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Second-generation uncemented total hip arthroplasty: a minimum 20-year follow-up

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Aims
We present the clinical and radiological results at a minimum follow-up of 20 years using a second-generation uncemented total hip arthroplasty (THA). These results are compared to our previously published results using a first-generation hip arthroplasty followed for 20 years.

Methods
A total of 62 uncemented THAs in 60 patients were performed between 1993 and 1994. The titanium femoral component used in all cases was a Taperloc with a reduced distal stem. The acetabular component was a fully porous coated threaded hemispheric titanium shell (T-Tap ST). The outcome of every femoral and acetabular component with regard to retention or revision was determined for all 62 THAs. Complete clinical follow-up at a minimum of 20 years was obtained on every living patient. Radiological follow-up was obtained on all but one.

Results
Two femoral components (3.2%) required revision. One stem was revised secondary to a periprosthetic fracture one year postoperatively and one was revised for late sepsis. No femoral component was revised for aseptic loosening. Six acetabular components had required revision, five for aseptic loosening. One additional acetabular component was revised for sepsis. Radiologically, all femoral components remained well fixed. One acetabular was judged loose by radiological criteria. The mean Harris Hip Score improved from 46 points (30 to 67) preoperatively to 89 points (78 to 100) at final follow-up. With revision for aseptic loosening as the endpoint, survival of the acetabular component was 95% (95% confidence interval (CI) 90 to 98) at 25 years. Femoral component survival was 100%.

Conclusion
The most significant finding of this report was the low prevalence of aseptic loosening and revision of the femoral component at a mean follow-up of 22 years. A second important finding was the survival of over 90% of the hemispheric threaded ring acetabular components. While these shells remain controversial, in this series they performed well.

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Introduction
The advent of uncemented total hip arthroplasty (THA) was a direct response to the high rate of component loosening reported in association with first-generation techniques of cementing. These poor results were particularly striking in high-risk patients such as the young and obese.[1-3] The central goal of porous coated implants was to promote fixation by stable osseous ingrowth, thereby decreasing the prevalence of mechanical loosening. The results using several early cementless THAs were discouraging. They were plagued by thigh pain, subsidence, and early mechanical failure.[4-6] Changes in the design of both femoral and acetabular components have focused on achieving long-term durable fixation and enhanced clinical outcomes. Tapered femoral components are widely used in clinical practice today. To determine the long-term durability of these extensively used devices, studies

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Table I. Primary diagnosis.

Diagnosis	Hips, n
Osteoarthritis	48
Rheumatoid arthritis	10
Developmental dysplasia	2
Avascular necrosis	2

with a minimum follow-up of 20 years are needed. Fully porous coated hemispheric acetabular components are considered by many to be the gold standard for acetabular fixation. Threaded ring components remain controversial. The question must be answered whether a fully porous coated hemispheric acetabular shell with threads will achieve long-term fixation.

The first-generation Taperloc (Zimmer Biomet, Warsaw, Indiana, USA) femoral component was a wedge shaped, titanium stem proximally porous coated with plasma spray. It was a non-modular component with a 28 mm titanium femoral head. The first-generation T-Tap (Zimmer Biomet) acetabular component was a non-porous coated, conically shaped threaded ring. Previously, we reported the mean 20-year results using this first-generation titanium cementless THA.[7] Of the 58 patients (65 hips) surviving a minimum of 18 years (18 to 22.6) post-index procedure, no femoral component required revision for aseptic loosening; however, eight stems (12%) had been revised. The T-Tap acetabular component used in this series functioned poorly. At final follow-up, 57% had been revised.

We began using a second-generation uncemented THA in 1993. Over a ten-year period, significant changes in the design of both the femoral and acetabular components had been made. On the femoral side, the tapered stem now had a modular head-neck junction. The diameter of the distal non-porous coated portion of the stem was reduced to allow easier insertion in hips with a narrow femoral isthmus. The proximally porous coated portion of the stem was left unchanged. The acetabular shell was changed from a conically shaped threaded component without porous coating to a fully porous coated hemisphere with threads.

