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Robotic Tensor Device for Optimal Soft Tissue Balance in TKA

Jun Okamoto, Tomoyuki Matsumoto, Hirotsugu Muratsu, Masahiro Kurosaka,
Yoshihiro Muragaki and Hiroshi Iseki

Abstract— **Soft tissue balance measurement is necessary for effective total knee arthroplasty (TKA). If optimal ligament balance is not achieved during surgery, it results in laxity of the knee or repeat surgery.**

In this paper, a newly developed robotic tensor system for measurement of soft tissue balance during TKA is described. The development concepts of the system were to measure collateral ligament balance (joint gap distance and varus angle) after cutting of the tibia and femur and to generate arbitrary lifting force to the knee joint during surgery.

The system was created according to the development concepts. The prototype system has an active prismatic joint and a passive rotation joint to assess the joint gap and varus angle. The maximum lifting force is 250 N, the measurement range of the joint gap is 30 mm, and the varus angle is ±15°. To confirm the force control ability, a basic experiment was performed. The input target force was 100, 150, 200, 250 N, and the output result showed an error within 3N. This experimental result shows that the newly developed system appears to have better accuracy than previous instrumental methods.

I. INTRODUCTION

Total knee arthroplasty (TKA) is a technique that aims to achieve stable tibiofemoral and patellofemoral joints. The number of cases of TKA is increasing along with the rapid aging of society. TKA is an operation to replace the knee joint damaged by osteoarthritis or rheumatoid arthritis with a prosthetic joint. Recently, owing to the improved technology of preoperative planning software and surgical navigation systems, it is possible to perform precise osteotomy during TKA according to the preoperative plan [1-5]. However, for a successful outcome, construction of the appropriate soft tissue balance is important, along with accurate alignment between the femur and tibia [6]. In TKA, the soft tissue balance refers to the tension balance between the medial collateral ligament (MCL) and the lateral collateral ligament (LCL), both of which are preserved after the operation. Failure to achieve the proper soft tissue balance leads to knee joint laxity or wearing of the prosthetic joint even if ideal bone alignment is achieved. In the worst case, it results in repeat surgery. Thus, soft tissue assessment is essential for good TKA outcomes, and measuring the balance during TKA has now become a standard procedure.

At present, there are two methods to evaluate soft tissue balance, a manipulative procedure or an instrumental assessment using a tensor, balancer, and tension meter [7-10]. Since the manipulative method has as a disadvantage its subjective judgment, the instrumental method has become mainstream. A tensor is a device that is installed after the resection of the bones. It provides a constant lifting force between the tibia and femur and measures the joint gap distance and the varus angle. In general, the ideal soft tissue balance is a “parallel gap” (Fig. 1), which means that the cutting lines of the tibia and femur are parallel at the extension and flexion positions of the knee [6]. Surgeons adjust the tension of the MCL and LCL by cutting the fibers of the ligaments towards the parallel gap while checking the tensor’s varus angle. A balancer or tension meter plays similar roles during surgery.

Thus, the instrumental method is useful for soft tissue balance assessment, but precise and reproducible measurements cannot be achieved because the lifting force is generated by a classical mechanism, such as a torque wrench or coil springs, without considering friction loss. This problem comes from the sterile surgical condition that limits the choice of electrical components. In order to overcome this measurement inaccuracy, we are developing a robotic tensor that generates a precise lifting force under sterile conditions. The present paper provides an overview of the developed robotic tensor and the results of a basic experiment of constant lifting force control.

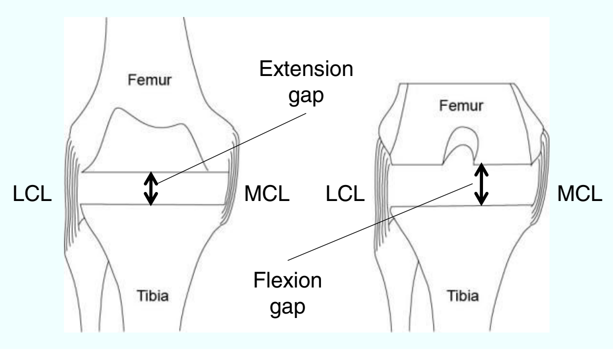

Fig.1 Ideal “parallel gap” between a femur and tibia

II. ROBOTIC TENSOR SYSTEM

A. *Development concept*

The concept of the robotic tensor is as follows.

