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PROTOCOL

# Nexus Evaluation Primary Trident II UNcemented shEll (NEPTUNE)

## A LONGITUDINAL COHORT STUDY OF THE HYDROXYAPATITE COATED TRIDENT II ACETABULAR SYSTEM IN TOTAL HIP ARTHROPLASTY

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### Aims

**The primary aim of this study is to assess the survival of the uncemented hydroxyapatite (HA) coated Trident II acetabular component as part of a hybrid total hip arthroplasty (THA) using a cemented Exeter stem. The secondary aims are to assess the complications, joint-specific function, health-related quality of life, and radiological signs of loosening of the acetabular component.**

### Methods

**A single-centre, prospective cohort study of 125 implants will be undertaken. Patients undergoing hybrid THA at the study centre will be recruited. Inclusion criteria are patients suitable for the use of the uncemented acetabular component, aged 18 to 75 years, willing and able to comply with the study protocol, and provide informed consent. Exclusion criteria includes patients not meeting study inclusion criteria, inadequate bone stock to support fixation of the prosthesis, a BMI > 40 kg/m$^2$, or THA performed for pain relief in those with severely restricted mobility.**

### Results

**Implant survival, complications, functional outcomes and radiological assessment up to ten years following index THA (one, two, five, seven, and ten years) will be performed. Functional assessment will include the Oxford Hip Score, Forgotten Joint Score, 12-Item Short Form Health Survey, EuroQol five-dimension health questionnaire, and pain and patient satisfaction. Radiological assessment with assess for acetabula lucent lines, lysis, and loosening according to DeLee and Charnley zones.**

### Conclusion

**This study is part of a stepwise introduction of a new device to orthopaedic practice, and careful monitoring of implants should be carried out as part of the Beyond Compliance principles. The results of this study will provide functional, radiological, and survival data to either support the ongoing use of the HA acetabulum or highlight potential limitations of this new implant before wide adoption.**

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**Keywords:** Total hip arthroplasty, Uncemented, Hydroxyapatite, Outcome, Survival

## Introduction

Total hip arthroplasty (THA) is one of the most successful and cost-effective of all surgical procedures in terms of alleviating pain and enhancing physical function.[1,2] It is estimated that 58% of THA last 25 years, but this data was based on older implants with outdated bearing surfaces and consisted mostly of cemented implants.[3] Improving implant survivorship would not only be cost-effective, provided the increased implant cost did not out weight the associated cost of revision surgery, but also avoid patient morbidity associated with a failing arthroplasty and

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revision surgery.[1,4,5] Implant failure and revision in the longer term is generally due to aseptic causes and acetabular loosening is more common than femoral loosening.[6] Uncemented acetabula fixation is becoming more prevalent in the UK over the last decade accounting for approximately 70% of THA; however, whether this is associated with improved survival compared to cemented fixation is not clear.[7,8] There are numerous options for uncemented fixation, which are generally based either on ingrowth or ongrowth of the bone.

The Trident acetabular system (Stryker, USA) is an uncement cup that was first released in 1999.[9] A hydroxyapatite (HA) coating is an option in this system which is added to the porous metal to improve the biological fixation.[10] Calcium hydroxyapatite is a naturally occurring substance found in bone and enamel and has been used clinically for over 30 years.[11] It is well accepted that the additional HA improves early bone ongrowth and mechanical fixation of implants.[12] The original Trident acetabular system is a cementless shell used for THA which has a longstanding track record (13A Orthopaedic Data Evaluation Panel (ODEP) rating),[13] and was one of the most commonly implanted uncemented acetabular component in the UK in 2022.[7] The device manufacturer recently introduced the evolution of this product, the Trident II acetabular shell. This implant was launched in 2017, which is CE marked, and is now widely available for the UK market. However, it has minimal clinical outcomes data to support its use. As part of a stepwise introduction of devices to orthopaedic practice, careful monitoring of implants should be carried out when local teams amend their surgical practice.

## Study objectives

### Objectives

**Primary objective.** The primary objective is to assess the survival of the uncemented HA-coated Trident II acetabular component as part of THA using a cemented Exeter stem.

**Secondary objectives.** The secondary objectives are to assess the complications, joint-specific function, health-related quality of life (HRQoL), and radiological signs of loosening of the Trident II acetabular component.

### Endpoints

**Primary endpoint.** The primary endpoint is implant survival up to ten years. Data will be collected at one, two, five, seven, and ten years, with analysis and reporting at two, five, and ten years postimplantation. All failures or revision (including intension to revise) of the Trident II components, as well as liner revisions, will be documented.

