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ORIGINAL ARTICLE

Early Results of a Modular Cementless Tibial Component for Total Knee Arthroplasty

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Abstract

Cementless components in TKA have been used for almost 3 decades, despite mixed success rates. However, biologic fixation remains attractive, especially for younger patients, because of the potential of unlimited durability. This paper is the first to report results on a modular tibial base plate using trabecular metal as a fixation surface. Twenty-four primary TKAs were evaluated clinical and radiographically at mean 1.9 year followup. Excellent clinical results were obtained. There was no significant subsidence or change in orientation of any component. One component was probably loose radiographically but was insufficiently symptomatic to warrant revision. Five components showed nonprogressive radiolucent lines. One reoperation was performed for stiffness, at which time the components were well fixed. Thus, it would appear that excellent bony fixation can be achieved with a modular cementless tibial component with excellent short-term clinical results.

Introduction

Cementless components in total knee arthroplasty (TKA) have been used for three decades, with mixed results, especially for fixation. As such, cemented components have continued to be endorsed as the gold standard [1-5]. However, cementless fixation remains attractive, especially for younger and more active patients, in whom cemented fixation may be less durable, with a greater risk of polyethylene wear/osteolysis from third body wear [1,6,7]. Therefore, an optimum implant would be cementless and reliably achieve durable bony fixation.

Previous cementless devices suffered from poor design characteristics such as improper pore size, debonding of the porous coating, and excessively thin polyethylene inserts [8]. Newer technologies such as hydroxyapatite coating have to achieve better osseointegration at early follow-up with limited subsidence [9]. Similarly, nonmodular trabecular metal (TM) tibial components have demonstrated excellent fixation and mid-term durability [10,11].

This study evaluates the early radiographic fixation status and changes and clinical outcomes of a modular tibial component with a TM coating intended for cementless fixation. To the best of our knowledge, this is the first report on this implant.

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Patients/Methods

A total of 24 primary TKAs (16 right sided) indicated for painful OA unresponsive to conservative medical therapy were performed in 21 patients by the senior author (RKS) from 2007 to 2009. The cohort consisted of 5 females and 16 males. The mean age at the time of surgery was 64.78 (range 46.94-74.95; SD 7.00). The mean age of males was 66.39 (range 55.54-74.95; SD 5.69). The average age of females was 59.94 (46.94-68.84; 8.71). Three patients had bilateral TKAs, with 2 patients having simultaneous bilateral TKAs. In no case was a TM tray abandoned for a cemented component. These data are summarized in Table 1.

Table 1: Demographics

Number of Patients	21
Males/Females	16/5
Average Age for cohort in years (range; SD)	64.78 (46.94-74.95; 7.00)
Average Age Males in years (range; SD)	66.39 (55.54-74.95; 5.69)
Average Age Females in years (range; SD)	59.94 (46.94-68.84; 8.71)
Average Follow-up in in years (range; SD)	1.78 (.08-4.14;1.25)

All of the surgeries were performed using a mini-midvastus approach and used an uncemented Zimmer® NexGen® Trabecular Metal™ Tibial Tray (Figure 1), a cemented posteriorly stabilized Zimmer® NexGen® LPS-flex femur and cemented all-polyethylene patellar components. Post-operatively patients were allowed immediate weight bearing as tolerated status with the use of crutches or a walker. Continuous passive motion was not used with any of the patients. Thomboprophylaxis was achieved with use of aspirin and calf pumps.

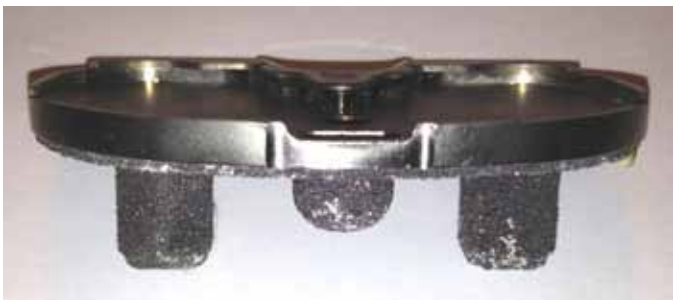

Figure 1: Zimmer® NexGen® Trabecular Metal™ Modular Tibial Tray. The implant has the standard locking mechanism, and has 3 pegs coated in trabecular metal for bone ingrowth.