1. It measures the soft tissue balance (the gap between the tibia and femur and the varus angle) after the two bones are cut during TKA.

2. It has a mechanism that consists of two plates that push out the femur from the tibia.

J. Okamoto, Y. Muragaki and H. Iseki are with the Institute of Advanced Biomedical Engineering & Science, Tokyo Women's Medical University, Tokyo 162-8666, Japan (corresponding author: +81-3-5367-9945 (ext 6003); Fax: +81-3-5312-1844; E-mail: j-okamoto@abmes.twmu.ac.jp).

T. Matsumoto and M. Kurosaka are with the Department of Orthopaedic Surgery, Kobe Graduate School of Medicine, Kobe 650-0017, Japan.

H. Muratsu is with the Department of Orthopaedic Surgery, Steel Memorial Hirohata Hospital, Himeji 671-1122, Japan.

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3. It generates an arbitrary constant lifting force (from 100 to 250 N) between the femur and tibia.

4. The plate attached to the tibia has spikes to fix itself to the edge face of the bone.

5. The measurement can be performed in the regular patella position (not everted).

6. The joint gap distance and varus angle are displayed as Fig. 2 during the surgery under the condition of femur lifting [11-15].

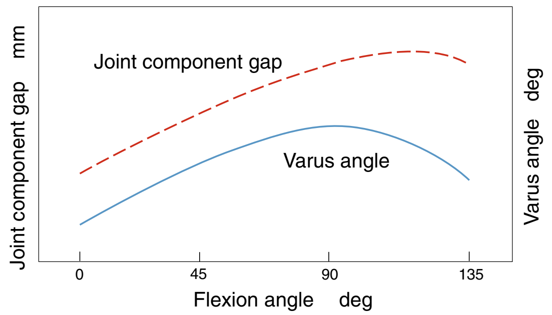

Fig.2 Ideal measured data of soft tissue balance during TKA

B. The mechanism of the developed system

Fig. 3, 4 shows the newly developed robotic tensor. The system consists of three parts: a lower platform plate with spikes, an upper seesaw plate, and an extra-articular main body. A force sensor (9021A, Kistler Instrument Corp., Michigan, USA) is attached under the upper seesaw plate. The lower platform plate is fixed to the cutting surface of the tibia, the upper seesaw plate is lifted by a constant force, and the joint lifting force is generated. The offset connection arms from the main body connecting the two independent plates at the antero-medial corner of the tibia are passed through the medial parapatellar arthrotomy. The seesaw plate is attached to the offset connection arm of the main body via a single shaft, providing a central pivot in the coronal plane. The maximum lifting force is designed to be 250 N. The joint gap distance is up to 30 mm, and the varus angle can be measured to ±15°. These values are measured by two rotary encoders (MEH-12-2000PC, Microtec Laboratory Inc., Sagamihara, Japan). The main part of the device is made of stainless steel.

