Orthopaedics & Traumatology: Surgery & Research 100 (2014) S225–S229

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Workshops of the SOO (2013, Tours). Original article

Cementless RM Pressfit® Cup. A clinical and radiological study of 91 cases with at least four years follow-up

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ARTICLE INFO

Keywords:
Total hip arthroplasty
Cementless acetabular cup
Osseointegration

ABSTRACT

Cementless metal-back acetabular cups have good long-term results, but some problems have appeared due to the shell's stiffness, modularity and required bearing surfaces. The RM Pressfit® Cup is a single-piece polyethylene cementless acetabular cup that is covered by a thin layer of titanium. This allows for bone integration without limitations related to the stiffness of a metal-back shell. There is very little published information about this new, innovative implant design. The purpose of this study was to evaluate the clinical and radiological results from a continuous series of 91 cups (85 patients) with a follow-up of at least 4 years. No patients were lost to follow-up. The Harris Hip Score (HHS) was used to assess the clinical outcome. To assess the radiological outcomes, digital X-rays were used to evaluate the cup position and integration; wear was measured using Livermore's technique. The clinical results were excellent: the mean HHS was 94 and 82% of cases had good or excellent scores. Three of the cups had to be revised because of dislocation brought on by incorrect positioning. X-rays revealed that three implants had shifted during the first 6 weeks, but had stabilized afterwards. Bone integration on X-rays was satisfactory in all cases with no signs of osteolysis. The configuration of the bone trabeculae showed that loads between the implant and peri-acetabular cancellous bone were evenly distributed. The wear of the polyethylene cup-ceramic head bearing was 0.07 mm/year. The results of this series are consistent with recent published studies with the RM Pressfit® Cup.
Level of evidence: IV.

1. Introduction

Although cemented polyethylene (PE) cups have been shown to provide reliable results [1–3], osteolysis due to PE wear debris is a long-term problem [4,5]. To overcome this problem, cementless metal-back cups have allowed new bearings (metal-metal and ceramic-ceramic) to be used. These theoretically eliminate wear problems, while improving stability because they can be paired with larger diameter heads. Although the outcomes are satisfactory [6], the stiffness of the press-fit metal-back shell increases loads on the edges of the acetabulum and decreases loads on the acetabular roof, where bone density decreases [7–14]. Aseptic loosening is one the main complications of cementless total hip arthroplasty [3,6]. The observed bone trabeculae alterations may contribute to this phenomenon.

Because of disappointing outcomes with metal cups and PE inserts [15], but satisfactory results with the RM Classic® Cup [16,17], we started using the RM Pressfit® Cup (Mathys, Switzerland). The RM Classic® cup [18] is a predecessor to the RM Pressfit® Cup and has a 94% survival rate after 20 years [17]. The thin coating of titanium on the cup should allow for bone integration, while preserving the PE's elasticity, which resembles that of bone [19], to help with bone integration and load distribution.

Since there are few published studies about this innovative implant [20,21], we felt that a short-term review of patients was justified. The purpose of this study was to evaluate the functional outcomes, integration of the RM Pressfit® Cup into bone and changes in the bone trabeculae in patients with at least 4 years of follow-up.

2. Material and methods

The inclusion criteria consisted of RM Pressfit® Cup implantation during primary total hip arthroplasty (THA) and at least 48 months of follow-up. Contraindications to implantation were lack of acetabular coverage and osteoporotic bone. The RM Pressfit® Cup (Fig. 1) is an UHMWPE cup coated with a thin layer of pure titanium (TiCP) that has no structural stiffness. This allows the

