Influence of axial force and characteristics of axial force affecting on total knee replacement constraint test

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Abstract

The result of testing for determination of Total Knee Replacement (TKR) Constraint (ASTM F1223) is necessary for surgeons for matching the knee prosthesis with the different degrees of severities of knee osteoarthritis patients. In the knee replacement constraint test, the axial compressive load and translation displacement are the control and the adjusting variables. The magnitude of axial compressive load during testing is affected by the slope of knee bearing surface. According to ASTM 1223 standard, the axial compressive load is not clarifyingly mentioned. Namely, it should be equal 710 N during testing or only in state of initiation. It may lead to testers to perform the test into different two modes which consequently in possibly different constraint result. Therefore, the objective of this research is to clarify the differences in test results when applying two axial compressive load characteristics during testing. The six-axis testing machine (Prosim Universal Joint Simulator) was used to determine the anterior posterior constraint (AP) of fix bearing posterior sacrifice (FB PS) system. Bovine serum was directly applied to the bearing surfaces as a lubricant. An initial axial compressive load 710 N was used. Two axial compressive load characteristics during testing, 1) keeping the axial force at given value as mentioned during testing (load-controlled testing) and 2) with allowing the change in axial compressive load during testing (displacement-controlled test), were used. From the results, the AP load resistance hysteresis loop patterns obtained by both testing modes were similar. The magnitude in forward direction load resistance is higher, while the backward AP load resistance showed the lower, in case of displacement control mode. It resulted in span between AP load resistance was larger. Moreover, the higher constraint in case of displacement control was indicated. Thus, if the test modes are not mentioned in test result, the surgeons will be possibly choosing the wrong TKR for their patient.

Keywords: Total knee replacement (TKR), TKR constraint, TKR testing
1. Introduction
Before knee replacement surgery, patients are required to undergo an assessment of their knee osteoarthritis condition, in order to match the appropriate total knee prostheses. The available bone stock and soft tissue capacities for stabilization, are the parameters surgeons use to assess knee osteoarthritis conditions [1]. For example, patients with good soft tissue restraints, may require a lesser constraint prosthesis. Whereas patients with major bone loss or destroyed ligamentous structures, may require a prosthesis with a higher degree of constraint. Measurements for the constraint of total knee prosthesis are defined according to the Standard Test Method for Determination of Total Knee Replacement Constraint (ASTM F1223). According to ASTM F1223-14, the axial compressive load of 710 N is mentioned to apply during the test. Also, both bovine serum and deionized water is allowed to use as lubricant between the knee insert and the femoral component. In constraints testing, the femoral component and the tibial component will be moved relatively in only the testing direction, while other directions movements will not be allowed. From the year 2005 until present, there are many studies aiming to evaluate the disadvantage of the current TKR constraint test. Firstly, Moran et al. (2008) [2] assessed the constraint of the TKR device experimentally in order to validate their computer simulation technique developed based on the ASTM guideline. In their study, the axial compressive load of 200 N was applied initially by using the MTS 858 Bionix test machine. However, after testing, they found that the measured axial compressive load found fluctuated. Secondary, Haider and Walker (2005) [3] used the test methods base on ASTM F1223 of 2005 version to assess the constraint of three commercial knee designs. However, their test was conducted by application of the constant axial compressive load. Under Haider and Walker’s works, the secondary motions were discovered. Thirdly, Halewood et al. (2018) [4] conducted the AP constraint test with Instron 5565 that also allowed to control the constant axial compressive load from 700 N and 2000 N during testing. From Halewood et al. study, it was found that a secondary motion was also occurred. Moreover, the different axial compressive load resulted in the different constraints result. From the above studies, we could realize that the axial compressive load characteristics should have the effects on the constraint results. However, no research works have been performed to understand the effect of axial load characteristics on the constraint result. Moreover, the ASTM standard itself does not include guidance on the axial load characteristics. It mentions only using the axial compressive load at the set point of 710 N. Thus, the current research work aims to clarify the differences in constraint test results when applying two axial compressive load characteristics during testing.

