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ORIGINAL PAPER

Randomised clinical trial assessing migration of uncemented primary total hip replacement stems, with and without autologous impaction bone grafting

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Abstract

Purpose Uncemented stems in primary total hip replacement (THR) are concerning in the elderly due to ectatic femoral canals and cortical thinning resulting in higher incidence of fracture and subsidence in this population. To obviate this concern, the authors developed a technique using autologous impaction bone grafting to achieve a better fitting femoral stem. The aim of this randomised clinical trial was to assess the efficacy of the technique.

Methods From 2013 to 2015, a total of 98 consecutive participants (100 primary THR procedures) were inducted into a single-institution, single-blinded, randomised clinical trial assessing, with radiostereometric analysis (RSA), the efficacy of autologous impaction bone grafting in uncemented primary THR compared with traditional uncemented primary THR technique. The primary outcome measure was femoral component migration using RSA. Secondary outcomes were post-operative proximal femoral bone density (using DEXA), hip function and quality of life using Oxford Hip Score (OHS) and Short Form-12 Health Survey (SF-12), hip pain and patient satisfaction.

Results There was no difference in femoral component stability ($p > 0.5$) or calcar resorption between the Graft and No Graft Groups at two years. There was also no difference in OHS, SF-12, pain or satisfaction between the Graft and No Graft Groups at two years ($p > 0.39$).

Conclusions Autologous impaction bone grafting in uncemented primary THR has shown its short-term post-operative outcomes to be equivalent to standard uncemented technique, whilst offering a better fit in patients who are between femoral stem sizes.

Australian clinical trial registration number ACTRN12618000652279.

Keywords Uncemented total hip arthroplasty · Cementless total hip arthroplasty · THR · Autologous impaction bone grafting · Radiostereometric analysis · Dual X-ray absorptiometry

Introduction

Uncemented stems in primary total hip replacement (THR) are increasingly popular. There has been widespread uptake of this technique internationally with 63% of primary THR procedures in Australia being uncemented [1] and 93% in the USA [2]. These high rates are not universally reflected internationally, however, with the proportion of uncemented THR procedures in the UK being 39% [3] and 21% in Sweden [4].

There are several claimed benefits of uncemented THR. Eliminating cement from the fixation matrix allows direct bone-implant contact [5], thereby limiting the number of interfaces that may fail whilst allowing bony ingrowth often facilitated by the use of hydroxyapatite-coated stems [6]. The uncemented THR technique also avoids the complication of bone cement implantation syndrome which is characterised

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by intra-operative hypoxia, hypotension and unexpected loss of consciousness occurring around the time of cementation [7]. Reservations remain, however, with the use of uncemented press-fit stems in primary THR.

The concerns regarding uncemented stems in primary THR are argued to include increased stem migration potential [8] and proximal femoral osteolysis secondary to altered strain patterns, known as stress shielding [9]. The loss of periprosthetic bone following uncemented THR is a common occurrence [10, 11] especially in the short term following surgery [12]. Stress shielding is argued to be the most important mechanism leading to periprosthetic bone loss in the femur [13, 14]; however, other contributing factors are femoral ageing, osteolysis due to particulate debris and metabolic disturbance [10].

Periprosthetic fracture is another recognised complication in uncemented stems [15, 16]. This risk is inherent in femoral stem systems relying on compaction of the femoral canal cancellous bone to achieve stability. To address these concerns, especially in the osteoporotic population, the authors of this study modified an existing technique of autologous bone grafting first utilised in revision THR surgery [17]. This technique was implemented in uncemented primary THR with a view to achieving better fit and fill of the femoral canal without compromising prosthetic stability or longevity whilst maximising the bone-implant interface area and preserving bone density around the femoral component.

A single-blinded, randomised clinical trial was performed to test the efficacy of autologous impaction bone grafting in uncemented primary THR compared to traditional uncemented primary THR. The primary outcome measure was femoral component migration (as a measure of prosthesis fixation stability), and secondary outcomes were proximal femoral bone density, hip function, quality of life, post-operative hip pain and post-operative satisfaction.

Material and methods

This single-institution, single-blinded, randomised clinical trial was designed according to CONSORT guidelines [18] and conducted from 2013 to 2015 in Perth, Western Australia. Approval for the study was obtained from the Hospital Research Ethics Committee, with its conduct in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments. The trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12618000652279).