The aim of this study is to evaluate, at a minimum of 20 years follow-up, the durability of fixation using a second-generation uncemented primary THA. These results are compared to our previously published results with first-generation components followed for 20 years.

Methods

Between September 1993 and November 1994, 172 consecutive primary uncemented THAs were performed on 162 patients using second-generation components. In all, 60 patients (62 hips) survived a minimum 20 years following the index procedure and are the focus of this review. Our institutional review board approved the

Fig. 1

Photograph of the first- (left) and second- (right) generation Taperloc femoral components. The second-generation is modular and has a reduced profile distal to the porous coating.

present study and informed consent was obtained from every patient. All surgeries were performed by a single surgeon (JRM) at one centre. The mean age of 31 females (32 hips) and 29 males (30 hips) at the time of surgery was 57 (27 to 74). The average body mass index was 29 kg/m^2 (20.7 to 42.6). The indication for primary THA was osteoarthritis in 48 hips, (77.4%), rheumatoid arthritis in ten hips, (16.3%), avascular necrosis in two hips, (3.2%), and developmental dysplasia in two hips, (3.2%) (Table I). Among the 60 living patients (62 hips), five had undergone isolated revision of the acetabular component, one had required femoral component revision and one patient had undergone revision of both components. In the 59 patients (61 hips) who had not required revision of both the acetabular and femoral components, clinical follow-up was obtained on every patient at a mean of 22 years (20 to 25). Radiological follow-up was obtained on all but one patient.

The second-generation Taperloc femoral component was used in all hips in this series. Both the first and

Fig. 2

Photograph of the first- (left) and second- (right) generation T-Tap and T-Tap ST acetabular components. The second-generation T-Tap is a fully porous coated hemisphere with threads.

second-generation Taperloc stems are made of wrought titanium alloy Ti-6Al4V and have a tapered rectangular shape designed to achieve fixation mediolaterally within the proximal aspect of the femur. The first-generation Taperloc femoral component was a nonmodular collarless stem with a 28 mm titanium head. The second-generation Taperloc stem has a modular head-neck articulation and a reduced distal stem designed for patients with a narrow femoral isthmus. A modular 28 mm diameter cobalt chromium femoral head was used in all cases (Figure 1).

The acetabular component used in all patients was the T-Tap ST. The first-generation T-Tap component was a conically shaped threaded ring titanium shell without porous coating. The second-generation T-Tap is a threaded hemispheric shell, fully coated with plasma spray. The polyethylene used in both components was manufactured with Himont 1900 resin (Himont, Wilmington, Delaware, USA), which is Ca+ stearate free (Figure 2).

Operative technique. Surgery was performed using the posterolateral approach. A transverse incision was made in the posterior capsule rather than a complete posterior capsulectomy. The femoral neck was cut in situ prior to dislocating the hip. The posterior capsule was repaired during wound closure.

The proximal femur was broached serially in 2.5 mm increments until a press-fit was achieved. The rasping of the femoral canal was performed to match the native version of the proximal femur. The femoral component used was the same size as the last rasp. The acetabulum was concentrically reamed in 2 mm increments until circumferential contact with the bleeding cancellous bone was obtained. The acetabulum was under-reamed by 1 mm. The alignment chosen for the acetabular component was 45° of abduction and 15° of anteversion. In all hips, an intraoperative radiograph was obtained to assess the position of the components and the length of the leg. Antibiotics were administered preoperatively and continued for 48 hours following surgery. Patients were allowed full weightbearing with a walker or crutches for four weeks and then advanced as tolerated. Anticoagulation consisted of warfarin administered orally the day of surgery and continued for 30 days following surgery.

