

BMJ Open Better early functional outcome after short stem total hip arthroplasty? A prospective blinded randomised controlled multicentre trial comparing the Collum Femoris Preserving stem with a Zweymuller straight cementless stem total hip replacement for the treatment of primary osteoarthritis of the hip

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ABSTRACT

Objectives Primary aim was to compare the functional results at 3 months and 2 years between short and conventional cementless stem total hip arthroplasty (THA). Secondary aim was to determine the feasibility of a double-blind implant-related trial.

Design A prospective blinded randomised controlled multicentre trial in patients with osteoarthritis of the hip. All patients, research assistants, clinical assessors, investigators and data analysts were blinded to the type of prosthesis. Population: 150 patients between 18 and 70 years with osteoarthritis of the hip, 75 in the short stem and 75 in the conventional stem group. Mean age: 60 years (SD 7). Interventions: the Collum Femoris Preserving short stem versus the Zweymuller Alloclassic conventional stem.

Main outcome measures The Dutch version of the Hip Disability and Osteoarthritis Outcome Score (HOOS). Secondary outcomes measures: Harris Hip Score, the Physical Component Scale of the SF12, the Timed Up and Go test, Pain and the EQ-5D. Feasibility outcomes: continued blinding, protocol adherence and follow-up success rate.

Results No significant difference between the two groups. Mean HOOS total score in the short stem group increased 32.7 points from 36.6 (95% CI 32.9 to 40.2) preoperatively to 69.3 (95% CI 66.4 to 72.1) at 3 months follow-up. Mean HOOS total score in the conventional straight stem group increased 36.3 points from 37.1 (95% CI 33.9 to 40.3) preoperatively to 73.4 (95% CI 70.3 to 76.4) at 3 months follow-up. 91.2% of patients remained blinded at 2 years follow-up. Both protocol adherence and follow-up success rate were 98%.

Strengths and limitations of this study

- Short stem cementless total hip arthroplasty potentially offers bone preservation and improved functional outcome. However, these benefits have yet to be confirmed in a randomised controlled trial (RCT).
- Hip implants are rarely compared directly in double-blinded RCTs. This study has, however, shown that a valid direct comparison of two hip implants using strict methodological safeguards is a feasible concept.
- In this multicentre RCT, all efforts were made to ensure methodological quality, thereby reducing the risk of bias.
- Maximally blinded (patients, clinical assessors, investigators and data analysts are blinded for the type of implant).
- This study provides surgical outcomes at 3 months and 2 years. The longevity of these implants can only be compared with a long-term follow-up. We will, therefore, continue to follow up these patients.

Conclusions Functional result at 3 months and 2 years after short stem THA is not superior to conventional cementless THA. There were more perioperative and postoperative complications in the short stem group. Direct comparison of two hip implants in a double-blinded randomised controlled trial is feasible.

Trial registration number NTR1560.



INTRODUCTION

Total hip arthroplasty (THA) is one of the most successful surgical procedures of the last century.¹ Conventional hip implants have shown 10-year survival rates of more than 90% for cementless as well as cemented stems.^{2,3} There is a recent increase of cementless hip replacements, especially in young and more active patients.^{4,5}

Answering the demands of an increasingly young and active patient population, recent developments in hip arthroplasty are aimed towards minimising tissue damage and retaining bone stock without compromising implant stability. This resulted in the introduction of innovative bone-preserving and soft-tissue-preserving implants, such as short stem THA.⁶ These innovations aim to accelerate early postoperative rehabilitation, improve long-lasting functional outcome and preserve bone stock for future revisions.

Despite their already widespread use in clinical practise, the potential functional benefits of short stem THA have yet to be confirmed in a randomised controlled trial (RCT).⁷ Due to a lack of adequate regulation, many innovative hip implants have reached the market without sound premarketing tests and clinical comparison with conventional implants. Many device innovations in hip as well as knee arthroplasty were easily adopted by clinicians and are currently commonly used, without any convincing high-quality evidence supporting their use.⁸ Some of these new designs have led to failure rates of 2–10 times the standard of national joint registries.⁹ The need for a phased evidence-based introduction of implants is now more clear than ever, and the spread of undocumented new implants should be part of orthopaedic history.¹⁰

We aimed to compare the functional result at 3 months and 2 years of THA using a Collum Femoris Preserving (CFP) stem (Waldemar Link, Hamburg, Germany) with THA using a conventional straight stem, the Alloclassic Zweymuller stem (Zimmer-Biomet, Warsaw, USA).

In the early 1980s, Pipino *et al* introduced the Biodynamic stem, with the aim to reduce proximal bone loss and reduce stress shielding by retaining normal biomechanical stresses in the bone.^{11,12} The main innovation was the preservation of the femoral neck, thereby preserving proximal bone stock for future revisions. Furthermore, preservation of the trochanteric region of the femur potentially enables a more gluteus-muscle-sparing approach.¹³ Lastly, following the curvature of the retained native neck of femur theoretically would result in more physiological offset reconstruction.

The initial Biodynamic stem showed good medium-term and long-term survival rates.^{11,12,14} The Biodynamic was later replaced by the CFP stem.^{14,15} Excellent survival rates of the CFP stem after a mean follow-up of 5.1 years (min 2.0; max 11.2) were reported in nine case series with a total number of 1001 patients.^{7,15–23}

The Zweymuller Alloclassic stem was standard of care in both participating hospitals and is widely used worldwide. This stem has shown a 10-year survival rate of 90%–100%.^{24–27} To obtain entry in neutral alignment,

this stem requires the use of a box chisel cutting a slot in the lateral trochanteric fossa and extensive intramedullary broaching particularly of the lateral cortex. This puts the insertion of the gluteus medius musculature at risk. Damage to the insertion of the gluteus musculature could be a cause of postoperative pain at the greater trochanter and reduced abductor strength, resulting in limping and a positive Trendelenburg gait.^{28–30}

Considering the performance of current conventional cementless stems, the use of a short stem is only justified if it either results in a superior short-term functional outcome or better survival rates compared with conventional straight stem THA.

