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Midterm Results of 506 Solid Trispiked Reflection Cementless Acetabular Components for Primary Total Hip Arthroplasty

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Abstract: The purpose of this prospective study was to evaluate the outcomes and survivorship of a trispiked, sintered bead–coated titanium shell with a polished inner surface, no screw holes, and an improved locking mechanism. A total of 506 total hip arthroplasties with a minimum 5-year follow-up were available for review at a mean of 7 years (range, 5-11 years). Three sockets (0.6%) were revised for reasons other than aseptic loosening, and 14 (2.8%) polyethylene liners were exchanged. There was no difference in revision rate between non–cross-linked and highly cross-linked liners (P = .4). There were no cases of radiographic loosening. Retroacetabular osteolysis was identified in 2%. The overall 5-year and 10-year Kaplan-Meier survivorship was 97.5% and 97.4%, respectively, whereas survivorship of the shell was 99.8%. **Keywords:** total hip arthroplasty, cementless fixation, cross-linked polyethylene, acetabular component.

Modular cementless sockets have replaced cemented sockets as the preferred socket for primary total hip arthroplasty (THA) in many countries. Both cemented all-polyethylene (PE) cups and cementless sockets have benefited from stepwise improvements in surgical techniques and designs and have been reported with comparable long-term results [1-10]. The socket has been associated with higher revision rates than the stem in various national joint replacement registries with aseptic loosening and PE wear being by far the most frequent indications for revision of THA after 3 years [11-15].

The bone ingrowth of contemporary cementless sockets with surface porosities of 30% to 45% is good and reliable [16,17]. However, initial stability is of paramount importance for good bone ingrowth. This can be achieved with screws, pegs, fins, or spikes [18-22]. Screws have been associated with fretting wear, corrosion, impingement on the liner, PE debris, and neurovascular injury [19,23]. Failure of the first-generation acetabular components has resulted from the combination of a poor PE locking mechanism, PE wear, acetabular osteolysis, and migration [17,24-26]. In an effort to decrease backside wear and improve clinical results, the trispiked Reflection cup (Smith & Nephew, Memphis, Tenn) was designed as a second-generation solid titanium shell without screw holes, a polished inner surface, and improved locking mechanism. A porous coating (Porocoat; Smith & Nephew) was used to achieve bone ingrowth [27-31].

The purpose of this prospective study was (1) to evaluate the midterm clinical and radiographic results and survivorship of this second-generation cementless acetabular component used in a large cohort of primary THA and (2) to evaluate whether age, sex, and cross-linking of the PE liner would influence the midterm survivorship of this socket.

Materials and Methods

In our institution, 491 patients underwent 559 primary THA using the Reflection trispiked acetabular component (Smith & Nephew) between July 1997 and July 2003. The mean age at time of surgery was 65 years (range, 26-95 years) in 246 male and 245 female

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patients. Forty-nine percent of the cases (247 THA) were in patients younger than 65 years at time of surgery. The indications for arthroplasty were primary osteoarthritis (n = 481; 86%), avascular necrosis of the femoral head (n = 39; 7%), postchildhood hip disorders (n = 11; 2%), inflammatory arthritis (n = 11; 2%), or another indication (neck of femur fracture and sequelae of septic arthritis) (n = 17; 3%). The socket was used in consecutive patients who were not included in another study and when the acetabular bone was deemed suitable for usage of this socket as described below.

The Reflection cup (Smith & Nephew) is a hemispheric titanium acetabular component with diameters ranging from 40 to 68 mm in 2-mm increments (Fig. 1). The outer shell is coated with a 2-layer to 3-layer sintered bead coating with a mean pore size of approximately 170 μm and a mean of 20% to 40% porosity [27,28]. Three dome spikes are fixed to the outer shell at a 120° angle apart. The spikes are not coated to minimize any bone loss in case of revision surgery. There is one threaded apical hole to engage the impactor. After placement, the apical hole is sealed with a threaded cover. The locking mechanism provides improved stability to the liner thereby minimizing micromotion at the shell/liner interface [29-31]. The inner surface of the socket is polished to minimize backside wear of the liner. A conventional ethylene oxide–sterilized PE liner or a 10-Mrad γ-irradiated highly cross-linked PE (XLPE) liner was used during the period of study. The following various PE liner options exist: neutral, 20° overhang, 35° overhang, and 4 mm lateralized neutral or anteverted (20°) liners.

