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Design and evaluation of an actuated knee implant for postoperative ligament imbalance correction☆

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ABSTRACT

In Total Knee Arthroplasty (TKA), the collateral ligament tensioning stage cannot be standardised for all patients and relies heavily on the surgeon's experience and perception. Intraoperative inaccuracies are practically unavoidable and may give rise to severe postoperative complications, leading to the need for revision surgery already a few years after primary TKA. This work proposes a novel instrumented tibial component able to detect collateral ligament laxity conditions right after primary TKA and, if needed, to compensate for them in the postoperative period. A miniaturised actuation system, designed to be embedded in the tibial baseplate, was initially evaluated by means of 3D simulations and then fabricated as a full-scale prototype. Stability and force sensors tests carried out on a knee simulator allowed to assess the effectiveness of the proposed design under normal working conditions and provided valuable insights for future work and improvements.

1. Introduction

A key achievement of Total Knee Arthroplasty (TKA) lies in intraoperatively setting up proper tension conditions of the two knee collateral ligaments [1]. This stage, which directly determines the postoperative Knee Joint (KJ) function and the implant lifespan, cannot be standardised and is typically carried out by evaluating variable and user-dependent loads [2]. Over the last decades, various assistive tools have been developed to help surgeons during this crucial TKA ligament tensioning stage.

A few examples of instrumented knee distractors can be found in the literature [3,4]. By controlling miniaturised mechanical structures, surgeons are able to monitor important intraoperative parameters such as tibiofemoral gaps and loads. Another type of assistive tools is represented by instrumented tibial baseplates: the use of embedded sensors, such as strain gauges [5], allows surgeons to perform fine-tuning adjustments in ligament tension during the component positioning process. Although, the optimal balance conditions that surgeons can determine during surgery inevitably face with the intraoperative inaccuracies introduced by the replacement of the employed sensing devices with the permanent prosthetic components.

In this context, over the last decade, the development of instrumented knee implants has been accepted as a way forward. For instance, dedicated telemetry systems and microelectronics components embedded in the prosthesis can provide unique intra- and postoperative KJ kinematics data [2,6,7]. Besides improving the quality of the surgical procedure itself, such in vivo data made available to surgeons have turned out to be very helpful for clinicians and prosthesis designers as well.

However, no assistive tool has been developed to specifically address the problem of postoperative ligament imbalance. The crucial knee stabilisation process highly depends on the surgeon's experience and perception [8,9]. The morphofunctional evolution that the prosthetic KJ normally undergoes during the rehabilitation period and in its aftermath may alter the collateral ligament tension values set during surgery. Some studies reported that some degree of postoperative collateral ligament laxity may be accepted [10] and even spontaneously corrected after TKA [11]. However, suboptimal balance conditions generally lead to postoperative complications and, in the worst-case scenario, to revision surgery (whose number is steadily increasing [12]). This suggests therefore to consider the possibility to compensate for intraoperative inaccuracies in the postoperative period; this can be achieved by means of a miniaturised actuation system embedded in the knee prosthesis.

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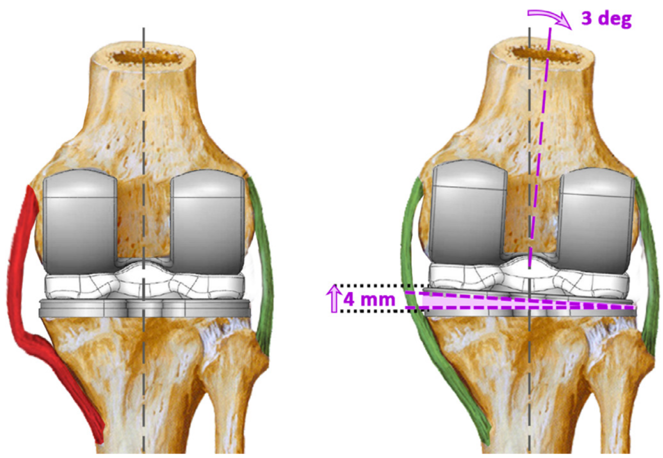

Fig. 1. A lax collateral ligament (left) can be properly re-tensioned by lifting the tibial tray up on the corresponding side (right).

The aim of this work was to propose a novel instrumented knee implant able to detect collateral ligament laxity conditions following primary TKA and, if needed, to restore optimal balance conditions before the occurrence of more severe complications. In the long term, the proposed device is intended to strongly reduce the need for revision surgery.