Surgical trials are historically dominated by non-randomised observational studies.³¹ Blinding and random treatment allocation in non-pharmacological hip osteoarthritis trials was often not reported, and overall reported quality was low.^{32,33} Hip implants are rarely compared directly in double-blinded RCTs, since implant-related blinded surgical trials pose specific challenges. For instance, more rigorous methods are required to achieve allocation concealment and implement blinding, thereby ensuring similar distributions of prognostic factors in the intervention and control groups and preventing a serious risk of bias.³¹ Therefore, the second aim of our study was assessing the feasibility of a double-blinded randomised controlled hip implant trial. Trial feasibility will be assessed based on continued blinding, protocol adherence and follow-up success rate at 2 years follow-up.

Aim

The purpose of this study was to compare the functional result of THA using the CFP stem with THA using an Alloclassic Zweymuller stem, measured by the Dutch version of the Hip disability and Osteoarthritis Outcome Score (HOOS) at 3 months and up to 2 year follow-up.³⁴ We hypothesised that short stem THA would result in a better functional result at 3 months and 2 years compared with conventional Zweymuller straight stem THA as reflected in higher HOOS scores.

METHODS

Trial design

We conducted a prospective double-blinded randomised controlled multicentre trial at two centres, A and B, both in the Netherlands. A total of 150 patients were included in the period from August 2009 to October 2012. A total of 100 patients from centre A and 50 patients from centre B were included. Three orthopaedic surgeons from centre A and two from centre B participated in this trial. All procedures were performed using a direct lateral transgluteal approach, although the short stem group required less gluteal dissection to expose the femoral neck and entry in to the femoral canal. The protocol was approved by the medical ethics committee (Verenigde Commissies Mensgebonden Onderzoek, Nieuwegein, the Netherlands). This trial is conducted according to the



Declaration of Helsinki and is registered in the Dutch trial register: <http://www.trialregister.nl> file number: NTR1560. All participants provided a written informed consent and were assigned to an anonymous study identification number. There were no changes in the trial design after initiation of the trial. A more detailed version of the protocol was previously published: <http://bmjopen.bmj.com/content/6/3/e010472>, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4809092/>.³⁵

We used stratified block randomisation consisting of a random sequence of blocks of 10 consecutive surgical procedures each. Randomisation was performed in the operating theatre, after anaesthetic induction and just before incision, using a sequentially numbered opaque sealed envelope.

Our primary endpoint was physical functioning measured with the Dutch version of HOOS validated by De Groot *et al* at 3 months and up to 2 year follow-up.^{34 36} HOOS is a patient-administered questionnaire consisting of five subscales; pain, other symptoms, function in daily living (activities of daily living), function in sport and recreation (Sport/Rec) and hip-related quality of life (QOL). A score of 100 indicates no symptoms and 0 indicates extreme symptoms.

Secondary outcome measures were: physical functioning measured with another Patient-Reported Outcome Measure (PROM): the modified Harris Hip Score (mHHS), physical health measured with the Physical Component Scale of the SF-12 questionnaire (PCS-12),³⁷⁻⁴⁰ walking ability measured with the Timed Up and Go (TUG) test, pain assessed on an 11-point Numeric Rating Scale (NRS), abductor strength assessed through a Trendelenburg test and QOL assessed with the EQ-5D score.⁴¹⁻⁴⁵ Comorbidity was measured by asking patients for their medical history at baseline (prior to surgery). Specifically, patients were asked if pulmonary (yes/no) or cardiac comorbidities (yes/no) were present. The TUG test measures the time it takes to get up from a chair, walk 3 m back and forth and sit back down on the chair. During the Trendelenburg test, the patient is asked to slowly raise the contralateral foot from the ground, flexing the hip to approximately 30 degrees and raising the non-stance side of the pelvis as high as possible. Inability to maintain the pelvis in this position for 30 s is considered a positive Trendelenburg test. A trained blinded researcher performed all clinical tests.

All PROMs (eg, HOOS, mHHS, SF-12 and EQ-5D) were administered at baseline, 6 weeks, 3, 6, 12 and 24 months. The safety of the intervention was evaluated by recording the number of reinterventions, defined as any ipsilateral hip reoperation, and the complications.

The second aim of this study was to assess the feasibility of a double-blinded randomised controlled hip implant trial determined by the continued blinding rate, protocol adherence and follow-up success rate at 2 years follow-up. This aim was exploratory and a clear definition of 'feasible' is difficult. We consider a more than 90% success rate on all three items an acceptable threshold.

We applied several methodological safeguards to reduce the risk of bias, maximise protocol adherence and reduce the risk of withdrawals. Selection bias was prevented by approaching all consecutive eligible patients and by randomising patients shortly before surgery. Patient performance bias was prevented by blinding patients for the type of prosthesis. Detection bias was prevented through blinded assessment and data analysis. All clinical assessors remained blinded for the type of prosthesis during the follow-up period, and data processing and analysis was performed by blinded researchers (VS and LVB). Surgeon performance bias was prevented by analysing the learning curve and possible pitfalls prior to initiating the trial and establishing minimum requirements for surgeons before participation.⁴⁶ Based on this study, the minimum required number of performed procedures prior to participating in this study was initially determined at five for each surgeon. However, to ensure adequate proficiency, the participating surgeons performed 10 procedures prior to participating in the trial. Attrition bias was reduced by actively stimulating patients to complete all questionnaires during the follow-up visits and involving patients with the trial progress, thereby minimising drop-out and lost to follow-up. Furthermore, the data were verified for completeness and inconsistencies. Publication bias was prevented by publishing the protocol.³⁵ Deblinded patients, withdrawals and protocol deviations were included in the intention-to-treat analysis.

