

Development of a New Diagnostic Test Kit for Knee Ligament Injury and an Evaluation of its Efficacy

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Abstract

This study aims to develop a new knee ligament displacement tester which is capable of collaterally reproducing 30° and 90° knee flexion while testing the knee ligament displacement and to investigate its efficacy. The SSY (new knee ligament displacement tester) device was manufactured and clinically applied as described in the following sections. While the Telos device yielded a standard deviation of $\pm 9.76^\circ$ and $\pm 5.92^\circ$ at 30° and 90° of knee flexion (respectively) in ACL (Anterior Cruciate Ligament) and PCL (Posterior Cruciate Ligament) laxity testing, the SSY device yielded results of $\pm 3.20^\circ$ and $\pm 2.75^\circ$, indicating improvements of 60% and 54%, respectively. It is thus considered useful as a new supplementary device for the measurement of knee joint laxity

Keywords: ACL (Anterior Cruciate Ligament), Knee, Ligament, PCL (Posterior Cruciate Ligament), Telos Device

1. Introduction

Exercise is currently the most frequently performed leisure activity in modern society (24.8%), which implies a shift in leisure trends from rest to sports¹. However, the recent increase in high-energy exercise means that more people are becoming prone to exercise-induced injuries, particularly those of the knee. In one year, the number of patients with internal knee injuries, such as cruciate ligament or meniscus tears, increased as much as 23.3% (from 45,966 in 2011 to 56,679 in 2012^{2,3}, and it is of note that Anterior Cruciate Ligament (ACL) injuries account for over 90% of all cruciate ligament injuries⁴. Cruciate ligament injuries are diagnosed with physical,

radiological, magnetic resonance imaging (MRI) examination, and by using the Telos device, and the KT 2000⁵. (The uses of the latter three are elaborated on here). MRI gives a clear anatomical image that can easily determine a ligament injury, but is extremely expensive. The KT 2000 knee ligament arthrometer is effective in showing laxity of the ACL and Posterior Cruciate Ligament (PCL), but are only used by 69.2% of hospitals in the Seoul metropolitan area⁶. The Telos device measures the laxity (sagittal displacement) of the tibia relative to the femur, by comparing radiographs taken with pressure applied to the knee after fixing the femur and the tibia, and is considered to be an accurate diagnostic tool for knee joint injury and functionality⁷.

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However, this knee ligament displacement tester is structured to uniformly measure collateral flexion angles at 90° of knee flexion during ACL and PCL laxity testing, and thus have a low reproducibility of the femoro-tibial angle measured in the Lachman position (F-T angle 20° – 30°). To address this limitation, this study aims to develop a new knee ligament displacement tester (hereinafter referred to as the SSY device), which is capable of collaterally reproducing 30° and 90° knee flexion while testing the knee ligament displacement⁸, and to investigate its efficacy.

2. Methodology

2.1 Experimental Materials Used

2.1.1 Characteristics of Models: Independent Variable

A round steel frame (with a thickness of 0.4 cm and a diameter of 52 cm) and 4 plastic bases (each with a thickness of 0.9 cm and a diameter of 15 cm).

2.1.2 Femoral Fixation Device

A pair of steel plates (each with a thickness of 0.4 cm, width of 25 cm, and a length of 15 cm), a pair of air pouches (each measuring 12 cm $\times$ 23 cm), 1 air pump, and 1 analog air pressure gauge (unit: mmHg).

2.1.3 Ankle Fixation Device

2 steel rods (each with a length of 15 cm and a diameter of 15 cm).

2.1.4 Support Device

A rectangular steel frame (with a thickness of 0.4 cm, with of 5.8 cm, and length of 9 cm), 1 round gear with a diameter of 36 cm, 1 linear gear (with a width of 35 cm, length of 2 cm, and height of 2 cm), and 2 double-direction linchpins.

2.1.5 Load Cell Pressure Sensor (Force Gauge)

90 kg/198 lb maximum load, 0.1 kg/02 lb measurement unit, 30–90 % humidity, 0.5 kg/1 lb error range, and two AAA $\times$ 1.5 V batteries as a power source.

2.2 Production Process

2.2.1 The Telos Device

The Telos system consists of a right-angled U-shape frame, a femoral fixation device, an ankle fixation device, a pressure gauge, and a one-piece support appliance (Figure 1.) for the testing of displacement of the medial and lateral ligaments of the knee joint, and of the medial, lateral, anterior, and posterior ligaments of the ankle joint, to enable an accurate radiographic diagnosis of ligament damage with radiographs.



Figure 1. Telos device.

2.3 SSY Device

2.3.1 Frame

The 0.4-cm-thick and 52-cm diameter circular steel frame is a device used to fix the ankle, and contains 60 holes with diameters of 15 cm, spaced at 1-cm intervals to keep the angles constant. The octagonal frame of the circular frame is horizontally symmetrical, and forms a 30° angle relative to the horizontally facing sides. Four plastic pillars supports the frame, each with a thickness of 0.9 cm and a diameter of 15 cm.

