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# Migration and clinical outcomes of a novel cementless hydroxyapatite-coated titanium acetabular shell: two-year follow-up of a randomized controlled trial using radiostereometric analysis

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## Aims

**The objective of this study was to compare the two-year migration and clinical outcomes of a new cementless hydroxyapatite (HA)-coated titanium acetabular shell with its previous version, which shared the same geometrical design but a different manufacturing process for applying the titanium surface.**

## Methods

**Overall, 87 patients undergoing total hip arthroplasty (THA) were randomized to either a Trident II HA or Trident HA shell, each cementless with clusterholes and HA-coating. All components were used in combination with a cemented Exeter V40 femoral stem. Implant migration was measured using radiostereometric analysis (RSA), with radiographs taken within two days of surgery (baseline), and at three, 12, and 24 months postoperatively. Proximal acetabular component migration was the primary outcome measure. Clinical scores and patient-reported outcome measures (PROMs) were collected at each follow-up.**

## Results

**Mean proximal migrations at three, 12, and 24 months were 0.08 mm (95% confidence interval (CI) 0.03 to 0.14), 0.11 mm (95% CI 0.06 to 0.16), and 0.14 mm (95% CI 0.09 to 0.20), respectively, in the Trident II HA group, versus 0.11 mm (95% CI 0.06 to 0.16), 0.12 mm (95% CI 0.07 to 0.17), and 0.14 mm (95% CI 0.09 to 0.19) in the Trident HA group (p = 0.875). No significant differences in translations or rotations between the two designs were found in any other direction. Clinical scores and PROMs were comparable between groups, except for an initially greater postoperative improvement in Hip disability and Osteoarthritis Outcome Symptoms score in the Trident HA group (p = 0.033).**

## Conclusion

**The Trident II clusterhole HA shell has comparable migration with its predecessor, the Trident hemispherical HA cluster shell, suggesting a similar risk of long-term aseptic loosening.**

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## Introduction

Aseptic loosening of the acetabular component remains one of the most common causes for revision surgery following total hip arthroplasty (THA), according to registry data (20% to 35%).[1,2] This finding demonstrates a need for better fixation of existing acetabular components. For cementless components this would relate to creating better biological fixation (bone ongrowth) to the implant surface, thus safeguarding long-term fixation.

The Trident acetabular component (Stryker, USA) is a well-proven design with a reported ten-year revision rate of 2.39% (95% confidence interval (CI) 2.26 to 2.53) in combination with the cemented Exeter V40 stem in the National Joint Registry for England, Wales, Northern Ireland,

**Table I.** Baseline characteristics.

| Characteristic | Trident HA | Trident II HA |
|---|---|---|
| Patients, n | 40 | 38 |
| Mean age, yrs (SD) | 70 (3.9) | 70 (5.0) |
| Male sex, n (%) | 14 (35) | 20 (53) |
| Mean BMI, kg/m² (SD) | 27 (3.6) | 27 (3.0) |
| **Ahlbäck grade, n (%)** | | |
| I | 5 (13) | 7 (18) |
| II | 18 (45) | 22 (58) |
| III | 12 (30) | 9 (24) |
| IV | 5 (13) | 0 (0) |
| **Charnley classification, n (%)** | | |
| A | 24 (60) | 18 (47) |
| B | 16 (40) | 20 (53) |
| **ASA grade, n (%)** | | |
| I | 5 (13) | 6 (16) |
| II | 31 (78) | 30 (79) |
| III | 4 (10) | 2 (5) |

ASA, American Society of Anesthesiologists; HA, hydroxyapatite; SD, standard deviation.