Sample size calculation was based on the HOOS pain subscale. De Groot *et al* found a mean HOOS pain score of 65.4 points with an SD of 14.3 in patients 9.5 months after THA.³⁴ We considered a 10% difference in outcome clinically relevant, resulting in a 7-point difference. Based on these assumptions (SD 14.3 and a difference of 7 points), setting α at 0.05 and the power level at 80% a sample size of 67 in each group was required to detect a statistically significant difference. We expected a maximum drop-out rate of 10%, resulting in a total of 150 patients (75 patients in the curved stem group and 75 patients in the straight stem group).

To investigate the effect of both implants, we used generalised estimating equations (GEEs) for longitudinal analysis in SPSS (IBM). This method takes into account the dependency of observations within a patient and the fact that not all patients may be assessed at each time point (missing data). All patients who withdrew from the trial after surgery and patients who underwent revision surgery were included in an intention-to-treat analysis. In the primary GEE model, the outcome variable studied (eg, physical function on HOOS) was analysed as a dependent variable, using implant allocation (1, CFP; 0, Zweymuller) and time as key independent variables. The primary endpoint of the study was on the effect at 3 months, but all time moments were analysed in the same GEE model.

In the secondary GEE model, the secondary outcome measures were analysed in a similar way. We described the incidence of reoperations of both groups using

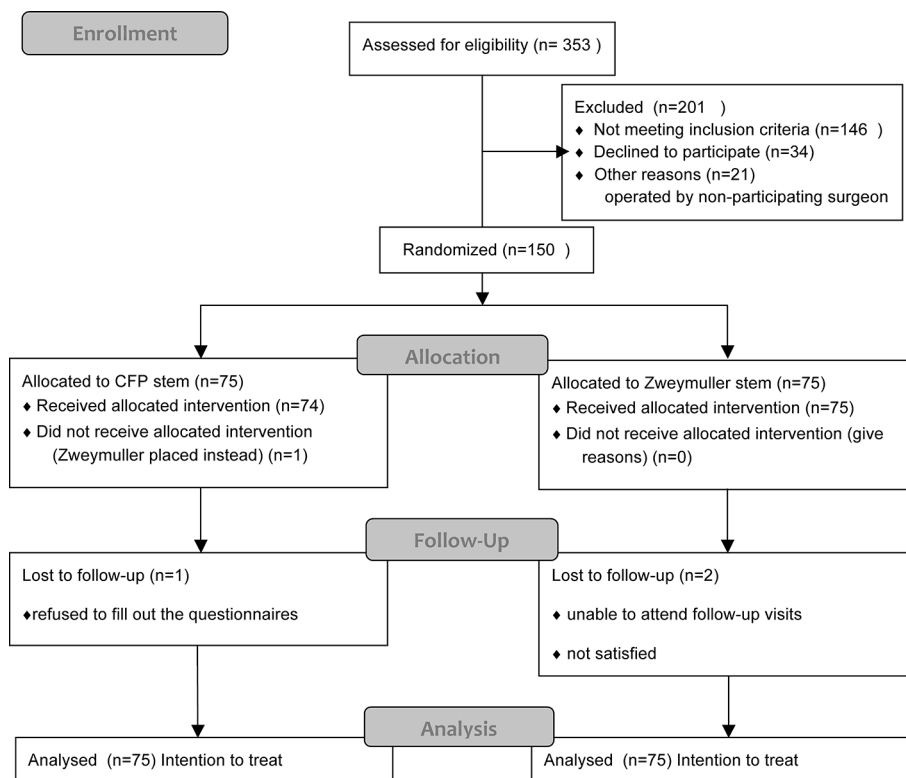


Figure 1 Consolidated Standards Of Reporting Trials flow chart. CFP, Collum Femoris Preserving.

descriptive statistics. For all analyses, a two-tailed value of $p < 0.05$ was considered to be significant.

RESULTS

Patient characteristics

During the enrolment period, 353 patients were considered eligible for inclusion (figure 1). The first patient was included on 24 August 2009, while the last patient was included on 24 October 2012.

A total of 55 patients were excluded, despite being eligible: a non-participating surgeon operated 21 patients and 34 patients refused informed consent. A total of 150 patients were randomised, 100 in hospital A and 50 in hospital B.

The short stem group consisted of 75 patients: 54 women and 21 men. The conventional stem group consisted of 75 patients: 53 women and 22 men. There were significantly more patients with a cardiac comorbidity in the

conventional stem group ($p = 0.04$). Remaining baseline characteristics were similar between both groups (table 1). Surgical characteristics are displayed in table 2. There were no significant differences.