Clinical follow-up. The Harris Hip Score (HHS) was recorded for all patients preoperatively and at latest follow-up.[8] Patients were specifically questioned about the presence of thigh pain. The level of activity was evaluated using the classification of Johnston et al.[9]

Radiological assessment. Radiological evaluation at a mean of 22 years (20 to 25) consisted of anteroposterior (AP) views of the hip and pelvis and a true lateral view of the hip. The femur was divided into the seven zones described by Gruen et al.[10] The presence of radiolucencies were assessed in each of the zones. All radiographs were assessed by an independent author who was not the operating surgeon. Progressive radiolucencies were identified and recorded. Osteolysis was defined as a radiolucency with a scalloped or cystic appearance, or a progressive radiolucency greater than 2 mm in width, which was not present on the immediate postoperative radiograph. Osteolysis was classified using the criteria of Goetz et al.[4] Femoral component stability was evaluated by the criteria of Engh et al.[11] Subsidence was determined by a comparison of two measurements between serial radiographs as described by Pellegrini et al.[12] A difference of greater than 3 mm was required for this determination. Femoral component loosening was defined as progressive migration of the implants. Acetabular components were evaluated for radiolucencies and osteolysis in the zones described by DeLee and Charnley.[13] Fixation of the acetabular component was assessed by the criteria of Massin et al.[14] It was considered loose if there was migration from the inter-teardrop or vertical line, a

Table II. Level of activity.

Classification	Patients, n (hips)
Heavy manual labour	0 (0)
Moderate manual labour	2 (2)
Light labour	10 (11)
Semi-sedentary	47 (48)
Sedentary	1 (1)

continuous radiolucency or a change > 4° in the angle of abduction.

Statistical analysis. Kaplan-Meier survival analysis[15] with 95% confidence intervals (CIs) was used to estimate a cumulative survival function for the femoral and acetabular components, with revision for any reason and revision for aseptic loosening as the endpoints. Student *t*-test, Fisher's exact test, and the paired *t*-test were used to determine statistical significance.[16] A p-value < 0.05 was considered to indicate statistical significance. SAS v9.3 software (SAS Institute, Cary, North Carolina, USA) was used for analysis.

Results

A total of 60 patients (62 hips) were alive at a minimum follow-up of 20 years required for this review. In all, 60 stems remained in situ and two (3.2%) had been revised, none for aseptic loosening. One required revision secondary to a periprosthetic fracture one year postoperatively. One additional femoral component was revised for late sepsis at 16 years postoperatively. In our previously published report, 12% of the first-generation Taperloc femoral components required revision at a mean follow-up of 20 years. The difference in the rate of revision between first and second-generation femoral components was statistically significant (p = 0.008, Fisher's exact test). Overall, six (9.7%) of the 62 acetabular components had required revision surgery. Five components were revised for aseptic loosening at seven, seven, 11, 14, and 17 years postoperatively. One well fixed shell was revised for sepsis at 16 years. The rate of revision of the first-generation T-Tap acetabular shell in our prior report was 57%. The difference in the rate of revision between first and second-generation components was statistically significant (p = 0.001, Fisher's exact test).

The average HHS improved from 46 (30 to 67) preoperatively to 89 (78 to 100) at the time of final follow-up. This difference was statistically significant (p < 0.001, paired *t*-test). Thigh pain was present in one hip (1.6%). No patient performed strenuous manual labor, two patients with two hips performed moderate manual labour, ten patients with 11 hips performed light manual labour, 47 patients with 48 hips were semi-sedentary, and one patient with one hip was sedentary (Table II).

Radiographs were obtained on 60 of the 61 hips in 59 living patients who had not undergone revision of both the femoral and acetabular component. The mean duration of follow-up was 22 years (20 to 25). No femoral component was loose by radiological criteria. One stem had subsided 3 mm in the first month postoperatively and had remained stable for 24 years. It was rated as having stable fibrous ingrowth. All remaining femoral components were in place and well fixed. Radiolucencies in the porous coated region of the stem occurred in seven hips (11.6%), most commonly in Gruen zone one. All measured 1.5 mm or less. Mild focal osteolysis confined to Gruen zone one was identified around one stem (1.6%). Moderate osteolysis was identified around two stems (3.3%). Major osteolysis occurred in one hip (1.6%).

