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# Lospa 와 Scorpio NRG 고굴곡형 인공 슬관절 전 치환술의 2 년 추시 결과의 비교

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# Comparison of Two Year Follow-Up Results in High Flexion Total Knee Arthroplasty with Lospa and Scorpio NRG

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**Purpose:** The purpose of this study is to evaluate the clinical and radiologic results after high flexion Lospa (Corentec Inc.) and Scorpio NRG (Stryker Inc.) total knee arthroplasty.
**Materials and Methods:** We prospectively compared 205 knees in 128 patients who underwent arthroplasty using Lospa (group A) and 164 knees in 102 patients who underwent arthroplasty using Scorpio NRG (group B) from September 2010 to March 2012 at Department of Orthopaedic Surgery, Sun General Hospital (Daejeon, Korea). Mean follow-up period was 23 months in group A and 24 months in group B. The radiologic analysis included the change of mechanical axis deviation and femoro-tibial angle, implant position ($\alpha$, $\beta$, $\gamma$, $\delta$), and patellar tilt. The clinical results were evaluated according to hospital for special surgery (HSS), knee society score (KSS), and range of motion.
**Results:** Mechanical axis deviations were change in varus from 34.8 mm to 2.6 mm (p=0.02) in group A, and change in varus from 34.3 mm to 3.1 mm (p=0.04) in group B; no statistically significant difference was observed between them (p=0.13). Femoro-tibial angles were varus $4.3^0$ to valgus 6.6° (p=0.02) in group A, and varus $4.4^0$ to valgus $6.5^0$ (p=0.03) in group B; no significant difference was observed between them (p=0.25). No significant difference in implant position was observed between the two groups (p=0.25 in $\alpha$, p=0.17 in $\delta$, $\beta$=0.12 in $\gamma$, p=0.17 in $\delta$). Mean HSS improved from 48.5 to 93.6 (p=0.02) in group A, and from 41.4 to 94.4 (p=0.01) in group B.
**Conclusion:** Lospa total knee arthroplasty showed excellent early radiologic, clinical results and no statistically significant difference in the results was observed between Lospa and Scorpio NRG.

**Key words:** total knee arthroplasty, high flexion, Lospa

## Introduction

The purpose of total knee arthroplasty is to relieve pain with maximum recovery of joint functions and kinetics to those of healthy knee joints.

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Conventional treatment designs have sufficiently recovered the approximately 100-110º flexion angle required for daily activities. However, the increased expectations of patients about their post-treatment activities, such as sitting with their legs crossed or squatting, have necessitated a higher flexion angle of 110-130º, which has led to the demand for high-flexion designs. In the last few years, the rapid developments in designs and materials for knee arthroplasty have significantly improved the functions of prosthetic joints. In particular, many prosthetic products with various designs that minimize instability after surgery and improve the range of motions have been released by different manufacturers. Many studies have reported that the use of high-flexion prosthetic joint designs has produced results equivalent or superior to those of conventional designs in terms of stability and functions. High-flexion designs enable a more than 125º flexion by reducing the backside radius of the femoral component and increasing the offset of the

posterior condyle that increases the rollback and the posterior translation of the femur. Even if increased posterior offset reduces the risk of impingement due to the increased radius of the posterior femoral component and increases the range of motion, additional resection of the femoral bone negatively affects the preservation of bones. Some designs use excessive resection of posterior bones (12.5 mm) for high-flexion prosthetic knee joints to increase the offset upon flexion and the untoward results such as overhang of the posterior femoral component or loosening of the prosthesis when the increase in the actual offset is not confirmed. The Lospa (Corentec Inc., Cheonan, Korea) prosthetic knee has a single-radius femoral component with a medium degree of flexion stability. Its cam-post engagement at 75º enables smooth posterior translation of the femur while preventing its dislocation. With its high-flexion friendly design, its circular femoral component requires 10mm resection of the posterior femoral bones, and its wider and deeper patellar-femoral groove is favorably designed for high-flexion patella movement. Local researchers used the statistical results of osteoarthro measurements in Koreans to reduce the overhang of prostheses or disharmonized prosthesis sizes by minimizing the deviations of the anterior, posterior, left, and right joint sizes. This study was conducted to investigate the clinical and radiologic evaluations and the stability of Lospa, a newly developed prosthesis for total knee arthroplasty in South Korea, and to compare them with those of Scorpio NRG (Stryker Inc., Mahwah, NJ, USA), a high-flexion design product inserted in the posterior femoral area after 8mm posterior femoral resection and which has established functionality and stability. The authors of this study established the hypothesis that the clinical, radiologic, and stability results of Lospa are similar to those of Scorpio NRG, as they have similar design concepts.

