Diagnostic performance of dynamic four-dimensional computed tomography (4D CT) for analyzing wrist ligament injuries - a reproducibility study of the image acquisition protocol.

Published: 01-08-2024
Last updated: 21-12-2024

The study wants to investigate the intra-patient test-retest reliability to show the robustness of the acquisition protocol to contribute to the standardization of a 4D CT wrist image acquisition protocol, with the use of a forearm fixation device...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational non invasive

Summary

ID

NL-OMON56913

Source
ToetsingOnline

Brief title
4D CT ligament wrist injuries imaging acquisition procedure

Condition

- Tendon, ligament and cartilage disorders

Synonym
wrist instability

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO subsidie

Intervention

Keyword: 4D CT, imaging acquisition, wrist ligament injury

Outcome measures

Primary outcome

Main endpoint of the study: evaluate the test-retest reliability of 4DCT dynamic scanning of the radius, ulna and carpal bones. Motion analysis will be performed using the following 4D CT parameters: the scapholunate distance (SLD), lunatecapitate angle (LCA), radiolunate angle (RLA), radioscaphoid angle (RSA), scapholunate angle (SLA), radioulnar angle, sigmoid notch to ulnar head joint distance, radioulnar ratio, and radioulnar line distance. The kinematic values of normal wrists will be used as reference for analyzing the unstable wrists. A multivariate linear regression analysis will be performed to analyse the effect of demographic variables (age and sex) on the 4D CT parameters measured. Besides, , the test-retest reliability will be calculated with the CMC and the intraclass correlation coefficient (IC). This is used to evaluate the similarity between the two motion patterns. The total waveform reliability present between test and retest will be evaluated using the RMSD. When the two motion patterns are similar, the CMC tends towards 1, whereas in dissimilar waveforms, it tends towards 0.

Secondary outcome

x

Study description

Background summary

The wrist is a complex array of joints. It involves articulation of eight small carpal bones, two forearm bones and five hand bones, with intricate inter- and intra-osseous kinematics. The wrist facilitates multidirectional movement in a synergistic manner that allow for the unique range of mobility of the hand and forearm. Intrinsic (interosseous) and extrinsic (capsular) ligaments are the primary passive stabilizers of the wrist. The muscles of the hand and forearm are secondary, dynamic stabilizers.
Of all the injuries, hand and wrist injuries have the highest social and economic impact; annual health costs and loss of labor productivity of approximately 540 million Euros1. Part of the wrist injuries concerns ligament lesions which, untreated, will progress to carpal instability and finally osteoarthritis2-5. Out of the annual 25.000 wrist injuries, approximately 10% will lead to instability2-5, for which reconstruction and salvage operations are needed, costing each ¤3.700 including physiotherapy; a total of 9.25M¤. After surgery, patients get 3-6 months revalidation and are unable to work, costing ¤410 per day7; a total of ¤55.350 per person or 138M¤ in total. If patients are diagnosed earlier, less surgeries will be necessary, drastically decreasing the societal costs and patient discomfort.

Patients with an early diagnosis of wrist ligament injuries may benefit from less-invasive treatment options, have a better prognosis, and experience less residual disability 13. However, (pre)dynamic carpal instabilities demonstrate abnormalities only during motion. That is why the diagnosis of these wrist disorders currently relies largely on clinical findings, as patients with (pre)dynamic instability often have normal appearances on static conventional imaging studies, including plain radiographs, magnetic resonance imaging (MRI) and ultrasound 14-17. Real-time fluoroscopy is currently the only imaging modality that can be used to detect dynamic abnormalities in these patients18. However, fluoroscopy suffers from several drawbacks: images are limited to 2-dimensions, bone superimposition is constantly present, and the sensitivity of the examination is highly operator dependent. This makes it impossible to reproducibly and objectively quantify any abnormalities, if present.

In cases of inconclusive radiographic evaluation, MRI or CT arthrography can be used to assess ligament structural integrity but not ligament sufficiency, which can be particularly problematic in patients with partial ligament tears. The sensitivity and specificity of these static imaging techniques are relatively low compared to arthroscopy and varies from 60-80% and 70-90%, respectively.

Because of its high sensitivity and specificity, wrist arthroscopy is still the gold standard for diagnosing intra-articular pathology and ligament tears of the wrist19,20. Arthroscopy however, is an invasive and relatively expensive procedure with a complication rate of 2%. Another drawback of arthroscopy is the fact that the function of the ligaments can still not be dynamically assessed for three reasons: 1) the wrist and soft tissue are distended during the procedure to open the wrist joints for introduction of the scope and instruments preventing movement and 2) the patient is unable to move the wrist because of the anesthesia and 3) movements of the wrist is not possible because of the rigidity of the scope that has been inserted into the wrist.