**Secondary endpoints.** Data on safety will be collected at one, two, five, seven, and ten years, with analysis and reporting at two, five, and ten years postimplantation. All intraoperative and postoperative adverse events and clinical complications will be recorded. Data on clinical outcomes will be collected at one, two, five, seven, and ten years, with analysis and reporting at two, five, and tenyears postimplantation). This will be assessed using validated outcome measures. Radiographs will be assessed for lucent lines and signs of loosening.

**Study design.** This will be a single-centre, phase four, post-market surveillance, prospective cohort study. This is a ten-year study of the Trident II acetabular component as part of THA at the Royal Infirmary of Edinburgh, NHS Lothian, UK.

Patients will receive a Trident II acetabular component as part of primary THA at the study centre. This component is CE marked and widely available for use by UK surgeons. The Trident II shells are HA-coated, cementless, press-fit acetabular shells composed of a Titanium (Ti-6Al-4V) substrate featuring a CpTi roughened surface with PureFix HA. The cup is available in a range of sizes and is indicated for primary and revision procedures.

A standard operative technique will be employed by all study surgeons, using the posterior approach. This will be used in combination with a cemented Exeter stem. The routine postoperative patient care protocol of the study centre will be employed.

## Study population

**Number of participants.** A total of 125 patients undergoing planned primary THA will be recruited at the study centre.

**Inclusion criteria.** Inclusion criteria are: patients undergoing planned primary THA with standard implants, suitable for the use of the uncemented Trident II acetabular component; patients aged 18 to 75 years; patients willing and able to comply with the study protocol; and patients that provide informed consent.

**Exclusion criteria.** Exclusion criteria are: patients not meeting study inclusion criteria; bone stock that is inadequate for support or fixation of the prosthesis; patients with a BMI > 40 kg/m$^2$; and procedures performed for pain relief in those with severely restricted mobility.

## Participant selection and enrolment

**Identifying participants.** Suitable patients offered a THA in the orthopaedic clinics of participating surgeons will be made aware of the study by their surgeon, and study information will be provided. Should the patient wish, they will be able to contact the research team to discuss the study. The surgeon will inform the research team of a potential research patient and highlight the date of the preadmission clinic that the research team should be available to attend to consent and carry out the baseline data capture, but at this stage do not need to identify them. When those patients attend the routine preoperative

clinic prior to THA, the surgeon will discuss the operation and implant choice with the patient. If agreeable, the patient will be consented by a member of the research team at that clinic visit.

**Consenting participants.** Formal study consent will be obtained and documented by a suitably trained member of the clinical research team. Written study information will be provided to the patient by the surgical team (at time of offering surgery in the outpatient clinic), and, as such, they will have time to consider prior to attending the preoperative clinic. The patient will be able to discuss the study with their surgeon and/or member of the research team prior to consent being given. The study will clearly be marked as voluntary, and the patient will be made aware of what will happen should they take part or not taking part in the study.

**Withdrawal of study participants.** Participants are free to withdraw from the study at any point or a participant can be withdrawn by the Investigator. If withdrawal occurs, it should be documented in the participant's case report form, if possible. The participant will have the option of withdrawal from all aspects of the trial, but continued use of data collected up to that point.

Participants may be withdrawn for the following reasons: serious adverse event (e.g. death); patient withdrawal; revision/removal of study device; lost to follow-up; serious adverse event (e.g. death); patient withdrawal; revision/removal of study device; and lost to follow-up.

**Co-enrolment.** Co-enrolment will be allowed to non-interventional studies that, in the view of the project management group, will not influence or interact with the outcomes evaluated in this trial in accordance with co-sponsor policies (Academic and Clinical Central Office for Research and Development (ACCORD) co-enrolment Policy).[14]

## Study assessments

**Implant survival.** Failures or revisions, including intension to revise, of the Trident II components (including liner revisions) will be documented.

**Safety and clinical complications.** All intraoperative and postoperative adverse events and complications will be recorded. We will survey the patient and review their case notes for the known potential clinical complications associated with THA: deep vein thrombosis; dislocation; infection; and failure for any reason that results in reoperation.

