A polycarbonate-urethane pliable cup for the treatment of femoral neck fractures in the elderly

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Introduction: The hip is a synovial joint comprised of synovial fluid and cartilage on both the femoral head and acetabulum. The hip joint has excellent tribological characteristics such as low friction, high load carrying capabilities, high shock absorption and long endurance. Considering the different elasticities between the standard hip protheses and the surrounding host tissue we propose a newly-developed pliable cup consisting of a “Buffer” made of a polycarbonate-urethane (PCU) plastic material replacing the cartilage in the acetabulum. The advantages of using the PCU cup include: minimal reaming, a press-fit surgical technique, and restoration of the shock absorption characteristics seen in the natural hip. Furthermore, the compliance of the PCU material not only restores the shock absorption but also ensures that the normally occurring micro-elasto-hydrodynamic lubrication is restored and friction is reduced, thus decreasing the amount of wear debris. The purpose of this clinical study was to evaluate the safety of this new acetabular Buffer in elderly patients affected by medial fractures of the femoral neck. Furthermore we tested the hypothesis that this acetabular Buffer could improve the clinical outcomes and patient satisfaction.

Methods: Between September 2006 and February 2009 at the Rizzoli Orthopaedic Institute, thirty patients were enrolled in the study. The study protocol was approved by our ethics committee and we obtained a signed informed consent form all patients included in the study. Inclusion criteria were: male or female between 65 and 90 years of age, dislocated intracapsular femoral neck fractures according to Garden’s classification requiring hip joint replacement, body weight < 100 kg, natural femoral head size range 43 and 53 mm, and prior ambulating status. Patients were excluded on the following criteria: malignant tumor, leg amputation, partial or full leg paralysis, post CVA, post TIA one year prior to surgery, and concurrent significant injuries. An uncemented tapered shape stem made in a titanium alloy (Conus, Zimmer) with a CoCr alloy large diameter head (6 mm less than the acetabular component) was implanted via an antero-lateral approach in all patients.

Results: Eleven males, 19 females were enrolled with a mean age of 81 (range 65 to 89). Clinical assessment was performed at 1, 3, 6, and at 12 months following surgery. Outcomes included: radiological assessment, Harris Hip Score (HHS), and Range of Motion (ROM). Four patients completed 24 months follow-up, 15 patients completed a 12 months follow-up and 11 patients completed a 6 months follow up. (Average follow up = 11.4 months) At the final follow-up, 20 of the 30 patients (66%) had no hip pain whatsoever. Eight patients at 6 months follow-up had some groin pain (HHS pain sub-score of 40 out of 44, with the 44 being no pain).

One patient had moderate pain and one had severe pain with very restricted ROM. The X-rays showed a changed position of the femoral head. This patient underwent revision of the implant, where subluxation of the acetabular Buffer was found. The ROM in 29 out of the 30 operated hips was similar to the contralateral hip.

Discussion: One of the major potential causes of failure of currently used methods is the composition of the implants. Specifically, all available implants are composed of stiff materials, such as metals, ceramics or polymers. Indeed, these materials were designed to reduce wear rate to a minimum. However, they failed to provide the significant function of shock-absorption, a function provided naturally by cartilage. The direct contact between rigid implant components and the acetabular bone, especially in osteoporotic patients whose bones are weak and whose cartilage is greatly diminished (or altogether missing), is suspected to be the major cause of surgical failures of current devices.(1-3) The impact of two hard materials -- the bone on one hand and the metal on the other, especially under strained conditions such as walking -- can cause high impact loads and a pronounced degree of wear. Wear particles cause an ensuing inflammation process that can lead to intolerable pain for the patient. (3-6)

The Acetabular Buffer reduces the pressure between the metal head and acetabular bone. Moreover the large femoral head (sizes 40-50mm) reduces the risk of dislocation or subluxation.

In conclusion, optimizing joint tribology should be a goal of hip replacement. Our preliminary results demonstrate the safety and the efficacy of this new system and material and support the laboratory and animal recommendations for the use of this material in hip replacement prostheses. (7-9). The potential advantages of the PCU pliable acetabular cup are minimal bone removal, preservation of acetabular bone stock over time thus avoiding acetabular protrusion, and restoration of the natural shock-absorbing characteristics seen in the natural hip.

These preliminary results should be confirmed at a longer follow up.

References: