A Miniaturised Actuation System Embedded in an Instrumented Knee Implant for Postoperative Ligament Imbalance Correction

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

Abstract— **During Total Knee Arthroplasty surgery, the orthopaedic surgeon has to set up proper balance conditions for the two lateral ligaments of the knee. Such ligament tensioning procedure is performed manually and mainly depends on the surgeon's experience. Unfortunately, inaccuracies are unavoidable and may give rise to serious postoperative complications. In the worst-case scenario, the only solution to this problem is represented by revision surgery. In order to cope with this problem, this work proposes a novel instrumented tibial component able to detect knee imbalance conditions in the postoperative period. A miniaturised actuation system embedded in the tibial baseplate allows to restore optimal balance conditions without resorting to revision surgery.**

I. INTRODUCTION

Ligament tensioning is a key operation during Total Knee Arthroplasty (TKA) surgery [1]. Besides aligning the prosthesis to the mechanical axis of the lower limb, the orthopaedic surgeon must intraoperatively set up proper tension conditions for the two lateral ligaments of the knee. Such process mainly depends on the accuracy of the bone cuts stage and directly influences the postoperative prosthetic knee function. After the surgery, joint instabilities may arise if one of the two lateral ligaments is looser than necessary [2], thus reducing the prosthesis lifespan (that is 15 to 20 years, on average). If too severe complications take place (misalignments, component loosening and polyethylene early wear [3]), the only solution is represented by revision surgery already a few years after primary TKA.

In the last decades, a host of instruments have been proposed as assistance tools for achieving optimal ligament balance conditions during TKA surgery. One of the most interesting devices is the instrumented knee distractor proposed by Marmignon et al. [4]. It is based on two mobile femoral plates, each one controlled by one scissor jack mechanism embedded in the tibial platform. Such design allows to intraoperatively monitor tibiofemoral gaps and efforts, but the generated distraction forces are too low with respect to normal knee joint operating conditions [5]. By replacing the two scissor jack mechanisms with two fluid inflatable rubber bladders [6], the device manages to generate appropriate distraction forces but can no longer control the two mobile plates orientation. Another interesting device that it is worth to mention is the instrumented tibial baseplate proposed by Crottet et al. [7]. Six strain gauges are embedded in the tibial tray in order to measure the net tibiofemoral forces intraoperatively applied by the surgeon. With such information, fine-tuning adjustments of ligament tension values can be obtained during the components positioning process. Nevertheless, it is evident the loss of accuracy once the actual prosthetic components have to replace the force-sensing device.

Other instrumented knee implants that have been proposed more recently [8, 9] do not propose an effective solution to the problem of ligament tensioning during TKA surgery. Thus, such operation still greatly depends on the surgeon's experience and perception. Unfortunately, intraoperative inaccuracies are unavoidable [10] and the number of revision surgeries continues to rise as more people undergo TKA surgery each year. Under such circumstances, over the last decade the orthopaedic community has started looking for a way to reduce the number (and the costs) of implant failures from a different perspective. The development of smart knee implants seems the most promising approach: prosthetic components would no longer be passive metal pieces, but active devices able to cope with unexpected complications. The possibility to compensate for the unavoidable inaccuracies of TKA surgery and restore optimal balance conditions in the postoperative period should strongly reduce the need for revision surgery.

This project focuses on the postoperative need for re-tightening a loose lateral ligament. In primary TKA [11] and tibial osteotomy [12], 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. 1) without substantially modifying the prosthesis alignment to the lower limb mechanical axis [1, 2].

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The instrumented tibial component developed by our research team is able to postoperatively monitor and assess ligament balance conditions, thanks to four piezoelectric elements embedded in the tibial baseplate that serve as both force sensors and energy harvesters [13]. During a follow-up visit in the aftermath of 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 [14]. This allows to detect any imbalance condition and to define the appropriate correcting action in terms of ligament re-tensioning. In order for such operation to be performed, a miniaturised actuation system embedded in the tibial component has already been discussed [15] and designed. This current work presents the model design and illustrates the fabrication of a first full-scale prototype for the validation of the actuation principle. The results presented here are to be intended as a proof-of-concept of the proposed novel mechanism for further development.