**Patient-reported outcome assessments.** The Oxford Hip Score is a patient-reported outcome measure that was developed specifically to measure the impact of pain and functional disability in patients undergoing hip arthroplasty.[15,16] It consists of 12 questions and is scored using a five-item Likert response format, reported on a 0 to 48 scale, with higher scores representing better outcomes. It is an extensively validated and widely adopted outcome measure in patients undergoing THA and has established meaningful clinical values.[17]

The Forgotten Joint Score (FJS) is a patient-reported outcome scale to assess joint awareness in hips and knees during various activities of daily living.[18] It uses a five-point Likert response format and consists of 12 questions. The raw score is transformed to range from 0 to 100 points. High scores indicate good outcome (i.e. a high degree of being able to forget about the affected joint in daily life). The FJS has a low ceiling effect and especially discriminates between good, very good, and excellent outcome after THA. In its validation study, it showed high internal consistency and discriminated well between patient groups known to show different outcome and has established meaningful clinical values.[19,20]

The 12-Item Short Form Health Survery (SF-12) is a 12-item questionnaire used to assess generic health outcomes from the patient's perspective.[21] The SF-12 results in two scores: the physical (PCS) and mental component summary (MCS). This score is calculated using norm-based methodology and population mean scores. Both PCS and MCS have a population mean score of 50 with an standard deviation of 10.

The EuroQol five-dimension health questionnaire is a standardized instrument with five items for use as a measure of self-reported HRQoL.[22,23] The three-level version will be employed, which allows the respondent options for reply to the five questions asked. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status. It is one of the most frequently used measures to gain quality of life scores for analysis in health economy as utility weights for calculating quality-adjusted life years can be obtained.[1]

Global hip pain severity will be assessed using an 11-point (0 to 10) numerical rating scale (NRS), where 0 represents no pain and 10 the worst possible pain. The validity and sensitivity of the NRS have been documented.[24,25] As it has been suggested that using multiple measurements of pain status, as opposed to a single value of 'current pain', may provide more realistic and meaningful measurements of pain intensity,[26] separate assessments will be made of 'worst pain' and 'perceived mean daily pain' as has been specifically recommended for use in osteoarthritis clinical trials.[27]

Satisfaction questions are reported using a five-point Likert response format hip (very satisfied, satisfied, unsure, dissatisfied or very dissatisfied). Specifically, questions will ask patients about: overall satisfaction with their operated hip; how well the surgery relieves pain in the operated joint; and how well surgery increases the ability to perform regular activities of daily living and to perform heavy work or sport activities.[28]

**Table I.** Patient visit schedule of the study cohort.

| Assessment | Preoperative | One year | Two years | Five years | Seven years | Ten years |
|---|---|---|---|---|---|---|
| Patient consent* | X | | | | | |
| Baseline demographic data | X | | | | | |
| Survival and compilations | | | | | | |
| Patient questionnaire | | X | X | X | X | X |
| Case note review | | X | X | X | X | X |
| Clinical outcomes | | | | | | |
| OHS | X | X | X | X | X | X |
| FJS | X | X | X | X | X | X |
| SF-12 | X | X | X | X | X | X |
| EQ-5D | X | X | X | X | X | X |
| Pain scores | X | X | X | X | X | X |
| Satisfaction | | X | X | X | X | X |
| Radiological evaluation† | X | X | | X | | X |

*Consent taken prior to any research activity.
†Radiographs taken as part of routine clinical practice preoperatively and at one year, and additionally at five and ten years.
EQ-5D, EuroQol five-dimension health questionnaire; FJS, Forgotten Joint Score; OHS, Oxford Hip Score; SF-12, 12-Item Short Form Health Survey.

**Radiological assessments.** Evaluation of preoperative radiographs will be used to determine the Tonnis grade,[29] and implant alignment and height, and for lucent lines or lysis on standardized anterior-posterior digital images postoperatively (Picture Archiving Communication System; Kodak Carestream, USA). Radiographs will be assessed at one, five, and ten years for lucent lines (< 2 mm) and lysis (> 2 mm) according to Gruen zones[30] in the femur, and DeLee and Charnley[31] zones for the acetabulum. Trial participant radiographs will be reviewed and graded by two surgeons. It will not be possible to blind the reviewers to allocation as this will be apparent on the radiograph. The surgeons will review and report the films separately. In the event of disagreement, the surgeons will discuss the individual radiographs and reach a consensus opinion.

**Data collection.** Informed consent, baseline demographic data, and preoperative assessment will be collected at time of surgical preadmission clinic. Postoperative assessments will be performed in person if the patient attends for a planned follow-up or remotely via phone call/postal questionnaire. Routinely performed radiographs taken as part of the clinical process preoperatively, during the hospital stay, and at one year will be available for review. Additional five- and ten-year radiographs will be taken. The patient visit schedule over the ten-year study period is outlined in Table I.

**Source data documentation.** Source documents are the study specific documentation detailed above.

**Case report forms.** Paper case report forms will be used, with electronic data storage of study variables on NHS computers as outlined above.

## Data management

**Personal data.** Patient names, addresses, and telephone numbers will be collected to allow the questionnaire follow-up to be performed. These will be stored for the duration of the study. Personal identifiable data will be stored on NHS computers and on paper study files (e.g. names on consent forms). All information will be kept in a locked room within the Department of Orthopaedics at the Royal Infirmary of Edinburgh. No identifiable information will leave the NHS.