Radiological analysis of 55 acetabular components which had not required revision showed a mean abduction angle of 42° (28 to 52°). Radiolucencies in one zone occurred in five hips, and in two zones in one hip.

Table III. Comparative data on the first- and second-generation components at 20 years.

Variable	First-generation components, previous report	Second-generation components, current report
Patients, n	58	60
Hips, n	65	62
Femoral component	Monoblock Taperloc	Taperloc with reduced distal stem
Acetabular component	T-Tap	T-Tap ST
Surgical approach	Posterolateral	Posterolateral
Complications, n of hips (%)	3 (5)	3 (4.8)
Femoral revision for any reason, n of hips (%)	8 (12)	2 (3.2)
Femoral revision for aseptic loosening, n of hips (%)	0 (0)	0 (0)
Acetabular revision for any reason, n of hips (%)	37 (57)	6 (9.7)
Acetabular revision for aseptic loosening, n of hips (%)	35 (54)	5 (8.1)
Age of patient at time of surgery, yrs (range)	50 (20 to 75)	57 (27 to 74)
Sex, n (hips)		
Male	32 (33)	29 (30)
Female	26 (32)	31 (32)
Mean duration of follow-up yrs, mean (range)	20 (18 to 22.6)	22 (20 to 25)
Harris Hip Score, mean (SD)		
Preoperative	49.29 ± 12.93	46 ± 9.09
Postoperative	85.35 ± 10.05	89 ± 10.4
Thigh pain, n (%)	2 (3)	1 (1.6)
Loose femoral component, n of hips (%)	1 (1.5)	0 (0)
Loose acetabluar component, n of hips (%)	N/R	1 (1.6)
Femoral osteolysis, n (%)	4 (6)	4 (6)
Acetabular osteolysis, n (%)	N/R	13 (21)

N/R, not reported.

