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**Bone regeneration using rhFGF-2-impregnated gelatin hydrogel for early-stage osteonecrosis of the femoral head**

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**O**steonecrosis of the Femoral Head (ONFH) is a multifactorial disease that can cause femoral head collapse, pain, gait disorders. ONFH is common among young people in their 30s and 40s. In the clinic, although patients are diagnosed, 70-80% of untreated patients experience femoral head collapse and have to undergo total hip arthroplasty. In the past decades, minimally invasive regenerative therapy has been desired for the early stages of ONFH. The purpose of this study was to evaluate the safety and clinical outcomes of rhFGF-2 gelatin hydrogel. Ten ONFH patients up to precollapse stage-2 underwent a single local administration of 800- $\mu$ g rhFGF-2 gelatin hydrogel and were followed up for one year. Primary outcomes included adverse events and complications. Secondary outcomes included changes in Harris Hip Scores, VAS pain scores, UCLA scores, radiological changes as determined via X-ray, CT, and MRI images. There were 14 adverse events (five patients). Patients completely recovered from all adverse events without problem. The surgery was performed with a minimally invasive technique (1 cm of skin incision), and walking was allowed from the day after surgery. Mean clinical scores improved significantly after four years compared with before surgery. There was only one case of femoral head collapse, and it had the greatest necrosis volume fraction and was considered to be in the early collapse stage at the time of operation. The other nine cases did not involve ONFH stage progression, and collapse was prevented. CT and MRI images confirmed bone regeneration in the ONFH. Clinical application of rhFGF-2 gelatin hydrogel for precollapse stage of ONFH was feasible and safe. Our research is ongoing; further phase II multiple center study has been started in January 2016.

**Biography**

Yutaka Kuroda is currently working as an Assistant Professor of Department of Orthopedic Surgery, Kyoto University. In 1994, he has received the BE. degree in Economics from Keio University, Medical Doctor License at St. Marianna University School of Medicine in 1999 and Medicine Doctor's degree (PhD) at Graduate School of Medicine, Kyoto University in 2011. His researches focus on the bone regeneration using growth factor and osteonecrosis of the femoral head. He is also a Member of the Japanese Investigation Committee of Health and Welfare on the establishment of guidelines for osteonecrosis of the femoral head.

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