Fig. 1. The Reflection trispiked socket obtains immediate fixation with the spikes that allow for reliable bone ingrowth at intermediate follow-up. Note the polished inner surface. None of the sockets were revised for aseptic loosening.

The direct lateral Hardinge approach was used in all cases under direct supervision of one of the senior authors. The acetabular bone was underreamed by 1 mm less than the final component. Trial components were first used with the desired acetabular cup inclination and anteversion angle of 45° and 15°, respectively. The Reflection trispiked cup was used if coverage of the socket by the acetabular bone was at least 75% and the surgeon deemed the patient had adequate bone quality to provide initial fixation. If the coverage was less than 75% or bone quality was questionable, a multihole socket with screw fixation and augmentation by bone graft was used. The final component was then impacted with 2 spikes seating in the superior quadrants of the acetabulum at the 10-o'clock and 2-o'clock positions. The third spike was thus in the 6-o'clock position. Stability of cup fixation was assessed with the impactor left attached to the cup and by toggling of the pelvis with careful inspection of any socket movement. All cups were intraoperatively assessed as being stable. Seating of the socket into the acetabular bone was assessed through the apical screw hole in the dome of the shell after removal of the cup impactor. The maximum accepted distance between the outer diameter of the socket and the acetabular bone was 2 mm. Additional impaction of the socket was done if this distance was more than 2 mm. The apical screw hole was then sealed with a flat plug screw, and a trial liner was left in place. The femoral canal was then prepared for the stem, and a trial reduction was done. If the component sizes and positions were accepted to obtain adequate hip stability, then the final liner and stem were inserted. Femoral component cement fixation was used in 115 hips, and cementless fixation, in 444 hips. A cobalt-chrome head with a head diameter of 28 mm was used in 544 hips, with a 32-mm head in 15 hips. A highly cross-linked PE liner was used in 257 sockets. The usage of XLPE was not subjected to control and was left to the decision of the surgeon. Cross-linked PE was used in 24% of THA in patients older than 65 years and 72% of THA in patients younger than 65 years.

Patients were reviewed clinically for 12-Item Short-Form Health Survey (SF-12) (mental and physical), Western Ontario and McMaster Universities Arthritis Index (WOMAC), and Harris Hip Scores (HSS) preoperatively; at 6 weeks, 3 months, and 1 year postoperatively; and every two years thereafter. Any complications requiring surgery were documented. If the patients did not have a minimum 5-year follow-up visit, either they were contacted by telephone or the family physician was contacted to inform about the revision status and the survivorship of the patient. Approval by the institutional review board of the hospital was obtained for this study.

Anteroposterior and cross-table lateral digital radiographic views of the hip were evaluated by 2 independent observers (K.C. and Y.T.) for component inclination,

