Original Article

Strain measurements of the tibial insert of a knee prosthesis using a knee motion simulator

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ABSTRACT

Objective: The longevity of a knee prosthesis is influenced by the wear of the tibial insert due to its posture and movement. In this study, we assumed that the strain on the tibial insert is one of the main reasons for its wear and investigated the influence of the knee varus-valgus angles on the mechanical stress of the tibial insert.

Methods: Knee prosthesis motion was simulated using a knee motion simulator based on a parallel-link six degrees-of-freedom actuator and the principal strain and pressure distribution of the tibial insert were measured. In particular, the early stance phase obtained from *in vivo* X-ray images was examined because the knee is applied to the largest load during extension/flexion movement. The knee varus-valgus angles were 0° (neutral alignment), 3°, and 5° malalignment.

Results: Under a neutral orientation, the pressure was higher at the middle and posterior condyles. The first and second principal strains were larger at the high and low pressure areas, respectively. Even for a 3° malalignment, the load was concentrated at one condyle and the positive first principal strain increased dramatically at the high pressure area. The negative second principal strain was large at the low pressure area on the other condyle. The maximum equivalent strain was 1.3–2.1 times larger at the high pressure area. For a 5° malalignment, the maximum equivalent strain increased slightly.

Conclusion: These strain and pressure measurements can provide the mechanical stress of the tibial insert in detail for determining the longevity of an artificial knee joint.

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1. Introduction

Total Knee Arthroplasty (TKA) is a successful surgical treatment with knee prostheses and can relieve pain and enable recovery from knee deformability for severe knee injury patients such as those suffering from osteoarthritis and rheumatoid arthritis. A greater than 90% implant survival rate at 10 to 15 years has been reported. Unfortunately, a significant number of failures occur due to the severe *in vivo* mechanical environment, thus requiring

revision surgeries.¹ The alignment of the knee prosthesis during replacement surgery can affect its long-term lifetime. A knee prosthesis consists of a femoral component, tibial component, and polyethylene tibial insert. Malalignment of the tibial component alters the distribution of tibial loading, resulting in increased shear forces and wear at the tibiofemoral interface. According to clinical reports, a tibial malalignment of >3° varus increases the risk of medial bone collapse² and causes an 11 times higher failure rate in TKAs with varus tibial malalignment.³ Furthermore, an increase of 1.2 times in the wear of implants mounted with a >3° varus malalignment has been reported using an *ex vivo* knee wear simulator.⁴ Therefore, the tibial component should be placed in neutral alignment.⁵ The femoral component has the medial and

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lateral condyles, and the load is balanced between the two condyles during a normal gait cycle. However, with as little as a 3° variation in alignment, the pressure distribution and total load in both condyles changes significantly.⁶ In particular, the tibial forces may determine the wear of polyethylene, the stress distribution in the implant, and the stress transfer to bone. Previously, the tibial forces were measured using a strain gage embedded in the stem of a tibial component with a knee simulator⁷ and *in vivo*.^{8,9} However,

the stress of the surface between the polyethylene tibial insert and the femoral component should be more important when considering the wear of polyethylene.

In this study, we focused on the strain as one of the main reasons for the wear of polyethylene and investigated the mechanical stress of the tibial insert at a neutral alignment and during varus-valgus malalignment. In the experiment, a mobile-bearing knee prosthesis was mounted on a knee motion simulator

Fig. 1. Artificial knee joint simulator. (A: mobile-bearing left knee prosthesis, B: Schema, C: Artificial knee joint, D: 3-axis strain gages on the back side of the tibial insert, E: Artificial knee joint with a pressure sensor between the tibial component and the tibial insert.)

based on a parallel-link 6 degrees-of-freedom (DOF) actuator. The early stance phase of the knee motion obtained from X-ray *in vivo* images was simulated because the knee is applied to the largest load during extension/flexion movement. Particularly, assuming that the tibial insert is a thin plate under plane stress, we measured the principal strain and the pressure distribution of the tibial insert of a mobile-bearing knee prosthesis using the tri-axial strain gages and the thin film pressure sensor between the tibial component and tibial insert, respectively.