Patients were assessed by the surgeons in an outpatient setting with relevant history, examination, review of imaging, pathology and medical records to ascertain their appropriateness for primary THR. Informed consent was obtained from all individual participants included in the study. Inclusion criteria allowed consenting male and female patients, aged 50 to 90 years with either Dorr type-B or C femora [19], degenerative native hip joint pathology not significantly affecting femoral bone stock (assessed by plain X-ray of hips during initial consultation with surgeon; Figs. 1 and 2), who were free from local hip joint infection or significant systemic disease, not significantly affected by neuromuscular or sensory pathology, not immunosuppressed, not morbidly obese (BMI $\leq$ 40) and able to comply with the postoperative follow-up investigations to be inducted into the study.

Previous research examining subsidence of uncemented THR stems using RSA [16] in a normally distributed group with two years post-operative mean subsidence of 2.7 mm and standard deviation of 4.3 was used to calculate sample size. Using PS—Power and Sample Size Program [20] (version 3.12), it was anticipated that 22 Graft and 22 No Graft subjects were required to reject the null hypothesis that the mean subsidence of the Graft and No Graft groups were equal with probability (power) of 0.8. Group sizes were increased to 50 in accordance with recommendations regarding Oxford Hip Score (OHS) sample size in joint replacement surgery [21] and to allow for attrition.

Patients were enrolled by the surgeons and computer randomised by research coordinator (SH) to either Graft or No Graft groups on the day of surgery. The patients DEXA assessors and RSA assessor were blinded to group allocation as this was indiscernible both clinically and from post-operative imaging. The patients were followed-up for two years post-operatively. This duration of follow-up has been shown to be an appropriate surrogate measure for future prosthetic migration [22–24] with most bone remodelling occurring in this period [25]. Patient flow is detailed in Fig. 3.

Surgical technique

Both surgeons shared operating workload with each surgeon operating on approximately half of the patients from each

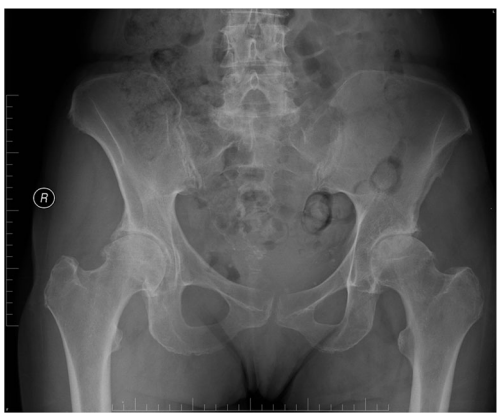

Fig. 1 Patient A: pre-operative plain X-ray

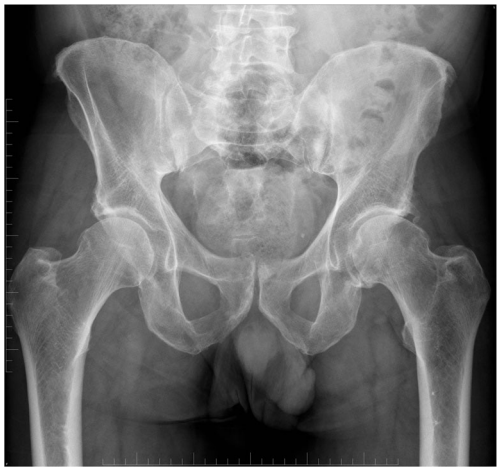

Fig. 2 Patient B: pre-operative plain X-ray

group. The autologous impaction grafting technique was performed by using the uncemented Corail (DePuy Synthes, USA) system with a posterior approach to the patient in the lateral position. Pre-operative planning, surgical technique and rehabilitation care pathways were standardised. The surgical technique is described in detail in a separate paper by Ilyas and colleagues [26]. The THR technique implemented was in keeping with standard Corail uncemented arthroplasty procedure [27] apart from several additional steps. Firstly, prior to femoral neck osteotomy, the femoral head is reamed to collect cancellous bone graft. This graft is then "wrung out" in a dry gauze pack to separate morcellised bone chips from fat. Following femoral canal broaching autologous bone graft is impacted into the femoral canal using an undersized femoral broach. A non-collared femoral stem is then implanted in the usual manner. The graft envelope occupying space in the femoral canal typically requires stem one to two sizes smaller than would be used with standard uncemented technique. The additional steps for autologous impaction grafting account for less than five minutes of operative time. Apart from the long-handled spoon used to place the graft into to femoral canal, no additional equipment outside of the standard Corail set was used. Routine plain X-rays were taken day one post-operatively (Figs. 4 and 5).

