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Clinical Results of Posterior Cruciate Ligament Retaining TKA with Alumina Ceramic Condylar Prosthesis -Comparison to Co-Cr Alloy Prosthesis-

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Running Title: Clinical results of alumina ceramic TKA

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Abstract

In a prospective study, 194 knees undergoing total knee arthroplasty (110 knees with alumina ceramic prostheses; 84 knees with Co-Cr alloy prostheses) were clinically and radiologically evaluated. Average follow-up period was 66 months (36 to 124 months). Average age at the time of surgery was 66 years. In the ceramic prostheses, two revision surgeries were performed because of breakage of the tibial tray and late infection, whereas two revisions of the Co-Cr alloy prostheses were carried out due to loosening and late infection. In the other patients, there were no significant differences in clinical parameters (HSS knee score and range of motion) between the two prostheses. In radiological evaluation, we could not find any radiolucent lines around the femoral ceramic component, while radiolucency was present in 3 knees (3.6%) around the Co-Cr femoral component. Beneath the tibial tray, 3 knees (2.7%) showed a radiolucent line around the former prosthesis, while 8 knees (9.5%) demonstrated a radiolucent line around the latter prosthesis. Chi-square tests showed a significant difference in the occurrence of radiolucent line around both of the femoral and

tibial prosthesis.

This study demonstrated that clinical results of the alumina ceramic PCL retaining total knee prosthesis are comparable to the standard Co-Cr alloy PCL retaining total knee prosthesis. Although we could not draw any conclusions regarding the superiority of the ceramic prosthesis with respect to UHMWPE wear and long-term survivorship, this report encouraged a long-term follow-up study on ceramic prostheses.

Keywords: Clinical results, Alumina ceramic prosthesis, Co-Cr prosthesis, TKA,

Introduction

Alumina ceramics have been noted as useful material in joint replacement because of their biocompatibility and wear properties in relation to UHMWPE [3, 13]. Application of alumina ceramics to total hip prosthesis has been investigated for the past two decades [4, 7, 9, 15]. On the other hand, fewer efforts have been made to apply these materials to total knee prosthesis compare to hip prosthesis [1, 10].

In 1992, our group developed a posterior cruciate ligament (PCL) retaining LFA-I total knee system, which is composed of an alumina ceramic femoral component and a titanium-alloy tibial component with a polyethylene insert [17, 18]. For a design of the component, computer assisted design (CAD) system based on CT scan data of 100 normal

Japanese knees was used. Sagittal shape of the femoral component surface was simulated to the surface of anatomical femoral shape in order to maintain the physiological knee kinematics. Although the femoral component has a beam structure on the inside surface of the condyle, the thickness was almost the same as that of the commonly used cobalt chromium (Co-Cr) alloy component (Fig.1). The cost of PCL retaining LFA-I total knee system is the same as that of Co-Cr component.

In wear tests in a knee simulator, the degree of polyethylene wear in the ceramic knee was 20 % of that in the Co-Cr knee. In static destruction test, the ceramic knee has the ultimate strength of over ten thousand Newtons [17]. However, no studies have been conducted to compare clinical results between the two types of total knee prosthesis. The purpose of this study is to compare the mid-term clinical results of PCL retaining total knee arthroplasty between the alumina ceramic knee and the Co-Cr knee.

Materilas and Methods

In a prospective study, 221 medial compartmental osteoarthritic knees underwent PCL retaining total knee arthroplasty in two hospitals. Under the same surgical indications, the ceramic knee (LFA-I, Kyocera, Kyoto, Japan) was used in one hospital, and the Co-Cr knee (Kinemax, Howmedica, Rutherford, NJ, USA) was used in the other hospital. Two orthopaedic surgeons performed the operative procedures in the two hospitals. There were no

major technical differences between the operations that had been done on the ceramic knees and those done on the Co-Cr knees. The knee joint was exposed using a medial parapatellar approach. Varus deformities were corrected with resection of bone and release of soft tissue. The anterior cruciate ligament was resected while the PCL was preserved. After soft tissue release, anatomic measured resection of the femur and tibia was performed. The patella was resurfaced in all patients. To fix each component, bone cement (Surgical Simplex, Howmedica, Rutherford, NJ, USA) was used in each patient. A longitudinal lateral capsular release with preservation of lateral superior genicular artery, was performed if the patella dislocated laterally with the capsule open during trial flexion. Postoperative management was the same in each hospital. Briefly, continuous passive motion was performed after the drainage tube was removed. Weight bearing was permitted immediately after surgery as tolerated. No patient received a manipulation under general anesthesia.

