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Original research

Survivorship of a modular acetabular cup system: medium- to long-term follow-up

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ABSTRACT

Background: Total hip arthroplasty (THA) requires components that meet a variety of patient factors and needs. This investigation evaluated survivorship of the PINNACLE Acetabular Cup System in primary total hip arthroplasty at 5-10 years.
Methods: In total, 1592 hips (1473 subjects) were enrolled in a multi-center, non-comparative, open-label study of the PINNACLE system: $N = 896$ metal-on-polyethylene (MOP), $N = 667$ metal-on-metal (MOM), $N = 27$ ceramic-on-polyethylene, and $N = 2$ unknown articulation. Harris Hip Score, Short Form 36, Western Ontario and McMaster Universities Osteoarthritis Index, and radiographs were collected through 10 years. Kaplan-Meier device survivorship was estimated.
Results: There were 41 revisions (23 MOP, 17 MOM, 1 ceramic-on-polyethylene) through 10 years: 56.5% of MOP revisions were for instability and 41.2% of MOM revisions were for adverse local tissue reaction. Kaplan-Meier device survivorship (N with further follow-up) was 97.0% ($N = 720$) at 5 years and 94.7% ($N = 77$) at 10 years.
Conclusions: Medium- to long-term survivorship estimates were similar or better than other studies and registries for the PINNACLE system.
Level of Evidence: III.

Introduction

Modern techniques in total hip arthroplasty (THA) provide reliable improvement in hip function and reduction in pain. Technical developments, such as cross-linked polyethylene (PE) and alternate bearing surfaces, including ceramic-on-ceramic and metal-on metal (MOM), have extended the application of THA to younger, more active patients. In order to accommodate these changes, surgeons require hip components that provide flexibility in choosing the most suitable hip system for the patient, while maximizing the durability and long-term stability of the implants. The PINNACLE Acetabular Cup System (DePuy Synthes Joint Reconstruction, Warsaw, IN) provides a 2-piece modular acetabular implant (cup and liner) that allows the surgeon the flexibility to choose different levels of fixation of the cup, such as press fit or the use of multiple screws. The design also provides the freedom to choose from several liner options, and the modularity of the system facilitates changing the liner without removing the metal cup, which may reduce the need to revise an otherwise well-positioned, ingrown cup in revision situations.

The primary objective of this investigation was to evaluate the survivorship of the PINNACLE Acetabular Cup System in primary THA at 5 years, and up to 10 years post-operatively if sufficient data were available. Kaplan-Meier (KM) methodology was utilized for estimating device survivorship at 5-10 years post-operatively to adjust for patients who were lost to follow-up; unrevised patients were censored at the time of their last follow-up.

Material and methods

Subjects and participating centers

Between July 2000 and June 2007, 1592 primary THAs in 1473 patients were enrolled in a multi-center, non-comparative,

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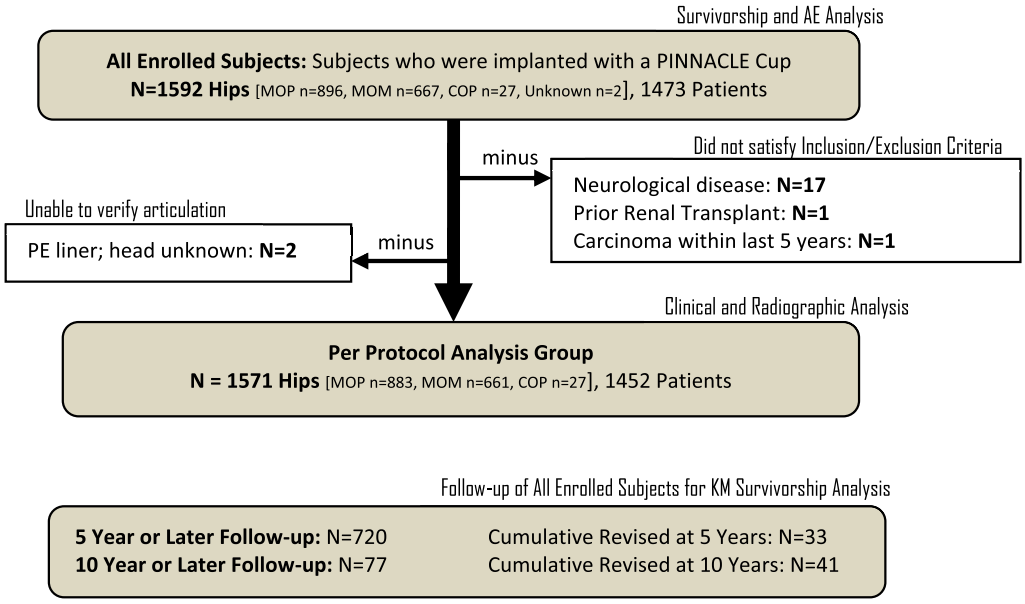