Radiostereometric analysis

Radiostereometric analysis (RSA) is a highly accurate method of measuring three-dimensional prosthesis migration [24]. The RSA investigations were conducted within one week post-operatively, and again at three month, one year and two year post-operative time points. The RSA investigations were performed as per standard protocol [28] with 1-mm tantalum beads implanted intra-operatively into the proximal femur as reference markers (Figs. 6 and 7). The prosthetic femoral head was used as a reference to assess femoral component micromotion as the Corail stems did not have tantalum beads attached. The imaging was performed using the supine uniplanar method [24] with calibration cage 43 and analysed using UmRSA 6.0 software (RSA Biomedical, Sweden). The three-dimensional femoral prosthesis translation was reported in millimetres on the *X*-axis (mediolateral), *Y*-axis (craniocaudal) and *Z*-axis (anteroposterior). The mean error of rigid body fitting was set at 0.35 mm, and double examinations assessing RSA accuracy were performed on three patients. The ideal condition number range assessing reference marker distribution is less than 150 [24].

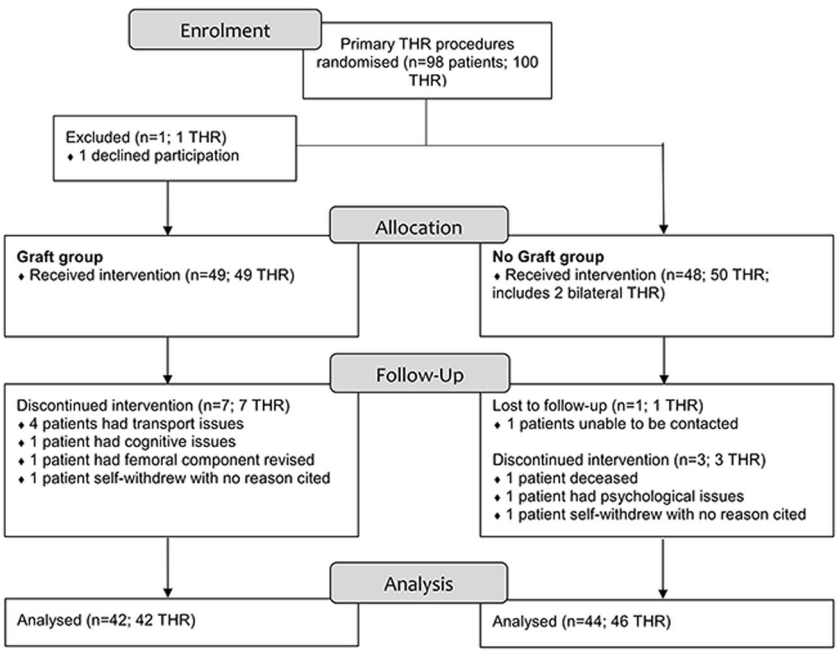

Fig. 3 Patient flow diagram until 2-year post-operative follow-up

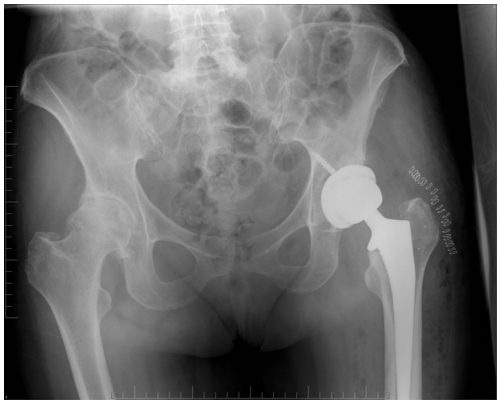

Fig. 4 Patient A: post-operative plain X-ray

Dual-energy X-ray absorptiometry

Bone densitometry is a precise method for measuring periprosthetic bone mineral density (BMD) in femoral implants [29]. Data pertaining to BMD were collected using dual-energy X-ray absorptiometry (DEXA) within one week post-operatively, and again at the three month, one year and two year post-operative time points. The BMD was investigated using a single machine (Medilink Medix DR, Software version 4.0.0.4, France). Periprosthetic femoral BMD in the coronal plane was measured in grams/cm^2 in regions corresponding to Gruen zones [30] (Fig. 8) by assessors. Bone mineral density changes are expressed as a percentage change from the baseline post-operative measurement.