Primary outcome

No significant difference in HOOS total and subscale scores was found between the two groups at any follow-up time points (figure 2). Both groups equally improved in HOOS total scores as well as in the HOOS subscale scores 3 months after surgery. Mean HOOS total score in the short stem group increased 32.7 points from 36.6 (95% CI 32.9 to 40.2) preoperatively to 69.3 (95% CI 66.4 to 72.1) at 3 months follow-up. Mean HOOS total score in the conventional straight stem group increased 36.3 points from 37.1 (95% CI 33.9 to 40.3) preoperatively to 73.4 (95% CI 70.3 to 76.4) at 3 months follow-up. Both groups demonstrated a particular increase in the mean HOOS pain subscale of 37.7 points and 40.4 points in

Table 1 Baseline characteristics of the participating patients

| Group | Age (year) | BMI | Gender (n) | ASA level (n) | Cardiac comorbidity* (n) | Pulmonal comorbidity (n) |
|--------------------------|----------------|----------------|------------|---------------|--------------------------|--------------------------|
| | Mean \pm SD | Mean \pm SD | M:F | I:II:III | Yes:no | Yes:no |
| Short stem (n=75) | 60.3 \pm 6.8 | 27.2 \pm 4.2 | 21:54 | 37:37:1 | 8: 67 | 4: 71 |
| Conventional stem (n=75) | 60.5 \pm 7.1 | 26.4 \pm 4.3 | 22:53 | 26:45:4 | 17: 55 | 6: 66 |

*Significance at $p < 0.05$.

ASA, American Society of Anaesthesiologists; BMI, body mass index; F, female; M, male.

**Table 2** Surgical characteristics of the participating patients

| | Short stem (n=75) Mean±SD | Conventional stem (n=75) Mean±SD |
|-------------------------------------------|---------------------------------|----------------------------------------|
| Blood loss (mL) | 410.3±211.7 | 441.0±369.8 |
| Duration surgery (hour) | 1:01±0:19 | 0:56±0:12 |
| Post-op HB (mmol/L) | 8.7±0.69 | 8.7±0.70 |
| Type of anaesthesia (n) General:spinal | 37: 38 | 41: 32* |
| Side (n) R:L | 44: 31 | 55: 20 |

HB, haemoglobin; L, left; R, right.

*Two missing.

the short and conventional straight stem groups, respectively. The short stem preoperative HOOS pain subscale increased from 45.7 (95% CI 41.6 to 49.8) to 83.4 (95% CI 80.6 to 86.3) at 3 months follow-up. The conventional straight stem HOOS pain subscale increased from 44.6 (95% CI 41.1 to 48.0) to 85.0 (95% CI 81.9 to 88.1) at 3 months follow-up.

Patients continued to improve during the first year to a HOOS total score of 78.7 (95% CI 75.3 to 82.2) and 82.5 (95% CI 79.4 to 85.7) in the short and conventional straight stem groups, respectively, and remained stable during the second year.

Secondary outcome

There were no significant differences between the two groups in the secondary outcomes. Both groups demonstrated a similar improvement from baseline in physical function as measured with mHHS, PCS-12, Pain-NRS score, TUG, Trendelenburg test and EQ5D (table 3, figures 3 and 4). For the majority of these outcomes, the main improvements were found at 3 months and continued to improve at 6 months and up to 1 year follow-up. During the second year, the improvements remained stable. We found improvements on all outcome measures as soon as 6 weeks after surgery, except on the TUG test and the Trendelenburg test. At 6 weeks, patients showed no change on the performance of the TUG test, and significantly more patients showed a positive Trendelenburg test at 6 weeks compared with baseline, with a decrease at 1 and 2 years follow-up (figure 3 and table 3).

Complications

The minor and major complications are displayed in table 4.

There was an early deep infection at 5 weeks postoperatively in the straight stem group requiring debridement antibiotics and implant retention. There was one late infection in the short stem group 19 months postoperatively, requiring a two-stage revision to a straight stem. There were no other major complications in the straight stem group. In the short stem group, however, two femoral

fractures occurred while preparing the femur for the stem. In one short stem patient, a small fracture occurred in the calcar region, requiring metal wiring to secure the fracture, followed by partial weight bearing for the first 6 weeks postoperatively. The other periprosthetic fracture, a Vancouver B1-type spiral fracture in the diaphysis region, required metal wiring along with plating to secure the fracture, followed by non-weight bearing for the first 6 weeks postoperatively. There was one early dislocation on the second postoperative day in the short stem group for which the cup was revised. There was no aseptic stem loosening in either group within the 2-year follow-up.

Trial feasibility

At the end of the 2-year follow-up period, 91.3% (n=137) of the participating patients remained blinded. All clinical assessors and data analysts remained blinded. Protocol adherence was 98% (n=147). Three protocol deviations occurred during surgery. In two patients, the T.O.P. cup instrument set was unsterile and a Trilogy (Zimmer-Biomet, Warsaw, USA) cementless cup was placed instead. Both patients however received the allocated stem. In one patient, a straight stem was placed despite the patient being allocated to a short stem. The surgeon assessed the patient's bone as too osteoporotic for placement of a short stem.

Follow-up success rate was 98% (n=147). At 2 years follow-up, a total of three patients had withdrawn from the study: one patient in the short stem group refused to fill out the questionnaires and withdrew within the first year; one patient in the straight stem group was unable to attend the follow-up visits or fill out the questionnaires and withdrew after 1 year follow-up; a third patient in the straight stem group was not fully satisfied with the results of the operation and withdrew after 1 year follow-up.

DISCUSSION

Key findings

Both groups demonstrated significant functional improvement at 3 months and continued to improve up to 1 year follow-up compared with preoperatively. However, we did not find a significant difference in these outcomes between the two groups at any of the time points. Therefore, we found no evidence for superior patient-reported short-term functional result after short stem THA compared with conventional straight stem THA.