2. Methods

A mobile-bearing left knee prosthesis (Teijin Nakashima Medical Co., LTD. Japan) was used in this study (Fig. 1A). This mobile-bearing prosthesis exhibits good congruity and mobility at the tibio-femoral bearing surface, and provides a low contact stress and constraint force, resulting in improving the wear resistance. Additionally, it also solves the kinematic contact of a fixed-bearing knee.¹⁰ Furthermore, the tibial insert has a raised surface with an internal post that fits into the femoral component and substitutes for the posterior cruciate ligament. When the medial and lateral condyles of this prosthesis are compared, the tibial insert geometries are the same. However, the femoral component is different and the contact area is larger at the lateral condyle.

Fig. 1B shows the knee motion simulator, which is mainly based on a parallel-link 6 DOF motion base with hydraulic actuators (Tokyo Simitu Sokki, Japan).^{11–13} The femoral and tibial components were fixed to acrylonitrile butadiene styrene (ABS) femoral and tibial bone models (Fig. 1C) and then mounted on the simulator. Assuming that the tibial insert is a thin plate under plane stress, the strains (ε_a , ε_b , ε_c) were measured using three tri-axial strain gages (KFG-1-120-D17-11N30C3, Kyowa, Japan) placed on the surface of each condyle at every 10 mm distance in the X direction between the tibial insert and the tibial component (Fig. 1D). To neglect the thickness of the strain gage as much as possible, the tibial component with the strain gages was covered entirely with a thin film. The first and second principal strains (ε_1 and ε_2), direction (θ), and shear strain (γ) were calculated from the strains (ε_a , ε_b , ε_c) using the following equations based on the Rosette theory:

$$\varepsilon_1 = \frac{1}{2} \left[\varepsilon_a + \varepsilon_c + \sqrt{2 \left\{ (\varepsilon_a - \varepsilon_b)^2 + (\varepsilon_b - \varepsilon_c)^2 \right\}} \right],$$

$$\varepsilon_2 = \frac{1}{2} \left[\varepsilon_a + \varepsilon_c - \sqrt{2 \left\{ (\varepsilon_a - \varepsilon_b)^2 + (\varepsilon_b - \varepsilon_c)^2 \right\}} \right],$$

$$\theta = \frac{1}{2} \tan^{-1} \frac{2\varepsilon_b - \varepsilon_a - \varepsilon_c}{\varepsilon_a - \varepsilon_c},$$

$$\gamma = \sqrt{2 \left\{ (\varepsilon_a - \varepsilon_b)^2 - (\varepsilon_b - \varepsilon_c)^2 \right\}},$$

$$\varepsilon_{VON} = \sqrt{\varepsilon_1^2 + \varepsilon_2^2 - \varepsilon_1 \varepsilon_2}.$$

In particular, we assumed that the tibial insert was a thin plate under plane stress and calculated the equivalent stress (ε_{VON}). The pressure was measured using a digital electronic stress sensor (K-Scan, Tekscan Inc., US) placed between the tibial insert and the tibial component (Fig. 1E). For strain and pressure measurements, the sampling rate was set to 100 Hz.

To achieve the motion of an artificial knee *in vivo*, this simulator was controlled based on the three-dimensional kinematics of femoral and tibial components obtained using X-ray images during walking,¹⁴ such as adduction/abduction rotation around the X axis, extension/flexion rotation around the Y axis, internal/external rotation around the Z axis, posterior/anterior movement in the X axis direction, medial/lateral movement in the Y axis direction, and up/down movement in the Z axis direction (Fig. 1). We assumed that the walking speed was low and particularly focused on the early stance phase of knee motion because the knee is applied to the largest load during extension/flexion movement (Fig. 2). Therefore, the maximum flexion angle was less than 15°. A compressive posterior load of 1.0 kN, parallel to the tibial surface, was applied, and the knee varus-valgus angles were 3° and 5° in addition to the neutral position (0°).

