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Original Article

Do Changes in the Production Process Affect the Outcome of Ceramic Liners: A 3-Year Follow-Up Study

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ABSTRACT

Background: In 2011, the current liner was withdrawn from the market because of the potential risk for liner fracture secondary to increased pressures used to assemble the metal locking ring. The present study provides a short-term follow-up of patients with this implant.
Methods: We retrospectively evaluated 63 consecutive hips in 53 patients operated by a single surgeon using a recalled ceramic-on-ceramic bearing. There were 30 women and 23 men with an average age of 50.6 years (range 20.3-63.5 years). The mean follow-up was 36.8 months.
Results: Six hips in 6 patients were revised (9.5%) because of a liner-fracture during the follow-up period. All liner fractures were identified on computer tomography imaging. Nine patients had self-reported episodes of squeaking (14.3%). All 6 patients that underwent revision surgery for liner fracture described squeaking before revision. There were no revisions for other causes. Two of the revised patients had a subsequent dislocation (33%).
Conclusion: The recalled ceramic liner lots have an increased liner fracture rate. Patients with mechanical symptoms or squeaking should undergo computer tomography to rule out liner facture.

Aseptic loosening secondary to plastic wear is the most common reason for revision total hip arthroplasty (THA) [1,2]. To minimize wear and increase the longevity, Boutin [3] introduced the ceramic-on-ceramic bearing in 1970.

Several studies documented superior wear-rates and excellent tribologic properties of ceramic-on-ceramic bearings [4,5]. In a long-term study, Petsatodis et al [6] demonstrated a survival rate of 84.4% at 20-year follow-up. In addition, ceramic-on-ceramic has no adverse tissue reaction to wear particles [7], and bearing failure is usually not associated with osteolysis and component loosening.

However, the risk of fracture and squeaking have been reasons for concern [8,9]. The incidence of squeaking is reported to be between 0.8% and 20.9% [8,10-18], and the incidence of a ceramic head fracture has been reduced to 0.004% since the introduction of third generation ceramic bearings [19]. Sedel [20] published a 10-year fracture risk of 0.05% for ceramic-on-ceramic bearings. Other studies [10,17,21] reported ceramic-on-ceramic fracture rates of 0.18% to 1.1%.

In March 2011, Smith and Nephew (Smith & Nephew, Memphis, TN) voluntarily initiated a recall of its R3 ceramic liner because of a manufacturing defect that affected some of the implant lots. For the recalled lots, the titanium locking ring was pressed onto the ceramic liner with higher pressures than manufacturing specifications allowed. This could potentially weaken the liner and make it susceptible to fracture [22].

The present study investigates (1) the liner fracture rate of the recalled R3 ceramic liner, and evaluates (2) if mechanical symptoms and squeaking are associated with liner fractures. The study also reports the short-term complication rate of liner exchange revision surgery in this population (3).

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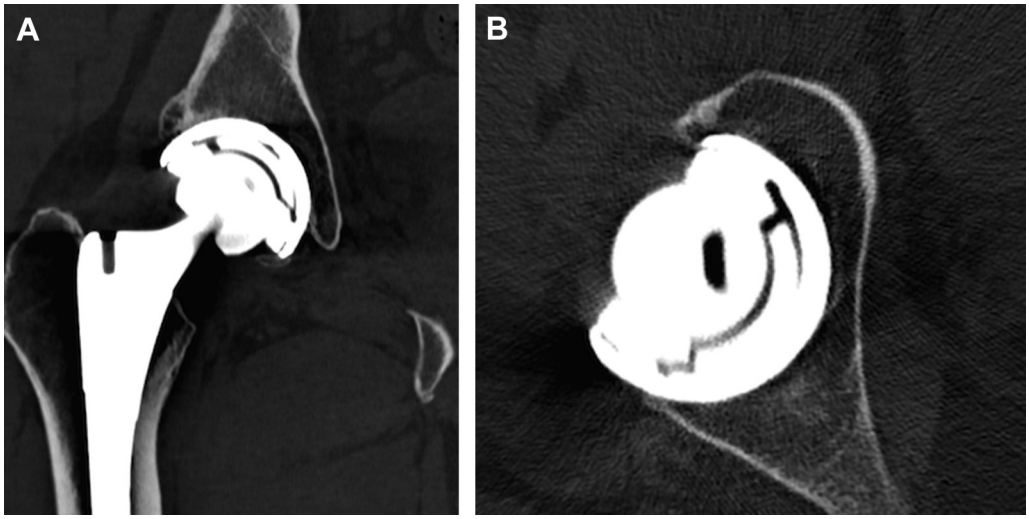

Fig. 1. (A) Coronal computed tomography (CT) scan of a fractured ceramic liner. (B) Axial CT scan of a fractured ceramic liner.