Limitations

This study has some limitations. All efforts were made to conceal the randomisation sequence for the operating surgeon. However, envelope randomisation is more vulnerable to tampering and therefore generally considered to be inferior to computer or distant randomisation. Initial efforts to perform digital randomisation were, however, unsuccessful due to persistent technical difficulties. Despite all efforts to achieve concealment of

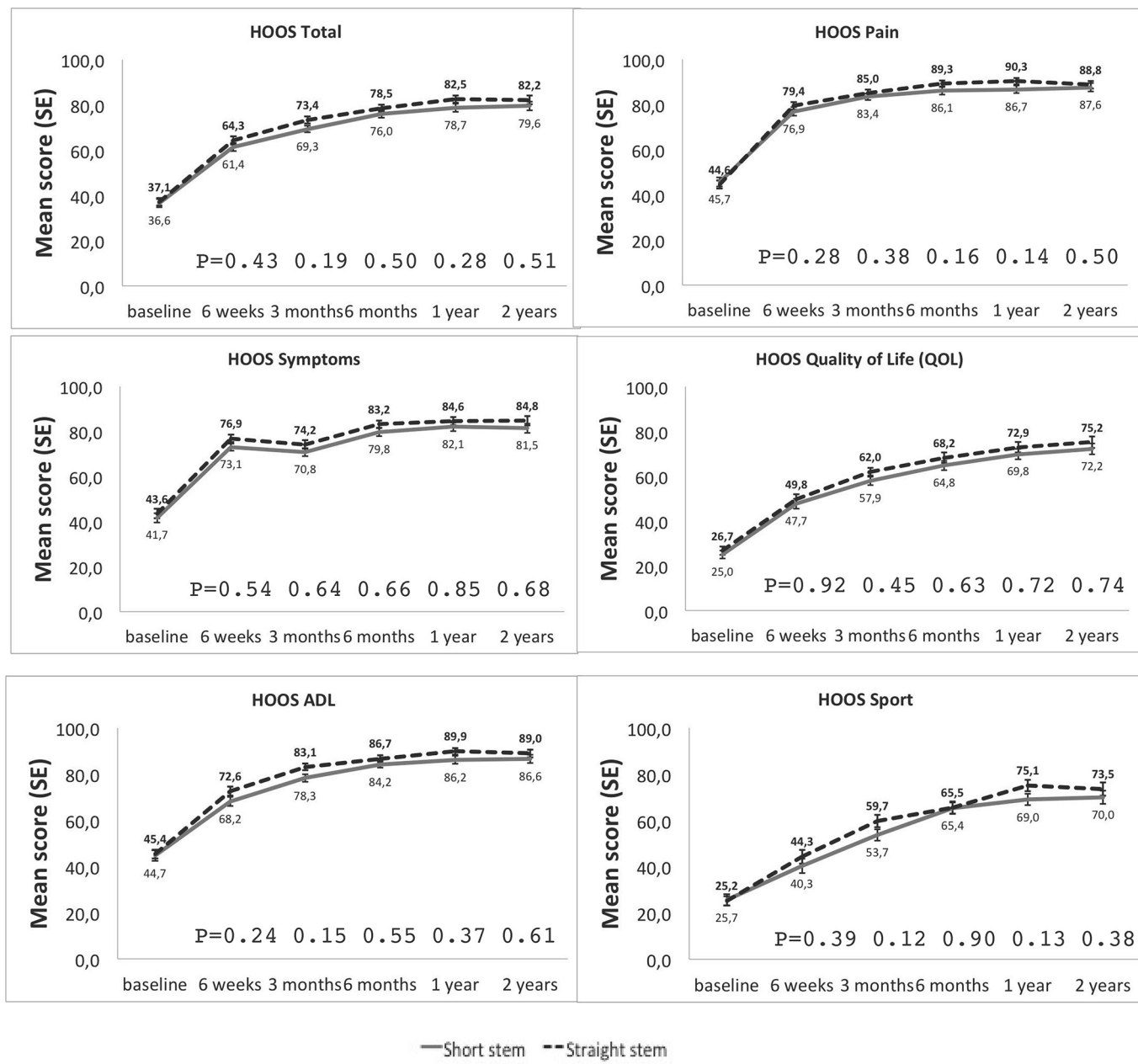


Figure 2 HOOS total and subscale scores at each time point and accompanying p values. ADL, activities of daily living; HOOS, Hip disability and Osteoarthritis Outcome Score.

treatment allocation, three protocol violations occurred. In two patients, a Trilogy (Zimmer, Warsaw, USA) cementless cup was placed instead of a T.O.P. cup due to sterility issues with the T.O.P. cup instruments. In one patient, an Zweymuller Alloclassic stem was placed instead of the allocated CFP stem. This patient had severe osteoporotic bone, unsuitable for a CFP stem according to the surgeon. This reveals a certain preference by this surgeon for conventional stems in patients with osteoporotic bone. The results of the intention-to-treat analysis did not differ from the per protocol analysis.

In our study, a total number of 205 patients were eligible to participate in the study, 150 of which were randomised resulting in a recruitment success rate of 73% (figure 1). A total of 55 patients were considered

eligible to participate but declined participation (n=34) or were operated/listed for the operation by a non-participating surgeon (n=21) (figure 1). Patient characteristics of non-participating eligible patients were not collected, which leaves a risk for selection bias. Potential selection bias may limit the generalisability of our study results to the overall primary hip osteoarthritis patient population.