Patient reported outcome measures

Pre-operative surgical review included standard pre-operative assessment, demographic and anthropomorphic data collection by blinded surgeons and clinic staff. Patient-reported outcome measures (PROMs) consisting of Oxford Hip Score (OHS), Short Form 12 health survey (SF-12) and pain-rating using Numerical Rating Scale (NRS) were collected at the pre-operative, three month, one year and two year time points. Patient satisfaction was assessed at the same time points post-operatively.

The OHS is a 12-item questionnaire providing reliable, valid and responsive data regarding patient perception of hip problems [31]. The scoring for each item of the OHS was rated 0 (worst outcome) to 4 (best outcome) and with a cumulative score out of a maximum of 48.

The SF-12 is a reliable, validated, self-reported patient questionnaire comprised of mental health composite (MCS) and physical health composite (PCS) scores used to provide a measure of general health in patients [32]. The mean SF-12 score was calculated using the weighted means of 12 questions, where a zero score indicates the lowest level of health and 100 indicating the highest level of health.

The NRS is a valid and reliable instrument to measure pain in the clinical setting [33]. The NRS assessed pain on an 11-point scale with 0 indicating the lowest level of pain and 10 indicating the highest level of pain.

Patient satisfaction with the surgical outcome was measured post-operatively on a 5-point scale, corresponding to the descriptors Very Dissatisfied, Dissatisfied, Neutral, Satisfied and Very Satisfied.