**Data information flow.** All patients will be assigned a unique identification number, which will be incorporated in all documentation to and from the participants. Any identifiable data will be removed from paper records prior to storage. Patient details will be held in a secure, password-protected database, and the key that links the identification number to patient details will be held in a distinct password-protected location.

**Transfer of data.** Data collected or generated by the study (including personal data) will not be transferred to any external individuals or organizations outside of the sponsoring organization(s).

**Data controller.** A data controller is an organization that determines the purposes for which, and the manner in which, any personal data are processed. The University of Edinburgh and NHS Lothian are joint data controllers along with any other entities involved in delivering the study that may be a data controller in accordance with applicable laws (e.g. the site).

**Data breaches.** Any data breaches will be reported to the University of Edinburgh and NHS Lothian Data Protection Officers, who will onward report to the relevant authority according to the appropriate timelines if required.

## Statistics and data analysis

**Proposed analyses.** A descriptive analysis of participant demographic and baseline scores will determine the cohort case-mix and allow contrast to other hip arthroplasty patient cohorts. The primary objective is evaluation

of ten-year device survivorship, which will be assessed with Kaplan-Meier survival curves. The patient outcome scores will be assessed with repeated measures analysis of variance models to account for the repeated data collection timepoints.

Results will be presented as an adjusted mean difference with its corresponding 95% confidence intervals. Planed cohort analyses will occur at two, five, and ten years.

**Adverse events.** As the study is not a clinical trial of an investigational medicinal product (CTIMP) and the medical devices are CE marked, there will be no formal adverse event reporting for this intervention. However, adverse events and implant failure will be recorded by the study team and reported as part of the study analysis.

We will review for the known potential clinical compilations associated with THA. These risks include deep vein thrombosis, dislocation, infection, and failure for any reason that results in reoperation. We will survey the patient and review their case notes to screen for any associated clinical complications at two, five, and ten years.

If the investigator becomes aware of any serious unexpected adverse event or reaction, this will require expedited reporting to the sponsor by the investigator. Readmission for elective surgery on a different joint does not constitute a serious adverse event or reaction.

## Oversight arrangements

**Inspection of records.** Investigators and institutions involved in the study will permit trial related monitoring and audits on behalf of the sponsor, research and ethics committee (REC) review, and regulatory inspection(s). In the event of audit or monitoring, the Investigator agrees to allow the representatives of the sponsor direct access to all study records and source documentation. In the event of regulatory inspection, the Investigator agrees to allow inspectors direct access to all study records and source documentation.

**Study monitoring and audit.** The ACCORD sponsor representative will assess the study to determine if an independent risk assessment is required. If required, the independent risk assessment will be carried out by the ACCORD quality assurance (QA) group to determine if an audit should be performed before/during/after the study and, if so, at what frequency.

Risk assessment, if required, will determine if audit by the ACCORD QA group is required. Should audit be required, details will be captured in an audit plan. Audit of Investigator sites, study management activities and study collaborative units, facilities, and third parties may be performed.

## Good clinical practice

**Ethical conduct.** The study will be conducted in accordance with the principles of the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice (ICH GCP).[32] Before the study can commence, all required approvals will be obtained and any conditions of approvals will be met.

**Investigator responsibilities.** The Investigator is responsible for the overall conduct of the study at the site and compliance with the protocol and any protocol amendments. In accordance with the principles of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guideline for Good Clinical Practice (GCP), the following areas listed in this section are also the responsibility of the Investigator.[33] Responsibilities may be delegated to an appropriate member of study site staff.

**Informed consent.** The Investigator is responsible for ensuring informed consent is obtained before any protocol specific procedures are carried out. The decision of a participant to participate in clinical research is voluntary and should be based on a clear understanding of what is involved.

Participants must receive adequate oral and written information. Appropriate participant information and informed consent forms will be provided. The oral explanation to the participant will be performed by the Investigator or qualified delegated person, and must cover all the elements specified in the participant information sheet and consent form.

The participant must be given every opportunity to clarify any points they do not understand and, if necessary, ask for more information. The participant must be given sufficient time to consider the information provided. It should be emphasized that the participant may withdraw their consent to participate at any time without loss of benefits to which they otherwise would be entitled.

The participant will be informed and agree to their medical records being inspected by regulatory authorities and representatives of the sponsor(s).

The Investigator or delegated member of the trial team and the participant will sign and date the informed consent form(s) to confirm that consent has been obtained. The participant will receive a copy of this document and a copy filed in the Investigator Site File (ISF) and participant's medical notes (if applicable).