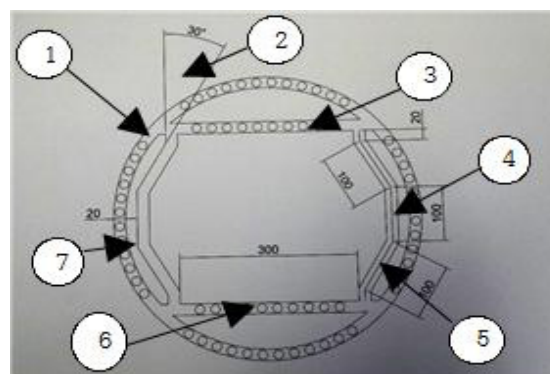


Figure 2. A schematic of the knee ligament tester.

Basic circular frame of the SSY device. surface used for 30° testing. Whole of the ankle fixation device for angle maintenance. Reference surface for medial and lateral knee ligament testing. 30° reference surface relative to. - 90° reference surface for ACL and PCL laxity testing. symmetrical octagonal frame.

2.3.2 Femoral Fixation Device

This device prevents the femur from moving during the knee laxity testing (which involves pulling and pushing of the tibia). It is composed of a pair of steel plates (each with a thickness of 0.4 cm, height of 25 cm, and width of 15 cm), a pair of airing pouches (each with a width of 12 cm and a length of 23 cm) which hold the leg tight to the plates, an air pump, and an analog pressure gauge to measure the air pressure applied on the knee (unit: mm/Hg) (Figure 3).

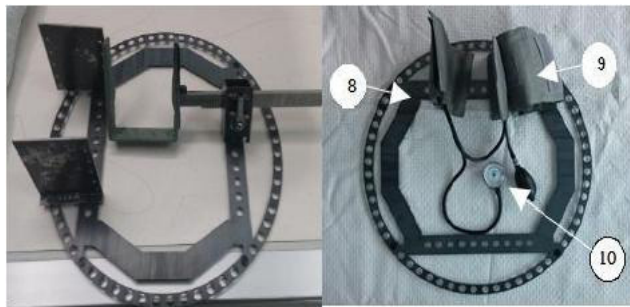


Figure 3. Femoral fixation device.

Octagonal frame. Femoral fixation device using air pressure. Air pressure gauge and air pump.

2.3.3 Ankle Fixation Device

This device fixes the ankle (with the femur fixed to the basic frame) in order to maintain the knee flexion angle at 30° or 90°. This 15-cm long steel rod with a diameter of 6-cm is covered in rubber to reduce pain on the contact surface of the ankle during testing (Figure 4).

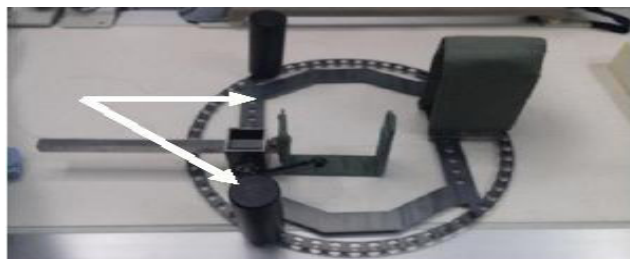


Figure 4. Ankle fixation device mounted to the circular frame.

2.3.4 Support Device

This device has the function of fixing the femur to the basic circular frame and securing the ankle, with the femur and tibia maintained at 30° and 90°, respectively. A constant load force is then applied to the knee. Using the handle of the linchpin, the torque of the circular gear is translated into linear movement, thus pushing or pulling the knee along the right-angled U-shape hook. One linchpin is used to push or pull the hook to apply force and maintain the force, and the other is used for rotating the circular gear, and is thus used as a device handle when pulling or pushing the hook (Figure 5).



Figure 5. U-shaped hook and device.

2.3.5 Load Cell Pressure Sensor

The load cell pressure sensor is a device that measures the force applied to the knee. It is located between the knee and the right-angled U-shape hook of the support device, and it measures the force applied to the knee during testing. The pressure sensor was manufactured with the following specifications: 90 kg/198 lb maximum load, 0.1 kg/0.2 lb measurement unit, 30–90 % humidity, ± 0.5 kg/1 lb error range, -0–35 °C surrounding temperature, 2 batteries (AAA $\times$ 1.5 V) as a power source, and a 12 mm LCD display (Figure 6).



Figure 6. Digital pressure sensor.

2.4 Efficacy for Clinical Application

The efficacy of the SSY device was evaluated by comparing the results of ACL and PCL laxity testing with those obtained using the Telos device (Figure 1). The tests were conducted on the same subjects in both trials (males, age $\geq$) and in the same manner (Figures 7–10).



Figure 7 and 8. New knee ligament test device Laxity test at 30° knee flexion.