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http://dx.doi.org/10.1016/j.otsr.2014.03.007
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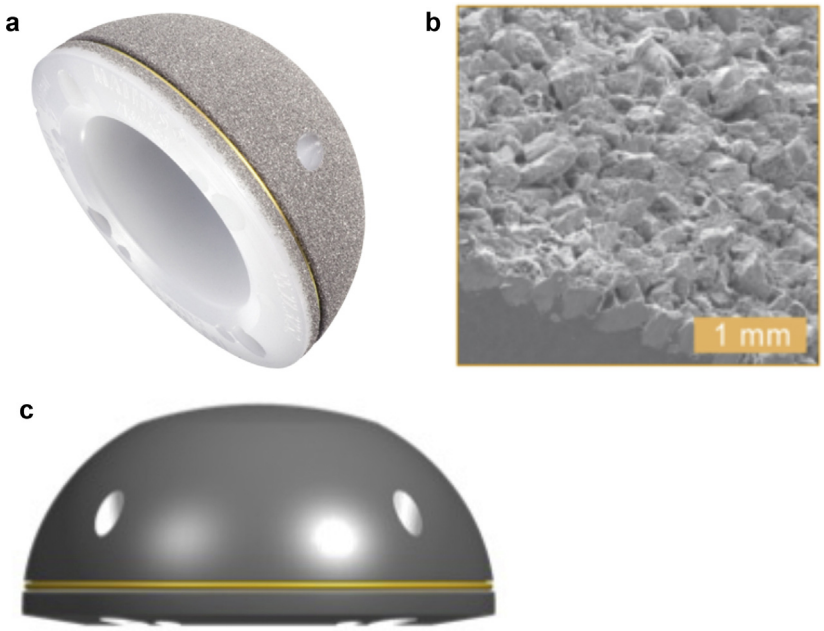

Fig. 1. a: RM Pressfit® Cup; b: titanium coating; c: elliptical design.

impacted cup to behave like the bone around it. The elliptical design with flattened pole improves its peripheral primary stability. There is 1.6 mm of press-fit on the equator. The cup cavity is completely hemispherical, with no cylindrical shape at its entry point.

Three different approaches were used in these patients: Bauer anterolateral (27 cases), Moore posterolateral (61 cases) and trochanterotomy (3 cases). After the acetabulum was reamed, the cup was impacted. A 28-mm diameter ceramic head was used in all cases; 35 of the femoral stems were cemented and 56 were not.

The clinical evaluation was carried out using the Harris Hip Score (HHS) [22] before the surgery and then at every clinical X-ray assessment. The outcome was considered excellent if the HHS was between 90 and 100, good if between 80 and 89, average if between 70 and 79, and poor if lower than 70. The preoperative, postoperative and last follow-up digital X-rays were analysed by the lead author. The magnification was determined by measuring the size of the replacement femoral head, which has a known diameter (28 mm), and used to interpret the distance-based measurements.

Cup inclination was measured relative to the pelvic tear-drop. Cup anteversion was estimated by comparing the size of the prosthetic ellipse on A/P hip and pelvis X-rays. Polyethylene wear was measured using the technique described by Livermore [23]. Movement of the implant was determined by looking at the hip centre and acetabular landmarks. The coordinates of the centre of the prosthetic head were measured relative to a line tangent to the lower edge of the pelvic tear-drop, and perpendicular to the line tangent to the internal edge of the ipsilateral pelvic tear-drop. A difference of more than 5° inclination on the A/P pelvis X-ray or shift of more than 5 mm in the location of the head centre were indicative of cup movement, according to the criteria described by Bonnomet [24].

To evaluate if the space between the spherical reamer-prepared cavity and the ellipse-shaped periphery of the cup had been filled, the maximum distance between the cup and the bone was measured at the fossa and at the superomedial edge of the cup immediately after the surgery and at the last follow-up (Fig. 2). Correlation tests were used to evaluate the effect of body mass index (BMI), age and frontal plane inclination of the cup on acetabular wear. The presence of bone cysts or sclerotic areas was evaluated using the DeLee and Charnley [25] zones. The presence of radiolucent lines on X-rays at the last follow-up was also evaluated, as this may be evidence of insufficient integration of the cup into bone. Changes in the bone trabeculae in the loaded zone were analysed as previously described [15]. The bone trabeculae were labelled as being denser, unchanged, blurred, missing or having massive osteolysis.