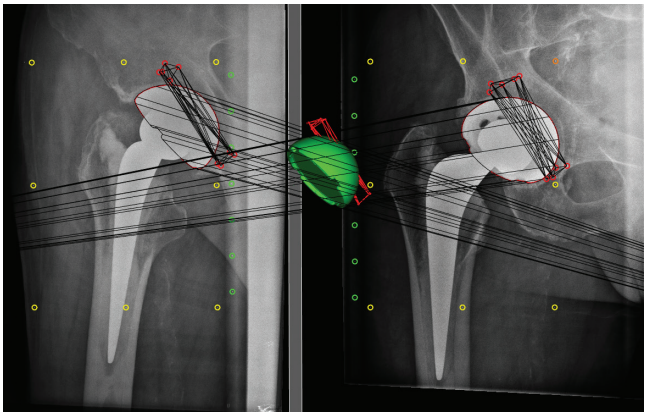

Fig. 1

Model-based radiostereometric analysis used for the migration analysis of the acetabular component relative to the pelvis. The computer-aided design model of the component is in green and the pelvic markers in red.

Isle of Man and States of Guernsey (NJR), and 3.9% (95% CI 3.7 to 4.1) in the Australian Orthopaedic Association National Joint Replacement Registry.[3,4] The Trident II acetabular system (Stryker, USA) was recently introduced for implantation, as the manufacturing technique was changed to optimize the production process to meet current production demands. The Trident II system includes different subtypes: the 3D-printed Trident II Tritanium (solidback, multihole, and clusterhole) shells, and the Trident II clusterhole hydroxyapatite (HA) (hemispherical and peripheral self-locking (PSL)) shells. The Trident II HA shells differ from previous Trident HA shells in having a plasma-sprayed rather than an arc-deposited commercially pure titanium (CPTi) surface; both are covered by PureFix HA coating.[5,6] Even though such changes in the manufacturing process may seem minimal, previously small changes in the manufacturing process and implant surfaces have been associated with unacceptable long-term failure rates.[7-11] Therefore, safe, phased, evidence-based introduction of new implants is important, even when only 'minor' changes to an implant or its production process have occurred.[12] Careful early evaluation, including migration analysis studies, helps to safeguard against the widespread use of new components that perform less well than an earlier version.

Radiostereometric analysis (RSA) is a highly accurate technique for analyzing implant migration.[13,14] Acetabular component migration, specifically proximal translation, as early as one to two years postoperatively is a good prognostic variable for the detection of implants at risk for future aseptic loosening.[14,15] Therefore, RSA is a suitable technique to provide analysis of acetabular components in THA, and monitor new implants to estimate their long-term risk of revision.[16]

The aim of the present study was to compare the two-year migration of the new Trident II clusterhole HA shell compared with its predecessor, the Trident hemispherical HA cluster shell, in THA patients. The hypothesis was that the new shell shows comparable migration with its predecessor, as both have exactly the same geometrical design, differing only in the application technique of the titanium surface. The secondary objective was to compare the clinical outcomes and patient-reported outcome measures (PROMs) between groups.

## Methods

The present study was conducted in Hässleholm Hospital (Sweden). Between February 2019 and May 2021, THA patients were randomized to a Trident II clusterhole HA cup or Trident hemispherical HA cluster shell. Male and non-pregnant female patients aged between 40 and 75 years who underwent primary THA and gave informed consent were eligible for inclusion. Exclusion criteria were BMI ≥ 35 kg/m², rheumatoid arthritis, contralateral THA within the preceding six months, and neuromuscular/neurosensory deficiency. Another exclusion criterion was the need for screw fixation to achieve acceptable initial fixation of the component. Randomization was done using a blocked randomization scheme in a 1:1 ratio. A sealed-envelope technique was used to ensure concealment of treatment allocation, and patients remained blinded to treatment allocation throughout the entire follow-up.

Both acetabular components were hemispherical clusterhole cementless HA-coated and identical in geometrical shape. The surface of the Trident II shell is plasma sprayed CPTi, whereas the Trident shell has an arc-deposited CPTi surface, but both are coated by PureFix HA. The innerchange locking mechanism remained the same for both designs and permitting use of the same liner types. Patients in both groups received the same Trident X3 polyethylene (PE) insert and cemented Exeter V40 femoral stem (Stryker). All operations were performed by four experienced hip surgeons (PL, MA, ML, TH (see Acknowledgements)) using the posterior approach, with a comparable number of procedures performed by each surgeon in both groups. Acetabular preparation comprised under-reaming by 1 mm. All implantations were performed without the use of navigation or robotic assistance.

