyclic efforts entity. The locking system is a key issue for the implant durability and the scissor lift mechanism is not a reliable solution.

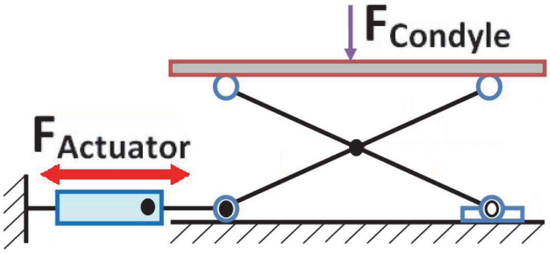

Figure 4: The tibiofemoral efforts are transmitted to the micromotor shaft via the scissor lift mechanism (Almouahed et al., 2012).

The available volume to host the actuation system is very small. We mainly have two exploitable volume regions: the hollow cylindrical tibial stem (17 mm diameter and 40 mm height) and the fixed tibial baseplate (75x50 mm, 4.5 mm thick). In addition to this, we can obtain further space by removing a reasonably small bone quantity from the resected tibia surface.

Everything must be carefully miniaturised. The research of suitable components itself is really complex and it gets strongly restricted by the biocompatibility issue. We immediately discard any invasive component, as well as any wireless power transmission technique which may cause biological damages.

We focused on three approaches to realise the desired actuation: (1) to embed a micromotor within the tibial baseplate, in order to move a miniaturised mechanical structure, (2) to exploit the presence of metallic/ferromagnetic components, properly disposed inside the tibial implant, to be moved without contact by exploiting the action of an external magnetic field and (3) to use an external tool to access to the prosthesis from outside, through two small incisions, so as to adjust an internal mechanism.

In the following, we will detail our research activity. We will consider each approach and highlight their advantages and drawbacks. After this analysis, we will motivate the final choice of the adopted approach.

2.1 Micromotor-based Approach

This is the most intuitive choice. Regardless of the chosen design, a very strong point of microactuators consists in the high accuracy level that they ensure in mechatronic applications. The control of electronic components can be very efficiently achieved and provides reliable data.

The scissor lift mechanism was set aside, but a priori we still have a wide variety of possible mechanical structures that can be embedded in the prosthesis. In these terms, while component sizing is not a big deal, a good trade-off must be found between their dimension and their power. More specifically, we need to find a micromotor which is small enough and, at the same time, sufficiently powerful. This is usually quite complicated, because small dimensions inevitably give reduced performances.

As previously explained, another problem is represented by the locking issue. The micromotor must be able to realise the actuation and keep the new adjusted position with high durability. This must be ensured by proper design solutions.

A further drawback of this approach is that the micromotor needs to be powered and controlled wirelessly. This is not easy to achieve, since even miniaturised motors are not low-power consumption devices (in general, 2-3 V power supply is needed). However, all the necessary components for motor control and data transmission (microprocessors, integrated circuit and telemetry system) must be positioned inside the prosthesis. As a consequence, they all need to be miniaturised and assembled in the optimal way so as to fit the very small available volume.

2.2 Magnetic Field Interaction-based Approach

This approach is based on the action of an external magnetic field properly generated around the knee. The idea is to embed four magnetic screws within the fixed tibial baseplate and control their screwing without any contact, by exploiting magnetic interaction. In their starting configuration, the screws are completely embedded in the tibial tray (Figure 5), located in their housings that are perpendicular to the baseplate surface. Screw heads are in contact with the upper mobile plate and, when unscrewed, they push it up and realize its lateral lift on the desired side. At least two screws for each side, medial and lateral, are needed in order to ensure good stability conditions.

The use of magnetic fields in biomedical applications is very common. From the biocompatibility point of view, then, a priori this approach should not be problematic. Magnetic fields can be generated with specific tools, often equipped with coils that are generally fixed to their lower limb only during the medical visit. Such devices are not invasive and usually fit to the patient's morphology.

A strong point of magnetic screws is that they actually are passive components that offer a very long lifespan. They do not require any power supply, not even during the actuation process. The tensile strength and resistance that they offer depend on their diameter (between 0.5 and 1.5 mm) and pitch, two values to be both optimised (preferably according to ISO standards) in order to optimise wear resistance properties.

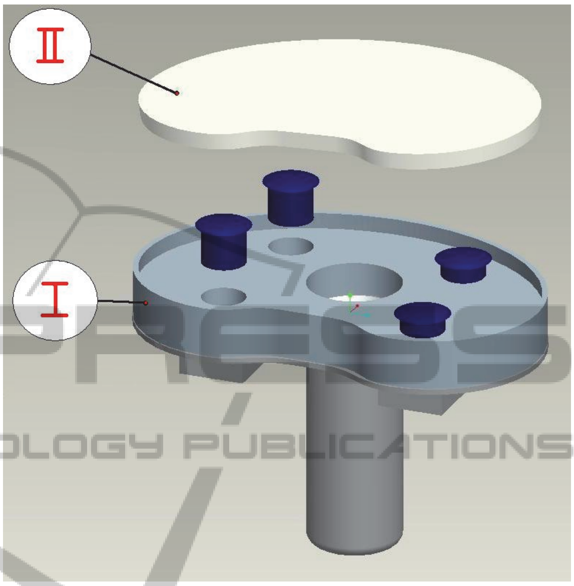

Figure 5: The screws embedded within the intermediate fixed tibial tray (I), in order to push up or down the upper mobile plate (II).