## Subjects and Methods

A total of 128 patients (205 cases; Group A) were enrolled in this study from September 2010 to March 2012. The patients underwent total knee arthroplasty by the same surgeon using Lospa at the Department of Orthopedic Surgery of Daejeon Sun Hospital, and were followed up for more than two years. For the control group, 102 patients (164 cases; Group B) who underwent total knee arthroplasty using Scorpio NRG were enrolled during the same period and were also followed up for more than two years. The results of the two groups were prospectively compared. This study was approved by the Institutional Review Board (IRB) of Daejeon Sun Hospital. The mean age of the subjects in Group A was 69.5 years (range: 54.0-83.0), and in Group B, 70.5 years (range: 56.0-84.0). The mean follow-up period in Group A was 23 months (range: 16-34 months), and in Group B, 24 months (range: 16-38 months) (Table 1). All the cases in both groups were of the posterior cruciate ligament sacrificing type, for which a fixed polyethylene insert was used. The indications all pointed to Kellgrene-Lawrence Type IV regenerative disease, apart from one case of rheumatoid arthritis in each group. The body mass index in Group A before the surgery was 24.02 kg/m$^2$, and in Group B, 24.92 kg/m$^2$. The mean femora-tibial angle before the surgery in Group A was varus 4.3º (0.3-7.9º), and in Group B, varus 4.4º (0.1-10.6º). No significant difference was observed between the groups (p = 0.11).

**Table 1. Demography of Group A (Lospa) and Group B (Scorpio NRG)**

| Variable | GroupA(n=205) | Group B(n=164) I |
|---|---|---|
| Age(yi) | 69.5±14.0 | 70.5±14.9 |
| Gender (female/male) | 107/21 | 83/19 |
| Laterality (right/left) | 108/97 | 77/87 |
| Tibia-femoral angle (°) | Varus 4.3±3.8 | Varus 4.4±6.2 |
| Range of motion ($^3$) | 106.4±11.0 | 107.1±10.0 |
| Follow-up (mo) | 16-34 | 16-38 |

Values are presented as mean±standard deviation or number.

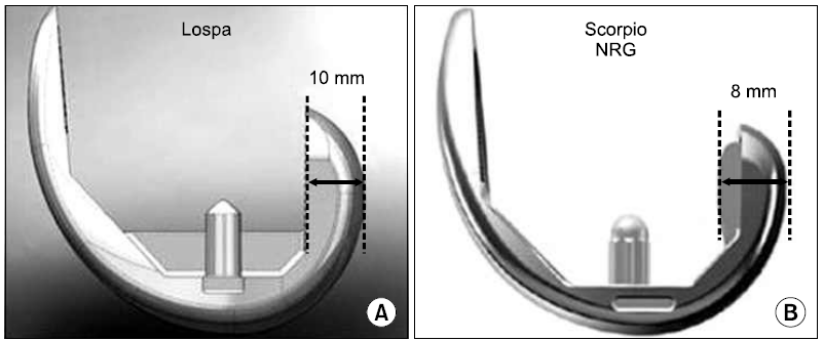


Figure 1. Deep flexion favoring design of (A) Lospa total knee arthroplasty requires cutting of the posterior condyle to 10 mm compared with 8 mm of (B) Scorpio NRG

