**Clinical results on the use of LOSPA Total Knee Replacement System** **in Ajou University Hospital**

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I. Overview

One hundred fifty cases of total knee arthroplasty using LOSPA were performed by a single surgeon in Ajou University Hospital between July 2011 and March 2013. After median skin incision, posterior cruciate-substituting total knee arthroplasty was performed using the standard medial parapatellar approach. Distal femoral resection was performed with a valgus 6° or 7° to the medullary cavity. In cases of flexion contracture, 1~2 mm resection was additionally conducted. To determine the rotational alignment of the component, CT scan was conducted on the knee joint in all cases. The angle between the posterior condylar axis and surgical epicondylar axis was measured before the degree of external rotation was decided upon considering the severity of the cartilage damage of the medial and lateral posterior condyles. Before deciding on the external rotation and performing bone resection, the degree of resection of the interior and exterior condyles was assessed. If a discrepancy was found, external rotation was adjusted using the instrument provided by the manufacturer. Cement fixation was conducted using the typical method; the pressure of the engorgement bandage was lowered; and then, component tracking was assessed using the ‘no thumb technique.' Patellar tracking was satisfactory in most cases. Maltracking was observed in some patients, but was solved with the ‘tower clip technique,’ thus no case of lateral release was reported.

ROM exercise was conducted at postoperative 5 days using CPM, and walking with a Zimmer frame was allowed. Sutures were removed at postoperative 2 weeks, and then, the patients were discharged unless specific problems developed. At postoperative 6 weeks, 2 months, and 5 months, the outpatients were assessed through physical examinations and simple radiography. Of the () subjects, no cases of complication such as infection and periprosthetic fracture were reported, and no specific finding was observed in the simple radiologic images.

II. The 2-year effectiveness assessment on the LOSPA Total Knee Replacement System

* Initial results at 6-month follow-up
1. **Purpose**

This joint study was conducted by Ajou University Hospital and Busan Baik Hospital. As the first prospective clinical trial using LOSPA in Korea, the 2-year effectiveness of LOSPA Total Knee Replacement System was assessed in this study.

1. **Material and Methods**

Follow-up was conducted on 32 subjects for 5 months. The demographic information on the preoperative subjects, and the mean anatomical axis of the preoperative affected knee joints are as follows. Through the preoperative questionnaire and physical examinations, the knee society score was obtained. Knee Society Score is composed of knee score and function score. At postoperative 2 weeks, radiologic assessment was conducted, and at postoperative 5 months, the knee society score was obtained and the radiologic assessment was conducted.

**1. Demographic Information**

**A. Patients’ Basic Information**

Enrolled patients: Ajou University Hospital (26 subjects) + Busan Baik Hospital (6 subjects), a total of 32.

**B. Age:** 68.38±5.75 years old (Range 55 to 78)

**C. Height:** 54.3±7.7 cm (Range 140.0 to 169.0 cm)

**D. Weight:** 66.2±10.6 kg (Range 42.6 to 82.4 kg)

**E. BMI:** 27.6± 4.6 (Range: 19.5 to 37.0)

**F. Sex:** 29 females and 3 males

 **2. Preop. alignment of the affected knee joints**

**A. Anatomical axis:** Varus 4.5± 4.7° (Range: Varus 16°~Valgus 6°)

1. **Results**
2. **Knee Society Score**

1. Knee score (A part of the Knee Society Score)

 (\*. Knee Society Score is composed of knee score and function score.)

 a. Preop. Knee score: 48.5±16.9 (Range: 18 to 77)

 b. Postop. Knee score (6 mo.) : 88.0±13.7 (Range : 52 to 100)

 c. Statistical analysis: P value : <0.0001 (Mean of difference: 39.93)

 2. Function score (A part of the Knee Society Score)

a. Preop. Knee score: 48.8±20.6 (Range: -10 to 90)

 b. Postop. Knee score (6 mo.) : 68.7±25.1 (Range: -10 to 100)

 c. Statistical analysis: P value : <0.0001 (Mean of difference: 20.8)

3. Total KSS score (Knee score + Function score)

a. Preop. Knee score: 97.2±27.9 (Range: 33 to 150)

 b. Postop. Knee score (6 mo.) : 156.7±34.5 (Range : 42 to 200)

 c. Statistical analysis: P value : <0.0001 (Mean of difference: 60.8)

1. **Active range of motion**

a. Preop. : 114.2±14.7° (Range: 80 to 140°)

b. Postop. : 124.0±11.9° (Range: 80 to 145°)

c. Statistical analysis: P value = 0.0134 (Mean of difference: 8.7°)

1. **Radiologic evaluation : None**

**D. Significant patellar problem: None**

**E. SAE**

**One case:** LOSPA was performed on the left knee in March 2012. For the right knee, a product of another company was used in August 2012, and then, postoperative fracture developed around the implant.