Fixation status was assessed by retrospectively evaluating serial standard Anterior-Posterior and Lateral radiographs, which were obtained immediately post-operatively and at an average of 1.78 years post-operatively. The presence or absence of lucencies was recorded at 13 coronal zones and 4 lateral zones as illustrated in Figure 2. Additionally, immediate postop and latest follow-up X-rays were evaluated for changes in femoral-tibial angle (FTA), coronal femoral component angle (cFCA), coronal tibial component angle (cTCA) and the posterior tibial slope. All Radiographs assessed were digital, with built-in measurement tools and image enhancement features. Finally, a chart review was performed to obtain information on postop ROM, recovery status, and complications.

Figure 2: Tibial Zones

Results

Table 2 summarizes the alignment measurement data. The average FTA change from immediate postop to the latest films was 0.33 degrees valgus from 4.25 valgus (range: 10 valgus - 4 varus) to 3.92 valgus (range: 9 valgus - 10 varus) with t(23)=0.725, p=0.476 showing no significant statistical difference. The average cFCA change from immediate postop to the latest films was 0.59 degrees varus with t(23)=0.394, p=0.697, showing no significant statistical difference. The average cTCA change from immediate postop to the latest films was 1.21 degrees valgus with t(23)=0.011, p=0.991 showing no significant statistical difference. The average cFCA change from immediate postop to the latest films was an increase by 0.72 degrees with t(23)= 0.449, p=0.658, showing no significant statistical difference.

Table 2: X-ray measurements

	Average 1st Postop Measurement (range)	**Average Most Recent Measurement (range)**	**Mean Difference (degrees)**	**Standard Deviation**	**T-test**	**P-value**
FTA	4.25 valgus (10 valgus -4 varus)	3.92 valgus (9 valgus - 10 varus)	0.3	4.58	0.725	0.476
cFCA	2.97	3.56	0.59	3.34	0.394	0.697
cTCA	1.24	0.029	1.21	2.14	0.011	0.991
PTS	4.31	5.03	0.72	4.58	0.449	0.658

Figure 3 demonstrates the radiographic appearance of a fully osseointegrated, well functioning component. Immediate post op films showed one knee with one non-pro-

gressive radiolucent line (RLLs) in coronal zone 1 and in one other patient on the lateral view there was another non-progressive radiolucent line in the anterior tray region that both subsequently cleared on the most recent follow-up films. On follow-up A/P films there were 5 components with non-progressive RLLs on AP views: 3 RLLs in zone 1, 2 RLLs in zone 3, 1 RLL in zone 5, 1 RLL in zone 9 and 3 RLLs in 13. On follow-up lateral films there were 6 components with non-progressive RLLs with 6 seen in the anterior tray and 2 in the posterior tray (Table 3). All RLLs were 1 mm or less in thickness.

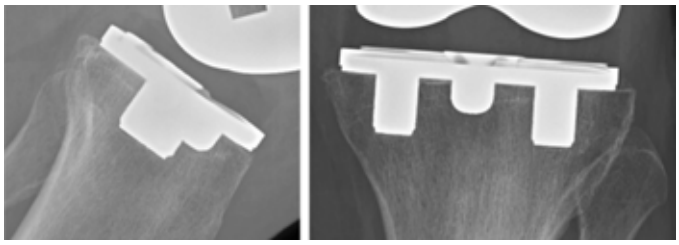

Figure 3: Example of well-fixed component without lucencies

Table 3: Fixation Status

	# of RLLs**	
Coronal Zone*	**Immediate post-op**	**Most recent**
1	1	3 (3 new, 1 resolved)
3	0	1
5	0	1
9	0	1
13	0	3

	# of RLLs**	
Lateral Zone*	**Immediate post-op**	**Most recent**
Anterior Tray	1	6 (6 new, 1 resolved)
Posterior Tray	0	2