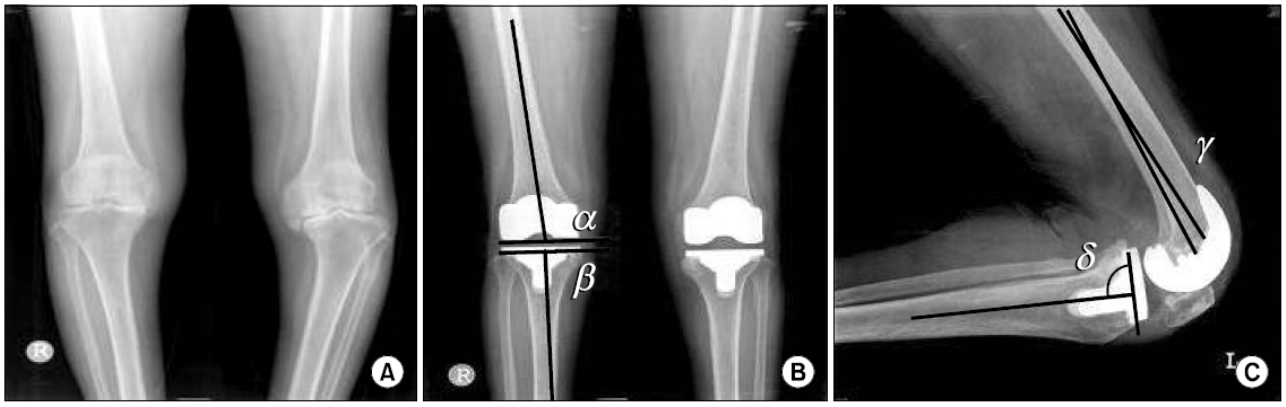


Figure 2. A 72-year-old female showed (A) advanced osteoarthritis on both knees with left knee subluxation. She underwent Lospa total knee arthroplasty and demonstrated well positioned implants. (B) The $\alpha$ angle was measured between the parallel to the femoral condyles and a line drawn along the femoral shaft axis. The 0 angle was calculated between the parallel to the tibial metal baseplate and a line drawn along the tibial axis shaft. (C) Whereas sagittal tibial $d$ and femoral $y$ angles were measured on lateral knee radiographs with the patient lying and the knee flexion.

The range of motion before the surgery in Group A was 106.4º (90-115º), and in Group B, 107.1º (95-116º). No significant difference was observed between the groups (p = 0.08). Both groups consisted of patients who underwent knee arthroplasty during the study period and patients who required a constrained prosthesis from their initial diagnosis as having had an unstable knee or an infection, or who had already undergone arthroplasty before they were excluded from this study. The prostheses were randomly selected regardless of the severity of the arthritis and the subject's age, sex, and BMI.

Only one surgeon performed all the surgeries. The flexion contracture of the knee and the maximum flexion angle were measured and recorded before the surgery for later clinical evaluation. The standard medial parapatellar approach was used for the surgery. The medial ligament was released in stages, and the tibia was resected first, followed by the femur, so that as much as possible, they would have identical flexion and extension angles. All the patients underwent patella replacement, apart from those with an 18mm or smaller patella. The prosthesis that replaced part of the patella, tibia, and femur was inserted using bone cement. The insert for the rear cruciate ligament substitution type was used for all the patients. The drainage tubes were removed from the patients two days after their surgery. All the patients were allowed to walk over the longest possible distance and to perform continuous passive motion exercise. An exercise to strengthen the quadriceps femoris muscles was also used.

Radiologic evaluations were used to measure the mechanical axis deviation and the change in the femoro-tibial angle before and after the surgery in both groups. For the implant position after the surgery, the varus (α) of the femur component and the valgus (β) of the tibial component were measured using anterior-posterior knee radiographs. The flexion angle (γ) of the femur component and the posterior tilt angle (δ) of the tibial component were also measured (Figure 2). For the radiologic evaluations of the patella movement, the classification of Bindelglass and Vince was used, and the patellar-femual position was expressed as central (< 5º), medial tilt (> 5º), and lateral tilt (> 5º) in Merchant's images. Clinical evaluations using a hospital for special surgery (HSS), the knee society score (KSS), and the change of range of motion before and after the surgery were conducted to compare the groups. The flexion contracture and the maximum flexion angle at the last observation point before and after the surgery were also measured for comparison.