At operation, nine spherical tantalum markers (ø 0.8 mm; RSA Biomedical, Sweden) per patient were inserted into the acetabular bone to facilitate RSA measurements. RSA radiographs were taken with the patient in supine position over a

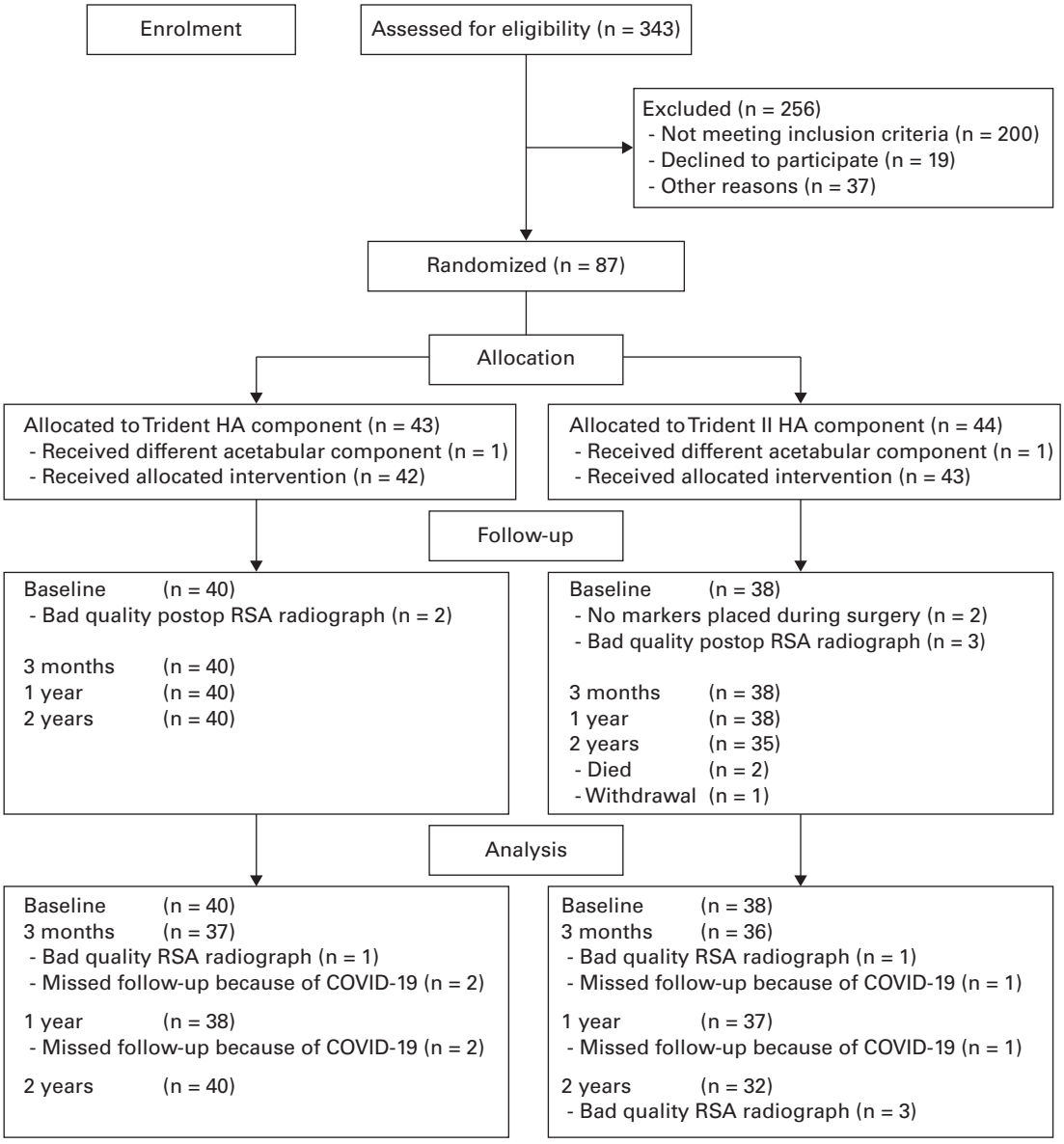


Fig. 2

CONSORT flowchart. HA, hydroxyapatite; RSA, radiostereometric anaysis.