Previous literature

De Groot *et al* assessed the HOOS scores of 68 patients 9 months after primary THA.³⁴ Compared with our study, however, they found consistently lower HOOS scores in all subscales irrespective of the follow-up period. For instance, their mean HOOS pain score at 9 months follow-up was 64.2, while the HOOS pain scores in our

**Table 3** Estimated mean and 95% CI of the Short Form 12 questionnaire Physical Component Scale (SF-12 PCS) and the Timed Up and Go (TUG) test

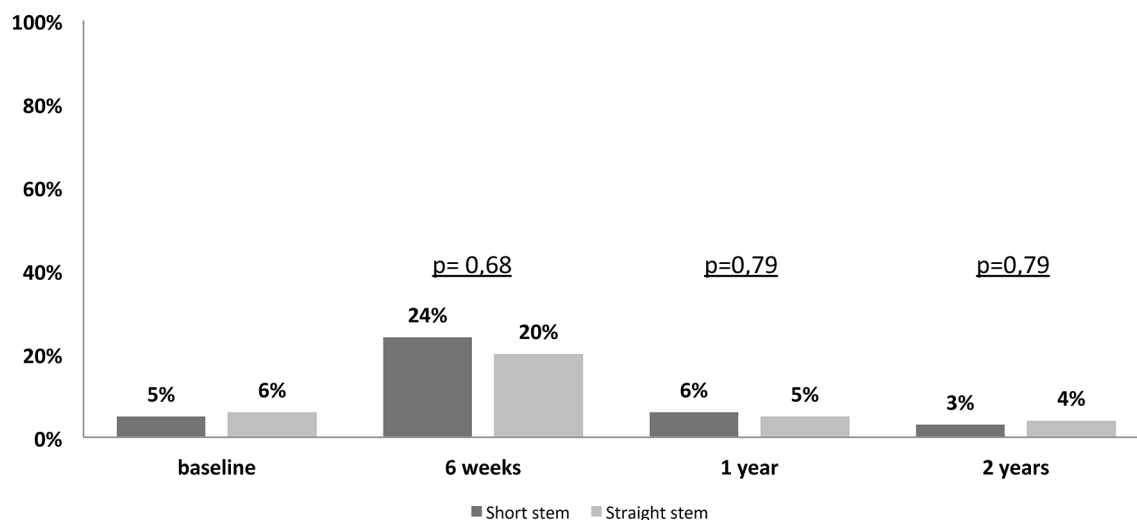
| | Short stem | 95% CI lower | 95% CI upper | Straight stem | 95% CI lower | 95% CI upper | p Value in change |
|------------------|------------|--------------|--------------|---------------|--------------|--------------|-------------------|
| SF-12 PCS | | | | | | | |
| Baseline | 33 | 32 | 35 | 34 | 32 | 36 | |
| 6 weeks | 36 | 34 | 38 | 37 | 35 | 39 | 0.83 |
| 3 months | 42 | 40 | 44 | 44 | 42 | 46 | 0.55 |
| 6 months | 46 | 44 | 48 | 46 | 44 | 48 | 0.52 |
| 1 year | 48 | 46 | 50 | 47 | 45 | 50 | 0.41 |
| 2 years | 49 | 47 | 51 | 46 | 44 | 49 | 0.08 |
| EQ5-D | | | | | | | |
| Baseline | 0.62 | 0.57 | 0.68 | 0.59 | 0.54 | 0.65 | |
| 6 weeks | 0.72 | 0.68 | 0.76 | 0.76 | 0.73 | 0.79 | 0.08 |
| 3 months | 0.82 | 0.79 | 0.85 | 0.81 | 0.78 | 0.85 | 0.55 |
| 6 months | 0.86 | 0.83 | 0.89 | 0.85 | 0.82 | 0.89 | 0.61 |
| 1 year | 0.88 | 0.85 | 0.91 | 0.85 | 0.80 | 0.89 | 0.97 |
| 2 years | 0.87 | 0.84 | 0.91 | 0.86 | 0.82 | 0.91 | 0.64 |
| TUG | | | | | | | |
| Baseline | 10.83 | 10.03 | 11.64 | 10.39 | 9.73 | 11.05 | |
| 6 weeks | 11.01 | 10.15 | 11.87 | 10.74 | 9.93 | 11.56 | 0.78 |
| 1 year | 9.14 | 7.71 | 10.58 | 8.46 | 8.02 | 8.91 | 0.79 |
| 2 years | 8.74 | 8.32 | 9.16 | 8.63 | 8.19 | 9.07 | 0.53 |

short stem and conventional straight stem groups were 76.9 (95% CI 73.2 to 80.7) and 79.4 (95% CI 76 to 82.8) already at 6 weeks and continued to improve during the first year (figure 2). Unfortunately, Groot *et al* did not elaborate on the surgical technique used. We therefore could not explain the discrepancy between our study and theirs. The mean age in their study was 63.1 (31–88), which was comparable to our study (table 1).

Other authors, however, reported HOOS scores after primary THA more similar to our study. A large retrospective series of 537 primary THAs found a HOOS score of 83.1 at 1 year follow-up.⁴⁷ Likewise, Nilsson *et al* reported a HOOS pain subscale score of 82.3 at 6 months follow-up.⁴⁸

Paulsen *et al* calculated the minimal postoperative HOOS score acceptable to patients after primary THA,