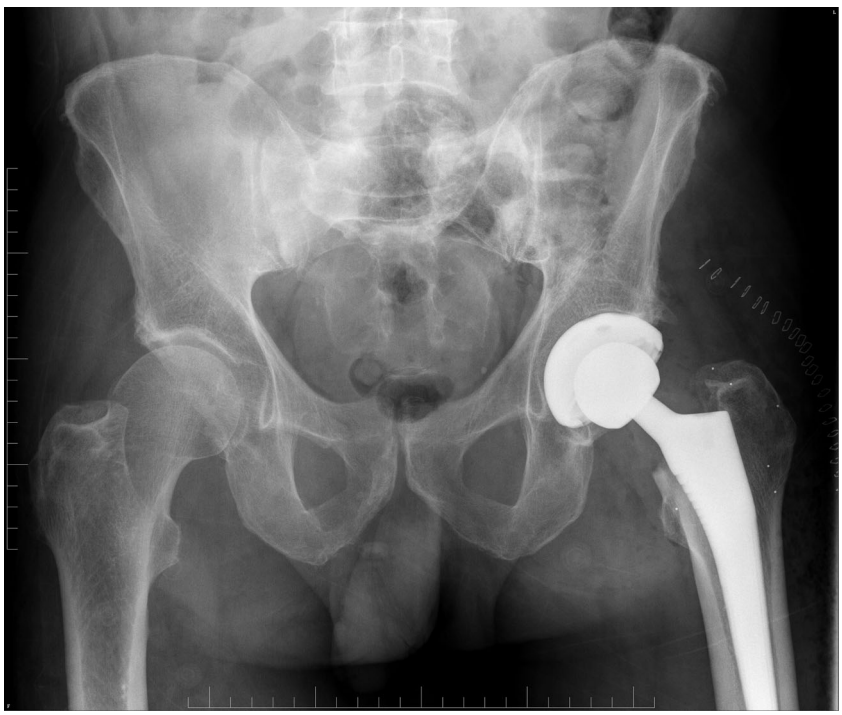

Fig. 5 Patient B: post-operative plain X-ray

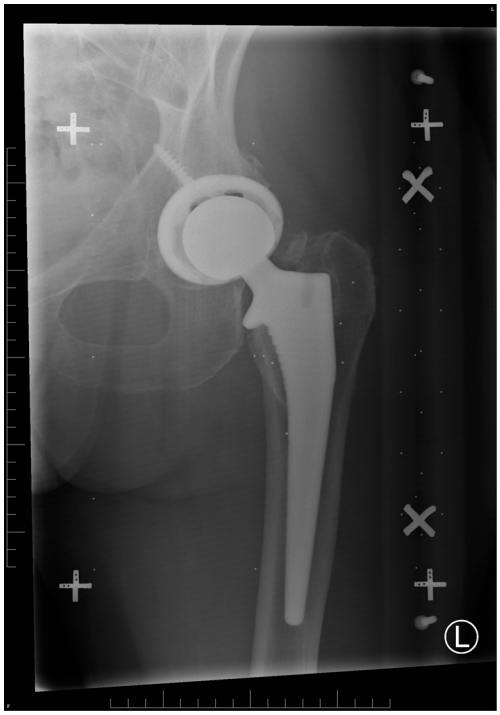

Fig. 6 Patient A: 2-years post-operative RSA image

Statistics

Data were input and analysed using IBM SPSS (Version 24, IBM Corporation, United States). A paired *t* test was used to analyse RSA, DEXA, OHS, SF-12 and pain. Chi-square test was used for post-operative satisfaction. A *p* value less than 0.05 was considered statistically significant.

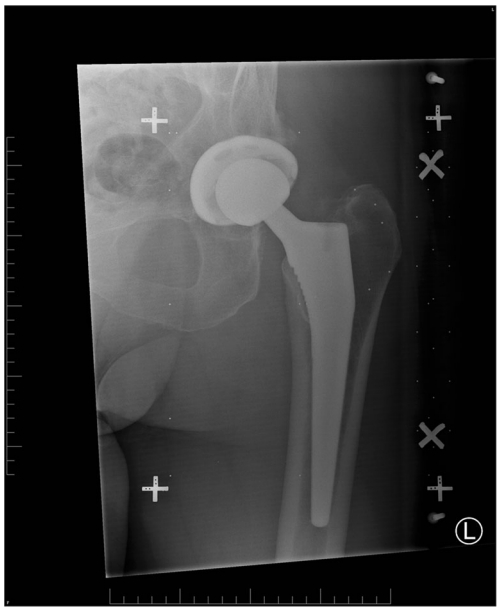

Fig. 7 Patient B: 2-years post-operative RSA image

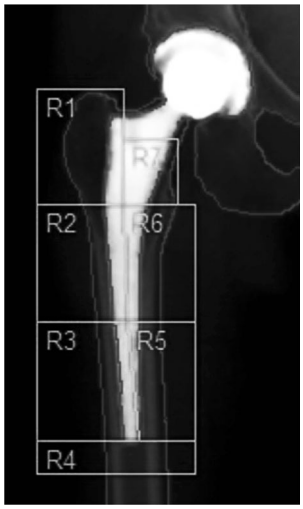

Fig. 8 Gruen zones

Results

Patients

A total of 98 consecutive participants (100 primary THR operations) gave informed consent and were randomised into Graft and No Graft groups. Surgery was deferred by one patient. A total of 49 patients (49 THR procedures) received a Graft and 48 (50 THR procedures, including 2 bilateral THR) had a No Graft procedure. There was no significant difference between groups in mean patient age, sex or body mass index (Appendix 1). There were three type C Dorr classification [19] femora in the Graft group (1 had incomplete RSA and DEXA data) and one in the No Graft group, with the remainder of the cohort classed type B. At the two year time point, seven Graft patients and four No Graft patients were withdrawn from the study.