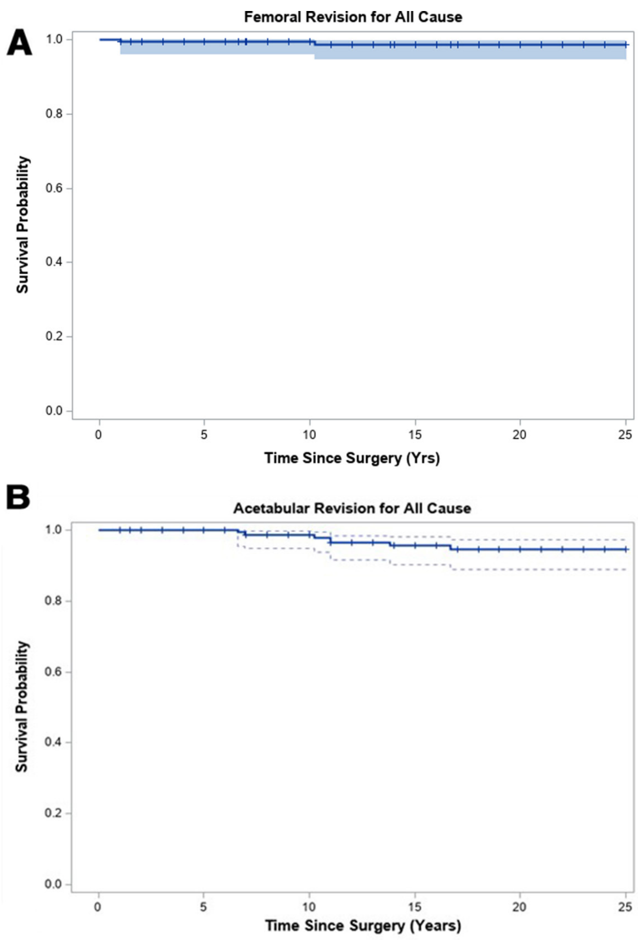

Fig. 3

(a) Survivorship Curve, with 95% confidence intervals (CIs), as determined by the Kaplan-Meier method. With revision of the stem for any reason as the end point, Kaplan-Meier analysis demonstrates a survival rate of 99% (95% CI 95 to 99) at 25 years for the entire series of 172 primary total hip arthrplasties. Patient deaths are depicted by the vertical lines on the graphs. (b) Survivorship Curve, with 95% CIs, as determined by the Kaplan-Meier method. With revision of the acetabular component for any reason as the endpoint, the 25-year survival rate was 94% (95% CI 89 to 97). Patient deaths are depicted by the vertical lines on the graphs.

A continuous radiolucency was identified around one acetabular component. Osteolysis was identified around 13 hips (21%); seven in zone one, two in zone two, one in zone three, and three in more than one zone. None of the acetabular components had migrated. The one shell with a continuous radiolucency was considered loose by radiological criteria (Table III).

While not the focus of this review, 102 patients (110 hips) died prior to achieving the minimum 20-year follow-up for this report. All 102 patients (110 hips) died with their femoral component in place. One acetabular component required revision for aseptic loosening at 11 years postoperatively.

Survival analysis. With revision for any reason as the endpoint, Kaplan-Meier analysis demonstrated a 99% chance of survival for the femoral component at 25 years (95% CI 95 to 99) and a 94% chance of survival for the acetabular component (95% CI 89 to 97) (Figure 3). With revision for aseptic loosening as the endpoint, Kaplan-Meier analysis estimated a 100% chance of survival for the femoral component at 25 years and a 95% chance of survival for the acetabular component (95% CI 90 to 98).

Discussion

The purpose of the present study was to evaluate the clinical and radiological results of a second-generation uncemented THA followed for a minimum of 20 years (20 to 25). This consecutive series of primary THA was performed by a single surgeon utilizing a uniform surgical approach. The most striking finding of this report was the low rate of loosening and revision of the femoral component. Of the 62 hips in 60 living patients who were followed for a minimum of 20 years, no femoral component had been revised for aseptic loosening and only two revised for any reason (3.2%). No femoral component was loose according to radiological criteria. A second significant and somewhat surprising finding of this report was the success of the T-Tap ST acetabular component. At a minimum follow-up of 20 years, six shells (9.7%) had been revised and only one was loose by radiological criteria.

Limitations of this study include the death of 102 patients (110 hips) prior to the 20-year follow-up. However, in each of these patients the outcome of the prosthetic components with regard to revision or retention was determined. Although this was a retrospective study, all patients were followed with data being collected prospectively. Strengths of this report include the long duration of follow-up, with the mean being 22 years (20 to 25). In addition, postoperative radiographs were obtained on all but one living patient at a minimum follow-up of 20 years. Future study with longer-term follow-up is warranted. This is especially critical with regards to the threaded acetabular component. While this component performed well in this series, its efficacy remains unproven.

The Taperloc femoral component is a wedge shaped titanium stem proximally porous coated with plasma spray. It is designed to achieve fixation mediolaterally in the proximal femur. The proximal portion of this stem has never been changed. There is now over 35 years of experience with this implant. Several reports with specific use of the first-generation non-modular Taperloc femoral component have been published. These reviews include diverse patient groups including the young, old, obese, and patients with Dorr type C bone.[17-20]

The first change to the original Taperloc stem was the introduction of a Morse taper in 1985. The advantages of a modular stem include the ability to adjust leg lengths, offset, and the potentiality to remove the femoral head for acetabular exposure during revision surgery.