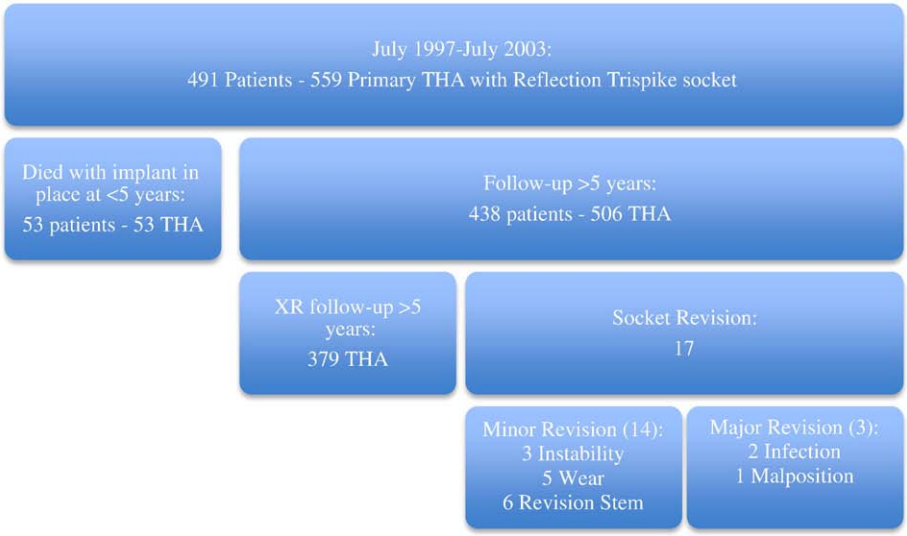

Fig. 2. Overview of the patient population.

osteolysis, and signs of aseptic loosening according to the criteria of Engh et al [32,33]. The location of osteolysis was recorded in the 3 zones described by De Lee and Charnley [34]. The sizes of the lines were categorized as follows: no radiolucent lines, less than 1 mm, 1 to 2 mm, and more than 2 mm. Inclination of the cup was measured as the angle between the interteardrop line and a line drawn from the cranial and caudal edge of the cup. If the interteardrop line was not clearly visible, then a line connecting the ischial tuberosities was used as the horizontal reference line [35]. The mean inclination angles of both observers were taken.

Similar to the Australian national joint registry, we made the distinction between major (shell revision) and minor (liner exchange) revisions [11]. Cox regression analysis was performed with age (< or ≥ 65 years) and sex as covariates to determine their effect on failure. The Kaplan-Meier (KM)–predicted survivorship method was used to generate survivorship curves with 95% confidence intervals at 5 and 10 years [36]. Kaplan-Meier analysis was repeatedly used with the following multiple end point variables: (1) revision of the socket for aseptic loosening as the end point (major revision), (2) revision of the liner/head exchange as the end point (minor revision), and (3) revision for any reason as the end point.

Results

Fifty-three patients (11%) with 53 THAs (9%) died with their implant in place before the minimum 5-year follow-up period (Fig. 2). The remaining 438 patients with 506 THAs were followed-up for a mean of 7 years (range, 5-11 years). The mean preoperative HHS and WOMAC scores were 43 and 40, respectively. At final follow-up, they were significantly improved to 90 and 79, respectively. The mean mental and physical SF-12 scores had improved from 52 to 54 and from 28 to 41, respectively (Fig. 3).

A total of 379 sockets were available for radiographic follow-up at a mean of 7 years (range, 5-11 years). The mean inclination angle of the cup was 45° (range, 26°-70°). Three hundred forty-eight sockets (92%) had no sclerotic lines; 5 had lines of less than 1 mm in zones 1 to 3, 21 in zones 1 to 2, and 2 in zones 2 to 3. Two sockets (0.5%) had sclerotic lines of more than 2 mm in zones 1 to 3. These sockets were radiographically stable because there was no change in position at several consecutive follow-up radiographs. Osteolysis around the socket (n = 8; 2%) was limited to zone 1 in 3 patients and to zone 2 in 4 patients. In one patient, the osteolysis extended from zone 1 to 3, but the socket remained radiographically stable without any sign of migration. Osteolysis around the stem was noted in 23 cases (6%) and was always limited to zone 1 (n = 20) or 7 (n = 3). None of the components were radiographically loose. All patients were asymptomatic.

