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Cementless Semi-Constrained Rotating Platform Total Knee Replacement: A Concise Follow-Up of a Previous Report at a Minimum of Twenty Years

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Abstract

Background: A previous report evaluated the initial 310 cementless, Buechel-Pappas (B-P), Semi-Constrained Rotating Platform total knee replacements in 257 patients followed for an average of 7.6 years, range 2 - 18 years. Diagnoses were osteoarthritis in 233 patients, post traumatic arthritis in 4 patients and rheumatoid arthritis in 22 patients. Knee Scores, using a strict knee scoring scale were 86.4% excellent, 12.3% good, 0.3% fair and 1.0% poor results. Survivorship, using an end point of revision for any mechanical reason (including component loosening, bearing wear and bearing dislocation) was 99.4%. Survivorship for a poor knee score (including persistent pain, loosening, instability and infection was 97.6%. The purpose of the present study is to report the updated results of this same patient cohort at a minimum follow-up of twenty years. **Methods:** The average age of patients at the time of surgery was 67 years, range 34 to 91 years. A total of 20 patients (22 knees) were still living, with a follow-up of 20 - 30 years (mean 23.47 years). The same strict knee scoring scale and survivorship analysis were used to evaluate patient outcomes at the 20 to 30 years interval. **Results:** Survivorship, in the current study, using the same end points as in the previous study, was 96.5% at the 20 and 30-year intervals. Late mechanical failure and osteolysis were not identified. **Conclusion:** This cementless, semi-constrained rotating platform total knee replacement has stood the test of time for more than 20 years and can be considered acceptable for long-term use, in properly selected patients.

Keywords

Knee Replacement, Cementless, Semi-Constrained Rotating

1. Background

The evaluation of 310 cementless B-P semi-constrained rotating platform total knee replacements in 257 patients was previously published in 2011 [1] after presentation at the ASTM Mobile Bearing Knee Conference held in St. Louis, Missouri in 2010 [2]. The purpose of the original publication was to justify subtle changes to the successful LCS rotating platform total knee replacement to improve its performance in terms of wear resistance and minimize or eliminate the 1% - 2% problem of subluxation/dislocation (also known as "spin out") of the rotating platform bearing [1]. The rationale for changing the unconstrained rotating platform into a semi-constrained device has been previously reported [2] [3] and was instrumental in its subsequent use as an FDA 510 K cleared device [4] [5] [6] [7]. This design improvement also followed previously published recommendations to the FDA for using improved contact stress analysis and survivorship when pursuing design changes or improvements of joint replacement devices [8].

All patients in the original study with end-stage arthritis between October 1991 and October 2009 received the Cementless B-P Semi-constrained Rotating Platform Total Knee Replacement, coated with titanium nitride (TiN) ceramic. In the original paper, at a minimum 2-year interval, the patella resurfaced in 127 (49.0%) cases and unresurfaced in 132 (51.0%) cases with no failures or patient preference noted in either group. Device-related complications were not seen. One infection occurred late (3.3 years) in an immune-compromised rheumatoid patient. The other major complications included tibial component loosening in 2 multiply-operated super obese (BMI > 50) male osteoarthritic patients, traumatic ligamentous instability in 2 patients and traumatic quadriceps ruptures in 2 patients, all of which recovered after surgical intervention.

The purpose of the present study is to evaluate the longer-term results of this cohort at a minimum follow-up of 20 years with an emphasis on reoperations, wear and osteolysis.

2. Methods

Patient demographic data and the flexion-extension gap balancing surgical technique have been previously described [1] [9] [10].

Buechel-Pappas cementless semi-constrained total knee replacements components (Endotec, Inc., Orlando, FL) were used in all patients.

Clinical evaluations were undertaken with the validated New Jersey Orthopaedic Hospital Knee Evaluation Scoring System which uses pain, function, range of motion, stability and strength parameters for a total of 100 points [11]. A score of 85 - 100 is considered excellent, 70 - 85 is good, 60 - 70 is fair and below 60 is poor.

Antero-posterior and lateral radiographs, Merchant view (when available) were evaluated for alignment, component position, radiolucent lines, polyethylene wear and osteolysis. Osteolysis was defined as a radiolucent lesion of 5 mm^2 or more with progressive radiolucencies compared to the pre-op or immediate post-op

radiographs.

3. Results

Our original study cohort included 257 patients (310 knees) with an average age of 67 years (range, 34 to 91 years) at the time of surgery. Since the time of the original study (2010), twenty patients (22 knees) were still living, with a follow-up of 20 - 30 years (mean 23.47 years). Of that group, knee scores were 95.5% excellent, 4.5% good, 0.0% fair and 0.0% poor. Post-operative Range of Motion, in the previous study, averaged 116˚ total arc, range 30˚ to 142˚. The current study averaged 112˚ total arc, range 70˚ to 134˚.

Available radiographs at greater than 20 years from index surgery were evaluated for component loosening or migration and osteolysis. One set of radiographs was reviewed, which failed to demonstrate loosening or lytic changes around the metallic components, see Figure 1.

Survivorship analysis [12] in the previous study using an end point of revision for any mechanical reason (including component loosening, bearing wear and bearing dislocation) was 99.4%. Using a poor clinical knee score as an endpoint (including persistent pain, loosening, instability and infection), the survivorship was 97.6% at an average of 7.6 years, with a confidence interval of 95% [12].

In the current study, combining the endpoints of reoperation for any reason or a poor clinical knee score, the survivorship was 96.5% at a mean of 23.47 years, range 20 - 30 years, see Figure 2.