**Study site staff.** The Investigator must be familiar with the protocol and the study requirements. It is the Investigator's responsibility to ensure that all staff assisting with the study are adequately informed about the protocol and their trial related duties.

**Data recording.** The Principal Investigator is responsible for the quality of the data recorded in the CRF at each Investigator Site.

**Investigator documentation.** The Principal Investigator will ensure that the required documentation is available in local ISFs.

**GCP training.** For non-CTIMP (i.e. non-drug) studies, all researchers are encouraged to undertake GCP training in order to understand the principles of GCP. However, this is not a mandatory requirement unless deemed so by the sponsor. GCP training status for all investigators should be indicated in their respective CVs.

**Confidentiality.** All laboratory specimens, evaluation forms, reports, and other records must be identified in a manner designed to maintain participant confidentiality. All records must be kept in a secure storage area with limited access. Clinical information will not be released without the written permission of the participant. The Investigator and study site staff involved with this study may not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished information, which is confidential or identifiable, and has been disclosed to those individuals for the purpose of the study. Prior written agreement from the sponsor or its designee must be obtained for the disclosure of any said confidential information to other parties.

**Data protection.** All Investigators and study site staff involved with this study must comply with the requirements of the appropriate data protection legislation (including the General Data Protection Regulation and Data Protection Act) with regard to the collection, storage, processing, and disclosure of personal information.

Computers used to collate the data will have limited access measures via user names and passwords. Published results will not contain any personal data and be of a form where individuals are not identified and re-identification is not likely to take place

## Study conduct responsibilities

**Protocol amendments.** Any changes in research activity, except those necessary to remove an apparent, immediate hazard to the participant in the case of an urgent safety measure, must be reviewed and approved by the Chief Investigator.

Amendments will be submitted to a sponsor representative for review and authorization before being submitted in writing to the appropriate REC, and local research and development (R&D) for approval prior to participants being enrolled into an amended protocol.

**Management of protocol non-compliance.** Prospective protocol deviations, i.e. protocol waivers, will not be approved by the sponsors and therefore will not be implemented, except where necessary to eliminate an immediate hazard to study participants. If this necessitates a subsequent protocol amendment, this should be submitted to the REC, and local R&D for review and approval if appropriate.

Protocol deviations will be recorded in a protocol deviation log and logs will be submitted to the sponsors every three months. Each protocol violation will be reported to the sponsor within three days of becoming aware of the violation. All protocol deviation logs and violation forms should be emailed to QA@accord.scot.

Deviations and violations are non-compliance events discovered after the event has occurred. Deviation logs will be maintained for each site in multicentre studies. An alternative frequency of deviation log submission to the sponsors may be agreed in writing with the sponsors.

**Serious breach requirements.** A serious breach is a breach which is likely to effect to a significant degree: the safety or physical or mental integrity of the participants of the trial; or the scientific value of the trial.

If a potential serious breach is identified by the Chief investigator, Principal Investigator, or delegates, the co-sponsors (seriousbreach@accord.scot) must be notified within 24 hours. It is the responsibility of the co-sponsors to assess the impact of the breach on the scientific value of the trial, to determine whether the incident constitutes a serious breach and report to research ethics committees as necessary.

**Study record retention.** All study documentation will be kept for a minimum of three years from the protocol defined end of study point. When the minimum retention period has elapsed, study documentation will not be destroyed without permission from the sponsor.

**End of study.** The end of study is defined as the last participant's last visit. The Investigators or the co-sponsor(s) have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the REC, R&D Office(s), and co-sponsors within 90 days, or 15 days if the study is terminated prematurely. The Investigators will inform participants of the premature study closure and ensure that the appropriate follow-up is arranged for all participants involved. End of study notification will be reported to the co-sponsors via email to resgov@accord.scot.

A summary report of the study will be provided to the REC within oneyear of the end of the study.

**Continuation of treatment following the end of study.** The study will end at ten years following surgery and patients will then return to standard NHS Lothian follow-up protocol for implants according to the ODEP rating of the implant at that time.

**Insurance and indemnity.** The co-sponsors are responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the Chief Investigator and staff.

The following arrangements are in place to fulfil the co-sponsors' responsibilities:

The Protocol has been designed by the Chief Investigator and researchers employed by the University and collaborators. The University has insurance in place (which includes no-fault compensation) for negligent harm caused by poor protocol design by the Chief Investigator (PG) and researchers employed by the University.

Sites participating in the study will be liable for clinical negligence and other negligent harm to individuals taking part in the study and covered by the duty of care owed to them by the sites concerned. The co-sponsors require individual sites participating in the study to arrange for their own insurance or indemnity in respect of these liabilities.

