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Technical note

Smart instrumentation for determination of ligament stiffness and ligament balance in total knee arthroplasty

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ABSTRACT

Ligament balance is an important and subjective task performed during total knee arthroplasty (TKA) procedure. For this reason, it is desirable to develop instruments to quantitatively assess the soft-tissue balance since excessive imbalance can accelerate prosthesis wear and lead to early surgical revision. The instrumented distractor proposed in this study can assist surgeons on performing ligament balance by measuring the distraction gap and applied load. Also the device allows the determination of the ligament stiffness which can contribute a better understanding of the intrinsic mechanical behavior of the knee joint. Instrumentation of the device involved the use of hall-sensors for measuring the distractor displacement and strain gauges to transduce the force. The sensors were calibrated and tested to demonstrate their suitability for surgical use. Results show the distraction gap can be measured reliably with 0.1 mm accuracy and the distractive loads could be assessed with an accuracy in the range of 4 N. These characteristics are consistent with those have been proposed, in this work, for a device that could assist on performing ligament balance while permitting surgeons evaluation based on his experience. Preliminary results from *in vitro* tests were in accordance with expected stiffness values for medial collateral ligament (MCL) and lateral collateral ligament (LCL).

1. Introduction

Total knee arthroplasty (TKA) has become a standard procedure for the treatment of degenerative diseases at the knee joint [1]. The main goals of TKA are relief of pain and restoration of motion [2,3]. Currently, there are several prosthesis designs on the market for different indications, each having a set of dedicated surgical instruments used during TKA procedure that depend on surgical specifications and surgeon preference [4]. To maximize the surgical outcome, the TKA procedures rely on the surgical principle of soft-tissue balancing (or ligament balancing) to manage post-operative knee stability and mobility, and avoid early implant failure [5,6]. Despite all the efforts on developing sets of instruments for TKA, ligament balance is still difficult to measure objectively during the operation, leaving its evaluation much to surgeon experience, feel and opinion [7].

The ligament balancing in TKA has the objective of distributing the tibialfemoral compressive forces symmetrically between the medial and lateral compartments as well as to reestablish an equivalent tibialfemoral gap in both flexion and extension [8]. Inadequate ligament balance can lead to unequal load distribution at the tibial-bearing surface consequently increasing prosthesis wear and resulting in early surgical revision [9,10]. Ideally an instrument that measures simultaneously tibialfemoral forces and flexion-extension gaps could assist surgeons to determine the optimal balance for the artificial knee and restore laxity characteristics similar to the natural intact knee [11]. Also a device that allows the determination of the soft-tissue biomechanical properties, such as ligament stiffness, can contribute a better understanding of the intrinsic mechanical behavior of the individual knee joint and benefit the post-operative outcome [12].

To help improve ligament balance a number of techniques and devices have been developed for assessing soft-tissue stiffness (i.e. distractor, tensers, spacer blocks, trial components, electric instruments, and navigation system) [5,11,13–20] but, to the best

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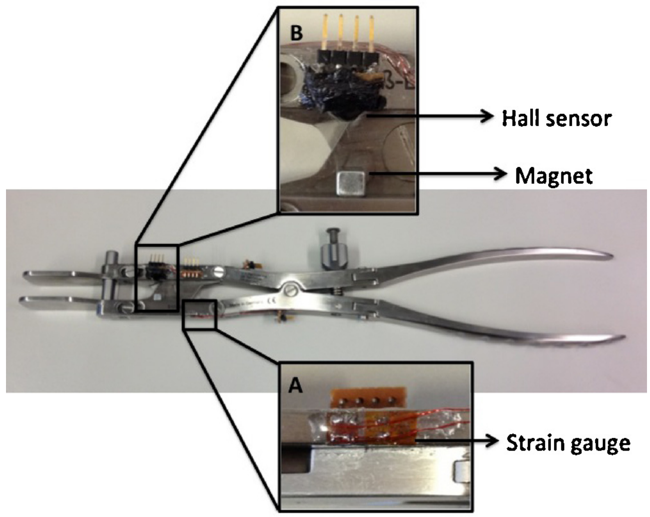

Fig. 1. Instrumented distractor prototype capable of continuous and real-time measurements of (A) tibial-femoral forces and (B) flexion-extension gaps.

knowledge of the authors, there are no TKA instrumentation that simultaneously allow a manual loading control by the surgeon while providing tibial-femoral force measurement and flexion-extension gap quantification. In fact, previous devices are either automatic controlled, making it impossible for the surgeon to experience a direct force feedback of the measurement, or they are manually controlled and provide rudimentary quantitative information.