II. SYSTEM DESCRIPTION

A. *Components and Working Principle*

On each side of the tibial baseplate, the miniaturised actuation system is based on the translation of one custom-designed wedge piece (Fig. 2). The wedge (30 mm wide, 10 mm long, 4 mm high) is guided inside a 1 mm deep rail in the baseplate. A leadscrew of standard M2x0.4 profile (2 mm pitch diameter, 0.4 mm pitch) is coupled to the wedge in order to control its lateral translation (10 mm maximum stroke). In such configuration (Fig. 2), the wedge acts like a translating nut when the leadscrew rotates.

The tibial baseplate embeds a total of two Wedge-Leadscrew (WL) systems of this type. In the starting position, both wedges are aligned to the center of the baseplate (their translation is null). A mobile tibial tray is shaped so as to be positioned from above onto the baseplate and fit the presence of the two WL systems. Without any actuation, the tray is fully contained inside the baseplate in a configuration that corresponds to that of classical tibial implants (Fig. 3, where, for sake of clarity, only one WL system is shown). As one of the two leadscrews starts to rotate, the corresponding wedge translates laterally, towards the baseplate outer border. By doing this, the wedge slides under the mobile tray and lifts it upwards. The greater the wedge translation, the greater the mobile tray lateral uplift. To figure out more easily this working principle, the reader may find it useful to consider the typical use of door wedges.

Each leadscrew is held in place by specific supports and is driven by a rotary stepper micromotor. The actuation system is entirely embedded in the tibial baseplate, as well as all the microelectronics components necessary for power supply and data transmission, that can be hosted inside the hollow tibial stem.

B. *Design Considerations*

Simulations on a detailed 3D CAD model of the proposed implant showed that a maximum wedge translation

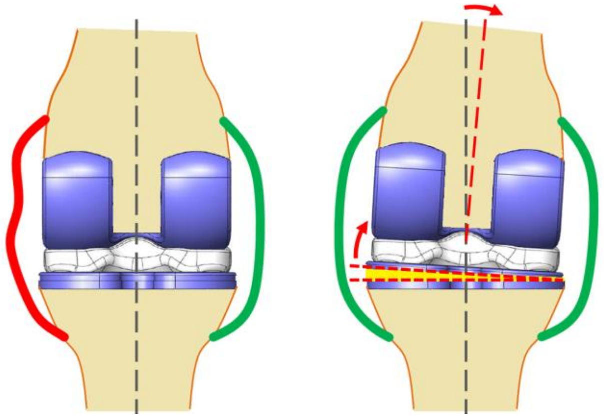

Figure 1. Simplified representation of knee lateral ligaments after TKA surgery. A too loose lateral ligament (left) can be properly re-tightened by lifting the tibial tray up on the corresponding side (right).

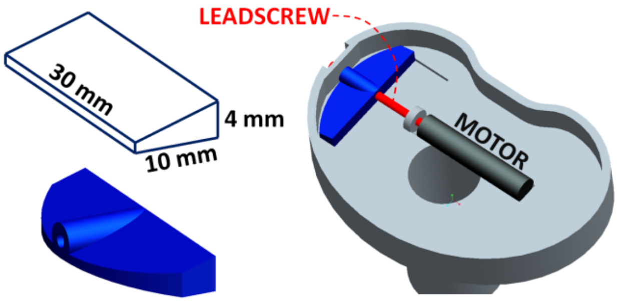

Figure 2. Inside the tibial baseplate, a custom-designed wedge is coupled to a leadscrew, which is driven by a micromotor. The leadscrew rotation produces the wedge lateral translation. For sake of clarity, only one side of the actuation system is represented here.

