Investigating carpal kinematics, dynamic 4-dimensional Rotational X-ray vs. quasi dynamic imaging. A Pilot study

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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-OMON32284

Source
ToetsingOnline

Brief title
Dynamisch vs quasi dynamisch onderzoek van de pols

Condition

- Tendon, ligament and cartilage disorders

Synonym
wrist instability - polsklachten

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,NWO-STW Project

Intervention

Keyword: Carpal biomechanics, Imaging, wrist's Kinematics

Outcome measures

Primary outcome

Kinematic values of carpal bones: translation and rotations

Information from this study will be used for an upcoming clinical accuracy

experiment to determine the diagnostic value of one the both method for wrist

instabilities.

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 beobserved 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.

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. The aim of this study is to compare two methods for descrbing carpal kinematics. The aim is to study wether there are any differences in dynamic acquired carpal kinematics vs those acquired with a semi dynamic method.

Study objective

The aim is to gain basic dynamic information for an upcoming accuracy studies whereby the diagnostic value of one of the both will be determined. understanding motion patterns will enable us to set up new definitions for diagnosing ligamentous wrist pathologies.

Study design

Pilot research comparing 2 diagnostic methods for describing carpal kinematics.

Study burden and risks

For healthy individuals this means a net radiation exposure of 0.5 mSv. This is comparable to 8 weeks natural background radiation in the Netherlands.

Contacts

Public
Academisch Medisch Centrum

Suite G4-226, AMC, Meibergdreef 9
1100 DD Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

Suite G4-226, AMC, Meibergdreef 9
1100 DD Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy volunteers, without and history of wrist trauma

Exclusion criteria

-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

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2008
Enrollment:	10
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	NL21670.018.08