At the follow-up examination, a total of 27 knees were excluded from this study (4 patients died, 14 patients had serious general diseases, 9 patients were lost during follow up). Subsequently, 110 ceramic knees (87 female and 23 male) and 84 Co-Cr knees (64 female and 20 male) were followed for 3 to 10 years. The average follow-up period in the ceramic knee group and Co-Cr knee group was 66 months (range, 36 to 124 months) and 69 months (range, 36 to 124 months). Average age at the time of arthroplasty in the ceramic knee group and Co-Cr knee group was 66.0 $\pm$ 6.9 years (range, 55 to 77 years) and 69.6. $\pm$ 7.0 (range, 60 to

81 years), respectively. Preoperative anatomical axis was 171.4±10.6° in the ceramic knee group, and 170.1±8.9° in the Co-Cr knee group. There were no significant differences between the two groups for gender, age, follow-up period, and preoperative varus deformity (alignment of the knee). During surgery, no difference concerning the amount of soft tissue release was observed between the two groups according to the surgery records.

Clinical evaluations were performed using the Hospital for Special Surgery (HSS) knee score and the range of knee motion. Radiological evaluations were carefully carried out with the standard observation items, including anatomical axis, component placement angles α, β, γ, δ according to knee society evaluation [5], radiolucent line, and osteolysis. To evaluate the radiolucent line, care was taken that the x-ray beam was directed to take precise anteroposterior and lateral views of the prosthesis. Statistical comparisons were made using the Student's t-test and the Chi-square test.

Results

In the ceramic knee group, 2 revision surgeries (1.8%) were performed because of breakage of the tibial tray (Fig. 2) and late infection, respectively. In the Co-Cr knee group, 2 revisions (2.4%) were carried out due to aseptic loosening of the components and late infection, respectively. There were no differences between the two groups regarding surgical time of revision surgery. Especially, in the ceramic knee group, technical difficulties of the

component removal were the same as that in Co-Cr knee group.

In clinical evaluation, the knee score averaged 86 ± 7 points in the ceramic knee group, and 85 ± 8 points in the Co-Cr knee group. The average flexion angle was 112 ± 17 degrees in the ceramic knee group and 113 ± 20 degrees in the Co-Cr knee group. There were no significant differences in these clinical parameters between the two groups.

In radiological evaluation, anatomical axis was 185.7±3.5° in the ceramic knee group, and 185.3±3.6° in the Co-Cr knee group. Component placement angles of α, β, γ, δ in the ceramic knee group were 97.0±3.4°, 89.0±2.5°, 2.7±3.2°, and 84.4±2.7° respectively. In the Co-Cr knee group, component placement angles of α, β, γ, δ were 95.7±2.6°, 90.6±2.7°, 1.1±2.2°, and 86.4±2.6° respectively. There were no significant differences between the two groups with respect to the femorotibial angle (anatomical axis) and the component placement angles.

However, we found significant differences in appearance of the radiolucent lines between the two groups. Around the femoral component, radiolucent lines thicker than 1 mm were not found in the ceramic knee group, while they were observed in 3 knees (3.6 %) at zone 1 in lateral X-ray films of the Co-Cr knee group. Around the tibial component, such lines were found in 3 knees (2.7 %) of the ceramic knee group at zone 1 in antero-posterior X-ray films (Fig. 3), while they were observed in 8 knees (9.5 %) of the Co-Cr knee group; 3 knees in zone 1 (Fig. 4), 2 knees in zone 2, 3 knees in zone 4 in antero-posterior X-ray films. The

appearance of a radiolucent line was significantly different between the two groups in the femoral component ($p<0.05$, $\chi2=3.90$) and the tibial component ($p<0.05$, $\chi2=3.96$) (Table 1).