The objective of the present work was to modify and expand the current capabilities of a standard manual distractor provided by Symbios Orthopédie SA, currently used in orthopaedic surgery, while maintaining the instrument shape and usage. The concept is based on the description of a similar tool used in human lumbar spine surgery [21]. The modified distractor aim to permit the simultaneous measurement of tibial-femoral forces and flexion-extension gaps during the TKA procedure, as well as the estimation of ligament stiffness.

2. Materials and methods

2.1. Specification

The specifications of the device were defined in a collaboration with surgeons and consist of force measurement independent of the surgeon's hand position on the distractor and of the position of the applied load in the tip of the tool, displacement measurement ranging between 13 mm and 27 mm with accuracy of 0.1 mm and force assessment up to 500 N with accuracy of 5 N. The first specification provides the practitioner a freedom to operate, while maintaining the measurement reliability. The force and displacement accuracy are also important in order to provide measurements within expected readouts from the knee structure.

2.2. Design

The distractor (single plate instrument) to be modified was provided by Symbios Orthopédie SA (Switzerland) and is part of the current instrumentation set provided to the hospitals to perform a TKA. The distractor's prototype is presented in Fig. 1 and it is capable of continuous, simultaneous and real-time measurements of tibial-femoral forces and flexion-extension gaps. Our method for measuring tibial-femoral forces was to detect mechanical deformations in the distractor, and for measuring the flexion-extension gap, to track the distance between the tips of the distractor.

The detection of mechanical deformations were made by strain gauges. The strain gauge positioning on the distractor was chosen based on finite element analysis (FEA) performed with the current distractor's shape and material properties. Also, the position of the strain gauges was chosen to minimize the dependency of the force on the variable position of the hands of the surgeon on the distractor handles and on the position of the applied load in the tip of the tool (Fig. 1A). The strain gauges were connected to a Wheatstone bridge in a half-bridge configuration. The half-bridge configuration was used to compensate for overall temperature drifts and it's resistance is a standard 120 Ω. The Wheatstone bridge was powered with 2.5 V and the output signal amplified using an instrumentation amplifier INA 114 (Texas Instruments).

In order to measure displacement an off-the-shelf hall sensor (Asahi Kasei Microdevices Corporation, HW-322B) was positioned on one shaft of the instrument in front of a magnet positioned on another shaft on the opposite side (Fig. 1B). The hall sensor was powered with a transconductance amplifier which provides a constant current of 10 mA. This configuration was chosen to provide a reliable measurement of the hall sensor signal output. The signal output was connected to another instrumentation amplifier INA 114. Both signals from the strain gauges and the hall-sensor were sampled to a computer with a National Instruments data acquisition board (NI-6259). For displaying real-time measurements a LabView (National Instruments) interface was used.

2.3. Procedure

The instrumented distractor calibration consisted of a semi-automated procedure. The displacement sensor was calibrated statically, after assembly to the distractor, using a digital caliper fixed to the tip of the distractor while the signals were sampled to the computer. This collected data was used to extract the coefficients based on a third order exponential decay curve fit. The strain sensors were initially calibrated using a load cell by fixing the tip of the distractor, one side to the load cell and the other side to a rigid structure, such that the instrumented arm was free to be operated. Afterwards, in case of drift, necessary corrections can be performed using shunt resistors. The signal conditioner's gain and span controls were set to obtain a full-scale electrical output signal. Once the distractor is calibrated, it can be used for measurements. During the measurement, the surgeon can see the force and displacement values on the computer screen through the Labview interface and the ligament stiffness can be estimated by the slope of a linear regression fitting the data.

2.4. Experimental measurements

To assess the suitability of the device for the purpose of ligament balancing, a control experiment with a spring, simulating the ligaments, was performed. The spring was fixated to the tip of the distractor and a series of dynamic movements of opening and closing the instrument was completed. The measurement protocol consisted of distracting the spring about 10 consecutive times following a procedure suggested by the surgeon to mimic surgical procedures. The rate of loading and unloading was target to be roughly 0.3 Hz while the force and distance were recorded.

2.5. In vitro measurements

After approval of the local ethical committee we were able to test the device *in vitro*, in two cadaveric legs. The cadaveric leg was positioned according the patient would be in a supine position and the knee exposed in flexion. A 15 cm straight vertical incision