**Table II.** Precision of the radiostereometric set-up presented as mean of the migration between the first and second examination of the double examinations.

| Component | Mean translation, mm (SD) | | | Mean rotation, ° (SD) | | |
|---|---|---|---|---|---|---|
| | Tx | Ty | Tz | Rx | Ry | Rz |
| Trident HA (36 doubles) | 0.00 (0.07) | 0.00 (0.06) | -0.02 (0.13) | -0.02 (0.32) | -0.02 (0.26) | 0.05 (0.33) |
| Trident II HA (33 doubles) | 0.01 (0.05) | 0.01 (0.05) | 0.00 (0.20) | 0.01 (0.32) | 0.02 (0.25) | 0.02 (0.22) |

HA, hydroxyapatite; Rx, Ry, Rz, rotations; SD, standard deviation; Tx, Ty, Tz, translations.

uniplanar calibration cage (Cage 41; RSA Biomedical, Sweden). The baseline radiograph, serving as reference for the migration calculations, was taken within two days of surgery (after full weightbearing) and subsequent radiographs were taken after three, 12, and 24 months postoperatively. Double examinations to determine the clinical RSA precision were acquired at one-year follow-up.[17]

RSA radiographs were analyzed using model-based RSA (RSA*core*; LUMC, Netherlands) with computer-aided design (CAD) models, following the RSA guidelines (Figure 1).[13] A mean error of rigid body fitting below 0.35 mm and a condition number below 120 were set as cut-off points for the pelvic markers. The same set of consistent markers in the pelvis was used in subsequent RSA examinations for each patient.

**Table III.** Clinical scores and patient-reported outcome measures of the two groups. Values are presented as means with 95% confidence intervals.

| PROM | Trident HA | Trident II HA | p-value* |
|---|---|---|---|
| **HSS** | | | 0.698 |
| Preoperative | 55.6 (52.0 to 59.2) | 56.8 (53.3 to 60.4) | |
| 3 mths | 89.2 (87.4 to 90.9) | 89.1 (86.3 to 91.8) | |
| 1 yr | 91.5 (88.8 to 94.1) | 93.2 (91.7 to 94.6) | |
| 2 yrs | 91.4 (88.6 to 94.2) | 93.5 (91.3 to 95.7) | |
| **HOOS Symptoms** | | | 0.033 |
| Preoperative | 49.6 (46.3 to 53.0) | 48.9 (44.2 to 53.2) | |
| 3 mths | 87.0 (83.5 to 90.4) | 81.0 (76.6 to 85.4) | |
| 1 yr | 89.7 (86.0 to 93.4) | 91.3 (87.4 to 95.3) | |
| 2 yrs | 91.5 (88.1 to 94.9) | 91.7 (88.4 to 95.0) | |
| **HOOS Pain** | | | 0.879 |
| Preoperative | 36.2 (31.6 to 40.9) | 35.9 (31.4 to 40.4) | |
| 3 mths | 87.8 (82.9 to 92.6) | 84.9 (80.1 to 89.8) | |
| 1 yr | 90.8 (86.2 to 95.4) | 88.5 (82.5 to 94.5) | |
| 2 yrs | 90.8 (86.7 to 94.9) | 90.6 (86.2 to 94.9) | |
| **HOOS ADL** | | | 0.856 |
| Preoperative | 42.8 (38.0 to 47.5) | 44.4 (39.6 to 49.2) | |
| 3 mths | 81.6 (77.4 to 85.9) | 80.5 (76.2 to 84.8) | |
| 1 yr | 87.1 (82.5 to 91.8) | 88.0 (83.0 to 92.9) | |
| 2 yrs | 89.1 (85.6 to 92.6) | 90.3 (86.3 to 94.3) | |
| **HOOS SR** | | | 0.750 |
| Preoperative | 19.0 (15.4 to 22.7) | 21.4 (15.8 to 26.9) | |
| 3 mths | 61.6 (53.9 to 69.2) | 68.1 (60.3 to 75.9) | |
| 1 yr | 74.3 (67.1 to 81.5) | 79.9 (71.5 to 88.3) | |
| 2 yrs | 74.9 (67.7 to 82.0) | 80.1 (73.1 to 87.1) | |
| **HOOS QoL** | | | 0.436 |
| Preoperative | 26.5 (22.0 to 30.9) | 22.2 (17.5 to 26.9) | |
| 3 mths | 72.2 (66.7 to 77.7) | 74.0 (68.2 to 79.8) | |
| 1 yr | 82.9 (77.5 to 87.6) | 80.6 (74.2 to 87.0) | |
| 2 yrs | 83.2 (78.7 to 87.6) | 84.2 (79.4 to 89.0) | |
| **FJS** | | | 0.764 |
| 3 mths | 62.0 (55.1 to 68.8) | 58.6 (51.4 to 65.8) | |
| 1 yr | 72.8 (65.5 to 80.2) | 74.3 (66.6 to 82.1) | |
| 2 yrs | 72.8 (66.2 to 79.4) | 73.2 (65.6 to 80.9) | |
| **EQ-5D-3L** | | | 0.432 |
| Preoperative | 0.72 (0.68 to 0.75) | 0.75 (0.72 to 0.78) | |
| 3 mths | 0.92 (0.90 to 0.95) | 0.91 (0.89 to 0.94) | |
| 1 yr | 0.93 (0.91 to 0.96) | 0.94 (0.92 to 0.96) | |
| 2 yrs | 0.93 (0.91 to 0.95) | 0.94 (0.92 to 0.96) | |