Seventeen sockets (3%) had undergone major or minor revision of either the shell or the liner, respectively. The KM survivorship analysis for any revision was 97.7% and 97.3% at 5 and 10 years and 98% and 97.6%

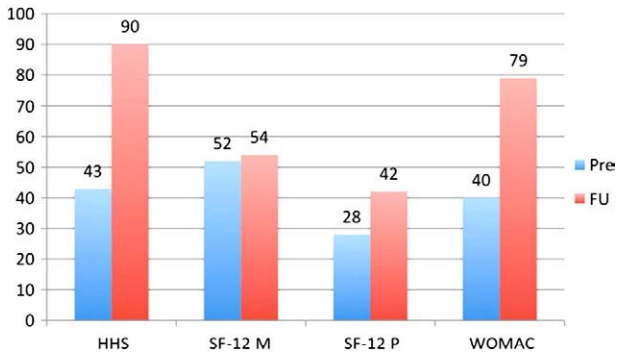

Fig. 3. Overview of the functional scores preoperatively and at final follow-up. FU indicates follow-up; SF-12 M, mental score; and SF-12 P, physical score.

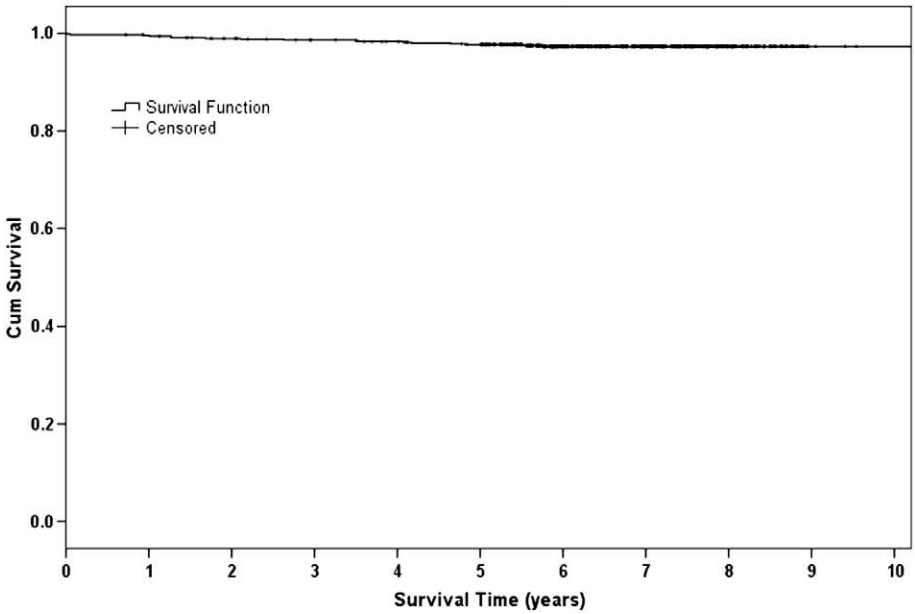

Fig. 4. The KM survivorship of the socket for any reason as the end point.

for any revision excluding infection (Fig. 4, Table 1). There was no difference in survivorship between sexes ($P = .2$). The overall survivorship excluding infection was significantly lower in the age group of 65 years or older at time of surgery ($P = .036$) (Table 1).

Three sockets (0.6%) were revised (major revision): 2 for infection and 1 for component malpositioning with residual instability. No socket was revised for aseptic loosening. The survivorship of the shell for any reason was 99.5% at 5 and 10 years and 99.8% for aseptic revisions at 5 and 10 years. There was no difference in revision rate or survivorship between sexes or age groups.

