

Concepts of the Modern Ceramic on Ceramic Total Hip Arthroplasty and Early Results

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Abstract: We reviewed the results of 70 total hip replacements utilizing a modern ceramic on ceramic total hip prosthesis in 60 patients. The age of the selected patients ranged from 25 to 76 years (mean, 46 years). The diagnoses at the time of implantation were osteoarthritis (33 patients), avascular necrosis (29 patients), developmental hip dysplasia (four patients), rheumatoid arthritis (one), and post-traumatic arthritis (three patients). All procedures were primary arthroplasties. The average time of follow-up was at least three years with the average being 39 months. Follow-up evaluation consisted of a physical examination, radiographs, a SF-12 questionnaire and a Harris hip score rating at 6 weeks, 3 months, 6 months, and then 12 months post-operatively. Yearly evaluations were performed after the initial 12 month follow-up period.

At the time of follow-up, no evidence of aseptic loosening was noted either clinically or radiographically. There were two dislocations, in which one required an immediate revision for anterior instability. Another revision was required for an acetabular cup migration in a patient with severe osteoporosis. There were no ceramic component fractures.

Experience with this ceramic on ceramic total hip implant has been encouraging. Problems which had plagued older ceramic-ceramic articulating hip models have largely been eliminated by using state of the art hybrid hip arthroplasty designs and reliably high grade alumina quality.

The use of alumina ceramics in total hip arthroplasty has dated back over 30 years ago in Europe. Boutin implanted the first ceramic-on-ceramic cemented hip replacement in France in 1970 [1]. During the next few years, early experience with ceramic couplings began to emerge from Germany. Biomechanical and biocompatibility testing confirmed alumina as being a safe wear and corrosion resistant material with a low coefficient of friction [2–6]. Griss [7] and Mittelmeier [8] began implanting both cementless and cemented versions of the alumina device with reasonable short-term outcomes. Despite improvements in taper technology, surface polishing, and ceramic grade, the earlier failures eroded confidence in these devices especially in light of Charnley's early successes with the standard metal-on-polyethylene prostheses. Later failures of the ceramic articulations were the result of loosening and not ceramic

fractures. Most notable is the experience with the Autophor (Smith & Nephew Richards, Memphis, TN), which was the only ceramic-ceramic prosthesis marketed in the United States at the time. This implant had multiple design flaws not involving the ceramic bearings. These included a mono-block screw-in acetabular component without surface coating, a large skirt causing impingement, and a cementless femoral stem designed for macro-interlocking without any biological coating. Hence, the results were less than satisfactory [9]. Yoon et al. also reported their experience with this ceramic-on-ceramic total hip system. They found the prosthesis to have a high rate of loosening after 5 years from implantation. Failure was largely from the fixation of the acetabular component and the resulting osteolysis was documented [10]. Almost two decades ensued before the next generation of ceramic devices was reintroduced to the United States.

Evidence began to implicate polyethylene as the cause of aseptic loosening of total hip replacements subsequently limiting their survival despite advancements in fixation, metallurgy and technique [11–14]. Polyethylene was also determined to be highly vulnerable to third body wear resulting in rapid accumulation of polyethylene debris and subsequent aseptic loosening. While the susceptibilities of polyethylene were being uncovered, advancements in both the fixation of implants and other bearing surface materials were being made. Efforts to identify alternate bearing materials intensified, and the redesigned and upgraded ceramic-on-ceramic coupling emerged as a potential solution. We present three-year results of our first 60 patients who were implanted with a modern ceramic-on-ceramic total hip replacement as part of the Food and Drug Administration approved Investigational Device Exemption protocol along with information for the general orthopaedic surgeon regarding the features of this device.

Materials and Methods

In 1997, the Food and Drug Administration granted an Investigational Device Exemption to Wright Medical Technology (Arlington, TN) for conducting a clinical research trial used the Transcend™ modern ceramic-on-ceramic total hip replacement (Fig. 1). As part of a larger multi-center study, the series presented include the first sixty patients in this clinical trial who were implanted with this device at our institution. All patients enrolled in this study signed a con-

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sent form detailing the risks, benefits, and the uncertainties regarding this technology.

At our institution, the patients who participated in this study received the Transcend cup, characterized by a roughened Ti plasma sprayed shell with a machined interior taper to accept the alumina (ceramic) liner. The femoral stem, also manufactured by Wright Medical Technology, was cemented in all patients in our series. Sizes of the acetabular component implanted ranged from 46 mm to 64 mm, and the ceramic ball head sizes ranged from 28 mm to 36 mm in diameter. Patients were evaluated preoperatively, postoperatively at six weeks, and then three, six, and twelve months, and then annually. All patients were interviewed and examined by the operating surgeon, and quantitatively measured by the Harris hip score and Short Form-12 [15,16]. Radiographs taken at each postoperative interval included anteroposterior and cross-table lateral views of the involved hip. These radiographs were assessed for migration of any components, osseous adaptive changes, overall alignment, and radiolucencies or heterotopic bone formation which were documented using classifications per Gruen et al. [17], and Brooker et al. [18].