Stem migration

The RSA investigations at two years post-operatively found the mean subsidence (negative *Y*-axis translation) of the Graft group to be − 0.76 mm (95% CI − 1.13 to − 0.38), compared to − 0.93 mm (95% CI − 0.70 to 0.19) in the No Graft group. This difference was not significant ($p = 0.51$) and nor was the difference in migration between groups on the *X*- and *Z*-axes (Table 1). There was one patient in the Graft group and three patients in the No Graft group with subsidence greater than 3 mm (Graft maximum 4.1 mm, No Graft maximum 5.9 mm) at two year post-operative follow-up. The two year post-operative subsidence in the Graft group type-C femora was − 0.03 and − 0.08 mm, and the No Graft group − 0.19 mm. Double examinations performed on three patients on their initial post-operative scan found mean measurement error of 0.05 mm, − 0.01 mm, and − 0.29 mm (*X*-, *Y*-, *Z*-axis

Table 1 Mean femoral prosthesis migration in millimetres from baseline to 2 years post-operatively

	Graft ($n = 31$)		No graft ($n = 41$)		
Axis	Mean (mm)	95% CI	Mean (mm)	95% CI	*P* value
X	0.14	− 0.74 to 0.36	0.06	− 0.70 to 0.19	*0.50*
Y	− 0.76	− 1.13 to − 0.38	− 0.93	− 1.35 to −0.51	*0.51*
Z	− 1.09	− 1.55 to − 0.62	− 1.28	− 1.75 to −0.81	*0.57*

CI, confidence interval

translation). There were 13 patients with condition numbers exceeding 150 and their results were interpreted cautiously.

Bone mineral density

There was no significant difference in mean BMD between the Graft and No Graft groups in any Gruen zone apart from Gruen zone 4 (Table 2). There was reduced BMD in both groups in all Gruen zones apart from Gruen zone 1. Both groups showed the highest amount of mean BMD loss in Gruen zone 7 with no significant difference between groups.

Patient reported outcome measures

Both groups reported improvement in mean OHS, SF-12 and pain from the pre-operative to two year post-operative time points with no significant difference in mean score (Table 3). Both groups were predominantly satisfied or very satisfied with their procedure at two year post-operative follow-up.

Complications

There was 1 femoral component revised at four months post-operatively due to prosthetic loosening secondary to an undersized stem in the Graft group and one intra-operative calcar crack in the No Graft group managed with cerclage wires.

Table 2 Mean bone density change (%) for Gruen zone 1–7 from baseline to 2 years post-operatively

	Graft ($n = 35$)		No Graft ($n = 45$)		
Gruen zone	Mean (%)	95% CI	Mean (%)	95% CI	*P* value
1	8	2 to 14	9	5 to 14	0.97
2	− 5	− 9 to − 1	− 4	− 7 to − 1	0.58
3	− 2	− 5 to 0	− 3	− 5 to − 1	0.69
4	− 4	− 6 to − 3	− 2	− 2 to − 1	0.01
5	− 5	− 8 to − 3	− 5	− 6 to − 3	0.73
6	− 6	− 10 to − 2	− 5	− 9 to − 1	0.70
7	− 15	− 20 to − 10	− 12	− 17 to − 6	0.15

CI, confidence interval

Discussion

The uncemented Corail stem has been shown to subside predominantly in the first six months post-operatively [34]. Clinically significant subsidence in Corail stems is said to be greater than 3 mm [35]. We found that both the groups migrated predominantly in the first three months before stabilising with no significant difference between groups at two year follow-up. The direction and magnitude of femoral component migration with early stabilisation is in keeping with previous RSA studies on uncemented THR [16, 34, 36]. It is argued that early subsidence does not necessarily equate to future instability in uncemented stems, as opposed to late subsidence and/or ongoing subsidence beyond two years [37]. This tendency toward early subsidence and stabilisation may not be "true" subsidence and rather a reflection of further impaction and secondary stabilisation following weight bearing [38]. The efficacious historical performance of the uncemented Corail stem suggests that its future stability should not be predicted solely on its early subsidence in isolation [34].

Similarity between groups was also seen in DEXA results. There was no significant difference in BMD demonstrated between groups at two year follow-up except in Gruen zone 4 where there was less BMD in the Graft group. This may be explained by the lower stiffness in the generally smaller femoral stems used in the Graft group leading to greater proximal stress transfer and increased distal bone resorption [39]. In a pattern consistent with stress shielding, a known issue in uncemented conventional femoral stems [40], Gruen zone 7 showed the highest amount of mean BMD loss in both groups, with both reporting favourably in the PROMs despite this. Hip function was similar across groups with consistent reporting of OHS improvement, comparable to previous research on uncemented Corail stems [41, 42]. The similarity of outcome measures between the Graft and No Graft groups is clinically important as it provides evidence in support of this grafting technique being equivalent to traditional uncemented THR in terms of stability, safety and functional outcomes, in addition to being clinically advantageous for several reasons.