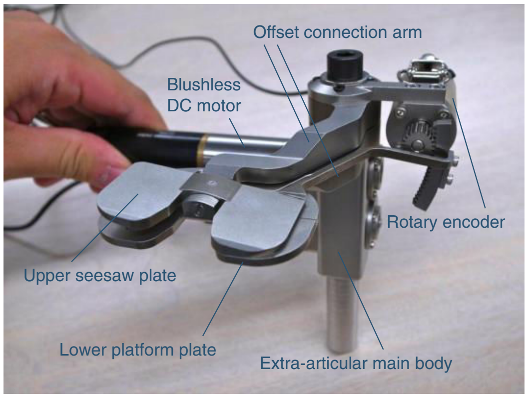

Fig.3 The robotic tensor for TKA soft tissue balance measurement

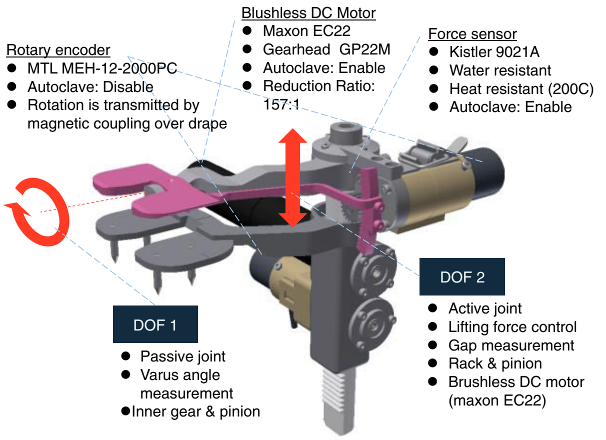

Fig.4 Detailed view of the robotic tensor mechanism

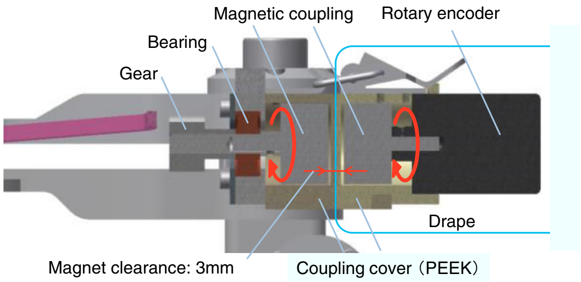

Fig.5 Detailed view of the rotary encoder unit using magnet couplings, PEEK coupling covers and draping

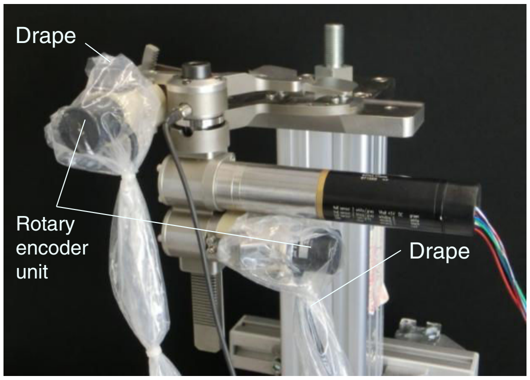

Fig.6 Rotary encoder units covered with drapes

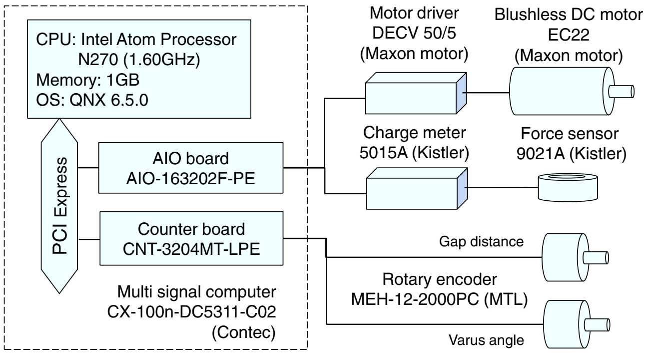

Fig.7 System architecture of the robotic tensor

To control the lifting force, a force control system was constructed using a brushless DC motor (EC22, Maxon motor ag, Sachseln, Switzerland), a rack-and-pinion mechanism, and a force sensor. The upper seesaw plate has a passive joint to measure the varus angle. Autoclave sterilization can be applied to the brushless motor and the force sensor, but the two rotary encoders cannot be effectively sterilized; thus, the rotary encoders are draped during the surgery, and the rotations of the mechanism are transmitted over the drape using non-contact magnetic coupling (Custom-made, Shoei-koki Co., Sendai, Japan). The whole system is autoclaved without the rotary encoder unit, and then the unit is attached to the system with a drape covering (Fig. 5, 6). The control system uses a Multi-signal computer (CX-100n-DC5311-C02, CONTEC Co., Ltd., Osaka, Japan) with QNX6.5.0 (QNX Software System Ltd., Ottawa, Canada) as the real-time operating system (Fig .7). The sampling cycle of the controller is 1 ms.