McLaughlin et al[17] published a 20- to 27-year follow-up using the Taperloc in 76 patients (91 hips) aged 50 years and under. In a subset of 39 hips using a first-generation non-modular stem, seven (17.9%) had required revision. In six hips, the component was removed because the non-modular head either obstructed acetabular exposure or resulted in instability of the hip following acetabular revision. In the remaining 52 hips with a modular Taperloc stem, only two stems had been revised (3.8%). Our findings are similar to these. At 20 years, using a non-modular Taperloc stem the rate of revision was 12%, and using a modular Taperloc 3.2%.

The second modification of the Taperloc stem in 1993 was the reduction in the diameter of the distal nonporous coated portion of the stem. The purpose of this change was to achieve proximal fixation and to reduce thigh pain. Several publications support our opinion. Cooper et al[21] found an increased rate of thigh pain and a predisposition to failure of osseointegration in tapered femoral components with greater canal fill at the mid and distal thirds of the stem. Warth et al[22] emphasized that "potting" of the non-porous coated portion of a tapered stem distally in the femoral canal was problematic. They emphasized the importance of achieving mediolateral stem stability to maximize metaphyseal engagement. Similar finding were reported by Ries et al.[23] In a contrasting opinion, Issa et al[24] hypothesized that insufficient distal canal filling may lead to thigh pain, prosthetic loosening and implant failure. The second-generation Taperloc femoral component has now been used for over 25 years. The authors recognize that the effect of using a tapered component with a reduced distal stem must be evaluated at long-term follow-up. In this series at mean follow-up of 22 years, the incidence of thigh pain was 1.6%, no femoral component required revision for aseptic loosening, and no stem was judged loose by radiological criteria.

Long-term results using the first-generation T-Tap acetabular shell have been poor. At 16- to 23-years follow-up, revision rates of 57% and 58% have been reported[7,20] Similar failure rates have been reported using several non-porous coated threaded acetabular shells at five to ten years.[25,26] As a result of these findings, the use of threaded acetabular components is considered controversial. Modifications in threaded shells have included roughened or porous coated surfaces and in some designs the change to a hemispheric geometry.[27-29] The CLS expansion shell (Centerpulse, Winterthur, Switzerland) is a fully porous coated titanium hemisphere with threads. Rozkydal et al[29] reported a 100% survival using the CLS expansion shell at ten years in patients with congenital hip disease. de Witte et al,[30] however, found an increase in the prevalence of aseptic loosening of this CLS expansion shell in the second decade after operation. In 1983 we began using the nonporous coated T-Tap acetabular shell for all primary THAs performed at our centre. Due to a high failure rate we discontinued the use of this implant in 1985. Between 1985 and 1992, we used a conically shaped threaded ring shell with porous coating. At a mean ten-year follow-up, the revision rate was an unacceptable 40%.[31] In our current review, the Kaplan-Meier survivorship of the porous coated T-Tap ST hemispheric acetabular shell with revision for any reason as the endpoint was 94% (95% CI 89 to 97). Many consider a hemispheric component with or without supplemental fixation as the gold standard for acetabular fixation in primary THA. Della Valle et al[32] reported a survival rate of 96% using the Harris Galante (Zimmer, Warsaw, Indiana, USA) acetabular shell at 20 years. Our 94% survivorship using the T-Tap ST at 25-years follow-up approaches these results.

The intent of this review was to compare our results at 20 years using a first- and second-generation uncemented THA. The core finding of this report was the reduction by an order of magnitude in the incidence of revision between first and second-generation components. In conclusion, this study shows excellent survival of the uncemented Taperloc femoral component and the T-Tap ST acetabular shell.

Take home message

- The most significant finding of this report was the substantial reduction in the rate of revision of the femoral and acetabular components using a second-generation cementless total hip arthroplasty compared with our earlier findings using first-generation devices at 20-years follow-up.

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- K. R. Lee: Co-edited the manuscript, Undertook statistical analysis.
- M. Johnson: Co-edited the manuscript, Researched the data.

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