In vivo kinematics of scapholunate interosseous ligament injuries

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PARTNERS HUMAN RESEARCH COMMITTEE

DETAILED PROTOCOL

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I. Background and Significance

The kinematics of scapholunate interosseous ligament (SLIL) injuries are poorly understood. Some patients are relatively asymptomatic while other patients have pain and difficulty with pushing and loading of the wrist. Even more confounding, some patients with complete injury and dissociation of the scaphoid from the lunate may be symptom free, while some patients with partial injuries describe substantial wrist dysfunction.

The kinematics of the wrist may provide insight into this dysfunction. *In vivo* kinematics of the normal wrist has been studied previously, but few studies have characterized the wrist with a SLIL injury. In addition, there are few studies evaluating validated patient-rated outcomes for patients with SLIL injury. The goal of this study would be to evaluate to what degree kinematic abnormalities affect patient-rated outcomes.

A dual fluoroscopic imaging technique has been used to study the kinematics of various joints and quantify the variations associated with ligament insufficiency or ligament reconstruction. We propose an *in-vivo* study on the wrist of patients with SLIL injury. This technique should identify any changes in carpal kinematics and may be able to be correlated to signs and symptoms of pain and osteoarthritis.

Our technique provides a direct technique for measurement of wrist kinematics. The system is not only a viable solution for the investigation of fully dynamic joint kinematics, but also has a low radiation dosage, is non-invasive, and can be constructed using any pair of readily available fluoroscopes. Thus, the DFIS provides an easy and powerful tool for accurately determining 6DOF positions of healthy, injured, and surgically treated wrists in 3D space.

(1) Wolfe SW et al. In vivo scaphoid, lunate, and capitate kinematics in flexion and extension. J Hand Surg Am 2000; 25A : 860-9.

(2) Crisco JJ et al. In vivo radiocarpal kinematics and the dart-thrower's motion. J Bone Joint Surg 2005; 87A: 2729- 2739.

(3) Moritomo H et al. Capitate-based kinematics of the midcarpal jooint during wrist radioulnar deviation: An in vivo three-dimenstional motion analysis. J Hand Surg 2004; 29A: 668-675.

(4) Li G et al. In vivo articular cartilage contact kinematics of the knee: an investigation using dual-orthogonal fluoroscopy and magnetic resonance image-based computer models. Am J Sports Med. 2005 Jan;33(1):102-7.

II. Specific aims

This represents a study on subjects with scapholunate interosseous ligament (SLIL) injury and *in-vivo* joint kinematics analysis based on a new three-dimensional imaging method which will integrate images from CT scan and from dual-orthogonal fluoroscopy.

We hypothesize that there is no relationship between *in vivo* kinematic abnormalities and patient-rated outcomes for scapholunate interosseous ligament injuries (SLIL)

Our secondary null hypotheses are that: There are no kinematic differences between subjects with unilateral, symptomatic, full thickness scapholunate ligament tears in comparison to the contralateral wrist without scapholunate ligament injury.

We also aim to answer to the below questions:

- What are baseline validated outcomes for subjects with SLIL injury?
- What are baseline physical measures (range of motion, Jamar Dynamometry)?

III. Subject selection

In this pilot study, we will recruit 10 subjects with the below inclusion criteria:

Inclusion Criteria

- Patients with a unilateral full thickness scapholunate ligament tear diagnosed by radiographs or advanced imaging.

Exclusion Criteria

- Patients < 18 years old
- Patients with partial thickness scapholunate ligament tears
- Patients with radiographic arthrosis
- Patients with prior wrist surgery
- Pregnancy

Subjects will be identified from the clinical practice of Dr Neal Chen, [redacted], [redacted], [redacted], and [redacted]. Plain radiographs of the interest wrist and contralateral wrist and MRI of the interest wrist will be performed to confirm the diagnosis as a routine practice. Consent procedures are detailed below.

[redacted].

IV. Subject Enrollment

A total number of 10 subjects will be considered for this pilot study. Post-hoc we will determine if our sample size is sufficient in order to perform a multivariable logistic regression analysis using the rule of thumb to avoid fitting a model with too many degrees of freedom in the modeling process. In case we need to enroll higher number of subjects, we will inform the IRB to get the approval beforehand.

Participation is voluntary. Prospective subjects will be invited in the clinic after being diagnosed and will be provided with a flyer explaining the study. The treating physician will ask the subject's permission to have researchers contact them. A researcher who is IRB approved study staff will contact the subject to confirm eligibility, explain the study, and set up the first study appointment.

At the first study visit, the study will first be explained in detail. After reading the consent form, subjects will be able to ask additional questions. [redacted] who is an expert research scientist with more than 9 years of experience in Bioengineering Lab and is an IRB approved study staff will obtain informed consent.

Study procedures

Pregnant or breast-feeding women will be excluded from participation. During each study visit, women of childbearing potential will be questioned and urine tested to determine whether they are possibly pregnant. If found pregnant, they will be disqualified from the study. If a pregnancy test is required, [redacted] will confirm the urine test kit results and sign the corresponding pregnancy test form. A credentialed, Massachusetts licensed physician or a licensed radiological technologist will be operating fluoroscopes.

V.I. Study visits

Subjects with a unilateral, full thickness scapholunate ligament tear documented by radiographs of the interest and contralateral wrist, MR arthrogram, or MRI of the interest wrist as well with no history or radiographic evidence of wrist injury will be enrolled. A CT scan of both wrists will be obtained. The contralateral wrist will serve as a matched control.