The stability of the prostheses in both groups was evaluated using the type and frequency of the complications, including the instability after the surgery (coronal and sagittal), the limitation of the joint movements, infection, venous thrombosis or pulmonary embolism, and loosening or wear of the prostheses at the last evaluation point. The radiologic and clinical evaluation results were analyzed using an independent t-test and an $x^2$ test (SPSS version 12; SPSS Inc., Chicago, IL, USA), and the significance level (p) was set at 0.05 or less.

## Results

In the results of the radiological evaluations, the mechanical axis deviation showed that the mean medial deviations in Group A were 34.8 mm (range: 9.0-52.5 mm) before the surgery and 2.6 mm (range: 1.0-4.1 mm) (p = 0.02) after the surgery; and in Group B, 34.3 mm (range: 10.1-53.3 mm) before the surgery and 3.1 mm (range: 1.1-5.2 mm) (p = 0.04) after the surgery.

**Table 2. Comparison of Mean Mechanical Axis Deviation (MAD) and Tibia-Femoral (T-F) Angle in Group A (Lospa) and Group B (Scorpio NRG)**

| Variable | GroupA(n=205) | Group B (n=164) | p-value **1** |
|---|---|---|---|
| Preoperation MAD (mm) | 34.8 (9.0-52.5) | 34.3 (10.1-53.3) | 0.09 |
| Postoperation MAD (mm) | 2.6(1.0-4.1) | 3.1 (1.1-5.2) | 0.13 |
| p-value | 0.02 | 0.04 | |
| Preoperation T-F angle (°) | Varus 4.3 (0.3-7.9) | Varus 4.4(0.1-10.6) | 0.11 |
| Postoperation T-F angle 0 | Valgus 6.6(5.1-8.1) | Valgus 6.5 (5.5-8.6) | 0.25 |
| p-value | 0.02 | 0.03 | |

Values are presented as median (range).

**Table 3. Comparison of Mean Postoperative Implant Position in Group A (Lospa) and Group B (Scorpio NRG)**

| Variable | GroupA(n=205) | Group B(n=164) | p-value |
|---|---|---|---|
| α angle (°) | 96.3 (94.0-98.0) | 96.9 (95.0-99.0) | 0.25 |
| β angle 0 | 90.7(86.0-91.0) | 90.4(91.0-93.0) | 0.17 |
| γ angle 0 | 1.0(0.0-4.0) | 1.6(1.0-4.0) | 0.12 |
| δ angle 0 | 88.2 (86.0-90.0) | 89.5(86.0-91.0) | 0.17 |

Values are presented as median (range).

No significant difference between them was observed (p = 0.13). The mean femoro-tibial angles were varus 4.3º (0.3-7.9º) before the surgery and valgus 6.6º (5.1 -8.1º) (p = 0.02) after the surgery in Group A, and varus 4.4º (0.1-10.6º) before the surgery and valgus 6.5º (5.5-8.6º) (p = 0.03) after the surgery in Group B. No significant difference was observed between them (p = 0.25) (Table 2). The mean α, β, γ, and δ results were 96.3, 90.7, 1.0, and 88.2º in Group A, and 96.9, 90.4, 1.6, and 89.5º in Group B. No significant difference was observed between the groups (p = 0.25 in α, p = 0.17 in β, p = 0.12 in γ, and p = 0.17 in δ) (Table 3). For the implant position, in Group A, a deviation of 3.0º or more from the baseline positions (α = 96.0º, β = 90.0º, γ = 0.0º, and δ = 3.0º) was shown in one case each for the β angle (0.6%) and the γ angle (0.6%); and in Group B, in three cases each for the β angle (1.8%) and the γ angle (1.8%). One case in Group B showed a 3.0mm or greater mechanical axis deviation. Based on the classification of Bindelglass and Vince, in Group A, 126 cases (61.6%) showed a central patellar-femoral position; 79 cases (38.4%), a lateral tilt; and 0 case, a mesial tilt; and in Group B, 68 cases (41.5%) showed a central position; 94 cases (57.3%), a lateral tilt; and 0 case, a medial tilt. No significant difference between the groups was observed (p = 0.14).