Material and Methods

The present single surgeon study includes 63 primary THAs (53 patients) using the withdrawn R3 liner (Smith & Nephew, Memphis, TN). All patients underwent surgery between March 2010 and March 2011 for end-stage hip disease (86.8% osteoarthritis, 9.4% avascular necrosis, and 3.8% developmental dysplasia). The study included 30 women and 23 men, who underwent 43 unilateral and 10 bilateral procedures. The mean age at the time of surgery was 50.6 years (range 20.3-63.5 years). The mean height 1.70 meters (range 1.57-1.88 m) and weight 79.8 kg (range 59.0-104.3 kg) resulted in a mean body mass index (BMI) of 27.8 kg/m^2 (range 19.9-33.8 kg/m^2). The mean follow-up interval was 36.8 months (range 1.1-51.0 months). Three patients (4.8%) had a follow-up of less than 24 months (range 1.1-3.1 months), and are considered lost to follow-up.

All procedures were performed using a minimally invasive posterior approach with a posterior soft-tissue repair in a lateral position, as previously described [23]. At the time, the senior author used ceramic-on-ceramic bearings for patients younger than 65 years of age that were not considered candidate for hip resurfacing. All patients underwent an uncemented femoral component implantation (85% Synergy femoral component [Smith & Nephew, Memphis, TN] and 15% Empirion femoral component [Smith & Nephew, Memphis, TN]). Thirty-six patients received a 32-mm head and 27 patients a 36-mm head. Thirty-six-millimeter heads were used for all patients with 52 mm and larger acetabular components. Twenty-seven 48 mm, nine 50 mm, twenty 52 mm, six 54 mm, and one 56 mm acetabular components were implanted.

Gender, age, BMI, initial diagnosis, date of surgery, date of follow-up, and implant size (femoral and acetabular components, liner, head size, and length) were recorded.

Yearly follow-up examinations were encouraged for all patients after the recall, in March 2011. Patients that had missed their follow-up were contacted by phone or email to exclude the presence of pain or mechanical symptoms. Patients underwent anteroposterior (AP) pelvis and cross-table lateral x-ray in yearly intervals. All patients were screened for the presence of mechanical symptoms included squeaking, clicking, grinding, or pain.

Patients with mechanical symptoms or pain underwent computed tomography (CT) scanning to rule out a liner fracture. All 9 patients with mechanical symptoms underwent a CT scan at their last follow-up. CT scanning was performed with a window level set to 2500 HU and a window width of 7000 HU to decrease artefacts from the titanium cup and enabled differentiation of the hyperdense titanium cup and less dense ceramic bearing (Fig. 1).

For patients with a ceramic liner fracture (Fig. 2), the authors documented cup abduction angle, acetabular component anteversion, hip offset, and leg length discrepancy on postoperative AP pelvis radiographs. The assessment of the postoperative component positioning was performed on a picture archiving and communication system, with commercial planning software (Sectra IDS7; Sectra, Linköping, Sweden). Cup version was analyzed on AP pelvis radiographs as described by Lewinnek et al [24] and validated by Lu et al [25]. Using a best-fit ellipse tool (ImageJ software v1.46, NIH), cup version was calculated as arcsin of the short vs the long leg of the ellipse. Relative anteversion or retroversion was assessed using the cross-table lateral radiographs using the technique described by Yao et al [26]. Cup inclination was measured in relation to the horizontal interteardrop reference line. The target zones for anteversion and inclination were defined as 10°-30° and 30°-50°, respectively [24].

The study was approved by the institutional review board at the authors' institution.

Results

Nine patients had reported episodes of mechanical symptoms (14.3%) and underwent CT scanning to rule out liner fracture. Six of 9 patients were diagnosed with a ceramic liner fracture and underwent revision surgery (67%). There was no fracture in any patient without mechanical symptoms. Four men and 2 women underwent revision for liner fracture. The patients who underwent revision surgery had a mean age at the time of surgery of 53.6 years (range 32-61 years), an average height of 1.77 meters (range 1.63-1.91 m) and a weight of 89.1 kg (range 77.1-104.3 kg) resulting in a mean BMI of 28.4 kg/m^2 (range 24.3-33.1 kg/m^2). There was no difference in age ($P = .423$) and BMI ($P = .695$) between patients with and without liner fracture. 66.7% of patients with a liner fracture were male compared with 43% of the overall study population.

Liner fractures occurred in 1 of 27 patients (4%) with 48 mm, 1 of 9 patients (11%) with 50 mm, and 4 of 6 patients (67%) with 54 mm acetabular liner. None of the patients had a traumatic event before the liner fracture, and details of the clinical history are presented in Table 1. The mean time span between the initial surgery and the revision for the fractured liner was 42.6 months (range 30.1-51.9