*The p-values stated in this table indicate the between-group mean differences in improvement between baseline and two-year follow-up, including all measurements during follow-up, derived with a generalized estimating equation approach.
ADL, activities of daily living; EQ-5D-3L, EuroQol Group five-dimension, three-level questionnaire; FJS, Forgotten Joint Score; HA, hydroxyapatite; HOOS, Hip disability and Osteoarthritis Outcome Score; HSS, Harris Hip Score; PROM, patient-reported outcome measure; QoL, quality of life; SR, sports and recreation.

If pelvic bone markers were occluded by the metal implant, a marker configuration model was used where possible to meet the criteria for RSA.[18] Acetabular component migration was expressed as translations along and rotations about the transverse axis (x-axis), longitudinal axis (y-axis), and sagittal axis (z-axis) relative to the pelvis. Rotations about the three axes were calculated using the rotations of the y-axis of the CAD model itself, ignoring the rotations of the component about its rotation symmetry axis.[19] RSA measurements of left-sided THAs were transformed to match right-sided implants.

The primary outcome measure was the mean proximal (longitudinal) migration at two-year follow-up, as early proximal migration is associated with late revision due to aseptic loosening.[14,15] Secondary outcome measures included the translations along and rotations about the other axes, as well as clinical scores (Harris Hip Score (HSS))[20] and PROMs at disease and general health level (Hip disability and Osteoarthritis Outcome Score (HOOS),[21] Forgotten Joint Score (FJS),[22] and EuroQol Group five-dimension three-level health-related quality of life instrument (EQ-5D-3L) index).[23]

**Statistical analysis.** To detect a clinically relevant difference in proximal acetabular component migration between groups of 0.2 mm, with an α of 0.05 and power of 90%, 22 patients per group were needed.[15,24] The sample size calculation is based on normally distributed proximal migration within each group with standard deviation (SD) of 0.2 mm. Patients with inappropriate marking of the acetabular bone or poor-quality baseline RSA radiographs could not be analyzed and were excluded. Taking the latter into account, and to compensate for loss to follow-up, our aim was to include at least 40 patients in each group.

Migration results were compared between groups using a linear mixed-effects model (LMM), which deals effectively with missing values and takes within-subject correlation into account. The model consisted of a group variable (i.e. Trident II HA or Trident HA), a time (follow-up visit) variable, and an interaction term between group and time. A random-intercept term was used and the remaining variability was modelled with a heterogeneous autoregressive order-1 covariance structure. As the clinical scores were not normally distributed, a comparable generalized estimating equation (GEE) approach was used to compare these scores between groups during the follow-up period. A p-value < 0.05 was considered statistically significant. Means were reported with SD or 95% CIs. Analyses were performed using SPSS v. 25 (IBM, USA) and R software v. 4.2.1 (R foundation for Statistical Computing, Austria).