3. Results

Eighty-five patients (91 hips) were included, 52 men and 33 women. The mean age of at the time of the procedure was 61.5 years (range 33–81) and the mean BMI was 26.9 (range 16–35). The indications consisted of 72 cases of primary osteoarthritis (OA), eight of aseptic osteonecrosis, six of OA secondary to dysplasia, four of trauma sequelae and one of slipped capital femoral epiphysis sequelae. The mean follow-up was 53 months. No patients

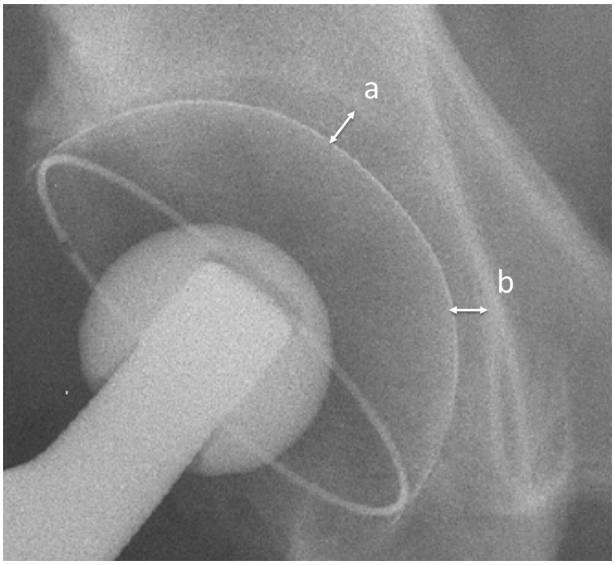

Fig. 2. Measurement of the maximum gap between the reamed cavity and the periphery of the ellipse-shaped cup at the roof (a) and the fossa (b).

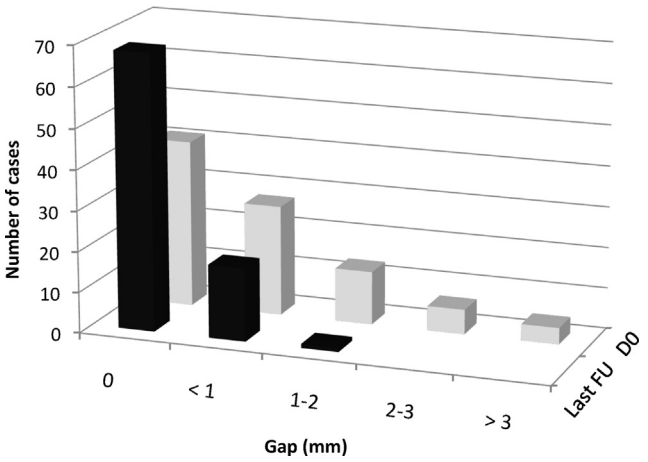

Fig. 3. Distribution of gaps in the acetabular roof between postoperative (D0, grey bars) and the last follow-up (Last FU, black bars).

were lost to follow-up, but three died for reasons unrelated to the arthroplasty with their implants still in place.

The mean HHS went from 57 before the surgery to 94 at the last follow-up, with 82% of cases having good or excellent results. Two patients experienced a dislocation that was reduced under general anaesthesia, with no recurrence. Three patients experienced repeated dislocations, and were revised with dual-mobility cup. The cups in the latter three patients were not anteverted and had greater than 45° inclination (47, 48 and 57°). One patient suffered from iliopsoas impingement syndrome that was not a hindrance.

A full radiological file was available for 86 of the 91 cases. The mean cup inclination was 48.4° immediately after the surgery and 48.8° at the last follow-up. Cup inclination was more than 50° in 40% of cases. One cup had tipped 5° horizontally, one had tipped 10° vertically and another had moved 5 mm medially. These shifts were observed at the 45th day after surgery and did not progress further.

There were no radiolucent lines around the acetabulum. An average gap of 2.2 mm between the superomedial edge of the cup and bone was present in 50 cases immediately after the surgery. In 25 of these cases, the gap was less than 1 mm. At the last follow-up, 32 cases no longer had a gap, 17 still had a gap of less than 1 mm and one had a gap of 1.8 mm (Fig. 3).