Fourteen liners (2.5%) were exchanged (minor revision). Six liners (1%) were exchanged during femoral revision surgery. Eight liners (1.4%) were exchanged during revision surgery directed toward the socket: 3 for instability and 5 for radiographic liner wear. These 5 liners were in the age group older than 65 years, and 4 of these 5 liners were non-XLPE liners. There was no difference in minor revision rate between sexes or

Table 1. There was no Significant Difference in Survivorship of the Socket Between Sex and Age for any Reason or Aseptic Indications for Revision as the End Point

		All Reasons for Revision					
		Revisions			KM Survivorship		
All Revisions	n	Number	Rate (%)	Sig.	5 y	10 y	Sig
Overall	559	17	3.0		97.7 ± 0.6	97.3 ± 0.6	
Sex							
Female	287	10	3.5	0.627	97 ± 0.9	97 ± 1	0.517
Male	272	7	2.6		98 ± 0.8	98 ± 0.9	
Age (y)							
<65	257	4	1.6	0.083	99 ± 0.7	99 ± 0.7	0.054
≥65	302	13	4.3		97 ± 0.9	97 ± 1	
		Aseptic Revisions Only					
		Revisions			KM Survivorship		
All revisions	n	Number	Rate (%)	Sig.	5 y	10 y	Sig
Overall	559	15	2.7		98 ± 0.6	97.6 ± 0.6	
Sex							
Female	287	10	3.5	0.299	97 ± 0.9	97 ± 1	0.214
Male	272	5	1.8		99 ± 0.6	98 ± 0.7	
Age (y)							
<65	257	3	1.2	0.063	99 ± 0.6	99 ± 0.6	0.036
≥65	302	12	4.0		97 ± 0.9	96 ± 1	

The KM survivorship of the socket in the age group older than 65 years at time of surgery was significantly lower for aseptic revision in comparison with the socket survivorship in the age group younger than 65 years at time of surgery ($P = .036$). n indicates number; Sig, significance level.

Table 2. There was no Difference in Minor Revision Rates Between Sex and Age Groups

		All and Aseptic Reasons for Revision					
		Revisions			KM Survivorship		
Minor Acetabular Revision	n	Number	Rate (%)	Sig	5 y	10 y	Sig
Overall	559	14	2.5		98.1 ± 0.5	97.8 ± 0.6	
Sex							
Female	287	9	3.1	0.421	98 ± 0.9	97 ± 0.9	0.308
Male	272	5	1.8		99 ± 0.6	98 ± 0.7	
Age (y)							
<65	257	3	1.2	0.101	99 ± 0.6	99 ± 0.6	0.055
≥65	302	11	3.6		97 ± 0.9	97 ± 1	

However, in the age group older than 65 years, 11 liners were exchanged in comparison with 3 liners in the younger age group.

between liners (XLPE vs non-XLPE (P = .36). Although there was no significant difference in minor revision rate between age groups, 11 liners had been exchanged in the age group older than 65 years vs 3 liners in the age group younger than 65 years. In the older age group, 5 revisions were directed toward the liner and 4 of the 5 liner exchanges were of non-XLPE liners (Table 2).

Discussion

The acetabular component is considered to be the weakest link in THA, with higher revision rates than the stem and with aseptic loosening being by far the most frequent failure mode of 75% to 83% after 6 months to 3 years [5,11,12,15]. There is little consensus whether cemented or cementless sockets have the best survival rates. In contrast to most of the Scandinavian countries, cementless sockets are the preferred treatment of choice in North America, Canada, and Australia [2,11,14,15]. Stepwise changes and improvements in surgical techniques and design features have led to reliable and comparable intermediate and long-term survival rates of cemented and cementless sockets of 90% and more [1-10].

Nonmodular cementless sockets have been reported with an excellent survivorship at 20 years [3], but the results of modular designs in cementless and hybrid THA are also promising [4-6]. Our prospective survivorship data of the cementless Reflection trispiked titanium shell demonstrated excellent fixation and survivorship at intermediate follow-up in addition to an extremely low incidence of osteolysis. These intermediate survivorship results compare favorably with those of other studies reporting on porous coated cups [18,23,37-39]. Moreover, none of the sockets were revised for aseptic loosening.