C .Calibration of the force sensor

The position of the force sensor is not located directly beneath the lifting force point. This causes non-linearity of the force measurement. To compensate this non-linearity, force error between raw data measured by the force sensor and real force data measured by a digital force gauge (ZP-500N, IMADA Co., Ltd., Toyohashi, Japan) was measured (Fig. 8). Fig. 9 shows the experimental result. To compensate this force error, the error data is approximated by cubic spline interpolation and subtracted from raw data. The mean value of the force error between real data and the compensated data was 0.65 ±0.37 N.

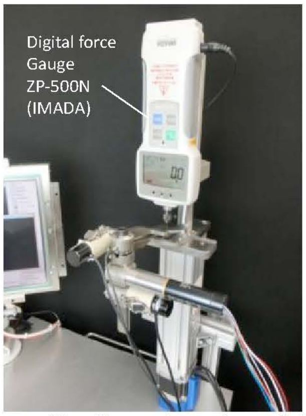

Fig.8 Force sensor calibration system using a digital force gauge

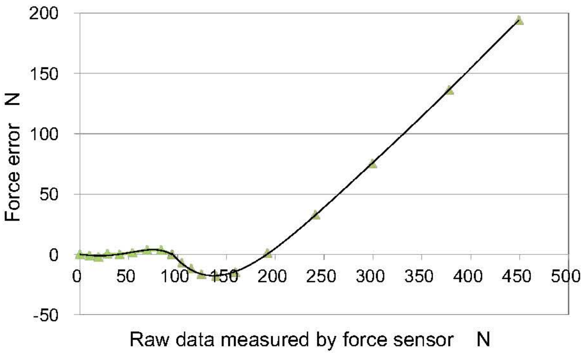

Fig.9 Force error between raw data measured by the force sensor and real force data measured by a digital force gauge

III. EXPERIMENT

A. Experimental setup

In order to assess the constant force control ability of the robotic tensor, a basic experiment was conducted. Fig.10 shows the block diagram of the force feedback control with a feed-forward method. The PID parameter and the feed-forward function were chosen experimentally. Fig. 11 shows the relationship between motor current and lifting force. The feed-forward function in Fig. 10 was used the linearized model of the data of Fig.11. The step input target force value was set at 100, 150, 200 and 250 N, and the output force was measured. Fig.12 shows the experimental environment of the simplified physical knee model during TKA. The model can be attached to the robotic tensor and can demonstrate the lifting procedure. The elasticity of the model between the femur and tibia is adjustable; the 100 N/mm spring was used as the hardest lateral ligament given the biomechanics.

