# Evaluation of New Patient-Specific Femoral Stem with an Adjustable Neck and Double Tapered body

+[1]Kim J.S.; [1]Shin T.J.; [3]Kim Y. S.; [1, 2]Sun D. H.; [4]Youn I. C.; [4]Choi K. W.
[1]R&D center, Corentec Co., Ltd., Cheonan, Korea
[2]Department of Orthopedic Surgery, Seoul St Mary's Hospital, Seoul, Korea
[3]Department of Orthopedic Surgery, Sun General Hospital, Daejeon, Korea
[4]Biomedical Research Center, Korea Institute of Science and Technology, Seoul, Korea
jskim@corentec.com

## INTRODUCTION:

The purpose of Patient-Specific Femoral (PSF) stem is to relieve pain and restore bearing function of the hip joint by matching leg/soft tissue length with a normal and rigid fixation in the proximal femur. In previous studies, various PSF stem was introduced and evaluated in clinical field. However, these PSF stem caused the mal-positioning and stress-shielding by filling the cancellous bone space[1], [2]. In this study, we suggested New PSF-stem with an adjustable neck and proven double-wedge tapered body with about two decades of clinical experience to resolve previous PSF-stem's problem.

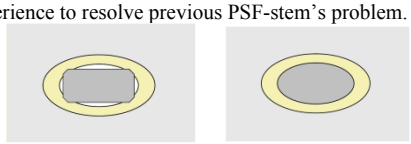

**Figure 1.** Comparison of the cross section of new PSF stem(Left) with the previous PSF stem(Right).

## MATERIALS AND METHODS:

The method designed for new PSF stem was composed of three steps, (1) Extraction of geometrical parameter, (2) Selection of stem design (BENCOX II STEM, Corentec, Inc.) and (3) Design of stem neck. In the first step, we extracted variables including femoral head position, femoral head offset and canal width from patient's X-ray image. In the second and last step, optimal-sized body was selected in 15 sizes(DDH1, DDH2, No.1~No.13) and the neck was modeled using extracted parameters in auto-parametric design program(Fig 2). We generated 580 3D-models of PSF-stems that have neck-to-shaft angle range 110°~150° and neck offset range 33.2~50mm. We performed FE analysis and ROM measurement for 3D-models to study the head dislocation or the stem fracture phenomenon in clinical use. For FE analysis, loading and boundary condition was followed by the test protocol based on ISO 7206-4[3]. The distal end of the stem fixed into the cement, was fully constrained as the boundary condition and a load of 2.3 kN was applied on the center of ball head. Material properties of the stem and the ball head were assumed with reference to Ti6Al4V and CoCr alloy(Stem: Young's modulus E=110GPa and poisson's ratio $\nu$=0.3, Ball head: E=220GPa and $\nu$=0.22). It is assumed that the stem and the ball head were fully bonded because the ball head has a role to transfer the load to the stem. Calculated von Mises stress(VMS) was compared with VMS obtained from clinically proven standard model. It was suggested that designed stems are safe if VMS of these models were lower than that of the standard model. For ROM measurement, the 3D assembly including the stem, the ball head, the liner and the cup was used to represent the actual in-vivo position. Measured ROM was compared with the normal ROM of the hip joint in adults.

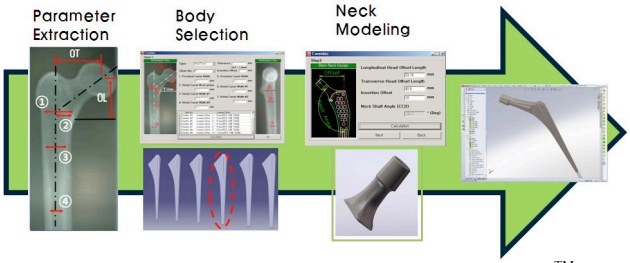


**Figure 2.** A process of auto-parametric design using SolidWorks™ API.

## RESULTS:

Fig 3 shows the VMS comparison table of 40 3D stem models designed with the body No.1. In this table, VMS of 34 models are lower than 314MPa of the standard model. Applying same comparison method to the stems with different body size, VMS of 316 3D models are lower than that of the standard model. Fig 4 shows ROM measurement result for all 3D models in all motion. All ROM values of 580 3D models are within ~~a~~ normal ROM range(Normal ROM: Flexion > 120°, extension > 15°, abduction >45°, addution >20°, internal rotation >45°, external rotation >45°)[4]. As a result, 316 of 580 3D models are classified as a safe by FE analysis and ROM measurement.

## DISCUSSION AND CONCLUSION:

PSF-stem with adjustable neck and double tapered body is suggested to be used in joint replacement after validation through FE analysis and ROM measurement. In addition, the stems proposed in this study improved previous patient-specific stem's limitations and can be applied to broader range of neck-to-shaft angles and neck offsets than commercial stems used in total hip replacements.

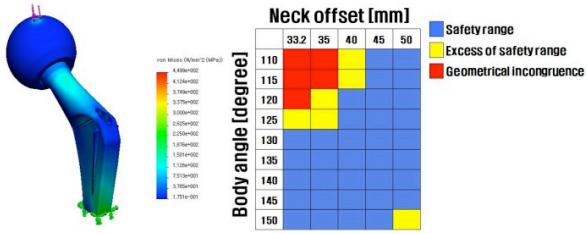


**Figure 3.** VMS comparison table for the new PSF stem

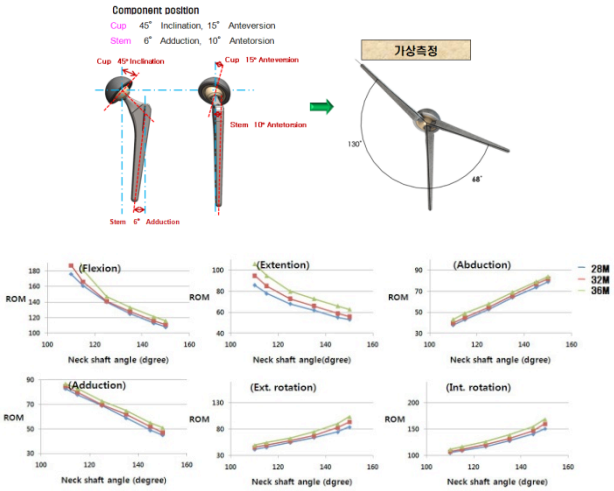


**Figure 4.** ROM measurement protocol and the result in all motion using 28, 32 and 36mm ball head.

## REFERENCES:

[1] W.L. Bargar. Shape the implant to the patient. A rationale for the use of custom-fit cementless total hip implants. Clin Orthop 249, 73-78, 1989.
[2] W.N. Capello, Fit the patient to the prosthesis. An argument against the routine use of custom hip implants. Clin. Orthop., 249, 56–59. 1989.
[3] ISO 7206-4. Implants for surgery-Partial and total hip joint prostheses-Part 4: Determination of endurance properties and performance of stemmed femoral components.
[4] Moritoshi Itoman. Hip, Shinheung Medscience, Inc., 2006.

**Acknowledgement**

This study was supported by Ministry of Knowledge Economy, Rep. of Korea (100299380-2007-21).