2. Materials

2.1. Implant description

The instrumented tibial component presented in this work further develops the smart knee implant previously proposed by our research team [13], which includes two sub-parts:

- for the evaluation of collateral ligament laxity conditions, four PiezoCeramics (PC) elements embedded in the tibial baseplate are employed as both force sensors and energy harvesters [14]. The collected data are meant to be processed and wirelessly transmitted to the clinician's computer by means of a self-powered telemetry system [15]. This allows to define a proper correcting action for restoring optimal balance conditions;
- for the detected imbalance correction, the miniaturised actuation system proposed by Collo et al. [16] is embedded in the tibial baseplate. In order to re-tension any detected lax collateral ligament, the height and inclination of the tibial tray can be adjusted on the corresponding side (Fig. 1). Such correcting action aims to reproduce the local adjustments carried out by means of spacer blocks during revision TKA [17] and tibial osteotomy [18].

2.2. Clinical needs

It is very important to detect any postoperative instability as early as possible; in the aftermath of the rehabilitation period, periodic follow-up visits allow the surgeon to monitor the prosthetic KJ postoperative function. Any collateral ligament laxity condition can be detected after analysing the data collected by four PC elements embedded in the tibial baseplate [13]. Accordingly, the surgeon defines an appropriate correcting action in terms of tibial tray lateral uplift (4 mm maximum, in order not to impair the prosthesis alignment to the lower limb mechanical axis [18]).

A progressive fine-tuning correction process is proposed by means of successive stages: actuation is performed a first time and the tibial tray is locked in the new raised position. Right after, the PC elements data are processed again to check the updated KJ function. If needed, further refinements can be carried out until optimal balance conditions are restored.

Only a continuous accurate monitoring of the evolution of the prosthetic KJ stability combined to the use of the proposed implant would allow to restore optimal balance conditions after primary TKA, without the need for revision surgery. To the author's knowledge, no other ongoing study copes with the problem of postoperative knee ligament imbalance using the same approach proposed in this work.

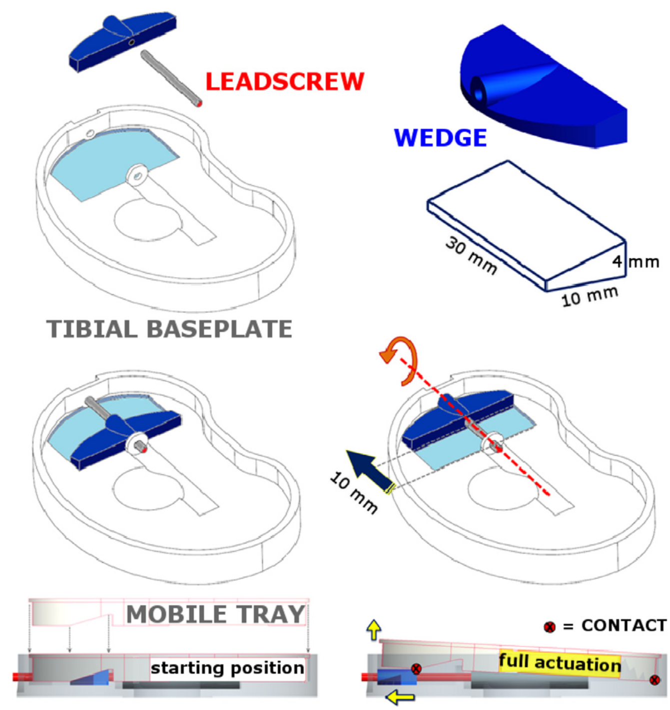

Fig. 2. The proposed Wedge-Leadscrew system.

2.3. Actuation system design

For sake of clarity, the description and the figures reported in the following refer to the actuation of only one side of the tibial platform (Fig. 2). The reader is invited to keep in mind that the instrumented tibial component actuation is achieved by means of two identical systems, one per each side of the tibial baseplate. More details are provided elsewhere [16].

The miniaturised actuation system is based on the translation of a wedge whose shape is custom-designed (30 mm wide, 10 mm long, 4 mm high). The wedge is guided inside a rail grooved in the tibial baseplate (Fig. 2). Via a threaded hole, the wedge is coupled to a leadscrew (ISO M2x0.4 profile: 2 mm pitch diameter, 0.4 mm pitch) which can only rotate without translating. As in a screw-nut configuration, any leadscrew revolution produces a corresponding wedge translation according to the thread pitch; herein, such assembly will be addressed as a Wedge-Leadscrew (WL) system.

A mobile tibial tray is shaped so as to be positioned from above onto the baseplate and fit the two WL systems. As depicted in Fig. 2, without any actuation the tray is fully contained inside the baseplate in a configuration that corresponds to that of conventional tibial platforms. In its starting position, the wedge is aligned to the center of the baseplate (null translation). As the leadscrew rotates, the 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.