2. Materials and Methods
The tests will be done in similarity with the ASTM-F1223 (2014) standard. Any changes of standard have been highlighted in the sections that follow.

2.1 Test equipment setup
The six-axis testing machine (Prosim Universal Joint Simulator) was used as the testing machine. Fixtures were designed and were produced to be suitable with the femoral and the tibial components used in the study. After that, the femoral component and tibial component were mounted to the fixture using polymethylmethacrylate (PMMA) bone cement as shown in Figure 1. Then, the tibial insert was locked up on the tibial tray as shown in Figure 1.
Later, fixture mounted with the femoral component was installed to the top part of the testing machine, which the flexion angle and varus-valgus (VV) rotation can be adjusted. Also, the tibial component mounted on fixture was installed on the lower part of the testing machine that anterior-posterior (AP) translation, medial-lateral (ML) translation, and internal-external (IE) rotation can be controlled. All the setting of the parts on testing machine is shown in Figure 2.

In the next step, the determination of neutral point of the tibial component relative with femoral component was set up. In neutral point setup, the 100 N axial compressive load was applied to the TKR. Then, tibial component was moved in AP direction. The lowest point of the tibial insert compared to femoral component was noticed. The lowest point is assigned to be the neutral point. Then, the pressure film was inserted between the femoral component and the tibial insert to identify the contact point where femoral component touch to tibial insert at difference flexion angles. The contact point measurement technique with pressure film was presented in TMETC12 [5].

For determining AP displacement limit, which was used to program in controlling the test, manual AP movement in both AP forward and backward direction of the tibial component withholds others movement direction was done. The AP movement was continuously done until the conditions of 1) slightly increasing or decreasing AP load with increasing displacement and 2) dramatically AP load
change. The maximum movement in forward and backward AP direction is assigned to constraint limit of AP movement. The determining AP limit of the TKR with 0°, 30°, 60° and 90° of knee flexion angles were shown in Table 1.

### Table 1. The AP displacement limit

| Knee flexion angles | Anterior translation (mm) | Posterior translation (mm) | Total displacement (mm) |
|---------------------|----------------------------|----------------------------|-------------------------|
| 0°                  | +1                         | -3                         | 4                       |
| 30°                 | +3.6                       | -7                         | 10.6                    |
| 60°                 | +9                         | 0                          | 9                       |
| 90°                 | +3                         | 0                          | 3                       |

2.2 **Implant & Lubrication**

The constraint test was conducted on fix bearing posterior substituted (FB PS) system of TKR. The TKR used had the symmetrical condylar geometries. The lubrication used was the bovine serum.

2.3 **Test method**

Before testing, bovine serum was applied onto the tibial insert surface [6]. In the constraint test, two experiments; 1) experiment to examine the hysteresis loop of AP load resistance and 2) experiment to determine AP constraint were carried out. Two experimental conditions 1) Control axial load to be at 710 N during the initial setting and during the test (load-controlled test), and 2) fix axial displacement after setting axial load at 710 N during the initial setting (displacement-controlled test) were studied.

For examine the hysteresis loop of AP resistance load, the AP displacement limit was applied and was used to program the machine. The AP motion rate during the test is 1 mm/sec and other movement direction is prohibited during the test. The AP resistance load correlated with movement distance was obtained and was used to construct the hysteresis loop of AP resistance load. After that, determining AP constraint was measured from the hysteresis loop base on the slope of the curve became constant or change dramatically

3. **Results and Discussion**

3.1 **The contact point of TKR at various flexion angles**

The contact point of various flexion angles was defined with the red area on the film as shown in Figure 3.

![Figure 3](image-url)
From Figure 3, the tibial insert shape was also mapped to tested film in order to recognize the position of contact area on TKR. At $0^\circ$ flexion angle, the contact point is near to the anterior side of tibial insert, while increasing the flexion angle, the contact point was moved closer to the posterior side.