The authors have found the autologous impaction grafting technique to be of assistance in certain situations. The envelope of bone graft is useful in achieving a better fit in patients

Table 3 Mean change in PROMs preoperatively to 2 years post-operatively

	Graft		No Graft		
	Mean (*n*)	95% CI	Mean (*n* = 45)	95% CI	*P* value
OHS	21.0 (36)	18.1 to 23.9	19.7	17.5 to 30.0	0.47
SF-12 PCS	14.1 (37)	10.5 to 17.7	15.0	11.7 to 18.3	0.70
SF-12 MCS	3.1 (37)	− 0.6 to 6.8	2.4	− 0.8 to 5.7	0.77
Pain	− 5.4 (37)	− 6.2 to − 4.5	− 5.0	− 5.8 to − 4.3	0.56

PROM, patient reported outcome measure; *OHS*, Oxford Hip Score; *SF-12*, Short Form 12 health survey; *MCS*, mental health composite; *PCS*, physical health composite; *CI*, confidence interval

who are between femoral stem sizes. In these patients, the surgeon has the option of either downsizing the stem with the risk of subsidence and leg shortening or, alternatively, upsizing with the risk of periprosthetic fracture or leg lengthening. Impacting morcellised bone provides a secure fit for the smaller sized stem and assists in avoiding these risks. An option in younger patients with appropriate metaphyseal morphology can be a short-stemmed prosthesis [43–45]: however, in elderly patients with osteoporotic bone, the authors routinely use conventional stems with morcellised graft. This is to reduce the cortical stress risers occurring at the corners of the rectangular-shaped (in cross-section) femoral prosthesis. This envelope of graft surrounding the prosthesis is thought to dissipate forces circumferentially, minimising the risk of fracture whilst achieving better fit, thereby increasing the "comfort level" of the surgeon when impacting osteoporotic bone.

This body of research has some limitations. This is a single-institution trial using two surgeons which limits its generalisability. The data loss and loss to follow-up sustained may introduce a source of bias when analysing outcome measures. Incomplete RSA data for some participants can be attributed to poor RSA baseline films ($n = 3/2$; Graft/No Graft) with issues precluding analysis including poorly exposed images and insufficient RSA beads implanted and/or visualised. Incomplete baseline and/or follow-up RSA, DEXA scans and PROM questionnaires accounted for the remainder of the missing data. Despite the data loss, the accuracy of RSA with implanted calibration markers is more accurate in assessing prosthesis micromotion than other techniques (e.g. plain X-ray films) due, in part, to the avoidance of magnification errors incurred when using a single X-ray source [46].

Whilst there is under-representation of type C femora in the sample, those in the study migrated comparably to the type B femora in both groups. Research is currently underway implementing this technique in patients with type C femora and poor BMD where the indication for primary uncemented THR has been controversial [47].

Conclusions

Autologous impaction bone grafting in uncemented primary THR has shown its short-term post-operative outcomes to be equivalent with traditional uncemented technique. The authors find the technique useful in providing a better fitting femoral component in patients who are between femoral stem sizes whilst affording a degree of comfort to the surgeon when impacting femoral prostheses in patients with osteoporotic bone.

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Data collection: Hollywood Private Hospital Physiotherapy Department, Perth, WA, Australia.

Statistical analysis: V.K. Bowden, PhD, School of Psychological Science, the University of Western Australia, 35 Stirling Highway, Perth, WA, Australia.

Authors contribution TK prepared research proposal. RJKK and DF performed surgery. ON collected and analysed RSA data. SKG Radiology and MR collected DEXA data. Hollywood Private Hospital Physiotherapy Department and SH collected patient reported outcome measure data. VKB performed statistical analysis. MR, RJKK, DF and SH prepared the manuscript.

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Compliance with ethical standards

Approval for the study was obtained from the Hospital Research Ethics Committee, with its conduct in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments.

Conflict of interest Prof. Khan reports personal fees from Global Orthopaedic Technology, personal fees from Zimmer Biomet, grants from AMPLITUDE, and Smith & Nephew, outside the submitted work.

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