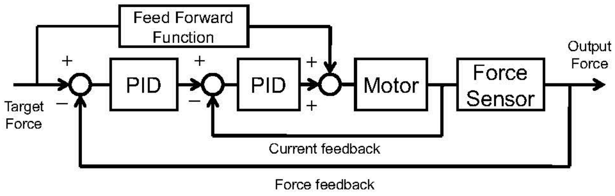

Fig.10 Block diagram of the force control for the robotic tensor

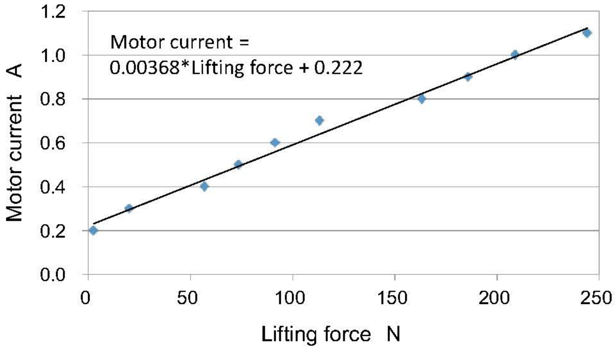

Fig.11 Relationship between motor current and lifting force

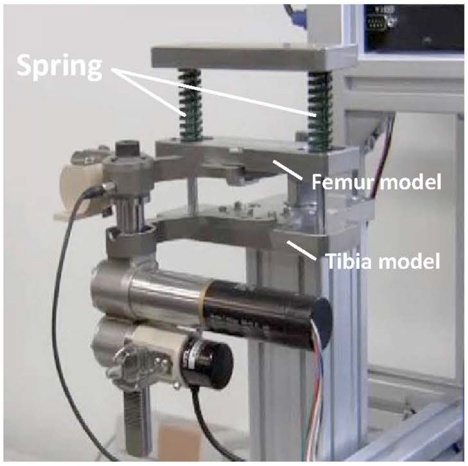

Fig.12 Experimental environment of a simplified physical knee model during TKA

B. Experimental Results

Fig.13 shows the experimental results. The mean error between the target force and the measured force at steady state is 1.26 ± 0.89 N. The cause of this error was probably generated by the non-linear factor of mechanical friction. To increase the precision of the force control, we will try to decrease the friction of the mechanism under the sterile condition, which does not permit the use of industrial grease or lubricant.

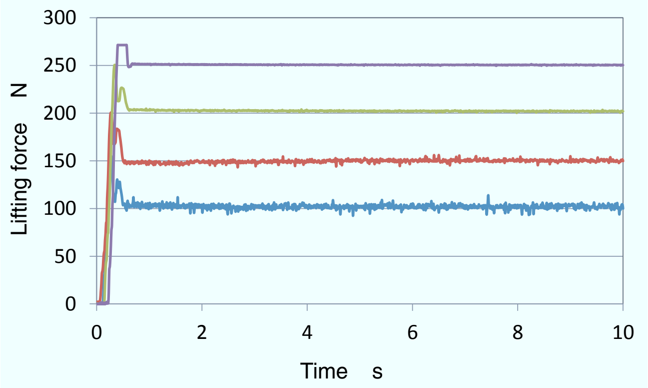

Fig.13 Experimental results of robotic tensor force control

IV. DISCUSSION

Given the experimental results, the maximum output force error in the static state was 1.26 ± 0.89 N. In consideration of force sensor error, the measurement error is even within 3 N. This error could be decreased by better lubrication, but even this result appears to have greater precision than previous instrumental methods. As a future issue, it is necessary to develop a device that measures the knee extension angle during surgery. To derive the graph shown in Fig.2, the extension angle must be observed with the joint gap and varus angle simultaneously. At this time, we are trying to use a goniometer. Furthermore, the viscoelasticity of the ligament should be considered. Since extension of the ligament continues if the force remains, it is necessary to define the duration of extension to measure the displacement of the gap.

In the near future, after cadaver trials and safety assessment, we will use the system in clinical cases. This system could contribute to the improvement of TKA, but if this method increases operative duration, the frequency of complications due to infection or embolism would increase. Thus, a simpler way of using the system needs to be developed. In addition, the ideal soft tissue balance is known to some extent (Fig.1), but, for example, the best balance in the deep flexion position is still unknown. In the same way, the appropriate constant force value has not been solved. The future task with the newly developed system is to create a database that compares data during surgery with postoperative results in order to determine the ideal soft tissue balance for improved TKA.

V. CONCLUSION

In this paper, a robotic tensor device for measurement of soft tissue balance during TKA was described and evaluated. The purpose of the system is to measure the joint gap distance and varus angle with a constant lifting force under sterile conditions. A basic experiment to examine the device's constant lifting force control was performed, and the system appeared able to control the output force with an error within 3N. After confirmation of safety, we plan to use the system in clinical cases to improve the TKA procedure from the biomechanical perspective.

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