## **Executive Summary**

# Comparative effectiveness research of computer assisted navigation in knee arthroplasty

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#### ☐ Introduction

The number of total knee arthroplasty (TKA) performed in each year has been increased too rapidly, and the computer assisted orthopedic surgery (CAOS) using navigation in TKA is on the increase. However, the effectiveness of CAOS is still controversial and there are no evidence for the cost-effectiveness in Korea. In this study, we evaluated the short- and long-term effectiveness as well as cost-effectiveness of CAOS compared with conventional TKA.

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We performed the systematic literature reviews and meta analyses to compare the revision rate between CAOS and conventional surgery in patients who underwent primary TKA. We searched the major medical databases (Ovid-Medline, EMBASE, the Cochrane Library, KoreaMed, KISS, KMBASE) and conducted manual searches in ten journals. The quality of studies was evaluated by using the Cochrane's risk of bias for randomized controlled trials (RCTs) and RoBANS (Risk of Bias Assessment tool for Non-randomized Study) for non-randomized studies. We estimated the odds ratio (OR, (95% credible interval)) and posterior probabilities that OR < 1 using the Bayesian 3-level hierarchical random effect model. Sensitivity analyses for revision related to TKA and subgroup analyses by funding source, length of follow-up were performed.

A retrospective cohort study was performed on patients who underwent primary TKA in ten medical institutions in Korea through the medical chart review. 1,131 patients underwent primary TKA in 2007 and 1,267 surgeries among 1,544 surgeries were included in this study. We compared the postoperative radiographic alignments, clinical outcomes, complications, and revision in patients cohort and the cohort was linked to claims database in NHIS (National Health Insurance Service) to identify the complications and revision. Logistic regression and linear regression were applied to compare the outlier and clinical functional score after adjusting surgeon's experience, implant type, body mass index, age, sex, bilateral/unilateral, mechanical femural tibial angle before surgery, extra-articular deformity.

The economic evaluation was conducted to compare CAOS with conventional TKA using a decision-Markov model in Korean healthcare system perspectives. In the cost-utilization analysis using QALY (quality adjusted life year), the transition probabilities and costs were calculated from the retrospective cohort data linked with claims database and quality of life from the literatures were used.

#### Results

Eight RCTs and nine non-randomized studies were selected for meta analysis. The posterior median of OR for revision was 0.89 (0.25-2.86) and the posterior probability that

OR < 1 was 63%. Results from sensitivity analyses and subgroup analyses were similar.

Among the 1,267 surgeries, 505 surgeries were CAOS and 762 surgeries were conventional TKA. The occurrence of outlier were no statistically significant difference in mechanical femural tibial angle, but CAOS reduced the occurrence of outlier in the coronal femoral component alignment( $\alpha$ ) angle (adjusted OR=0.66, 95% confidence interval (CI) : 0.44-0.99, p-value=0.0445) and the coronal tibial component alignment ( $\beta$ ) angle (adjusted OR=0.18, 95% CI : 0.10-0.31, p-value<0.001) compared with conventional TKA.

The clinical outcomes and complications were no statistically significant difference between two groups, and 4 (1.0%) revisions and 3 (0.59%) revisions were occurred from the retrospective cohort data linked with claims database in the CAOS and conventional TKA, respectively. There was no statistically significant difference (p-value=0.7063).

According to cost-utility analysis results, additional 2.18 QALYs cost KRW 479 million in the CAOS, and the incremental cost-utility ratio (ICUR) was estimated to be KRW 219 million per a QALY. Considering the threshold of Korean cost-effectiveness, KRW 20 to 30 million (Ahn et al., 2010; Ahn et al., 2012), CAOS is decided not to be cost-effective.

#### ☐ Conclusions

There was no significant difference between two groups in revision rate based on meta analysis results and retrospective cohort. CAOS improve the accuracy of the coronal femoral/tibial component alignment, but the clinical outcomes and the occurrence of complications including revision are similar. CAOS is not to be cost-effective compared with the conventional TKA because the QALYs gained were small and extra cost required too much in Korea. Cost-savings is achieved if the added cost of CAOS is KRW 30-40 thousand or less per operation. However, we considered only 5-year follow-up after TKA, the expanded study with 10-15 years follow-up are required to identify the long-term cost-effectiveness.

Navigation, Computer assisted orthopedic surgery, Total knee arthroplasty, Cost-effectiveness analysis