The study was approved by the local ethics committee (entry no. 2018/235), registered at ClinicalTrials.gov (NCT03724058), and conducted according to the CONSORT statement.[25] The present investigator-initiated study was funded by Stryker, which had no role in the collection, evaluation, or interpretation of the study results.

## Results

A total of 87 patients were randomized for this study: 44 to the Trident II HA and 43 to the Trident HA group. No patients were excluded because of the need for screw fixation. One patient randomized to the Trident II HA group received a Trident acetabular component by mistake and was excluded, as no RSA radiographs were taken. Another patient randomized to the Trident HA group received a solidback instead of a clusterhole component during surgery. In two other patients from the Trident II HA group, no markers were inserted into the pelvis. Finally, five patients (two Trident HA, three Trident II HA) were excluded because no markers were visible in the postoperative radiographs. This left 38 patients in the Trident II HA and 40 patients in the Trident HA group (Figure 2). Baseline

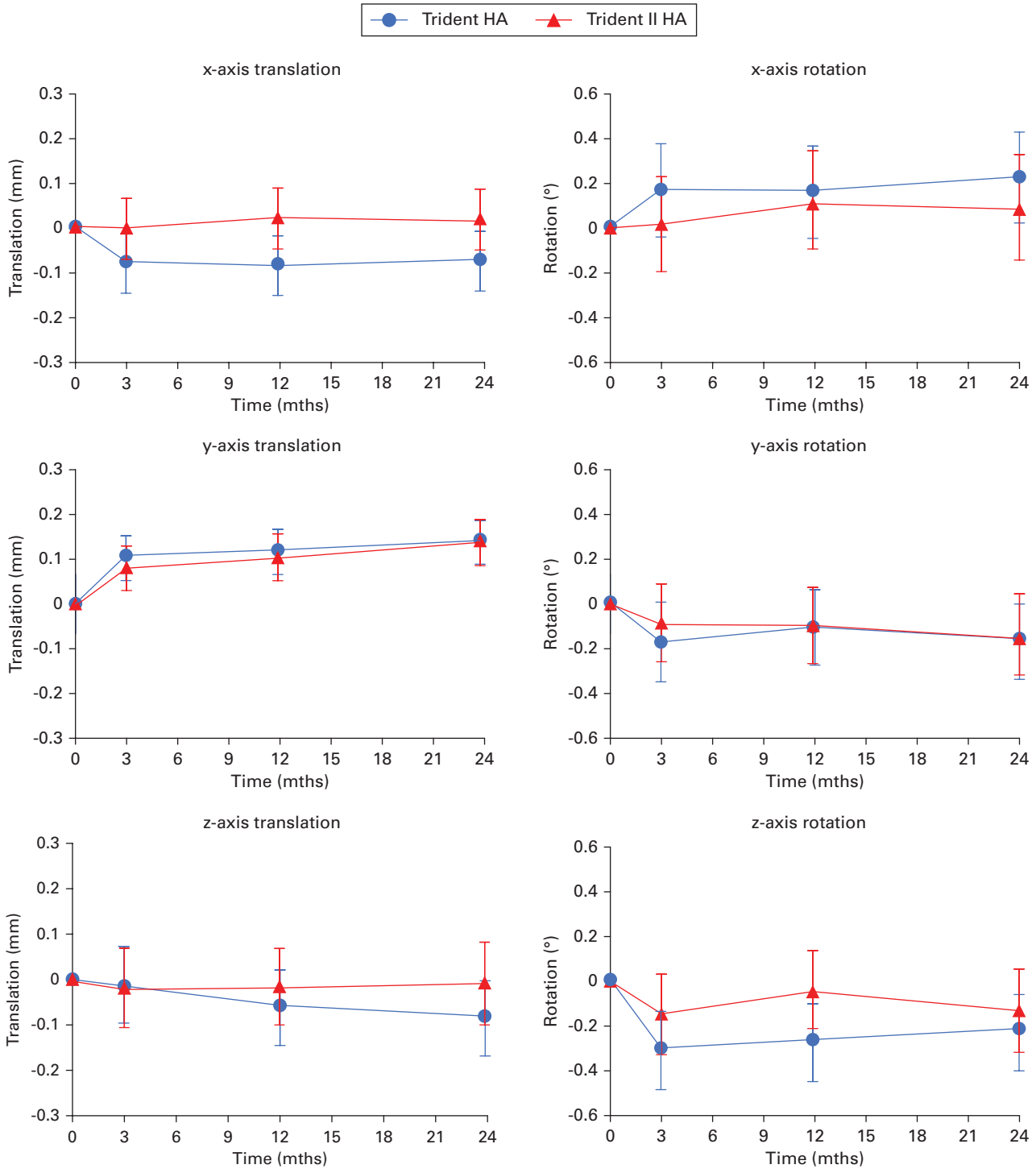


Fig. 3

Translations (mm) and rotations (°) of the acetabular components during the two-year follow-up period. Mean values of both study groups are presented with 95% confidence intervals (error bars). HA, hydroxyapatite.

characteristics of both groups are shown in Table I. After two years, 35 patients in the Trident II HA group and 40 patients in the Trident HA group were still enrolled in the study.

**RSA migration results.** The clinical precision of the RSA migration measurements of both groups was comparable (Table II). During the two-year follow-up, there was no significant difference in the proximal migration of the acetabular components along the y-axis ($p = 0.875$, LMM). Mean proximal migrations of the Trident II HA at three, 12, and 24 months were 0.08 mm (95% CI 0.03 to 0.14), 0.11 mm (95% CI 0.06 to 0.16), and

0.14 mm (95% CI 0.09 to 0.20), respectively. In the Trident HA group for the same intervals, these mean proximal migrations were 0.11 mm (95% CI 0.06 to 0.16), 0.12 mm (95% CI 0.07 to 0.17), and 0.14 mm (95% CI 0.09 to 0.19). Mean RSA migration data are presented in Figure 3. Mean translations along the transverse axis (x-axis) ($p = 0.084$) and sagittal axis (z-axis) ($p = 0.713$) were comparable between groups. No statistical differences were found in mean rotations: transverse axis (x-axis) ($p = 0.679$), longitudinal axis (y-axis) ($p = 0.943$), and sagittal axis (z-axis) ($p = 0.375$).