** all unlisted zones had no RLLs present*
*** all RLLs were non-progressive*

On clinical follow-up, one reoperation was done at 7 months post op and was needed due to poor ROM with pain and swelling, stiffness, and startup pain. In this particular case only the polyethylene insert was replaced, as the tibial implant was found to be well fixed intra-operatively. Another patient required fluid aspiration, was experiencing increased quad weakness and had a probable radiographically loose component (Figure 4), but opted not to revise at 18 months post op as pain was tolerable. A third patient at 17 months post op was experiencing knee pain and overactivity-induced pes bursitis and was given a cortisone shot, with symptom relief. Otherwise, generally patients recovered well, with no other notable symptomatic RLLs and with minimal residual pain symptoms. Average ROM post op was 0.6*(range 0-10) to 118.7* (range 80-140). Two out of 24 patients had a flexion contracture of 5* and 10*, with the rest having full extension. Sixteen out of 24 patients had flexion to 120* or greater postop (data summarized in Table 4).

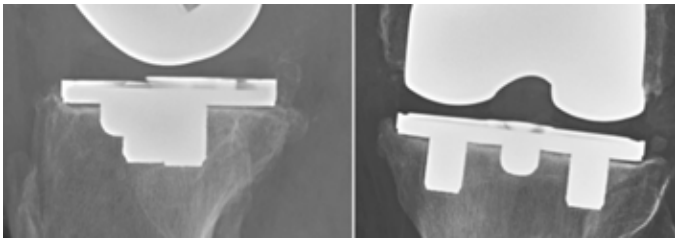

Figure 4: Example of worst appearing x-ray in series. In Zones, 4, 5, 6, 7, 8, 10, 11 and 12, there is evidence of bone ingrowth, despite radiolucent lines in other zones.

Table 4: Final post-op follow-up results

ROM Measurement	Average	Range	SD
Extension	0.625°	0°-10°	2.24
Flexion	118.7°	80°-140°	18.6

Discussion

This is the first report on a modular trabecular tibial component intended for cementless fixation during TKA. In general, this design reliably achieved early bony fixation. No components were revised and 1/24 was probably radiographically loose or fibrous stable. Compared to other cementless designs, this low failure rate compares favorably. For example, Moran et al found a 19% failure rate due to aseptic failure of the tibial component in a series of 108 primary total knee arthroplasties in 96 patients after an average follow-up of 64 months using an uncemented, porous-coated system (PCA designed by Howmedica, Rutherford, NJ) 4. Additionally, Goldberg et al observed a 13% failure rate in 124 TKAs on 99 patients after an average follow-up of 11 years in the surviving knees (Miller- Galante I, designed by Zimmer, Warsaw, IN), although only 1 revision was cited as being due to tibial component loosening. Additionally, Berger et al observed a 19% failure rate (7% due to tibial loosening) in a series of 108 TKAs (Miller-Galante I, designed by Zimmer, Warsaw, IN), performed on 82 patients after follow-up greater than 7 years, and average 11 year follow-up of surviving knees2. In addition, this modular version compares favorably to its nonmodular counterpart. Patients did not have prolonged pain postoperatively, and at latest follow-up, behaved like typical TKA patients.

Given the short follow-up, no comments can be made regarding durability of fixation. Longer term study will be needed. In addition, the femoral component was a high flex

PS design, possibly loading the implant posteriorly to a higher degree than a non-high flex or CR design would. Nevertheless, initial mechanical fixation appeared to be adequate to achieve bony ingrowth. Lastly, although the trabecular metal fixation surface has enjoyed success in multiple applications, the data from this study utilizing this particular tibial component design cannot be extrapolated to other tray designs or to femoral components. Nevertheless, use of a modular tibial tray designed for cementless fixation appears to be safe and effective.

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