In the joint performance scores, in Group A, the mean HSS results showed an improvement from 48.5 (range: 25.0-73.0) before the surgery to 93.6 (range: 78.0-98.0) at the last observation point (p = 0.02); and in Group B, from 41.4 (range: 22.0-71.0) before the surgery to 94.4 (range: 76.0-98.0) at the last observation point (p = 0.01). Both groups showed significant improvement, but no significant difference between the groups was observed (p = 0.12). The KSS results also showed improvement from 55.1 (range: 10.0-58.0) before the surgery to 93.4 (range: 62.0-98.0) at the last observation point (p = 0.03) in Group A, and from 55.6 (range: 11.0-59.0) before the surgery to 93.8 (range: 61.0-97.0) at the last observation point (p = 0.02) in Group B. Both groups showed significant improvements, but no significant difference between them (p = 0.12). The flexion contractures of the joints in Group A were 10.3º (0.0-30.0º) before the surgery and 4.0º (0.0-10.0º) after the surgery (p = 0.03); and in Group B, 13.1º (0.0-5.0º) before the surgery and 3.0º (0.0-13.0º) after the surgery (p = 0.01). Both groups showed significant improvements, but no significant difference between them (p = 0.11). For the range of motion, the angle from the maximum extension to the maximum flexion only up to the degree when the patient could actively extend his or her leg was measured using a goniometer. The mean results in Group A were 106.4º (90.0-1150.0º) before the surgery and 123.2º (110.0-136.0º) at the last observation point (p = 0.01); and in Group B, 107.1º (95.0-116.0º) before the surgery and 123.0º (105.0-135.0º) at the last observation point (p = 0.03). Both groups showed significant improvements but no significant difference between them (p = 0.16) (Table 4). One hundred twenty three cases (60%) in Group A and 26 cases (22%) in Group B showed a 130˚ or greater maximum flexion angle within four weeks after the surgery (mean angle: 132˚ in Group A, 131˚ in Group B), which was significantly different between the groups. In Group A, there were 176 cases (86%) of a 130º or greater maximum flexion angle at the last observation period; and in Group B, 103 (63%) cases. A significant difference between the groups was observed (p = 0.04). The mean durations of the compressed tourniquet use during the surgery were 45 minutes (40-85 minutes) in Group A and 48 minutes (42-88 minutes) in Group B. The mean amounts of blood lost were 714.2 ml (550-1,000 ml) in Group A and 737.3 ml (560-1,020 ml) in Group B.

**Table 4. Comparison of Mean HSS, KSS, and Average Range of Motion in Group A (Lospa) and Group B (Scorpio NRG)**

| Variable | GroupA(n=205) | Group B (n=164) | p-value |
|---|---|---|---|
| Preoperation HSS score* | 48.5 (25.0-73.0) | 41.4(22.0-71.0) | 0.17 |
| Postoperation HSS score* | 93.6 (78.0-98.0) | 94.4 (76.0-98.0) | 0.12 |
| Preoperation KSS score* | 55.1 (10.0-58.0) | 55.6(11.0-59.0) | 0.12 |
| Postoperation KSS score* | 93.4 (62.0-98.0) | 93.8(61.0-97.0) | 0.09 |
| Preoperation ROM$^{+}$ (°) | 106.4(90.0-115.0) | 107.1 (95.0-116.0) | 0.08 |
| Postoperation R0M$^{+}$ (°) | 123.2(110.0-136.0) | 123.0(105.0-135.0) | 0.16 |

Values are presented as 'median (range) or Average (range). HSS, Hospital for Special Surgery; KSS, Knee Society Score; ROM, range of motion.