(a) (b) (c)

Figure 1. Radiographs of a 71-year-old male patient, 26 years Post-Op. (a) Lateral X-ray of the right knee without a patella replacement; (b) Antero-posterior X-ray of both knees; (c) Lateral X-ray of the left knee with a rotating patella replacement.

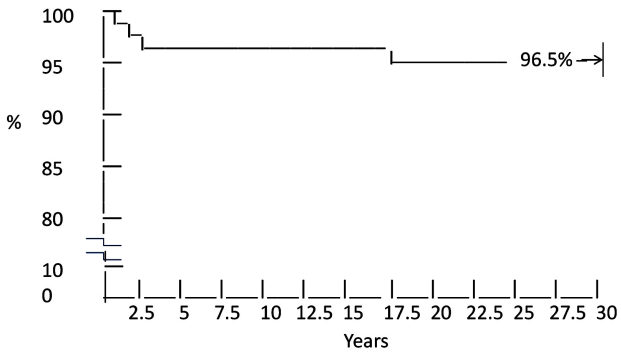

Figure 2. Survivorship analysis of current study at a minimum of 20 years, mean: 23.47 years (range: 20 - 30 years).

4. Complications

The original study complications, requiring implant revision or fracture management, are shown in Table 1.

Two tibial components subsided in two multiply-operated, super obese, Body Mass Index (BMI) > 50 kg/m^2 (318 lb. and 300 lb.) osteoarthritic male patients, one into valgus and the other into varus after 18 months and 11 months, respectively. In both cases, the tibial component settled into the previous fixed-valgus and fixed varus deformities, while cystic degeneration and evidence of avascular necrosis of the tibial plateau were noted under the tibial loading plates. Long-stemmed, modular revision tibial components, with screw-reinforced antibiotic cement were successfully used to correct the deformities without removing the well-fixed femoral components.

Soft tissue repairs, thicker polyethylene bearings and fracture bracing were used to successfully address the other major complications, without the need to remove well-fixed femoral and tibial components. The only infection was seen in an immune compromised rheumatoid female after 3.3 years, which required exchange revision surgery.

In the current study, one additional tibial component loosening was seen in a morbidly obese (BMI 41) (300 lbs) osteoarthritic male. The component subsided into varus after 10 months and required revision to a cemented long-stem tibial component. Also, a traumatic proximal tibial fracture was encountered after 17 years in a morbidly obese (BMI > 50) (300 lbs) osteoporotic female. The fracture failed to unite after electrical stimulation and bracing for 6 months, developed progressive anterior angulation and required surgical management. A long-stemmed revision tibial prosthesis was used to re-align and manage the proximal tibial fracture. Her index tibial component was solidly ingrown with bone at the time of revision and required multiple osteotomes for its successful removal.

Table 1. Complications requiring surgical management in 310 B-P total knee replacements in 257 patients.

Complication	Number of Occurrences	Time of Occurrence (Years)	Management
Supracondylar femur fracture	1	0.1	Fracture Bracing
Femoral component loosening	0	-	-
Tibial component loosening	2	0.9, 1.5	Cemented Revision with Long-Stem Tibial Component
Patellar component loosening	0	-	-
Bearing dislocation	0	-	-
Bearing wear	0	-	-
Patellar bearing wear	0	-	-
Ligamentous instability	2	1.0, 1.1	Thicker Bearing and/or MCLRepair
Deep infection	1	3.3	Exchange Revision
Poor Wound Healing	4	0.1, 0.1, 0.1, 0.1	Wound Revision and Primary Closure
Quadriceps Rupture	2	0.1, 0.2	Quadriceps Repair

No femoral or patella component loosening was seen. Additionally, as in the previous study, no semi-constrained rotating platform bearing wear, osteolysis or "spin-out" was seen in this current study.

5. Discussion

Multiple long term studies have demonstrated satisfactory clinical performance of the cemented and cementless Low Contact Stress (LCS) rotating platform total knee replacement [1] [2] [13]-[29]. Since its first implantation in 1978, [30] the major mechanical complications reported over the past 44 years have been associated with rotary dislocation (also known as "spin out") in 1.8% of cases with flexion instability [2] [3]. Additionally, wear debris synovitis and osteolysis have been increasing over time due to the adverse oxidation and subsequent wear effects of shelf-aged, gamma-in-air sterilization of ultra-high-molecular-weight polyethylene used for bearing surfaces [31]. This sterilization methodology, which has been largely abandoned since the mid-1990s, caused subsurface cracking and delamination, which became very sensitive to the higher contact stress levels seen in most fixed-bearing knee replacement designs. The lower contact stresses seen in the LCS rotating platform knee replacements allowed for a longer service life of the bearings before surface delamination eventually occurred [32].

This most recent minimum 20-year follow-up study of the cementless, semi-constrained, B-P rotating platform, designed by the original LCS knee designers, has demonstrated long term improvement in both areas of wear and instability. The use of ethylene oxide sterilization has greatly reduced or eliminated osteolysis while adding a tibial component rotational stop-pin to limit axial over-rotation, thus creating a semi-constrained device, which appears to have substantially reduced or eliminated "spin-out" dislocations.

6. Conclusion

The Cementless B-P, Semi-Constrained Rotating Platform Total Knee Replacement improves upon the successful LCS Rotating Platform design by addressing the small (1% - 2%) [1] but formidable complications of wear and instability. This device can be considered acceptable for long term clinical use in properly selected patients.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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