Sites which are part of the UK's NHS will have the benefit of NHS Indemnity.

Sites out with the UK will be responsible for arranging their own indemnity or insurance for their participation in the study, as well as for compliance with local law applicable to their participation in the study.

## Reporting, publications, and notification of results

**Authorship policy.** On completion of the study, the study data will be analyzed and tabulated, and a clinical study report prepared in accordance with ICH guidelines.[32]

## Discussion

Uncemented acetabular fixation is well established as part of THA and hybrid fixation (uncemented acetabulum and cemented stem) has been an accepted mix of fixation techniques since the 1980s.[34] This study aims to introduce a new product in medical practice as part of a hybrid THA as part of the beyond compliance principles.[35] The aim being to assess implant survival and patient reported outcomes up to ten years following index surgery.

There are various methods to attain fixation of uncemented THA components that have evolved over decades, in addition to the anatomical implant design with the aim to improve bone ingrowth, and therefore reduce loosening of the implant and improve survival. HA coating of the acetabular component is well established and had been employed for several decades, but often paired with older polyethylene liners which are at increased risk of wear and loosening.[36] A registry study using data from Nordic Arthroplasty Register Association compared the survivorship of HA-coated with non-HA-coated versions of three differing acetabular components between 1995 and 2013, and found no survival benefit associated with HA coating.[37] However, the majority of these implants may have been paired with older non-cross linked polyethylene as part of the bearing surface. One issue this study did highlight was a higher risk of infection with use of HA-coated cups and suggest this observation must be investigated further, which will be an aim of the current study.[37] Chen et al[38] conducted a systematic review and meta-analysis of the published literature between 1993 and 2012 which included level I to III studies, and demonstrated no difference in implant survivorship with HA-coated THA. However they did find a better functional outcome associated with patients undergoing HA THA, but this may have been from the observed benefits from the HA coated femoral stems which were associated with less thigh pain and less femoral osteolysis.[38] More recently, Tyagi et al[39] compared the 262 HA-coated acetabular components with 4,580 non-HA-coated and at a mean follow-up of nine years found no difference in the implant survival.

The limitations of the current study should be recognized. The size of the proposed cohort is a major limiting factor of the study when assessing implant survival. However, it is simply not possible to assess larger cohort as part of the study from a financial aspect and the findings of the study would need to be affirmed from arthroplasty registry data. The study aims to assess HA-coated multihole acetabular components, as it is not available in another design option (solid), which may be associated with backside wear and the potential for osteolysis with migration of the wear particles through the screw holes.[40,41] However, the survival difference between solid and multihole acetabular components with highly crossed polyethylene is not clear in the longer term.[42] There is no comparator group to which to compare the survival or functional outcome of the current cohort, to assess whether these patients are achieving their expected outcomes or if they are at an increased risk of revision. The authors plan to compare their functional outcomes and survival, at the proposed time points, with a cohort of patients already being followed up at the study centre as part of a randomized controlled trial using a fully cemented implant with the same femoral stem.[43] The final limitation is the relatively short follow-up of ten years, with majority of revisions occurring after this for loosening of the implant, but it was felt that attrition to follow-up beyond this point may not be meaningful to assessment.

### Take home message

- The Trident hydroxyapatite acetabular component is a new implant, and, as such, careful monitoring is essential as part of the Beyond Compliance principles.
- Functional, radiological, and survival data of this new implant will help establish its safe use before widespread adoption.

## Twitter

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## References

1. **Jenkins PJ**, **Clement ND**, **Hamilton DF**, **Gaston P**, **Patton JT**, **Howie CR**. Predicting the cost-effectiveness of total hip and knee replacement: a health economic analysis. *Bone Joint J*. 2013;95-B(1):115–121.
2. **Learmonth ID**, **Young C**, **Rorabeck C**. The operation of the century: total hip replacement. *Lancet*. 2007;370(9597):1508–1519.
3. **Evans JT**, **Walker RW**, **Evans JP**, **Blom AW**, **Sayers A**, **Whitehouse MR**. How long does a knee replacement last? A systematic review and meta-analysis of case series and national registry reports with more than 15 years of follow-up. *Lancet*. 2019;393(10172):655–663.
4. **Vanhegan IS**, **Malik AK**, **Jayakumar P**, **Ul Islam S**, **Haddad FS**. A financial analysis of revision hip arthroplasty. *J Bone Joint Surg Br*. 2012;94-B(5):619–623.