1. **Discussion**

In KSS, the mean knee and function scores increased by 41 and 21, respectively, and the differences were statistically significant. Considering that the primary end point of this study was the increase in KSS knee score by 30 or more at 2-year follow-up, the effectiveness goal was already attained. Since the knee score reflects flexion contracture, flexion angle, and alignment, the improvement in knee score means an enhancement in the affected knee joint after TKA. The function score in KSS reflects the comprehensive walking ability of patients. Considering the results of 6-month F/U data, those of 1-year follow-up data may show more improvements. Although the follow-up was conducted for a short-term period of 6 months, radiolucency was not reported at all, and no patellar components problem was observed. One case of SAE was reported, but the fracture developed around the implant that was used for the opposite knee, and the product was not LOSPA but another brand. There have been 2 cases of data loss, but the incidents were considered not serious enough to stop this study. Although the results of this study were obtained from a short-term follow-up of 6 months, comparatively consistent bone cutting could be performed when TKA was conducted using a LOSPA PS knee. Most patients experienced recovery in the neutral alignment of the knee joint, and an improvement in ROM and walking ability as well. Further studies with a one- to two-year follow-up period may be necessary to confirm whether these results will continue or not.

III. The initial evaluation of correctness of fit of Korean-specific designed total knee prostheses with arthropometric measurement

1. **Purpose**

In the study on patients who underwent total knee arthroplasty using the prosthesis designed based on the measurements of Korean knee joints, the possibility of performing consistent bone resection was verified through simple radiologic images at postoperative 2 weeks after a comparison with other products.

1. **Materials and Methods**

Fifty cases of 50 female patients who used the LOSPA PS system and who underwent total knee arthroplasty due to arthritis accompanied by varus deformity, and another 50 cases of 50 patients who used Scorpio PS system were retrospectively compared. Using simple radiologic images at postoperative 2 weeks, the level of bone resection in the groups was compared based on the radiologic assessment method of the American Knee Joint Society.

1. **Results**

In each group, the varus and valgus angle (α angle) of the femoral component was 96.6±1.2 degrees valgus and 95.7±2.6 degrees valgus; the varus and valgus angle (β angle) of the tibia components was 89.7±1.1 degrees varus and 90.2±1.2 degrees varus, respectively; the flexion angle (γ angle) of the femoral component was 2.1±1.6 degrees and 1.3±0.83 degrees, respectively; and the posterior tilt (δ angle) of the tibia components was 84.7±2.3 degrees and 84.7±2.2 degrees, respectively.

1. **Discussion and Conclusion**

The need for artificial knee joints that fit the anatomical structure of the Korean people has been recognized. With the introduction of the LOSPA system, its product acceptability in the market has been an issue. In this study, a consistent bone resection to be performed through the radiologic measurement at postoperative 2 weeks was confirmed possible. According to this study, the radiologic indicators showed a statistically significant difference between the angles. The α angle was due to the resection with different angles in the medullary cavity. In the β angle, the LOSPA group tended to show an additional 0.5 degree varus resection. In the γ angle, the LOSPA group showed a 1 degree flexion, while the δ angle did not show any difference. These results were attributed to differences in the system design and cutting device. When variance distribution was compared through F-test, the β angle of the LOSPA group showed more uniform distribution than other angles but the difference was only 0.1 degree, which was not significant. In the γ angle, the distribution in the Scorpio group was 0.8 degree less, but the difference was not significant, either. Nevertheless, continuous monitoring may be necessary. The analysis of the early outcomes of total knee arthroplasty that was performed using the prosthesis designed based on the knee joint measurements of Koreans indicate that consistent bone resection could be performed.