Discussion

Aseptic loosening is one of the major complications and causes of subsequent knee revisions [12, 14]. In theory, alternative bearing surfaces with lower wear rates could improve the longevity of total knee arthroplasty (TKA) by decreasing bearing wear and aseptic loosening. The present study demonstrated that in the mid-term follow-up evaluations, there were no significant differences in the clinical results between the two prosthetic knees. With respect to the radiolucent line, however, the ceramic knee showed some statistical tendency of superiority compared to the Co-Cr knee.

Previous literature reported that the ceramic knee prosthesis was fragile against impact loading in vitro and in vivo [6, 8, 18]. In this study, however, we did not experience any case of breakage in the ceramic component. These results indicated that progression of ceramic technology has solved the problem of the fragility at least in the clinical field.

The clinical and radiographic results reported here reflect the typical outcomes of TKA in terms of pain relief and improvement of function, comparable to those seen with traditional metal-on-polyethylene TKA [2, 16]. No complications related to the ceramic device were encountered at the present mid-term follow-up interval. With respect to

radiolucent lines, a previous five to nine year follow-up study of 192 kinematic total knee replacements reported that radiolucency was present around 40% of the tibial components and 30% of the femoral components [16]. Other four to six year results of the press-fit condylar modular total knee system reported that radiolucency of more than 1 mm was present around the tibial components in 17% and femoral components in 8% [11] of the cases. In the present study, radiolucency of more than 1 mm was present around the tibial components in 9.5% and femoral components in 3.6 % of the Co-Cr knee group. These results are consistent with those reported previously. On the other hand, radiolucency of more than 1 mm was present around the tibial components in 2.7% and femoral components in 0% of ceramic knees. These results encouraged us to conduct a long-term follow-up study on this ceramic total knee prosthesis.

In the present study, tibial component breakage occurred in one knee. This result indicated that mechanical properties of titanium tibial components must be improved. In order to achieve a more reliable total knee prosthesis, we are improving this aspect. In addition, based on the results of this study, we have developed a new PCL retaining knee prosthesis composed of a zirconia ceramic component. We removed the beam structure in this prosthesis. We are carrying out another follow-up study on this zirconia ceramic knee, in addition to continuing the present study on the alumina ceramic knee.

Some limitations of this study include poor randomization in the study design, a short follow-up period, and comparisons to one specific Co-Cr knee. Mid-term clinical data with

ceramic femoral component TKA can provide only limited information concerning their efficacy and safety. Long-term follow-up studies are necessary to confirm whether the reduction in bearing wear will result in significant improvements in component longevity.

Conclusion

The alumina ceramic knee showed some statistical tendency of superiority to the Co-Cr knee with respect to the radiolucent line found in radiological evaluations. Although we could not draw any conclusions regarding the superiority of the ceramic prosthesis concerning UHMWPE wear and long-term survivorship at present, this study encouraged a long-term follow-up on the ceramic prosthesis which we hope will be more conclusive.

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Table 1. Summary of clinical and radiological results with statistical differences.

	Ceramic knee	Co-Cr knee	p value
HSS score	86±7	85±8	NS
Knee flexion angle (degree)	112±17	113±20	NS
Occurrence of radiolucent lines			
Femoral component	0%	2.7%	$p<0.05$
Tibial component	2.7%	9.5%	$p<0.05$

Figure legends

Figure 1. The posterior cruciate ligament retaining LFA-I total knee system, composed of an alumina ceramic femoral component and a titanium-alloy tibial component with a polyethylene insert (LFA-I, Kyocera, Kyoto, Japan). The femoral component has a beam structure on the inside surface of the condyle, the thickness was almost the same as that of the commonly used Co-Cr alloy component.

Figure 2. A roentgenogram showing a breakage of the tibial tray in the ceramic knee. Revision surgery was performed in this case.

Figure 3. Radiolucent line thicker than 1 mm was found in the ceramic knee group at zone 1 in antero-posterior X-ray films.

Figure 4. A roentgenogram showing a radiolucent line thicker than 1 mm at zone 1 in the tibial component of the Co-Cr knee group.