5. **Koutalos AA**, **Varitimidis S**, **Malizos KN**, **Karachalios T**. Revision total hip arthroplasty for aseptic loosening compared with primary total hip arthroplasty for osteoarthritis: long-term clinical, functional and quality of life outcome data. *Hip Int.* 2022;11207000221115354.
6. **Clement ND**, **Biant LC**, **Breusch SJ**. Total hip arthroplasty: to cement or not to cement the acetabular socket? A critical review of the literature. *Arch Orthop Trauma Surg.* 2012;132(3):411–427.
7. **Brittain R**, **Howard P**, **Lawrence S**, **et al**. NJR statistical analysis, support and associated services. Natl Jt Regist | 18th Annual Report. https://www.ncbi.nlm.nih.gov/books/NBK576858/ (date last accessed 15 August 2022).
8. **Van Praet F**, **Mulier M**. To cement or not to cement acetabular cups in total hip arthroplasty: a systematic review and re-evaluation. *SICOT J.* 2019;5:35.
9. **Dammerer D**, **Blum P**, **Putzer D**, **Tscholl A**, **Liebensteiner MC**, **Thaler M**. Good mid-term results with the trident peripheral self-locking cup: a clinical evaluation and migration measurement with EBRA. *Arch Orthop Trauma Surg.* 2021;141(2):327–332.
10. **Yoshioka S**, **Nakano S**, **Kinoshita Y**, **et al**. Comparison of A highly porous titanium cup (Tritanium) and A conventional hydroxyapatite-coated porous titanium cup: A retrospective analysis of clinical and radiological outcomes in hip arthroplasty among Japanese patients. *J Orthop Sci.* 2018;23(6):967–972.
11. **Jeong J**, **Kim JH**, **Shim JH**, **Hwang NS**, **Heo CY**. Bioactive calcium phosphate materials and applications in bone regeneration. *Biomater Res.* 2019;23:4.
12. **Davey MS**, **Doyle TR**, **Murphy E**, **Fenelon C**, **Murphy CG**, **Cassar-Gheiti AJ**. Battle of the titans: Survivorship analysis of the 3 most common types of uncemented femoral stems used across national registries. *J Orthop.* 2023;43:41–47.
13. **No authors listed**. Trident Acetabular System PE-Acetabular Cup. Orthopaedic Data Evaluation Panel. https://www.odep.org.uk/product/trident-acetabular-system-pe/ (date last accessed 29 August 2023).
14. **No authors listed**. Academic and Clinical Central Office for Research and Development (ACCORD)) co-enrolment Policy. https://accord.scot/research-access-resources-researchers/policies (date last accessed 4 September 2023).
15. **Dawson J**, **Fitzpatrick R**, **Carr A**, **Murray D**. Questionnaire on the perceptions of patients about total hip replacement. *J Bone Joint Surg Br.* 1996;78(2):185–190.
16. **Murray DW**, **Fitzpatrick R**, **Rogers K**, **et al**. The use of the Oxford hip and knee scores. *J Bone Joint Surg Br.* 2007;89-B(8):1010–1014.
17. **Beard DJ**, **Harris K**, **Dawson J**, **et al**. Meaningful changes for the Oxford hip and knee scores after joint replacement surgery. *J Clin Epidemiol.* 2015;68(1):73–79.
18. **Behrend H**, **Giesinger K**, **Giesinger JM**, **Kuster MS**. The "Forgotten Joint" as the ultimate goal in joint arthroplasty. J Arthroplasty. 2012;27(3):430–436.
19. **Robinson PG**, **MacDonald DJ**, **Macpherson GJ**, **Patton JT**, **Clement ND**. Changes and thresholds in the Forgotten Joint Score after total hip arthroplasty: minimal clinically important difference, minimal important and detectable changes, and patient-acceptable symptom state. *Bone Joint J.* 2021;103-B(12):1759–1765.
20. **Hamilton DF**, **Loth FL**, **Giesinger JM**, **et al**. Validation of the English language Forgotten Joint Score-12 as an outcome measure for total hip and knee arthroplasty in a British population. *Bone Joint J.* 2017;99-B(2):218–224.
21. **Ware JE**, **Kosinski M**, **Keller SD**. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care.* 1996;34(3):220–233.
22. **Brooks R**. EuroQol: the current state of play. *Health Policy.* 1996;37(1):53–72.
23. **Clement ND**, **Afzal I**, **Peacock CJH**, **et al**. Mapping analysis to predict the associated EuroQol five-dimension three-level utility values from the Oxford Knee Score: a prediction and validation study. *Bone Jt Open.* 2022;3(7):573–581.
24. **Jensen MP**, **Karoly P**. Self-report scales and procedures for assessing pain in adults. In: Turk DC, Melzack R, eds. *Handbook of Pain Assessment.* 3rd edition. New York, New York, USA: Guildford Press, 2011.