A promising imaging method that could contribute to this field is 4D CT scanning. Using recently developed, continuous acquisition of 3D CT images during movement, it may be capable of assessing patients with suspected instability with higher diagnostic performance by facilitating kinematic assessment of wrist motions. The superior 3-dimensional spatial resolution allows this technique to accurately detect even slight positional changes of the bones, in contrast to 2D fluoroscopy21. While conventional static 3D imaging methods can provide valuable information about carpal bone anatomy and alignment, dynamic imaging has the advantage of assessing the carpus, distal radius and ulna, and joint spaces throughout the range of movements and capturing their complex interplay. This will provide a way to better understanding of normal wrist kinematics and improve diagnosis of subtle carpal instabilities and decrease the need for arthroscopy. Moreover, if surgical intervention is deemed appropriate, the source of the instability might be more precisely identified. Detailed knowledge of the nature of instability will allow clinicians to offer more specific and appropriate surgery for each patient. Following from this, the effect of surgical interventions on wrist kinematics can be more thoroughly investigated, helping to guide and shape further clinical treatment.

An important drawback of 4D CT scan is the radiation exposure, like in fluoroscopy. However, others have shown the possibility to get accurate 4D images of the moving wrist with a mean effective radiation dose of 0.15 mSv, which compares favorably with a normal background radiation for any individual (2 mSv per year).

A few studies have been published on wrist kinematics using 4D CT scans. These studies have demonstrated its potential for the evaluation of carpal instability, particularly in cases of inconclusive initial clinical assessment. However, the protocols used in these studies are not uniform or standardized and hardly any study have been performed to analyze the effect of the protocol used in the motion analysis outcome. Moreover, only one study performed a test-retest to determine the reproducibility of their protocol. However, this protocol uses a specific hand guiding device, which is not publicly available and will therefore not contribute to a standardized and uniform 4D CT wrist

image acquisition protocol28.

Study objective

The study wants to investigate the intra-patient test-retest reliability to show the robustness of the acquisition protocol to contribute to the standardization of a 4D CT wrist image acquisition protocol, with the use of a forearm fixation device instead of a hand guiding device.

Study design

Single institution, a diagnostic clinical study in the Radboud University Medical Center. We will include 20 patients with chronic unilateral wrist pain suspect ligament injury. Currently, in the standard clinical practice, a conventional X-ray of both wrists with a posterior- anterior (with and without clenched fist position) and lateral view are made to evaluate the injured wrist and compare it with the asymptomatic one. The following radiographic signs are evaluated by the radiologist: scapholunate distance, carpal angles (scapholunate, radiolunate, radioscaphoid, and lunocapitate), presence of dorsal or ventral intercalated segment instability (DISI or VISI resp.) and a scaphoid ring sign. Further investigation consists of a MRI, CT scan and arthroscopy.

For this study, we will test the reproducibility of the scanning protocol. Therefore, the patients will do the dynamic part of the protocol twice. Participants first undergo a static bilateral 3D CT scan in neutral wrist position for usage of reference. The field of view of this scan includes all carpal bones and the two forearm bones. The scan technique is a Toshiba delivered application and CE certified.

Subsequently, the forearms are placed in a supporting frame which minimizes lower-arm motion during 4DCT image acquisition. Prior to image acquisition, participants will undergo a training session on how to move their wrist according to the imaging protocol.

A bilateral dynamic 4DCT scan is made while actively moving the wrists according to a protocoled cycle of movements. To reduce radiation exposure, the z-axis coverage is reduced to 8 cm in the 4DCT scan. Videos of the wrist movements are shown to the participant during image acquisition, which will help the participants to perform the movements at a constant pace. This will provide images with highest quality and will provide the source data considering carpal bone movements and function of ligaments during active wrist motions. Following the initial dynamic CT scan, patients will walk one lap around the room before repositioning their arms in the supporting frames. The second bilateral 4DCT scan is performed with the same movements as during the first dynamic CT scan.

The total effective dose of this study is 0.07 mSv. This burden is a manageable risk compared to the natural background radiation in the Netherlands (2mSv).

Study burden and risks

The dynamic 4D CT scan of the wrist has an estimated total effective radiation dose of approximately
0.03 mSv. Since the patients will perform the scanning protocol twice, a total effective dose of this study is 0.07 mSv. This will not burden a trivial risk compared to the natural background radiation in the Netherlands (2mSv). Therefore, there is no additional risk associated with participation.
The goal of the study project is to investigate the imaging acquisition protocol and contribute to a standard or uniform scanning protocol for wrist injuries. Therefore, the comparison of the left and right wrist will provide an understanding on the validity of comparing the injured wrist with the uninjured wrists in clinical practice. The test-retest reliability will help to provide normal ranges which will help to correctly diagnose patients and help to prevent false-positive or false-negative indication for surgical treatment. So, by investigating the scanning protocol, we contribute to the optimization and standardization of the image acquisition and the results of this study (and the studies performed before) will benefit future patients with wrist injuries, as it could replace the costly and invasive procedure of arthroscopy with a more accessible and less intrusive alternative.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Informed consent from the patient.
• Suspicion of ligament wrist injury.

Exclusion criteria

• <18 years
• medical history of wrist fracture, and/or wrist surgery
• pregnancy

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2024
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	01-08-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-08-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL86370.091.24