Figure 1. Dataset flow diagram.

open-label study of the PINNACLE Acetabular Cup System. The study is registered on www.clinicaltrials.gov (NCT #00306930). Surgeries were performed by 17 surgeons at 17 centers throughout the USA; 1 additional site participated in patient follow-up. Enrollment was intended to be prospective, but at least 1 site enrolled some patients after their surgery had taken place. All subjects provided informed patient consent or authorization for release of medical records for participation in a hip study; some provided consent/authorization after the time of their surgery. Thirty-one patients signed an authorization for release of medical records for participation in a stem study, and their data were included in this study of the PINNACLE Acetabular Cup System. Institutional Review Board (IRB) approval was not required in the original study protocol because this study was considered to be a registry type of data collection for products which were cleared for market in the USA. Thirteen sites eventually obtained IRB approval, either from their own institution or Western IRB. Five sites did not obtain IRB approval. Regarding data collection, the sponsor is aware of various record-keeping irregularities at one or more centers that were not in accordance with the initial or subsequently revised study protocols. These record-keeping irregularities did not, in the sponsor's estimation, affect the integrity of the data. Some investigators, including those who did not obtain IRB approval, ended their study participation early at various times between 2005 and 2012, prior to the end of the study. The last patient follow-up for this study occurred in January 2013.

Patients were selected for inclusion into the study in accordance with the normal criteria for total hip replacement and in compliance with the labeling for the device. Additional inclusion criteria consisted of sufficient bone stock to support and seat the prosthesis and signed informed patient consent/authorization. Patients were excluded if they had prior renal transplant, history of active joint sepsis, recent high systemic dose of corticosteroids, carcinoma in the last 5 years, neurological disease (eg, Parkinson's disease), psycho-social disorders that would limit rehabilitation, and use of structural bone graft. Patient follow-up data were collected at 6 weeks, 6 months, and then annually, with the intention of collecting data through a minimum of 5 years and a maximum of 10 years post-operatively.

Study components

All surgeries utilized the PINNACLE Acetabular Cup System, which provides a variety of cup designs and size options. The PINNACLE cups are cementless titanium alloy cups, available with no screw holes or with various numbers and configurations of screw holes or spikes for adjunct fixation. The 100 Series (no screw holes), 300 Series (3 spikes), and Sector (3 screw holes) options are available in sizes 48-66 mm. The multi-hole (8-12 screw holes) option is available in sizes 48-72 mm, and the Bantam (multi-hole), which is intended for smaller patients or acetabular dimensions, is available in sizes 38-46 mm. All cups feature the POROCOAT Porous Coating on the back of the cup, with the option of hydroxyapatite coating over the POROCOAT on some cup designs. The inside of the PINNACLE Acetabular Cup consists of a central dome region and the Variable Interface Prosthesis taper. The taper design facilitates insertion, retention, and removal of the modular components.

For this study, the PINNACLE Acetabular Cup was used in conjunction with one of the 3 femoral head and acetabular liner combinations: metal-on-polyethylene (MOP), MOM, and ceramic-on-polyethylene (COP). Among the 1592 study hips, there were 56% (896/1592) MOP, 42% (667/1592) MOM, 2% (27/1592) COP, and 0.1% (2/1592) having a PE liner but of undetermined femoral head (MOP or COP). The choice of femoral stem, the type of articulation (MOP, MOM, or COP), and the size of all THA

Table 1
Demographics.

Variable	All subjects ($N = 1592$)	MOP ($N = 896$)	MOM ($N = 667$)
Age [y, mean (range)]	62.1 (18-100)	67.4 (19-91)	55.1 (20-100)
BMI [kg/mm^2, mean (range)]	29.7 (15.7-65.4)	29.3 (15.7-65.4)	30.3 (18.1-64.3)
Gender (male/female)	47.8/52.2	37.5%/62.5%	61.9%/38.1%
Diagnosis	OA: 86.7%	OA: 89.6%	OA: 83.2%
	AVN: 7.4%	AVN: 4.6%	AVN: 10.9%
	PTA: 1.6%	PTA: 1.3%	PTA: 1.8%
	RA: 1.6%	RA: 2.2%	RA: 0.6%
	Other: 2.7%	Other: 2.2%	Other: 3.4%

AVN, avascular necrosis; BMI, body mass index; OA, osteoarthritis; PTA, post-traumatic arthritis; RA, rheumatoid arthritis.