**Clinical results.** No significant differences in postoperative improvement in mean results for HSS, HOOS Pain, HOOS Activities of Daily Living, HOOS Sport and Recreation, HOOS Quality of Life, FJS, and EQ-5D-3L were found between the groups during the entire follow-up (Table III). Only the improvement in mean HOOS Symptoms was statistically different ($p = 0.033$, GEE), which was caused by a greater mean HOOS Symptoms in the Trident HA group at three months compared with the Trident II HA group. However, at two years postoperatively, the mean HOOS Symptoms of the Trident HA was comparable to the Trident II HA group, 91.5 (95% CI 88.1 to 94.9) versus 91.7 (95% CI 88.4 to 95.0), respectively (Table III).

**Adverse events.** There were no revisions of either the acetabular component or stem in any patient at the two-year follow-up. One patient in the Trident II HA group had a deep infection (periprosthetic joint infection) three weeks after surgery. Treatment was debridement, antibiotics, and implant retention (DAIR) (including an exchange of the femoral head and polyethylene liner and 12 weeks of antibiotics). As the acetabular shell and stem were left in place, this patient was not excluded.

## Discussion

The cementless Trident II clusterhole HA shell showed a comparable early migration pattern to its predecessor, the Trident hemispherical HA cluster shell. Moreover, mean proximal migration of both designs was below 0.2 mm at two years, which is the threshold predictive value for an increased risk of revision due to aseptic loosening.[15] This would suggest that for both components revision rates are expected to be less than 5% at ten years.[15] Besides proximal migration, acetabular components showing a mean increase in acetabular inclination of > 2.53° at two years are described to fail due to loosening.[14] The present study found no difference in mean sagittal rotation between the two implants with -0.13° (95% CI -0.31 to 0.06) and -0.23 (95% CI -0.40 to -0.06) in the Trident II HA and Trident HA group at two years, respectively, also indicating a comparable low risk for future loosening.