3.2 The hysteresis loop of AP resistance load

Before going to the AP resistance load result, the axial compressive load in both testing conditions with different test angles during the test is revealed as shown in Figure 4.

![Figure 4. The axial compressive load during the test; (a) 0° flexion angle, (b) 30° flexion angle, (c) 60° flexion angle and (d) 90° flexion angle](image)

From Figure 4, the characteristics of axial compressive load in two test conditions are not similarity. In load-controlled test (Orange line), the constant load characteristic throughout the test was observed, while displacement-controlled test (Blue line) gives the fluctuation of axial load characteristic. From axial load characteristic result, we could refer that two test conditions were successes controlled. Moreover, in the displacement-controlled testing, the fluctuation of axial load was occurred because the femoral component was fixed in the axial position during test, and when it was moved on the curve of tibial insert the axial load was changed. On the other hand, the load-controlled testing provides the constant axial load compressive because automatically adjusted by machine.

The hysteresis loop of AP resistance load was the plot between AP displacement and AP resistance. The hysteresis loop of AP resistance load for the tests as shown in Figure 5. From Figure 5, the hysteresis loop of load-controlled test (Orange line) was a significantly narrower span than that of the displacement-controlled test (Blue line). Moreover, it can be seen that, in the displacement-controlled test mode, the AP resistance load is higher magnitude than that of the load-controlled test mode in both forward and backward movement. It is due to that the higher axial compressive load acting on the TKRs results in increasing the friction between femoral component and tibial insert and finally affects to increase AP load resistance force.

3.3 The AP constraint

Determination of the AP constraint was performed with using the hysteresis loop of AP constraint. According to the ASTM stipulates, “dislocation of the components is imminent. . . or if a dangerous or unrealistic situation is about to occur was mention”. Then, the AP constraint was defined as the point at which the force-displacement graph started to plateau or overshoot (the slope of the curve became constant or dramatically change) as also shown in Figure 5. The constraint evaluation was manually chosen.
Figure 5. Determination of AP constraint; (a) 0° flexion angle, (b) 30° flexion angle, (c) 60° flexion angle and (d) 90° flexion angle

For example, in Figure 5(a), the blue dash line with red arrow was assigned by the dramatically change of slope of graph. The blue line indicates the constraint in the moving direction. The AP constraint results are summarized in Table 2. From Table 2, at 0 flexion angle, the total movable length in AP direction of TKR is 4 mm for load-controlled test and 3.2 mm for displacement-controlled test. When increasing flexion angle, the total movable length in AP direction was increasing until flexion angle of 30°. Then, when higher than 30° flexion angle was used to study, the total movable length in AP direction was reducing. Moreover, the trend of total movable length in AP direction various with flexion angle from both test condition is similar.

Table 2. The AP constraint results

| Knee flexion angles | Anterior translation (mm) | Posterior translation (mm) | Total translation length (mm) |
|---------------------|---------------------------|----------------------------|------------------------------|
|                     | Load controlled | Displacement controlled | Load controlled | Displacement controlled | Load controlled | Displacement controlled |
| 0°                  | +1            | 0.7                      | -3             | -2.5                    | 4              | 3.2                        |
| 30°                 | +3.6          | 2.8                      | -7             | -6                      | 10.6           | 8.8                        |
| 60°                 | +9            | 8                        | 0              | 1                       | 9              | 7                          |
| 90°                 | +3            | 2.7                      | 0              | 0.5                     | 3              | 2.2                        |

However, it found that the AP constraint in case of the load-controlled test is narrower than the displacement-controlled test in all test flexion angles. It is to that the fluctuation of axial compressive load in case of displacement-controlled test effect on easier change in AP load resistance.

4. Conclusion

According to the results, the tests with different axial load characteristics gave different constraint results of total knee replacement. Mostly, the displacement-controlled test gives a higher constraint than the load-controlled test mode, even though the same TKR was used. Thus, in order to correctly understand constraint results, the remarks of axial load type (constant/non-constant) should be included in constraint test reports, for the correct consideration of surgeons.
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