The stability evaluation showed no instability in Group A until the last observation point, and one case of sagittal and coronal instability in Group B, to resolve which a thicker polyethylene by 2mm was inserted (polyethylene thickness: 10mm→12mm) at the re-operation. Three cases (0.15%) in Group A and three cases (0.18%) in Group B showed 100º or less limited joint movement four weeks after the surgery. Those patients underwent manual loosening of their stiff joint under anesthesia. After the procedure, one case in Group A showed 120º flexion, and two cases, 125º; whereas in Group B, one case showed 110º flexion, and two cases, 115º. No continuous venous thrombosis or embolism was observed at the last observation point in both groups, and no loosening of the implant or the polyethylene wear was observed in any case. One case in Group A showed infection, but it was resolved with a 125º maximum flexion angle after debridement at the last observation point.

## Discussion

High-flexion prosthesis for knee replacement requires patellar stability in its design. Many researchers have reported no significant difference between a standard prosthesis and a high-flexion prosthesis for knee replacement, but some of them have reported that the high-flexion prosthesis showed significant improvement in joint movement without significant complications in the early-stage evaluation than as the standard products.

Laskin, Kim, et al. reported no significant difference in the flexion angles of a conventional prosthesis and a high-flexion prosthesis. However, Huang et al. reported that the use of a high-flexion prosthesis can produce an extra 10º flexion angle. A high-flexion prosthesis requires additional resection of posterior femoral bones, and some researchers have reported that this additional resection may cause early loosening of the prosthesis. In particular, the loosening of the femoral component has significantly been reported in the medium stage during the follow-up period due to the repetitive stress on the joint from the high flexion. In addition, the preservation of the remaining bones is a challenge for re-operation, as is the survival of the implanted prosthesis after the re-operation.

LPS Flex (Zimmer Inc., Warsaw, IN, USA), a high-flexion prosthesis for knee replacement, requires 12.5mm posterior femoral resection, whereas Scorpio NRG, with its high-flexion design, requires 8.0mm resection. Lospa, the product used in this study, requires 10.0mm bone resection, which is between those of LPS Flex and Scorpio NGR. The conventional prosthesis for knee arthroplasty--i.e., given its anterior-posterior length and left-right width--sometimes does not fit the knee cap of patients in clinical practice, particularly of Oriental people so the selection of products has been challenge for those. The authors feel the Lospa prosthesis used in this study had a better fit, but it was not actually measured. Therefore, an additional study with size measurement is required. The anatomically designed femoral component and the improved patellar movement demonstrated by the Lospa prosthesis improved the joint junction of the contact surface, and its single-radius femoral component design minimized the instability during the flexion. The Lospa prosthesis enables more natural movement during exercise, such as while going up the stairs or standing up from a chair. The polyethylene component is designed to have a double radius and a posterior cut-off for optimal flexion, and the surface of the component is designed favorably for rotation, which helps with rotation movements of patella such as sitting cross-legged. This study is significant because it compared the early-stage radiologic and clinical evaluations of the newly released prosthesis, Lospa, with those of a well-established conventional prosthesis. However, the clinical and mechanical issues that may occur in the later stage should be followed up.

The implant positions of Lospa in the radiographs were expressed with the α, β, γ, and δ angles of 96.3, 90.7, 1.0, and 88.2º in Group A, which did not significantly differ from the results of other studies and from the results of Group B. Previous studies have not found significantly better results of the Scorpio NRG prosthesis than of other high-flexion prostheses for knee replacement. However, the