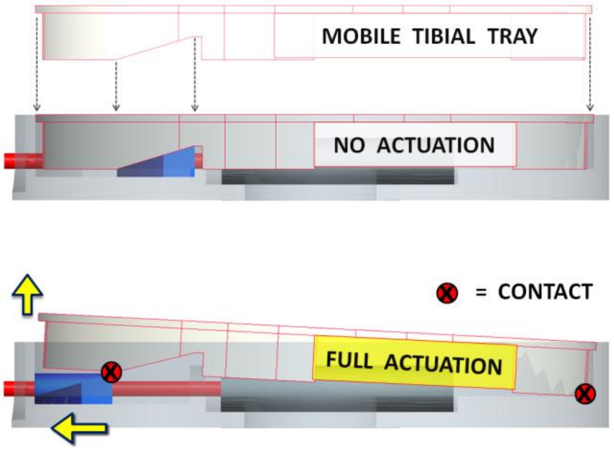

Figure 3. Exemple of actuation on one side of the prosthesis. A mobile tibial tray is initially fully contained in the tibial baseplate. When the leadscrew rotates, the wedge translates under the mobile tray and laterally lifts it upwards.

of 10 mm lifts the mobile tray up of 3.6 mm. This result, in line with the primary goal of this study, confirms the effectiveness of the selected design. Moreover, the model presented here has been conceived so as to be easily integrated into the former implant developed by our research team for imbalance detection [13].

Because of the embedded components, the overall thickness of the instrumented tibial platform gets to 9 mm, which is almost twice the thickness of classical tibial platforms. If this implied to remove a too significant amount of bone intraoperatively, during the bone cut stage, a thinner polyethylene insert could be employed, as suggested in [16]. The mobile tray always keeps a contact line with the actuated wedge, while pivoting inside the tibial baseplate on the non actuated side. Moreover, due to the components corresponding profiles, no uncontrolled rotation can take place. This is enough to ensure the platform stability during the actuation process.

As previously explained, the surgeon defines the mobile tray lateral uplift necessary to restore optimal balance conditions [17]. This quantity linearly depends on the wedge translation, which in turn can be accurately controlled via the leadscrew pitch and the number of micromotor steps. This allows a balance fine-tuning process that, ideally, has to be gradually carried out by successive stages: actuation is carried out a first time and, right after, ligament tensions are checked again [14]. Further refinement corrections can be made until optimal balance conditions are restored.

C. Mechanical Analysis

Actuation force – During the actuation, the patient is in lying position. Without the bodyweight, the only force acting inside the knee joint is the passive force of the two lateral ligaments. The value of such force varies among individuals and was estimated [18] as 150 N developed by each ligament. During its translation, the wedge must overcome this force, which is uniformly distributed perpendicularly to the mobile tibial tray surface (as a compression of the femur onto the tibia). The actuation force F developed by the translating wedge is given by (1) [19]:

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

where r is the screw thread mean radius (0.87 mm for M2x0.4 screw) and T is the torque applied on the leadscrew. The term $\kappa = a \ / \ b$ depends on the thread parameters, according to (2) and (3):

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

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

where α is the thread helix angle (4.18 deg for M2x0.4 screws), θ 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). The selected rotary stepper micromotor, combined to an integrated planetary gearhead (Faulhaber Precistep, ADM0620-2R-V2-05, 06/1K-1024:1), can provide T = 35 mNm intermittent torque. As a result, the wedge translation produces an actuation force F = 79.64 N. The wedge yields a mechanical advantage of 10/3, which gives about 265 N of lifting force, enough to face with the ligament passive force on the actuated side. In order to reduce friction losses, the combined use of miniaturised ball bearings and a specific coating (e. g.: bioceramics or ultrathin polymers) should be considered for both the wedge and its guide in the tibial baseplate.