Positive Trendelenburg Test

**Figure 3** The percentage of positive Trendelenburg test at each time point and accompanying p values.

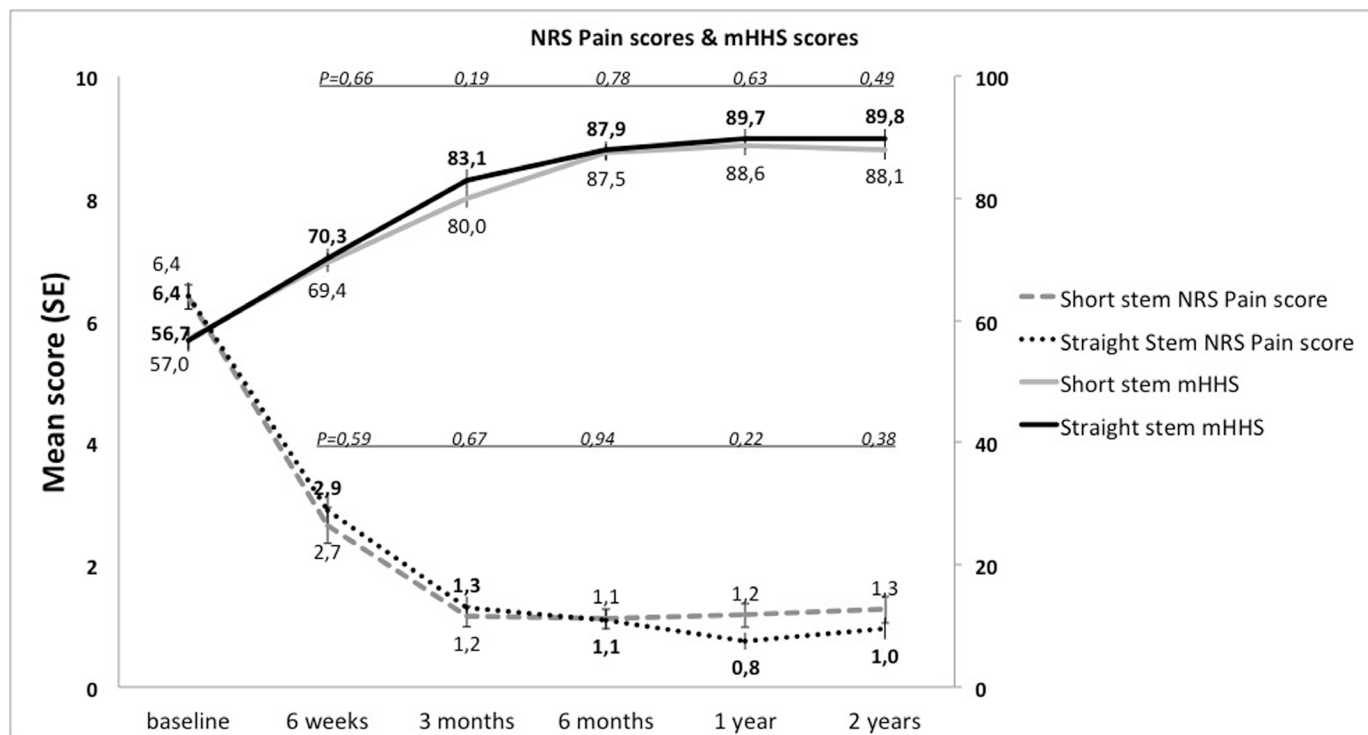


Figure 4 Estimated mean and SE at each time point with accompanying p values. Left-side scale: pain on a Numeric Rating Scale. Right-side scale: modified Harris Hip Score. mHHS, modified Harris Hip Score; NRS, Numeric Rating Scale.

also known as the patient-acceptable symptom state (PASS) in a large series of 1239 patients.⁴⁹ The PASS was calculated by determining the HOOS subscale cut-points in patients who answered 'Excellent', 'Very good' or 'Good' to the question: 'How would you describe the results of your operation'. The PASS cut-off point was 91 (95% CI 91 to 92) for HOOS pain and 83 (95% CI 82 to 84) for HOOS QOL. These cut-off points are even higher than our HOOS scores and those described in the literature.^{34 47 48 50}

Berliner *et al* calculated the preoperative threshold values of HOOS.⁴⁷ Patients with preoperative HOOS values below 32.5 or above 51 were less likely to experience a minimal clinically important difference of 9.1 points. Our preoperative HOOS total score was 36.5

(95% CI 32.9 to 40.2) in the short stem group and 37.1 (95% CI 33.9 to 40.3) in the conventional straight stem group. These scores are in the lower spectrum of the preoperative HOOS value range defined by Berliner *et al*, which could result in lower overall postoperative scores in our study.⁴⁷ This may explain the difference between the high PASS cut-off scores defined by Paulsen *et al* and the functional scores found in our study.⁴⁹ Our mean preoperative total HOOS scores and accompanying 95% CIs were, however, comparable and within that range in both groups, thereby suggesting a similar responsiveness to the surgical procedure.⁴⁷

In a 13-year follow-up study of THA using Zweymuller stems in 100 patients younger than 50 years, Schmolders *et al* demonstrated that despite an excellent 10-year

Table 4 Summary of minor and major complications in each group

| | Short stem | Straight stem | Action |
|----------------------------|------------|---------------|----------------------------------------------------------------------------|
| Minor complications | | | |
| Urinary tract infection | 0 | 1 | Antibiotics |
| Superficial infection | 1 | 2 | Antibiotics |
| Deep venous thrombosis | 1 | 0 | Therapeutic dose low-molecular-weight heparin |
| Major complications | | | |
| Early deep infection | 0 | 1 | Debridement antibiotics and implant retention (DAIR) |
| Late deep infection | 1 | 0 | Two-stage stem revision |
| Dislocation | 1 | 0 | Cup revision |
| Periprosthetic fracture | 2 | 0 | 1. Plate fixation and stem retention 2. Metal wiring and stem retention |



survival rate of 96.8%, radiolucent lines on radiographs affected the HOOS scores.⁵⁰ The median HOOS score in patients with radiolucent lines was 74 and 89 points in patients without radiolucent lines. A longer follow-up may reveal whether reduced stress shielding in short stems reduces radiolucent lines with higher functional scores.