comparison with Scorpio NRG is considered significant because clinical experience of Scorpio NRG use abounds. A two-year follow-up period is not long enough, especially for the range of motion or the maximum flexion angle, and the results may change over time. However, this period was considered long enough for the evaluation of the efficacy of prostheses for knee replacement if the patient conditions were maintained. The mean ranges of motion in Group A were 106.4º (90.0-115.0º) before the surgery, and significantly higher, 123.2º (110.0-136.0º), at the last observation point. The results of Group A were similar or slightly higher than those of Group B: 107.1º (95.0-116.0º) before the surgery and 123.0º (105.0-135.0º) at the last observation point, and were considered meaningful. Interestingly, 123 cases in (60%) Group A but only 36 cases (22%) in Group B showed a 130º or greater maximum flexion angle in the early four weeks, which proved Lospa's excellent early recovery of the range of motion and its more high-flexion-friendly design. This result could also be used as evidence that Lospa's design is closer to that of a high-flexion prosthesis for knee replacement. This study did not find a significant difference between the radiologic and clinical evaluations of Group A and Group B. However, the central position of the patella in the axial patellar-femoral radiographs was observed more often in Group A (based on the classification of Bindelglass and Vince, there were 126 cases of central patella in Group A and only 68 cases in Group B), which was considered indicative of more stable patella movement in the patella-femoral joint in Group A even if the difference was not statistically significant. This result may also be interpreted as a factor of the reduction of the subluxation of the patella. The two groups had similar surgical duration and blood loss results, which were taken to mean that their other surgical conditions were similar.

The limitations of this study included its short follow-up period for the evaluation of the efficacy and safety of the prosthesis for knee arthroplasty, and its small sample size. As the grouping was determined by order rather than by randomization, it might have been insufficient for objective statistics. Moreover, the long-term stability issues of prostheses, such as their loosening, wear, instability, and long-term survival, could not be confirmed.

However, this study is considered meaningful because it prospectively analyzed and compared the early-stage evaluation results of a newly released prosthesis for knee arthroplasty with those of a conventional product with a similar design.

## Conclusion

Lospa, a high-flexion and single-radius design prosthesis for knee arthroplasty, was implanted by the same surgeon, and its radiologic and clinical results were compared with those of Scorpio NRG during the same study period. The two groups showed similar radiologic and clinical evaluation results. However, Group A showed a higher flexion of 130º or greater during the two-year follow-up period. Further studies should be performed to investigate the survival rate and the medium- and long-term clinical and radiologic evaluations of prostheses in a larger number of samples.

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# Lospa 와 Scorpio NRG 고굴곡형 인공 슬관절 전 치환술의 2 년 추시 결과의 비교

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**목적:** 고굴곡형 Lospa (Corentec Inc.)와 Scorpio NRG (Strylsr Inc.) 인공 슬관절 치환술을 시행하고 임상적 및 방 4 선적 결과를 평가하고자 한다.
**대상 및 방법** : 2010 년 9 월부터 2012 년 3 월까지 Lospa 인공 슬관절 치환술을 시행받은: 128 명(205 예 ; A 군)과 동일 기간 중 Scarpb NEG 인공슬관절 치환술을 시행받은 102 명(164 예; B 군)을 전향적으로 비교하였다. 역학적 축의 변화와 대퇴-경골 간 각을 측정하였으며 술 후 치환물의 위치(α, $\beta$, $\gamma$, δ)와 슬개골 경사를 측정하였다. 또한 hospital for special surgery (HSS), knee society score (KSS)와 관절 운동 범위의 변화를 비교하였다.
**결과:** 역학적 축은 A 군이 술 전 내반 34.8 mm 에서 2.6 mm (p=0.02)로, B 군에서는 술 전 내반 34.3 mm 에서 3.1 mm (p=0.04)로 교정되었으며 두 군 간의 차기는 없었다(P=0.13). 대퇴-경골 각은 A 군은 내반 4.3P 에서 외반 6.6° (p=0.02)로, 많은 내반 4.4°에서 외반 6.5° (p=0.03)로 교정되었으며 두 군 간의 치이는 없었다(p=0.25). 평균 HSS 점수는 A 군이 술 전 48.5 점에서 최종추시상 93.6 점으로 향상되었으며(p=0.02) B 군은 41.4 점에서 94.4 점으로 향상되었다(p=0.01).
**결론:** Lospa 인공 슬관절 치환술은 우수한 방사선적, 임상적 초기 결과를 보여주었으며 Scorpio NEG 인공 슬관절 치환술과 결과에서 유의한 차이가 없었다.

**색인단어:** 인공 슬관절 치환술, 고굴곡, UDSpa

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