A gap at the fossa was present in 68 cases immediately after surgery and was 3.5 mm on average. At the last follow-up, a gap was still present in 33 cases (average of 3.1 mm); it was less than 1 mm in 24 cases (Fig. 4). There were no progressive cysts or osteolysis visible at the last follow-up.

When compared to preoperative X-rays, the bone trabeculae were denser (31 hips), unchanged (43 hips) or blurred (11 hips).

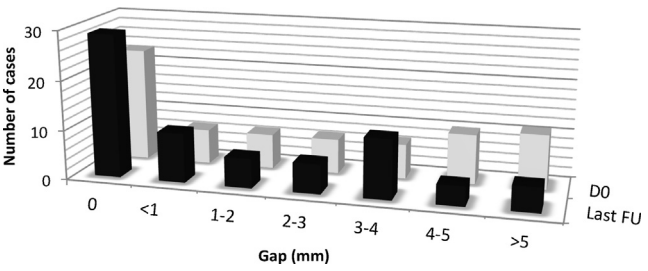

Fig. 4. Distribution of gaps in the acetabular fossa between postoperative (D0, grey bars) and the last follow-up (Last FU, black bars).

In 18 hips with localized preoperative superolateral sclerosis, the sclerosis had decreased in four cases and disappeared in 14 cases at the last follow-up (Fig. 5).

The average wear was 0.3 mm (range 0–2.3), which was less than 0.07 mm per year. Six cups had more than 1 mm wear and 52 had less than 0.5 mm wear. There was no correlation between the BMI or cup inclination in the frontal plane and wear. However, there was a significantly greater reduction in wear as age at the time of surgery increased. But this difference was not very large.

4. Discussion

This study with the RM Pressfit® Cup is the largest published series up to now. The clinical results were satisfactory and identical to those of short-term cemented and cementless THA [12,13,15,17,26,27]. However, our results will have to be confirmed in longer-term studies.

The revision rate of 3.3% can be attributed to the cup being too vertical and not tilted forward. These cases occurred early in our surgical experience. They can be explained by incorrect acetabulum preparation in its lower portion at the horns and a tendency for the cup holder to be too close to vertical when impacting the cup. The large number (40%) of cups with more than 50° inclination drives us to be very careful during impaction. Contrary to Charnley-type PE cups, the RM Pressfit® Cup does not have a cylindrical shape at its opening, which could also increase the likelihood of dislocation. However, the dislocation rate was similar to the one reported in Swedish [3] and New Zealanders registries [28].

In the current study, the wear rate of 0.07 mm/year is similar to the rate of 0.09 mm/year reported by Wyss [20] for the RM Pressfit® cup. Although controversial, some studies have shown premature wear of the polyethylene in vertical cups, which did not occur in the current study [13,27,29].

Pavkis [21] reported that two implants had shifted significantly between the implantation procedure and the second month, but then did not shift afterwards, which was similar to our findings. However, they reported having two implants shift after 2 years, while we found no further movement after the three initial shifts. Wyss [20] also found no implant movement after 5 years of follow-up. We believe that these initial movements are due to faulty impaction, followed by shifting in the cavity prepared by the final reamer.

The gap observed postoperatively between the cup and the acetabular fossa or roof of the acetabulum is related to the differences between the hemispherical reamer shape and the elliptical shape of the implant. This gap had a tendency to be reduced or disappear over time, and never caused poor fixation at the last follow-up. This was also found with metal-back cups [30,31].

The homogeneous appearance of the bone trabeculae, along with the resolution of the preoperative sclerosis, suggests that the implant more evenly distributes loads. This is opposite to cases with metal-back cups where the bone trabeculae can become scarce, even in patients with good outcomes [7–14].

The survival rate is 94% at 20 years with the RM Classic® Cups when aseptic loosening is used an end point [17]. Our results have the same trend, but will have to be confirmed with longer-term studies. The RM Pressfit® Cup combines the advantages of PE cups (maximum thickness due to lack of metal shell) with even load distribution into bone, without having the drawback of a stiff metal-back cup. If this cup needs to be revised, it is easier to remove and causes less damage to the bone stock than a metal-back cup does.

