

Accuracy of synthetic CT-images based on MRI-images compared to conventional CT-images for shoulder osteoarthritis evaluation and surgical planning

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The objectives are to determine the accuracy and reliability of sCT compared to conventional CT regarding (1) classification of shoulder osteoarthritis morphology and (2) planning for the 3D-position of a compound used for shoulder replacement surgery...

Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON56624

Source

ToetsingOnline

Brief title

Accuracy of sCT in osteoarthritis shoulders compared to CT

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym

Shoulder osteoarthritis

Research involving

Human

Sponsors and support

Primary sponsor: Overige Ziekenhuizen

Source(s) of monetary or material Support: AMS financed talent call
(<https://www.amsterdamumc.org/en/research/news/ams-financed-talent-call-open-for-applications.htm>)

Intervention

Keyword: Imaging, Instability, Osteoarthritis, Shoulder

Outcome measures

Primary outcome

3D parameter glenoid height.

Secondary outcome

Other 3D parameters (glenoid inclination, version, surface area, and width and humeral inclination, version and surface area) and morphology classifications systems that are used in the evaluation of shoulder osteoarthritis (Walch classification and Sirveaux classification).

Study description

Background summary

Shoulder osteoarthritis (OA) is a leading cause of chronic shoulder pain and is rising in prevalence

due to an aging population, currently showing a 20% prevalence above 65 years.¹⁻³

Shoulder replacement

surgery has become the gold standard and most executed surgery for severe shoulder OA and is expected to

demonstrate a 755.6% increase in 2030 compared to 2011.^{1,4,5} To ensure effective and safe treatment, ideally

two preoperative scans are made. CT is most suitable to determine OA severity and to determine glenoid

morphological parameters for surgical planning, whereas MRI or ultrasound determines the optimal type of

prosthesis by visualising damage to the rotator-cuff muscles.¹⁻⁶ However, ultrasound is often inconclusive and MRI is generally not performed, as making two scans is costly and requires more planning with the patient. Deep-learning software has the ability to create synthetic CT (sCT) images through MRI-images and allows for visualisation of both soft tissue and bony structures with a single scan. sCT has shown equivalence to conventional CT in bony structures, such as the hip and lumbar spine, and may be a one-stop-shop solution for the narrow shoulder structures as well.⁷⁻⁸ The additional information of soft-tissue damage supports decision making and patient selection, eliminates radiation exposure and improves the workflow, as only one scan needs to be planned. Furthermore, healthcare costs may be decreased by eliminating one scan and improved patient selection may prevent revision surgery.^{4,9,10} Between March 2022 and April 2023 a successful pilot study was performed with paired data of instability patients, which demonstrated equivalence of sCT to CT. This provided the basis for the algorithm to be trained with more complex structures, such as the osteoarthritic shoulder.

Study objective

The objectives are to determine the accuracy and reliability of sCT compared to conventional CT regarding (1) classification of shoulder osteoarthritis morphology and (2) planning for the 3D-position of a compound used for shoulder replacement surgery through glenoid parameters acquired with 3D planning software (Blueprint).

Study design

This prospective diagnostic study with equivalence design.

Study burden and risks

An additional MRI-scan will be made. An MRI of the shoulder typically takes 30 minutes. With the new technique 4:12 minutes will be added to this the scantime. The additional MRI was take +- 35 minuten.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

A subject must meet all of the following criteria in order to be eligible for this study:

1. An indication from the orthopaedic surgeon to undergo total shoulder arthroplasty and undergo a CT scan to evaluate osteoarthritis of the shoulder according to the standard care protocol;
2. 18 years or older.

Exclusion criteria

1. Patients with previous shoulder replacement surgery or fracture sequelae of

the humerus or glenoid.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-04-2024

Enrollment: 25

Type: Anticipated

Medical products/devices used

Generic name: BoneMRI;software/deep learning algorithm to generate sCT images

Registration: Yes - CE outside intended use

Ethics review

Approved WMO

Date: 08-03-2024

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 06-05-2024

Application type: Amendment

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL85845.100.24