3. Results

First, we evaluated the accuracy of the displacement and angle of the simulator. For displacement accuracy, markers attached to the simulator were imaged using two cameras (Procilica, Japan) during sinusoidal motion with a 10 mm amplitude. Angular accuracy was measured using a three-axis angle sensor (GU3025, Datatec, Japan) during sinusoidal motion with a 5° amplitude. The results show that the maximum displacement and angular errors were 1.0 mm and 0.2°, respectively. Next, the contact stress was measured to confirm the alignment of the artificial knee simulator. The bodyweight was assumed to be 1.0 kN and the loading conditions were heel strike (5.5° flexion) and toe-off (4.5° flexion). The stresses were 13.4 and 13.5 MPa, respectively, which are similar to those from a previous study (14.1 ± 2.5 MPa) using cadaver knee joints and a knee simulator.¹⁵

For neutral and 3° varus alignments during the early stance phase, Figs. 3 and 4 show the strain at the middle of the lateral condyle and medial condyle, respectively. The strain did not remain constant during knee motion. For neutral alignment, the highest value of ε_1 was observed at maximum flexion ($t/T=0.5$) for the medial condyle. However, it occurred during flexion ($t/T=0.2$) for the lateral condyle. Varus and valgus malalignments affect the strain. In particular, ε_1 increased dramatically. The trend of γ was similar with that of ε_1 for neutral alignment and varus-valgus

Fig. 2. Early stance phase of femoral insert kinematics.

Fig. 3. The strains (ε_1 , ε_2 , γ , and θ) at the middle of the medial condyle during the early phase of a single stance. (A: Neutral, B: Varus 3°.)

Fig. 4. The strains (ε_1 , ε_2 , γ , and θ) at the middle of the lateral condyle during the early phase of a single stance. (A: Neutral, B: Valgus 3°.)

malalignment; it increased with malalignment. There is a big difference in the principal strains during flexion ($0 < t/T < 0.5$) and extension ($0.5 < t/T < 1.0$), indicating that the tibial insert of the mobile-bearing prosthesis may move during knee motion.

Fig. 5(A) shows the strain and pressure distributions of the tibial insert for neutral alignment. The pressure was higher at the middle and posterior of each condyle. Regarding the strain, the positive ε_1 was higher in the high pressure area. In contrast, the negative ε_2 was higher in the low pressure area of the anterior condyle. Fig. 5(B) shows the strain and pressure distribution of the tibial

insert for 13.7° flexion during varus-valgus malalignment. Even for a 3° malalignment, the load was supported mainly at one condyle. A low pressure area was observed at the posterior of the lateral condyle for 3° varus malalignment; this area was seldom observed for a 5° varus malalignment. For valgus malalignment, a low pressure area was observed at the middle and posterior of the medial condyle. At the other condyle where the load was concentrated, the contact area and the high pressure area (>4.0 MPa) increased. Additionally, at the high load condyle, the positive ε_1 increased dramatically; on the other hand, the negative

Fig. 5. Pressure distribution and principal strain during the early phase of a single stance. (A: In neutral alignment, B: In the varus-valgus position at 13.7° flexion.)

Fig. 6. Maximum equivalent strain at the medial and lateral condyles for neutral alignment and malalignment during the early phase of a single stance.

ε_2 increased at the other condyle. In comparison with neutral alignment, for 3° varus malalignment, ε_1 increased by 1.5 times and 2.0 times at the central and posterior condyle, respectively. In addition, for 3° valgus malalignment, ε_1 increased by 2.7 times and 1.9 times at the central and anterior condyle, respectively. For 5° malalignment, the high pressure area and principal strain increased when compared with 3° malalignment. However, the increment ratio was smaller than that between neutral alignment and 3° malalignment. The ε_1 direction at the high pressure area was between the anterior-posterior and lateral-medial directions for both 3° and 5° malalignments. Fig. 6 shows the maximum ε_{VON} during the early phase of a single stance. For neutral alignment, it was relatively constant at the medial and lateral condyles, although it was slightly smaller at the posterior of the medial condyle. In comparison with neutral alignment, valgus malalignment increased ε_{VON} at the lateral condyle by 1.3 and 1.5 times at the posterior for 3° and 5° valgus malalignments, respectively, and by 1.6 times at the middle. Similarly, varus malalignment increased ε_{VON} at the medial condyle by 2.1 and 1.5 times at the posterior for 3° and 5° varus malalignments, respectively, and by 1.5 times at the middle.

