2-Year Clinical and Radiologic Outcomes of a Shoulder System with PE-Glenosphere and Inverted Humeral Metal Cap in Patients Undergoing Reverse Shoulder Arthroplasty - *prospective multi-center follow-up study –*

Jiyoung Yoon[1], Hyeon Jang Jeong[2], Kyu Ho Lee[2], YOUNGKI MIN, Joo Han Oh[2], Hyungki Cho
[1]National Police Hospital, [2]Seoul National University Bundang Hospital

INTRODUCTION:
The purpose of this study was to investigate the clinical safety and efficacy of a shoulder system with PE-glenosphere and inverted humeral metal cap in patients undergoing reverse shoulder arthroplasty.Various implant designs have been developed to address the challenges associated with reverse shoulder arthroplasty (RSA), including limitations on active range of motion (ROM) and complications such as scapular notching and glenoid loosening. AGILON® Shoulder System, which features a medialized glenoid with a lateralized humerus (MGLH) RSA implant configuration, characterizes a PE-glenosphere and an inverted humeral metal cap configuration for the articulating sliding partner. This shoulder system was designed to promote the restoration of active forward flexion and abduction, demonstrating significant improvements in active internal and external rotation, while also reducing the incidence of scapular notching and glenoid loosening.
METHODS: This was a multi-center, prospective, post-market study evaluating the clinical safety and efficacy of the AGILON® Shoulder System in patients undergoing RSA. Patients were evaluated clinically and radiologically at baseline, 6, 12, and 24-month postoperatively. Clinical assessments included visual analog scale for pain (pVAS), ROM, Constant score, subjective shoulder value (SSV), and American Shoulder and Elbow Surgeons (ASES) score. Radiological evaluations focused on scapular notching, graded according to the Sirveaux classification on anterior-posterior radiographs, and glenoid radiolucent lines.
RESULTS:
Seventeen men and forty-four women with a mean age of 73.0 ± 6 years were included in the current study. The pVAS at 6, 12, and 24 months postoperatively were significantly improved compared with preoperative score (all $P<.05$). The external rotation was significantly improved compared with that baseline (all $P<.05$), however, there were no significant differences in forward flexion and internal rotation at the back between preoperative and postoperative measurements at 6, 12, and 24 months (all $P>.05$). Scapular notching was present in 11 (21%) patients, which was classified as Sirveaux-Nerot grade I. Radiolucent lines were observed in six out of 61 prostheses (12%) around the humeral stem, and in one patient (1.9%) around the glenoid. Among 61 RSAs included, there were 2 reoperations for humerus fracture and impinged implant due to greater tuberosity, and one prosthesis revisions for glenoid loosening one year postoperatively.
DISCUSSION AND CONCLUSION: This study showed that a shoulder system with PE-glenosphere and inverted humeral metal cap is associated with significant improvements in clinical scores and a low PE-glenosphere loosening rate. However, the observed 21% incidence of scapular notching raises concerns, especially given the relatively short two-year follow-up period. Future studies with a longer follow-up periods and diverse populations are necessary to confirm these rates. Furthermore, in the advancement of such shoulder system designs to reduce complications, encountering setbacks and challenges is an inevitable part of the process.