This series included 27 women and 32 men with 70 total hips implanted. The average age was 46 years (range, 25 to 76 years). All patients had either moderate to severe pain preoperatively with Harris hip scores averaging 43 and combined SF-12 scores averaging 74.

All surgeries were primary total hip replacements utilizing a posterior approach. Several technique modifications were adapted using this ceramic-on-ceramic articulation [19]. Among these adaptations, one was utilizing a more horizontal cup placement ($<45^\circ$) to minimize any potential overload of the ceramic rim and reduce the risk of fatigue failure. The other was incorporating an increased cup anteversion ($>20^\circ$) to maximize posterior coverage from the horizontal cup placement and to compensate for the lack of an elevated lip on the ceramic liner. Specific attention was then given to identifying and removing anterior acetabular wall osteophytes to minimize potential impingement from the more horizontal anteverted cup placement. A conservative femoral neck cut was used to compensate for the limited availability of ceramic ball head lengths (0 mm–8 mm).



Fig. 1.

Skirts are not a good design feature of ceramics as they can increase the risk of impingement and therefore they are not offered. The use of trial cup liners preserved the undisturbed acetabular cup Morse taper, and placement of the final ceramic liner was done by hand to ensure proper seating into the taper. All patients were allowed to ambulate postoperatively with full weight-bearing as tolerated on the involved side. An assistive ambulatory device was used up to 3 months post-operatively.

In the 50 patients who underwent a unilateral total hip arthroplasty, the diagnoses were avascular necrosis (23), osteoarthritis (30), hip dysplasia (3), rheumatoid arthritis (1), and post-traumatic arthritis (3). Ten of our patients had a staged bilateral operation and their diagnoses included osteoarthritis (3), avascular necrosis (6), and hip dysplasia (1).

Results

Of the 60 patients in our series with a minimum two-year follow-up period, three patients had died secondary to causes unrelated to the index surgery. One of these patients had severe osteoporosis and had significant migration of the cup within the first 6 weeks postoperatively. Immediate postoperative radiographs in this patient revealed no evidence of any fracture. Ultimately, the patient underwent a revision surgery of the acetabular side with satisfactory postoperative results. The patient died of aspergilloza pneumonia a few months after the one year follow-up visit. There were two dislocations, of which one was revised immediately for anterior instability. The other was braced after closed reduction and has not re-dislocated in the following three years. In all, there were a total of six complications related to the total hip replacement surgery with others including one foot drop, one deep venous thrombosis, and one patient developing congestive heart failure. A total of two revisions were performed and no patients were lost to follow-up. None of the complications were attributed to the ceramic couple, and there were no fractures of the ceramic components thus far.

Of the remaining 66 hips being followed (4 hips lost to patient death) for at least two years, the average Harris hip score improved from 43 to 97. The outcome measured by the SF-12 also improved from a combined average score of 74 to 105. Both results are classified as good to excellent. Only one patient complains of continued pain secondary to avascular necrosis involving both knees.

Radiographs evaluated at the three year postoperative interval show no evidence of any significant component wear or loosening. There is one patient who has developed heterotopic ossification which was classified as Brooker grade I occurring at zones C and seven. There have been no fractures of any ceramic components in any of the patients (Fig. 2).

Discussion

The series presented represents a relatively small number of patients with short term follow-up, but is part of much larger United States FDA approved clinical trials using

modern ceramic-on-ceramic articulating total hip systems. Short-term results of these trials are equally encouraging with no reported fractures of any implanted ceramic component to date, which has been a significant concern in the past.