Locking issue – Knee prostheses continuously face with strong cyclic tibiofemoral efforts, as well as with uncontrollable vibrations and shear forces. The peak net tibiofemoral force that can be generated inside the knee joint during normal gait cycle is C_{MAX} = 2600 N [5]. Via the mobile tray, all compression forces act on the actuated wedge pushing it back to its initial position. Thus, the WL system undergoes strong axial efforts (about 466 N at C_{MAX}) via the threaded profile. In order not to transmit such forces to the motor shaft, two miniaturised ceramic thrust ball bearings (F2-6M, 2x6x3 mm, 460 N static load each) support the leadscrew at its ends. In addition to this, due to the design parameters, the wedge (nut) translation cannot cause the leadscrew rotation. Concerning the threaded profile resistance, the assessment of ultimate tensile and shear strength limits allows to conclude that no mechanical failure of the actuation system components is likely to take place. With such considerations, the proposed design provides with a passive locking system a priori reliable and resistant. A key feature is that the micromotor, which is too small to face with tibiofemoral efforts, does not participate at all in keeping the mobile platform in the desired actuated position. This guarantees also great lifespan conditions of the whole actuation system.

Sealing – For biocompatibility reasons, all the actuation system mechanical parts are assumed to be made in titanium alloy (Ti-6Al-4V Grade 5) [1], while the mechatronic components (all supplied by a tiny battery rechargeable by means of inductive coupling) are supposed to be properly sealed. To this aim, an elastic micro-membrane attached between the borders of the mobile tray and of the baseplate could create a sort of sealed volume to isolate all the components from the knee synovial fluids.

III. SIMULATIONS AND PROTOTYPING

A. Static Analysis

The system mechanical model was accurately studied by means of static force analysis. Static and dynamic analysis simulations were carried out on the 3D CAD model of the proposed instrumented tibial implant, in order to evaluate forces distribution and component deformation under normal working conditions. The force C_{MAX} = 2600 N [5] was reproduced as a compression effort uniformly distributed on the mobile tibial tray, which was blocked in fully actuated position (3.6 mm lateral lift). As expected, Von Mises stresses were mainly concentrated along the contact line between the tray and the wedge, as well as around the pivot point on the non actuated side. The yield-strength limit of the selected titanium alloy (880 MPa) was respected and no relevant deformation was detected.

B. Fabrication

A first full-scale prototype of the proposed tibial component was manufactured by means of a 3D printer. The tibial baseplate, the mobile tray and the wedge were all fabricated as plastic components and assembled together (Fig. 4). The actuation, performed manually, allowed to assess the effectiveness of the working principle and confirm the 3.6 mm lateral uplift corresponding to the maximum wedge translation (10 mm). This simple prototype has to be intended as a proof-of-concept of the proposed mechanism for further development. The ongoing fabrication of a fully functional steel prototype, which includes the aforementioned rotary stepper micromotor, will allow to run experimental tests. The use of a force sensor to check the actual value of the actuation force and fatigue tests with a knee simulator are planned in the very near future.

IV. CONCLUSIONS

A miniaturised actuation system for a novel instrumented tibial component of a fixed-bearing total knee prosthesis has been presented in this paper. The actuation system, embedded in the tibial baseplate, allows the surgeon to postoperatively monitor and restore optimal balance conditions without resorting to revision surgery. The possibility to compensate for primary TKA surgery inaccuracies in the postoperative period without the need for a second surgical operation is a unique feature offered by the proposed model. Smart design solutions ensure high robustness and durability of the whole system. A first full-scale prototype has allowed to validate the results of theoretical computations and 3D simulations, as well as the mechanism working principle. Further refinements will be defined after the experimental tests that will be carried out on a fully functional steel prototype. Normal knee kinematics conditions will be reproduced by means of a knee simulator, so as to evaluate the robustness and stability of the proposed system and to estimate its lifespan. Results will be presented in a future work.

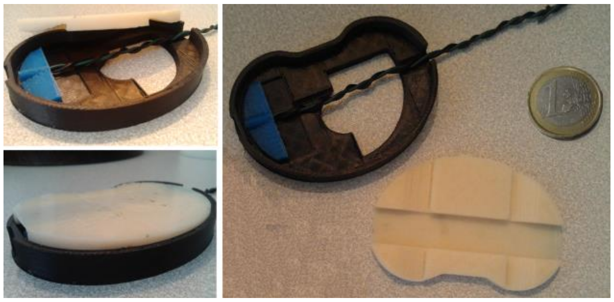

Figure 4. The fabrication of a full-scale prototype of the proposed tibial component by means of a 3D printer allowed to validate the actuation system working principle.

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