Investigating carpal kinematics after pisiformectomy by new developed 4-dimensional Rotational X-ray imaging - A pilot study

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The aim is to gain basic dynamic information of both healthy and operated wrists to eveluate the outcome of pisiformectomy. By comparing the healthy wrist of the patient with the operated wrist we expect to detect abnormal motion patterns which we...

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational invasive

Summary

ID

NL-OMON32217

Source
ToetsingOnline

Brief title
pisiformectomie 4D

Condition

- Bone disorders (excl congenital and fractures)

Synonym
wrist instability - wrist dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: Carpal biomechanics, pisiformectomy, 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 pisiformectomy. We expect to find different kinematic outcomes in the

operated wrist compared to the healthy wrist in the same patient.

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.

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.

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. The pisiform is a small bone in the proximal row of the wrist which only articulates by a smooth oval concave facet with the slightly convex triquatrum forming the pisotriquatral joint. This joint is enclosed by a loose but though capsule, formed by various soft-tissue structures from different directions. Together they provide the pisiform to be a stability factor of the wrist. These soft-tissue structers are: the tendon of the flexor carpi ulnaris(FCU), the abductor digiti quinti muscle, the pisometacarpal ligament, the pisohamate ligament, the extensor retinaculum, the flexor retinaculum, the anterior carpal ligament, the pisotriquatral joint capsule and a superficial fibrous band extending from the pisiform to the hook of the hamate.
Diseases of the pisiform are not infrequent and mainly consist of degenerative changes as pisotriquatral-arthrose and enthesopathy [9-11]. The major symptom of dysfunction at the pisotriquatral joint is pain in the hypothenar eminence [8]. When patients do not respond to non-operative treatment with local steroid injections, pisiformectomy is the first choice of treatment.

Due to a lack of biomechanical studies it was assumed that the pisiform bone does not play any role in the stability of the wrist joint and therefor dispensable in situations when the pisiform was affected. Concomitant to these assumptions many authors have described good short-time results in most patients after an excision of the pisiform.

Contrary to the previous findings Beckers and Koebke demonstrated that the pisiform mechanically contributes to the stability of wrist by preventing triquatral subluxation and also acts as a fulcrum for the powerful forces that are transmitted from the forearm to the hand. Despite the fact that their experiments were performed on cadaver wrists they showed that the extirpation of the pisiform alters wrist*s kinematic behavior. Although findings from the cadaver experiments might be foreboding there are no studies where kinematic effects of pisiformectomy have been studied in living patients. Therefore the aim of this study is to improve our understanding of the role of the pisiform and the pisotriquetral joint in stability of the wrist in patients undergoing an pisiformectomy operation.

We hypothesize that the abnormal carpal kinematics will be detectible in patients undergoing pisiformectomy. By quantitative analysis of the operated and the not operated patient wrists we hope to investigate the kinematic changes of such interventions afterwards.

For in vivo quantitative analysis of the wrists kinematics 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.
In vivo motion pattern measurement with 4D-RX imaging and processing is accurate and non-invasive. The accuracy of the method is 0.028±0.018 mm for translation and 0.13±0.07 degrees for rotation. This is the situation in which the system will be tested clinically. The reproducibility of two scans with a time delay is 0.19±0.04 mm for translation and 0.5±0.1 degrees for rotation.

Relevance for science, technology or society
In a professional setting wrist problems often lead to a strongly reduced capability of an employee to perform job related manual tasks. Apart from discomfort and pain for the patient, reduced manual performance is associated with economic damage to the employer. Since the functionality of the hand is essential in almost any professional environment improvement of wrist functionality will have a direct impact on economic value as well as social functioning of the patient involved.
This research will contribute to a better understanding of wrist*s principal biomechanics and dyskinematics after ligamentous injury which will give an onset for further investigation of mechanisms of various instability patterns. Better understanding of basic dynamic properties of the wrist results into further development a new technology for the acquisition of dynamic 3D images of a moving joint. This is crucial for functional assessment of the joint*s characteristics including degree joint function or malfunction. In this order better understanding of the wrists characteristics will improve therapy methods, the quality of life for the patients involved and will reduce the lost working time that will reduce the society*s expenses due to workers' compensation, medical expenses, and productivity losses.

Study objective

The aim is to gain basic dynamic information of both healthy and operated wrists to eveluate the outcome of pisiformectomy. By comparing the healthy wrist of the patient with the operated wrist we expect to detect abnormal motion patterns which we will quantify in measurable values.

Study design

This experiment is a Pilot study. The aim is to gain information of the outcome of pisiformectomy on the wrist movements and stability.
Both wrists of all patients will be scanned by our 4D-RX method during flexion/extension, radioulnar deviation. The scans of the healthy and operated wrists will be compared to eveluate and study the effects of pisiformectomy.

Study burden and risks

A group of patients with unilateral pisiformectomy in the history who*s healthy and affected wrist will be scanned. First a regular dose CT scan will be obtained to acquire volume reconstructions of carpal bones. Hereafter both wrists will be scanned by our 4D-RX method during flexion/extension motion (FEM) and radioulnar deviation (RUD). The total radiation exposure of the experiments is about 0.25 mSv which is comparable to 5 weeks natural background exposure in the Netherlands.

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

10 patients with a unilateral pisiformectomy in the history
18 jaar en ouder

Exclusion criteria

-Not able to understand the written informed consent.
-Pregnancy
- Injury of the contralateral wrist/hand

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2008
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	NL22707.018.08