25. **Von Korff M**, **Jensen MP**, **Karoly P**. Assessing global pain severity by self-report in clinical and health services research. *Spine (Phila Pa 1976).* 2000;25(24):3140–3151.
26. **Jensen MP**, **Turner LR**, **Turner JA**, **Romano JM**. The use of multiple-item scales for pain intensity measurement in chronic pain patients. *Pain.* 1996;67(1):35–40.
27. **Perrot S**, **Rozenberg S**, **Moyse D**, **Legout V**, **Marty M**. Comparison of daily, weekly or monthly pain assessments in hip and knee osteoarthritis. A 29-day prospective study. Jt Bone Spine. 2011;78(5):510–515.
28. **Hamilton DF**, **Lane JV**, **Gaston P**, **et al**. What determines patient satisfaction with surgery? A prospective cohort study of 4709 patients following total joint replacement. *BMJ Open.* 2013;3(4):e002525.
29. **Busse J**, **Gasteiger W**, **Tonnis D**. [A new method for roentgenologic evaluation of the hip joint--the hip factor]. *Arch orthop Unfall-Chir.* 1972;72(1):1–9. , . [Article in German].
30. **Gruen TA**, **McNeice GM**, **Amstutz HC**. "Modes of failure" of cemented stem-type femoral components: a radiographic analysis of loosening. *Clin Orthop Relat Res.* 1979;141:17–27.
31. **DeLee JG**, **Charnley J**. Radiological demarcation of cemented sockets in total hip replacement. *Clin Orthop Relat Res.* 1976;121(121):20–32.
32. **No authors listed**. ICH GCP - ICH harmonised guideline integrated addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2). https://ichgcp.net/ (date last accessed 29 August 2023).
33. **Vijayananthan A**, **Nawawi O**. The importance of Good Clinical Practice guidelines and its role in clinical trials. *Biomed Imaging Interv J.* 2008;4(1):e5.
34. **Harris WH**. Hybrid total hip replacement: rationale and intermediate clinical results. *Clin Orthop Relat Res.* 1996;333:155–164.
35. **No authors listed**. Beyond Compliance. https://www.beyondcompliance.org.uk/ (date last accessed 29 August 2023).
36. **Davis ET**, **Pagkalos J**, **Kopjar B**. A higher degree of polyethylene irradiation is associated with A reduced risk of revision for aseptic loosening in total hip arthroplasties using cemented acetabular components. *Bone Joint Res.* 2020;9(9):563–571.
37. **Lazarinis S**, **Mäkelä KT**, **Eskelinen A**, **et al**. Does hydroxyapatite coating of uncemented cups improve long-term survival? An analysis of 28,605 primary total hip arthroplasty procedures from the Nordic Arthroplasty Register Association (NARA). *Osteoarthritis Cartilage.* 2017;25(12):1980–1987.
38. **Chen Y-L**, **Lin T**, **Liu A**, **et al**. Does hydroxyapatite coating have no advantage over porous coating in primary total hip arthroplasty? A meta-analysis. Internet. *J Orthop Surg Res.* 2015;10:1–4.
39. **Tyagi V**, **Harris AHS**, **Giori NJ**. Survival of hydroxyapatite-coated versus non-hydroxyapatite-coated total hip arthroplasty implants in a veteran population. *J Arthroplasty.* 2022;37(6):1143–1145.
40. **Pérez-Coto I**, **Hernández-Vaquero D**, **Suárez-Vázquez A**, **Sandoval-García MÁ**, **Escandon-Rodriguez A**. Influence of clinical and radiological variables on the extent and distribution of periprosthetic osteolysis in total hip arthroplasty with a hydroxyapatite-coated multiple-hole acetabular component: a magnetic resonance imaging study. *J Arthroplasty.* 2014;29(10):2043–2048.
41. **Braun S**, **Vardag S**, **Mueller U**, **et al**. Backside wear, particle migration and effectiveness of screw hole plugs in acetabular hip joint replacement with cross-linked polyethylene. *Acta Biomater.* 2019;97:239–246.
42. **Jameson SS**, **Mason JM**, **Baker PN**, **Jettoo P**, **Deehan DJ**, **Reed MR**. Factors influencing revision risk following 15 740 single-brand hybrid hip arthroplasties: a cohort study from a National Joint Registry. *J Arthroplasty.* 2013;28(7):1152–1159.
43. **Gaston P**, **Clement ND**, **Ohly NE**, **Macpherson GJ**, **Hamilton DF**. Can arthroplasty stem influence outcome: a randomized controlled trial of stem length in cemented total hip arthroplasty. *J Arthroplasty.* 2023.



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