Registries typically report the survival of acetabular shells within the same implant brand portfolio, rather than naming specific subtypes.[1-3,26] It is therefore unclear from registry data whether the Trident hemispherical HA cluster shells perform as well as other shells from the Trident acetabular system, e.g. the Trident hemispherical solidback or the Trident PSL HA cluster shell. Multiple variants within the Trident II acetabular system also exist. Therefore, one should be aware of the potential camouflage effect if a specific variant deviates in performance from other versions of the same brand.[27] A recent case series by Ulrich et al[28] also illustrates the importance of being specific about the subtypes, as they incorrectly assumed that all Trident II shells are produced with 3D printing. Only the Trident II Tritanium shells are 3D-printed, whereas the Trident II HA shells are produced through a different manufacturing process (forging and machine finishing).

This RSA study is the first to assess the migration of the Trident II clusterhole HA-coated acetabular component, which is an important part of the phased, evidence-based introduction of new implants.[12,29-31] Other RSA studies have reported early migration of cementless HA-coated acetabular components. A study of a cementless titanium plasma-sprayed acetabular component with HA coating (EP-FIT PLUS; Smith & Nephew Orthopaedics, Switzerland), in combination with a cementless femoral stem, showed a mean proximal migration at two years of 0.10 mm.[32] Jørgensen et al[33] assessed the migration of a cementless hemispherical acetabular component with plasma-sprayed titanium and HA coating (Exceed ABT RingLoc-x; Zimmer Biomet, USA) in combination with a cementless femoral stem and reported a mean proximal migration of 0.20 mm (95% CI 0.10 to 0.30) at two years, which is slightly higher compared with the migration of the implants in our study.

A strength of the present study is its randomized design. This trial compares a cementless HA-coated shell with its geometrically identical predecessor, but which has a different manufacturing process for applying the CPTi coating. This enabled assessment of the effect of differences in applying the titanium layer in cementless shells on the migration of shells relative to the bone, and thereby whether the changes made in the manufacturing process had any impact. RSA was used to measure the component migration, which has been shown to be a highly accurate technique and is recommended in the phased evidence-based introduction of new implants.[13,31]

Limitations are present: first, only the clusterhole HA shell version of the Trident II acetabular system was evaluated in this study. Therefore, we caution against extrapolation of the migration results to other shells of the Trident II acetabular system, as small changes may affect implant stabilization. Our results show an expected low risk of long-term revision from aseptic loosening, but cannot be directly translated to all other subdesigns of the Trident II acetabular shells. Second, we excluded patients if screw fixation of the acetabular component was needed to create acceptable initial fixation. Although no patients were excluded because of this, it limits the generalizability of this study's findings to Trident II clusterhole HA cups when used without screws. A small case series recently reported failure of screw–shell interface of the Trident II clusterhole HA shell in two patients.[28] Finally, our study only assessed the migration of the Trident HA and Trident II HA shells in combination with the cemented Exeter V40 stem, which is a well-proven femoral stem.[34] Both shells may show different early migration patterns, and subsequent different long-term risk of loosening, when used in combination with a different femoral stem.[35]

In conclusion, the Trident II clusterhole HA shell showed comparable early migration results with its predecessor, the Trident hemispherical HA cluster shell, when used in combination with the cemented Exeter V40 femoral stem. These findings suggest a comparable low risk of future long-term mechanical loosening.

## Take home message

- The Trident II clusterhole hydroxyapatite (HA) shell, produced using a different manufacturing process, had early migration comparable to its predecessor during the first two postoperative years.
- The mean proximal migration of the Trident II clusterhole HA shell, when used in combination with the cemented Exeter V40 stem, at two years was lower than 0.2 mm. This indicates an expected revision risk at ten years below 5%.

## Supplementary material

CONSORT Group Checklist.

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