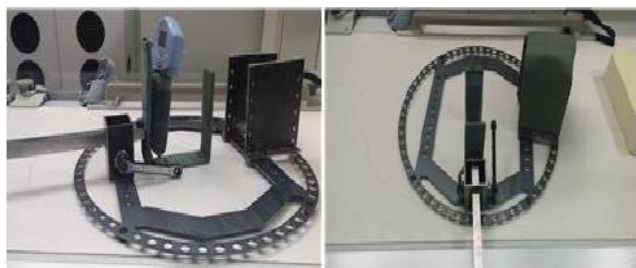


Figure 9 and 10. Laxity test at 90° knee flexion Knee medial and lateral laxity test.

2.4.1 Knee Medial and Lateral Ligament Laxity Testing

Medial and lateral ligament laxities were tested by measuring the changes in values between the state of no flexion and that of 30° flexion, and results were achieved by pushing the tibia in the lateral-medial direction and pushing in the medial-lateral direction, respectively (Figures 11–14).



Figure 11 and 12. Knee medial and lateral ligament laxity testing using the Telos device.



Figure 13 and 14. Knee medial and lateral ligament laxity testing with the SSY device.

2.4.2 ACL and PCL Laxity Testing

ACL and PCL laxity testing were performed to verify damage by pulling the tibia forward and backward in relation to the femur at a knee flexion of 30° and 90°, respectively (Figures 15–17).



Figure 15. PCL laxity testing at 90° using the Telos device.



Figure 16. ACL and PCL laxity testing at 90° flexion.



Figure 17. ACL and PCL laxity testing at 30° flexion.

3. Findings

- Angle changes were measured within the range of $\pm 3^\circ$ at femoro-tibial angles of 30° and 90° , and at an air pressure of ≥ 200 mm/Hg (applied for femoral fixation).
- Measurements using a 20-kg lead block throughout 30 repetitions using the pressure sensors (force gauge) yielded a concordance rate of 99.9%, which was statistically significant ($p < 0.01$).
- No inter-device differences were noticed throughout medial and lateral ligament testing because the two devices used the same testing method.
- While the Telos device yielded a standard deviation of $\pm 9.76^\circ$ and $\pm 5.92^\circ$ at 30° and 90° of knee flexion (respectively) in ACL and PCL laxity testing, the SSY device yielded results of $\pm 3.20^\circ$ and $\pm 2.75^\circ$, indicating improvements of 60% and 54%, respectively.

4. Discussion

Using a comparison of radiographs of both knees⁹, knee ligament injury can be defined together with the degree of its severity by observing the extent of laxity on the injured side relative to the non-injured side.

Table 4. Grading of the extent of knee joint laxity

Grade	Extent of Laxity	Symptoms
Grade	0–5 mm	Minimum tear, no evidence of instability.
Grade	5–10 mm	Slight tear, mild instability.
Grade	10–15 mm	Clinically significant tear, moderate instability.
Grade	≥ 15 mm	Complete tear, visible instability.

Radiographic knee joint laxity testing is used for diagnosing and quantifying the extent of instability associated with acute or chronic ligament damage, by evaluating the instability of the medial-lateral and anterior-posterior ligaments. Telos device stress testing is specified by the Ministry of Health and Welfare Notification No. 2013-56 as being one of the supplementary measurement items used for disability classification standards¹⁰,

and this testing method has gained significant importance. A radiographic finding of a displacement of 1 cm or greater verifies that ligament damage is clinically significant, and ACL and PCL damage are suspected if the difference in the displacement between the injured and non-injured knee joints is ≥ 6 mm in anterior drawer stress and ≥ 3 mm in posterior drawer stress, respectively. The Telos device is widely used because it delivers an objective diagnostic value determined by X-ray images compared to the KT-2000 arthrometer; however, it has low reproducibility of knee flexion angles when no force is applied and when force is applied to test the extent of laxity. Efforts have been made in previous studies to improve the reproducibility of angles by changing the position of the Telos device roller, but these have not yielded satisfactory results due to failure of femoral fixation or to structural problems with the device⁹. A comparison of results from the Telos device with those from the SSY device revealed that there were no differences in medial and lateral testing because both devices use the same testing method. However, in ACL and PCL laxity testing the SSY device showed improvements of 60% at 30° flexion (SD of Telos = $\pm 9.76^\circ$; SD of SSY = $\pm 3.20^\circ$) and 54% at 90° flexion ($\pm 5.92^\circ$ vs. $\pm 2.75^\circ$). The superior performance of the SSY device (which was developed by the author) compared to the Telos device was thus demonstrated, owing to improved femoral fixation, which was implemented through a device using air pressure. This device also simultaneously reduced pain on the thigh, and enhanced the angle reproducibility of the injured and non-injured sides. However, 100% angle reproducibility could not be achieved by the proposed device alone, and further research therefore appears necessary to overcome its limitation in reproducing knee angles depending on muscular changes of both knees and on other anatomical variables.

5. Conclusion

The SSY device demonstrated high reproducibility, and compared to the stress test using the Telos device shows an improvement of 67% at 30° flexion and 54% at 90° flexion for the diagnosis of ACL and PCL damage. Thus it is considered useful as a new supplementary device for the measurement of knee joint laxity.

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