We previously summarised the reported survival rates of short stem THA, including the CFP, in the period 1989 until 2013.⁷ We identified nine case series with a mean follow-up of 5.1 (3.0–11) years and a total of 1001 included patients.^{15–23} These studies demonstrated a mean revision per 100 observed component years rate of 0.21. All studies reported a revision per 100 observed component years of less than 1, which corresponds to a projected revision rate of less than 10% at 10 years follow-up. However, due to the lack of well-constructed long-term studies, these projected revision rates remain estimations based on linear assumptions. We will therefore continue to follow up the patients in our study to report the survival at 5 years follow-up.

Apart from possible bone-preserving features, femoral neck-preserving stems may facilitate soft-tissue-preserving surgery as well. A conventional lateral transgluteal approach was used in both groups, to prevent performance bias due to the confounding effect of variations of the surgical approach. Femoral neck preserving and short curved stems, however, do not require complete exposure of the fossa piriformis for its insertion contrary to conventional cementless straight stems. This enables preservation of the integrity of part of the gluteus insertion, despite using a lateral transgluteal approach.^{13 51} Moreover, short curved stems may provide easier insertion during an Anterior Minimally Invasive Supine approach. Nonetheless, successful survival rates and functional outcomes of minimally invasive hip approaches have been reported using both conventional and short stems.⁵²

Directly comparing the outcome of two hip implants inherently limits the generalisability of the results to other cementless hip stems. The cementless stem design spectrum ranges from relatively bulky in the trochanteric region, such as the Alloclassic Zweymuller, to more curved trochanteric sparing designs, such as the Corail (DePuy Synthes, West Chester, USA), the Taperloc (Zimmer-Biomet, Warsaw, USA) or the Accolade (Stryker, Kalamazoo, USA). Potential functional benefits of short stems will more likely become apparent when compared with bulky trochanter-filling stems, such as the Alloclassic Zweymuller, as apposed to trochanter-sparing stems. We may therefore cautiously assume that the absence of functional benefits of femoral neck preservation in our study is generalisable to other cementless stems.

There was a small incidence of complications, particularly of revisions, in both groups. However, there were more perioperative and postoperative major complications in the short stem group, including two perioperative fractures. Since the first fracture occurred in the

beginning of the trial and the second fracture in the second half of the trial, an association with a learning curve is not evident. However, it is likely that the risk of periprosthetic fractures is lower with years of experience with a certain stem.

A type I error is the risk of detecting an effect that is not present. In our study, we did not find a significant functional difference. A type II error, on the other hand, is the risk of failing to detect an effect that is present. This could be due to an insufficient sample size, particularly if the expected outcome is rare. Complications in total hip replacement are relatively rare. This study was sufficiently powered to provide information on the functional outcome of these implants. Drawing conclusions on their safety, however, has a risk of a type II error. Larger sample sizes are needed to detect these potential differences in complication risk. RCTs are logistically challenging, which limits their sample size. The aggregated results of future similar trials and long-term large-scale data from national joint registries may provide sufficient numbers to detect potential differences in complications.

Protecting against sources of bias

There remains a lack of well-constructed surgical randomised clinical trials in today's literature. A systematic review by Adie *et al* of 150 surgical RCTs demonstrated poor reporting of most of the Consolidated Standards Of Reporting Trials items with a mean score of 12.2 out of 22 items.⁵³ Merely 12% of the RCTs were blinded. Chess and Gagnier showed that orthopaedic RCTs are no exception.⁵⁴ After assessment of the reported methodological quality of RCTs in the top orthopaedic journals, they concluded that many of these studies likely have biased estimates of treatment effects.

Despite the widespread use of hip replacements, well-constructed comparative clinical trials assessing the clinical effectiveness of different types of THA implants are sparse. A comprehensive systematic review of published THR RCTs from 2008 by Tsertsvadze *et al* demonstrated a high risk of bias and poor reporting.⁵⁵ None of the THR trials included or reported the experience levels and skills of caregivers, and most of the trials did not report the blinding status of patients, study personnel and outcome assessors. This study is therefore unique in a sense that it aimed to provide a valid unbiased clinical comparison of two hip prosthetic implants. Strenuous efforts have been made to reduce bias in this RCT.

Conclusion

In this blinded RCT, we found no evidence for a better patient-reported functional result and less pain at 3 months and 2 years after short stem compared with conventional straight stem cementless THA. Physical functioning, physical health, walking ability, abductor strength and QOL were not superior in the short stem group. We did encounter more perioperative and postoperative complications in the short stem group. Direct

comparison of two hip implants in a double-blinded RCT is a feasible concept if strict deblinding preventive measures are applied to all study organisational levels.

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Patient consent Obtained.

Ethics approval Medical Research Ethics Committees United and Verenigde Commissies Mensgebonden Onderzoek, Nieuwegein, The Netherlands approved the trial on 16 September 2008, file number NL21637.100.08.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Anonymised dataset is available from the corresponding author and lead author after finalising the 5-year follow-up, after approval of a study protocol by the lead author. Consent was not obtained for data sharing but the presented data are anonymised and risk of identification is low.

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Better early functional outcome after short stem total hip arthroplasty? A prospective blinded randomised controlled multicentre trial comparing the Collum Femoris Preserving stem with a Zweymuller straight cementless stem total hip replacement for the treatment of primary osteoarthritis of the hip

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