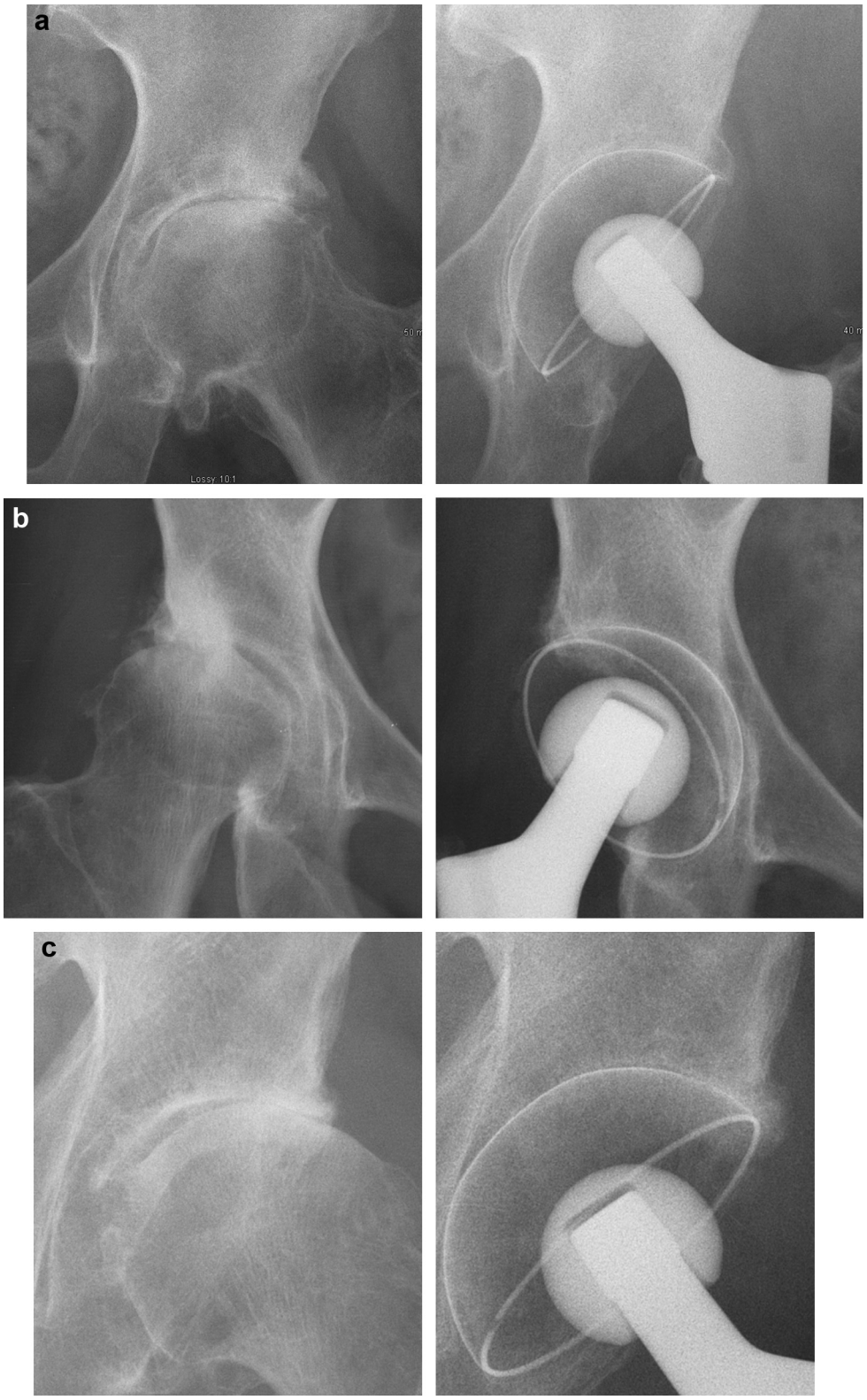

Fig. 5. Changes in bone trabeculae: a, b: uniform bone trabeculae at the last follow-up; the sclerotic areas observed before the surgery have disappeared; c: blurred structure at the last follow-up.

Disclosure of interest

Mathys has provided funding to the author's department.

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