4. Discussion

In this study, we measured the pressure and strain distributions of the tibial insert using an *ex vivo* knee simulator to investigate the mechanical stress of the tibial insert at a neutral alignment and during varus-valgus malalignment. Previously, several studies reported the pressure distribution of the tibial insert not only *in vivo*^{8,16} and *ex vivo*^{6,17–19} experiment but also numerical simulation.^{20–23} In this study, the maximum pressure increased by 1.7 times at 13.7° flexion for 5° varus malalignment, which is consistent with a previous report that the maximum pressure increased by 1.5 times at 15° flexion.¹⁸ In addition, in this study, we hypothesized that the strain of tibial insert was as one of the main reasons for the wear of polyethylene.

Our results show that the positive ε_1 and negative ε_2 were higher at the high and low pressure areas, respectively, for neutral alignment and varus-valgus malalignment. At the anterior of the medial condyle, the pressure was very small (<1.0 MPa), even for 3° varus malalignment (Fig. 5). Furthermore, both ε_1 and ε_2 did not increase. As a result, the maximum ε_{VON} did not increase (Fig. 6). However, at the other area, the maximum ε_{VON} increased at the condyle where the pressure increased for malalignment. Even for a 3° malalignment, the load was supported at one condyle and the high pressure area increased (Fig. 5). As a result, the tibial insert

was compressed by the femoral and tibial components and the strain would be induced vertically with respect to the bone axis. The maximum ε_{VON} for 5° malalignment increased when compared with 3° malalignment. However, the increment was not larger than that between neutral alignment and 3° malalignment. Even for 3° malalignment, the load was already supported at only one condyle. The pressure of this condyle increased slightly for 5° malalignment. However, the strain did not increase because the contact area and high pressure area remained stable during flexion. According to clinical data, the factors associated with medial bone collapse are varus tibial component malalignments of more than 3°. Our results show that the strain increased dramatically with a malalignment of at least 3°.

The tibial insert of the mobile-bearing prosthesis is not fixed to the tibial component and circumnutation can be allowed during flexion. Previous studies reported that the tibial insert rotated slightly even for a single stance with a high load.^{7,9} In this study, the tibial insert may also have rotated, resulting in the strain being different between extension and flexion. Additionally, there is a difference in the geometry of the femoral component between the medial and lateral condyles, and the contact area is larger for the lateral condyle than the medial condyle. Consequently, the contact area with a low pressure (>1.0 MPa) was larger at the lateral condyle and that with a high pressure (>3.0 MPa) was larger at the medial condyle.

In this study, assuming that the tibial insert is a thin plate under plane stress, we placed strain gages between the tibial component and tibial insert to measure the strain of the tibial insert. The wear of the tibial insert is basically caused by friction with the femoral component. First, we tried to place the strain gages between the tibial insert and the femoral component. However, the gages themselves were worn out. In the future, the strain gages should be embedded into the tibial insert.²⁴ In previous studies, the tibial insert was lubricated with bovine serum⁴ or petroleum jelly²⁵ during the measurements. The condition of the lubricant is important because the mobile-bearing prosthesis can be allowed to move during flexion and extension. However, in this study, we examined the early phase of a single stance, where the movement of the tibial insert is considerably small. Therefore, the effect of a lubricant was ignored.

5. Conclusion

In this study, we simulated the motion of a knee prosthesis during the early phase of a single stance using a motion simulator and evaluated the strain and pressure of the tibial insert for varus-valgus malalignment. The motion accuracy of our simulator was 1.0 mm and 0.2° and the simulator was controlled based on X-ray *in vivo* Images.¹⁴ The load was supported by only one condyle even for a 3° malalignment and the maximum equivalent strain increased dramatically at the high pressure area, which may increase the risk of the polyethylene tibial insert.

Conflict of interest statement

The authors have none to declare.

Ethical approval

This study does not contain any studies with human and animals participants performed by any of the authors.

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