Nowadays the control of magnetic fields is achieved with very high accuracy and magnetic interaction is actually exploited in many high-precision positioning devices. In our case, we could find some difficulties in localizing the action of the external field on one single screw, while avoiding any interaction with the other three. Operating conditions get severely complicated by the reduced spaces we face with. In order to have a good control of the screws through the biological tissues and the prosthetic parts, the magnetic field we need has to be very precise and strong. At the same time, the biocompatibility constraint imposes not to damage biological tissues. Then, the magnetic action should not be too powerful. In these terms, a good compromise has to be found.

Another biocompatibility aspect is represented by the presence of ferromagnetic elements inside the human body. The material chosen for composing the magnetic screws must not be dangerous for the patient and should not limit their daily life activities.

A more delicate issue is the mobility of magnetic screws and the resistance they oppose to motion. In other words, we want to adjust their screwing without making a too high effort; on the other hand, once in the new position, we want them to be solid and rigidly fixed, so as to provide a good resistance.

2.3 External Tool-based Approach

This is an alternative approach, based on an external tool employed to access to the prosthesis and adjust its shape. We start from the consideration that small skin incisions under 5 mm length leave no scar after recovery. The tibial baseplate of the installed TKA prosthesis can be accessed through two small incisions, a medial and a lateral one. The idea is to use a custom-designed tool, that we can define as a “double screwdriver”, in order to adjust the position of the upper mobile tibial plate.

In this particular design, the fixed tibial tray embeds a worm screw. Its thread is in contact with a corresponding worm gear part located on the lower surface of the mobile plate (Figure 6). The two threads considered together form a worm drive gear arrangement. Thanks to their relative position, the rotation of the screw produces the one-side shift of the mobile tibial plate. This movement modifies the inclination of the polyethylene insert only along the Medio-Lateral direction, without modifying the prosthesis alignment with respect to the lower limb mechanical axis. The overall tibial component thickness is 7 mm and the mobile plate can be lifted up to 3 mm maximum.

The most interesting aspect of this approach is its extremely low invasiveness: general anaesthesia procedure is not required and no scar will remain on the patient's skin. Consequently, the hospitalisation period can be greatly reduced and this represents a very interesting advantage to the patient.

The worm drive structure that is embedded within the tibial tray is actually a passive structure. It does not need any power supply and it ensures a very long lifespan. Only when the external tool is employed, the positioning mechanism responds to its solicitations and realizes the prosthesis actuation.

Another very strong point of the worm drive structure is its natural mechanical irreversibility. The worm screw rotation causes the worm gear motion and not viceversa. Once the desired inclination is set, tibiofemoral forces keep on pushing on the upper plate surface through the polyethylene insert. This action produces the rotation of the worm gear part which is rigidly fixed onto the lower surface of the mobile plate. Thanks to the system's irreversibility, this rotation does not produce any movement and the new position is solidly kept.

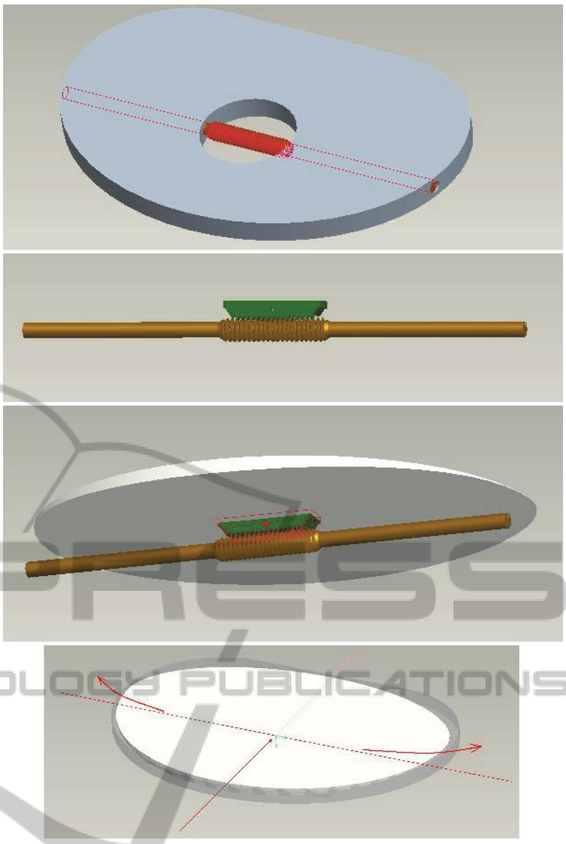

Figure 6: The worm drive gear arrangement is completely embedded in the tibial component and controls the medio-lateral translation of the upper mobile tibial plate.