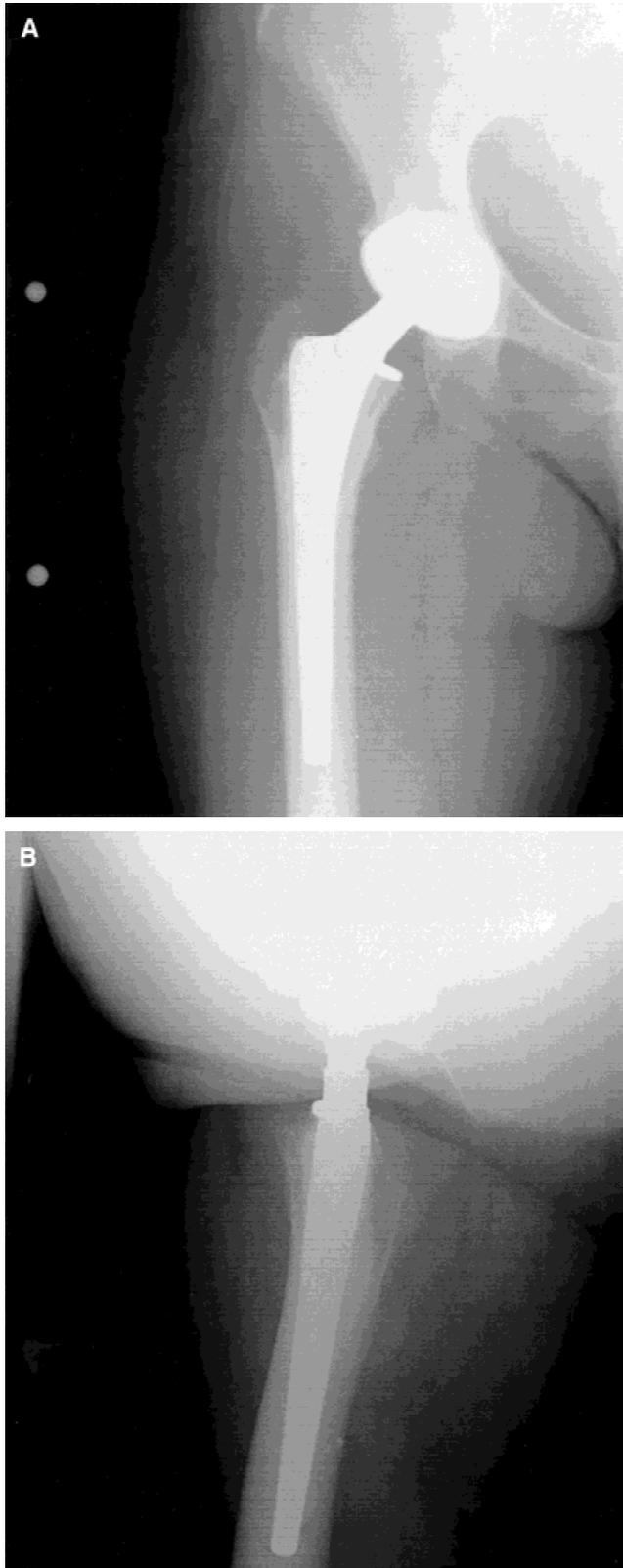


Fig. 2.

The modern ceramic-on-ceramic hip arthroplasty utilizes many of the advancements made in the fixation of implants, ceramic material properties, and quality testing methods. The development of improved cementing techniques on the femoral side has the theoretical advantage of achieving much longer implant life spans than implants with 20 year survivals employing older techniques. The excellent long-term follow-up results of metal backed cementless sockets have also largely inundated the all-polyethylene cemented sockets that had previous widespread use. These advancements in fixation of the implant to bone are still susceptible to osteolysis caused by the debris accumulation caused by the bearing surface of the metal-on-polyethylene articulation.

The alumina ceramic has many properties that make it an ideal bearing surface in total hip replacements. Its high density allows a very smooth surface finish ($ra\ 0.02$), which is superior to any metallic finish available today. The hydrophilic nature of alumina also affords better lubrication in an aqueous environment. The hardness of alumina provides remarkable resistance to wear. It is harder than metal, and particles caught between the ball and socket interface present little risk to third body wear [21]. Annual wear rate of a current day alumina-on-alumina articulation was determined to be $0.001\ mm$ [22]. This is considerably less than an alumina-on-polyethylene ($0.1\ mm$) or a metal-on-polyethylene ($0.2\ mm$) coupling [23]. Although metal-on-metal articulations have equivalent rates of wear, there are some concerns that this coupling can have some potentially harmful metal ion levels.

Several improvements in the processing and manufacturing of alumina ceramic were made to maximize its attractive properties. The grain size of the alumina, which is currently the ceramic of choice, has been reduced by a factor of three from alumina material used in earlier designs wrought with material fractures. In addition, refinements of the Morse taper [8], which facilitates the ceramic head attachment with the metal stem, have essentially eliminated the high rate of ceramic head fractures. Many more advancements to the processing of high grade alumina were adopted including clean room processing, improved sintering techniques, hot isostatic pressing, and laser marking [20]. Finally, with the inception of proof testing [24], the manufacturer is able to test the material without compromising the integrity of the components. This is a non-destructive test in which each component is subjected to an overload challenge where defective products are detected with great accuracy and components that pass this test are released for clinical use. This additional step has greatly afforded the ability to screen for and remove flawed devices. The biolox forte, the newest generation of ceramics, has fracture rates so low that it is equivalent to accepted risks of other mechanical failure (stem fracture, liner dissociation, etc.).

Conclusion

Despite almost 30 years of clinical use of the ceramic-on-ceramic bearings mostly in Europe, clinical trials have finally begun in the United States. The ceramic ball head

has been approved by the FDA, and it is currently being used in the ceramic-on-polyethylene coupling. However, the shortcomings of polyethylene are becoming clearer in its role in aseptic loosening and susceptibility to third body wear. Data suggests a ceramic-ceramic couple has a reduction of wear of over 200 times that of a standard metal-on-polyethylene articulation. Improvements in ceramic quality, in addition to enhanced understanding of taper technology, ceramic biomechanics, and tribology have increased the confidence in using this material for clinical applications. In the setting of precise operative technique and current materials, the modern ceramic-on-ceramic total hip arthroplasty can be implanted safely with encouraging short term outcomes. The ultimate merits of the ceramic articulation will not be evident until many years to come.

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