We prefer modular cementless sockets in virtually all our primary THA cases except in special circumstances (≈2%) such as postirradiation or when segmental allografts or trabecular metal shells are required. The modularity allows a greater versatility in terms of intraoperative adaptations to certain biomechanical requirements such as providing an offset option in the liner. However, this modularity also potentially lowers the threshold to conduct so-called minor revision surgery to deal with obvious radiographic PE wear or in case of recurrent instability. Furthermore, the threshold to change the liner during revision surgery primarily directed toward the stem is much lower than revising an all-cemented or monoblock socket. Therefore, similarly to some of the registries [11], we made the distinction between major and minor revisions of the socket. This evaluation showed that only 3 shells (0.6%) were revised. None was revised for aseptic loosening. Most revisions were liner exchanges (2.4%) indicating that the bone ingrowth could reliably be achieved with this implant and that the liner was the weakest link of the socket. Furthermore, most (90%) of the liner exchanges for PE wear were of non-XLPE liners. This problem might be addressed with XLPE, although long-term data are still not available, and we could not detect a significant difference in survivorship between both liners at intermediate term.

Some design features specific to this socket design can be important for the noted survivorships. First, the immediate postoperative fixation was reliable and was accomplished with the 3 spikes until sufficient bone ingrowth into the porous surface of the shell was achieved. Although there could be some concern regarding the spikes because they could theoretically induce an acetabular fracture by impaction of the socket, this was never encountered in our series. Second, only 2% of radiographically reviewed THA showed retroacetabular osteolysis either on the anteroposterior or cross-table view. This might be explained by the polar sealing of the socket in combination with the polished inner surface, thereby minimizing backside wear and extrusion of the PE debris through any screw holes [29-31,40]. Third, the locking mechanism was found to be reliable and easy to use and might have contributed to minimal backside wear by minimizing liner micromotion [29-31].

As shown by the registries and some long-term follow-up studies, multiple factors such as age, sex, primary diagnosis, and some design features play an important role for the survivorship of primary THA [11-15]. In general, male sex has been reported with a higher relative risk for failure, but this varies with age and fixation type [12,15,41]. Berry et al [2] identified female

sex, older age at time of surgery, and inflammatory diseases as strong predictors for an improved survivorship in a large series of 2000 cemented Charnley THA followed-up for 25 years. Age younger than 65 years and male sex were identified as the most important prognosticators for failure of THA in a randomized controlled trial of 250 Mallory-Head THA (Biomet, Warsaw, Ind) at 20 years [41]. At intermediate term, we could not detect an increased major revision rate in the age group younger than 65 years or in male patients. However, and somewhat surprisingly, we found a slightly increased overall revision rate in the age group older than 65 years. We believe that this could be explained by (1) the 6 liner revisions that were done during revision surgery directed toward the stem and (2) 4 liner revisions that were done for wear of non-XLPE liners, which were more frequently used in the older patient population.

As any case series, this study has some weaknesses. First, the usage of non-XLPE or XLPE was not subject of control. This was left to the decision of the surgeon, which explains the higher numbers of XLPE used in younger patients (68%). Furthermore, during the study period, the transition from non-XLPE to XLPE as the standard liner was being made in our institution. In addition, the higher rate of liner exchanges in the older patient population might be explained by the higher incidence of non-XLPE used in this population (75%) because 4 of 5 liner exchanges for PE wear were of non-XLPE liners. Second, the indication for revision surgery was at the discretion of the surgeon. In addition, liner exchanges during revisions directed toward the stem were included in the series. We acknowledge that this represents the worst-case scenario with regard to liner exchanges. Finally, there was a mixture of stems being used, which might influence the survivorship of a socket; however, we believe that this effect might be neutralized by the substantial number of 559 THAs in this series.

We conclude that the Reflection trispiked titanium shell demonstrated excellent fixation and survivorship at midterm follow-up with an extremely low rate of osteolysis, also in patients younger than 65 years at time of surgery. This acetabular component can be reliably used for the most primary THAs. This study supports the notion that the design changes associated with this second-generation acetabular system (ie, specific porous coating, polished inner surface, and improved locking mechanism) may represent an improvement from previous designs.

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