A further advantage of this approach is the fact that the external tool can be custom-designed. Thus, both its performances and control can be very accurately defined.

Unfortunately, the risk of infection is a really serious drawback. Even if nowadays sterilisation procedures are very reliable, especially in hospital environments, the introduction of any external body inside the knee articulation after TKA surgery is still not recommended. Any single bacterium that, by chance, enters in contact with the prosthesis-bone interface might be able to initiate an infection process. In the worst-case scenario, after just one month even the prosthetic detachment might take place.

Another problem of the proposed design is the fact that the medio-lateral translation of the mobile tibial plate modifies the tension of both the collateral ligaments at the same time. The tray slides laterally and gets lifted up on the side corresponding to the loose ligament. At the same time, the lift down of the plate on the other side inevitably releases the other ligament. In this sense, it gets more difficult to define a proper correcting action since the tension values of both the collateral ligaments must be continuously monitored.

3 SELECTED APPROACH AND PROPOSED MODEL

After the analysis of the advantages and drawbacks of each possibility, the micromotor approach was selected as the most reliable choice in terms of accuracy and performances. For our application, precision is a key issue and microactuators can be very reliably controlled. The drawbacks we considered about them (the dimensions/power compromise, the locking system and wireless alimentation and control) all represent technological limitations that can be overcome by proper design solutions.

The only micromotor technology that properly satisfies all the constraints of our project is that of piezoelectric motors. They can produce very strong actuation forces even if their dimensions are incredibly small. Moreover, besides a very long lifespan, they offer a nanometer positioning accuracy. A manufacturer we are currently in contact with produces such kind of microactuators with a very interesting feature: both the power supply and the motor control are carried out by radiofrequency. RFID transmission ensures low power consumption (less than 0.5 V obtained by electrical impulses at a given frequency) in conditions of perfect biocompatibility and very fast response times (less than 1 ms).

In this work we can introduce the original actuation design we are developing. A more detailed description will be object of a future publication, on which we are already working. Basically, the most relevant differences between this design and the previous ones stand in: (1) the direction in which actuation is realised and, consequently, (2) the type of micromotor we want to employ.

Tibiofemoral efforts act perpendicularly with respect to the mobile tibial plate that we want to lift up. As shown for the scissor mechanism model, a linear micromotor acting on the tibial baseplate plane would be greatly involved in the locking procedure, not being able to ensure system solidity.

In our new design, the mobile plate lift up is realised thanks to the displacement of some specific components inside the tibial baseplate. This displacement is driven by a screw-nut mechanism where the screw can only rotate and the nut translates. The screw head is rigidly connected to the shaft of a rotary piezoelectric micromotor, which can be wirelessly controlled by the clinician. Thus, the overall system positioning can be achieved with high precision.

The most interesting aspect of such design is that the micromotor is not involved in the locking procedure. The screw-nut system is properly dimensioned so as to be irreversible. This property is exploited to solidly keep the mobile tibial plate in its desired lifted up position.

Besides the realisation of a detailed 3D CAD model of the proposed tibial component, a theoretical mechanical study of the system has been carried out to evaluate the force distribution among the different components. Initial results showed that a 0.6 Nm torque is able to realise the actuation and laterally lift the mobile tibial plate up to 3.3 mm. Moreover, solidity and resistance are ensured by the screw-nut thread, which offers great tensile strength performances. These results are quite encouraging and we are currently working on their improvement and optimisation.

4 CONCLUSIONS AND PERSPECTIVES

In this paper we discussed an instrumented tibial component to be used both intraoperatively and postoperatively. The two objectives of our work consisted in being able to check collateral ligament tension conditions and correcting potential imbalances.

The first point was achieved by employing the instrumented tibial implant that had been previously proposed by our team. In this model, four piezoelectric elements were embedded into the tibial tray and their use successfully provided diagnostic data about ligament tension values.

In order to reach the second goal, the operation to be performed in order to restore proper ligament tension values consisted in adjusting the position of the tibial tray. The implant was initially supposed to be actuated by two scissor lift mechanisms. This design was not able to ensure proper blocking conditions and could not meet all the constraints of the project. Thus, the scissor lift mechanism was rejected in favour of another design which could be able to better face with normal knee operating conditions.

We considered three different approaches to realize the prosthesis actuation: the first one with a micromotor, the second one with a magnetic field and the last one with an external tool. Our research work consisted in evaluating the advantages and drawbacks of each case. This led us to select the micromotor approach as the most reliable one.

Different design solutions have been analysed and discussed. We are currently developing an original design of the actuated tibial implant, based on the use of two rotary piezoelectric motors. This model has been theoretically studied and simulations on a detailed 3D CAD model proved its feasibility. The 3D model optimisation stage will be followed by the realization of a prototype, which will be tested with a knee simulator. Results will be presented in a future work.

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