Clinical evaluation of wrist*s scapholunate ligament injury by new developed 4-dimensional Rotational X-ray imaging

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

Summary

ID

NL-OMON30480

Source
ToetsingOnline

Brief title
4D-RX

Condition

- Tendon, ligament and cartilage disorders

Synonym
wrist instability - Scapholunate ligament dissociation

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,STW Project: Samenwerking met Phillips

Intervention

Keyword: Carpal biomechanics, scapholunate ligament, wrist motion, wrist's Kinematics

Outcome measures

Primary outcome

Carpal kinematics are described by translation (in mm) and rotation (in

degrees) during a period of time as the 4th dimension.

From this study acquired information would able us to lay down the principles

of a new non-invasive tool for detection of carpal instabilities that occur

after ligament injury. We expect to find significant dynamic changes in

patients with a ligament injury. From these changes most predictive parameters

will be chosen to be used in our upcoming accuracy studies where the diagnostic

value of 4D-RX will be determined.

Secondary outcome

not applicable

Study description

Background summary

Wrist problems are responsible for a significant social-economic problem for the employers and the community as they are responsible for the longest absence period from work with substantial financial consequences due to workers' compensation, medical expenses, and productivity losses. Malfunctioning of the wrist often leads to reduced quality of life and has profound consequences for the patients involved. Due to the complex anatomy, diagnosis of wrist injuries is hampered by the various levels of trauma severity and the large number of possible trauma locations. Therefore it is of great importance for the patient and the medical doctor to recognize and properly diagnose problems in the wrist

at an early stage.

The year-prevalence of wrist complaints among Dutch adults in 1998 was estimated by the Dutch Institute for public health and environment (RIVM) at approximately 17.5%. Injuries to hand and wrist account for 28.6% of all attendances at the accident and emergency department. Since ligament injury is believed to be present in 5-25% of wrist traumas it is of great importance to diagnose a ligamentous injury at an early stage in order to avoid progression of wrist pathology. Scapholunate ligament (SLL) injury is the most common form of ligamentous injury of the wrist seen in 60% of the cases . If undiagnosed, SLL injury leads to progressive limitation of movement, chronic pain and other irreversible changes within the joint. If Untreated, SLL injury is by far the most frequent cause of degenerative osteoarthritis of the wrist.

The wrist is the most complex joint in the human body. It consists of 8 wrist bones, 26 ligaments and numerous articular surfaces. The complex movements of these bones during wrist motion are still poorly understood. Diagnosis is sometimes difficult owing to poor understanding of carpal kinematics; inconsistencies in the physical examination and limited value of imaging methods Treatment outcomes are variable by lack of quantitative data.
In order to functionally stabilize the wrist, numerous strong ligaments interconnect the wrist bones together and to other surrounding structures allowing them to function cohesively. Wrist stability can be described as the ability of the wrist to maintain a normal balance between the articulating bones under physiologic loads and movements without overloading or loss of motion control. However, the functional balance between the articulating bones may be disturbed due to ligament dysfunction. This can be observed as a loss of joint integrity and malfunctioning of the wrist during movements which is manifestated as pain, typical snaps, painful clicks and the sense of loss of control and strength during hand use.

In the current diagnostic practice, plain radiographs are acquired for the evaluation of the wrist after a trauma. Although for skeletal pathology static imaging modalities are in most cases sufficient to diagnose fractures and dislocations of bony structures, for dynamic abnormalities, static images are insufficient. Unless there is an obvious gap between wrist bones, ligamentous injury and its related abnormal wrist movements are missed. Current static diagnostic modalities have shown to have limited value in detection of wrist ligament injuries. (Arthrography: sensitivity 60-67%, specificity 70%-100% CT: 53% false negatives, MRI: sensitivity 33.3% and specificity of 48%).

Currently it is only possible to diagnose isolated injuries of ligaments with invasive methods such as arthroscopy which is now seen as the "gold standard". Beside the fact that it is a surgical procedure, it has also the disadvantage of being laborious, time consuming, and too expensive to use as a standard diagnostic tool. Consequently, SLL injury frequently goes undiagnosed and untreated, often being passed off as a simple sprain. As a result, late

recognition of SLL injuries often leads to damage of the joint that cannot be treated without residual problems in joint function. In these cases, the instability has progressed so much that the chances for success after surgical reconstruction are strongly diminished. Unfortunately this is a frequently observed situation for many patients seen in the clinic [12]. In this light the specific clinical problem that is addressed in the study is:

Due to lack of a validated non-invasive diagnostic tool, scapholunate ligament injuries in the wrist are currently not diagnosed after a wrist trauma. This makes an early intervention impossible causing irreversible damage to the wrist.

Previous cadaver studies have proven that total SLL ruptures result in detectible alterations of wrist kinematics. Since dynamic abnormalities are believed to be of greater value for detecting of partial and total ligamentous injuries, various authors have pleaded for a diagnostic technique that is both noninvasive and capable of documenting abnormal kinematics. Concomitant to these expectations we hypothesize that ligamentous injury of the wrist will be better detectible by dynamic diagnostic methods, implying that the wrist kinematics will be indicative for ligament function. By providing us quantitative data such tool enables us to diagnose ligament injuries and evaluate the benefits of such interventions afterwards.
We developed a new method for the acquisition of dynamic 3D images of a moving joint . In our method a 3D-rotational x-ray system is used to image a cyclic moving joint during a period of time. This results in multiple sets of projection images, which are reconstructed to a series of time resolved 3D images i.e. 4D-rotational X-ray. In this way we are able to investigate dynamic wrist behavior in a non-invasive way (figure 3). The resulting data are processed whereby movements can be quantified, and studied. By using these quantitative data we will be able to differentiate between normal and abnormal wrist kinematics which occur after ligament disruption. After describing these differences we expect to investigate the benefits of a reconstructive operation which we expect to be measurable in the terms of improved carpal kinematics.

Study objective

The aim is to gain basic dynamic information for an upcoming accuracy studies whereby the diagnostic value of 4D-RX will be determined. By comparing healthy individuals with those with scapholunate ligament dissociation we expect to detect abnormal motion patterns which we will quantify in measurable values. Delineation of specific motion patterns and discriminative values will enable us to set up new definitions for diagnosing ligamentous wrist pathologies. By Rescanning patients with scapholunate ligament rupture after a reconstructive procedure we expect to show the benefits of such interventions.

Study design

This study is a Pilot comparative case-control study. The aim is to gain information for upcoming accuracy studies whereby the diagnostic value of 4D-RX will be determined.
In all groups both wrists will be scanned by our 4D-RX method during flexion/extension, radioulnar deviation. Same scans are obtained once again while axial loading is extended during flexion/extension, radioulnar deviation.
3 months after a reconstructive procedure the operated wrist is scanned again to evaluate and study the effects of such operations. Scans are obtained during flexion/extension and radioulnar deviation.

Study burden and risks

For healthy individuals this means a net radiation exposure of 0.1-0.15 mSv. For people with scapholunate ligament dissociation this exposure will be 0.2 mSv.

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

controls: Healthy volunteers
For the second part of the study: People with a scapholunate ligament lesion proven previously by arthroscopy.
For the third part of the experiment patient from the second group are scanned after a reconstructive operation.

Exclusion criteria

For the first part of the study:
-Injury or disorders of the wrist in history
-Familiar with skeletal and/ or connective-tissue diseases
-Not able to understand the written informed consent.
-Pregnancy
;For the second part of the study
-Not able to understand the written informed consent.
-Pregnancy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	20

Type:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL16223.018.07