Participation in this study will require two visits at the Massachusetts General Hospital. A research assistant who is IRB approved study staff will contact the subject by telephone and/or email to schedule the visits and will ask the subject whether he/she would prefer to do the CT scan and Fluoroscopy in either one longer session or two separate shorter sessions.

The *first visit* after enrolling in this study will be to undergo a CT scan of both wrists. This visit will last approximately 60 minutes. The subject will lie motionless with outstretched hands on a table that slides into a square donut frame for about 2 minutes. Subjects will complete the PRWE, DASH, and SF-12 questionnaires. Questionnaires will be completed on paper. Range of motion of both wrists will be assessed using a goniometer. Grip force of both wrists will be assessed using Jamar Dynamometer. Pinch force will be assessed for both sides using pinch gauge.

The *second visit* will last approximately 60 minutes. Images of the both wrists will be taken with fluoroscopes, which are able to take digital x-ray pictures. During this visit, the subject will perform fully dynamic activities as described below, while the fluoroscopes take digital x-rays, one wrist at a time:

[redacted]

[redacted]

Each subject will be given a radiation protection apron, a protective thyroid shield, and protection for genital region. The first and second visits can be done in the same day or 2 separate days, whichever is more convenient for the subject.

The data obtained from these visits will be transferred to a computer and will be used to reconstruct three-dimensional wrist models. It will help researchers better understand the association of small bones in the wrist and whether any changes happen in their related movements after SLIL injury.

The CT scan of the contralateral side is designed to answer research questions. This CT scan is not a substitute for one a doctor would order. However, if we believe that we have found a medical problem in the CT, we will ask a doctor who is trained in the reading of CTs, a radiologist, to help us review the images. If the radiologist thinks that there may be abnormalities in the CT images, we will contact the subject and will help him/her get medical follow-up for the problem.

V.II. Devices to be used

Two fluoroscopes (BV Pulsera, Philips, Eindhoven, Netherlands) will be used to capture images of the wrist at each extreme motion. The fluoroscope has been developed to produce real-time 1K x 1K imaging resolution and has an image intensifier diameter of 31 cm. When using the two fluoroscopes to obtain orthogonal images, the total imaging volume can reach up to 30cm x 30cm x 30cm. Such a system will allow the investigator to capture the two images simultaneously, thus minimizing the amount of time that the subject must remain still. The operator will perform the imaging via a switch. The distance between the source of radiation and the personnel will be approximately 2 meters. The investigator will also be protected from radiation exposure with appropriate lead shielding. In order to monitor radiation exposure, badges will be worn during the imaging process.

The fluoroscope has a clearance of approximately 1 meter between the X-ray source and the receiver, allowing the subject to be imaged by the fluoroscopes simultaneously throughout the entire range of motion.

After scanning, the collected imaging data from the CT imaging and the fluoroscopy will be transferred to the computers of the Bioengineering Laboratory for further data processing. Each subject will be assigned a code for data storage and further processing, ensuring confidentiality. The laboratory computers are only accessible to the Bioengineering Laboratory members. The imaging files from this study will furthermore

be specifically password protected and therefore will only be accessible to the investigators.

The images of the wrist at each performed motion will be entered into the Rhinoceros® software program (Robert McNeel & Associates, Seattle, WA), where the contours of the wrist bones will be outlined and digitized. The digitized data will then be used to construct the contour lines of the bony cross-sections using piecewise polynomial curves. Reconstruction of the bony surfaces will be achieved by transforming these curves into piecewise polynomial surfaces using the Rhinoceros® program.

V. Biostatistical Analysis

A total number of 10 subjects will be considered for this pilot study. Post-hoc we will determine if our sample size is sufficient in order to perform a multivariable logistic regression analysis using the rule of thumb to avoid fitting a model with too many degrees of freedom in the modeling process. In case we need to enroll higher number of subjects, we will inform the IRB to obtain approval prior to proceeding.

Data obtained for statistical analysis will include scanning of each wrist at different positions beside a grip and leaning position. At each respective position, translations, rotations, and gap formation will be measured.

VI. Risks and Discomforts

Radiation risks: The following is the revised statement from [redacted] of the Radiation Safety Committee: The subject will be exposed to radiation from the x-rays during fluoroscopy. A milliSieverts (mSv) is a unit of measure of radiation dose. The worldwide average natural background dose from the earth and the sky for a human being is about 3 mSv per year.

For subjects, the total amount of radiation exposure from full participation in this study is equal to a whole body exposure of 0.071 mSv from fluoroscopy. This amount of radiation is about the same one would normally receive in 9 days from natural background sources from the earth and the sky.

The fluoroscopy scanning will be performed in a room specifically dedicated to this equipment and the study. No other laboratory work will be performed in this room during testing. The only persons present during scanning will be the subject and the personnel operating the fluoroscope. The room is located at the end of a hallway and its door will be closed while operating the fluoroscope.

The subjects will be provided with lead aprons (0.5 mm thickness), lead thyroid shields and lead gonad shields for protection against radiation exposure.

After positioning the subjects, the personnel handling the fluoroscope will be performing the scan via a hand switch. The distance between the source of radiation and the personnel will be approximately 2 meters. Furthermore, the personnel will be protected with lead aprons (0.5 mm thickness) and lead thyroid shields. In order to monitor exposure of personnel, radiation exposure badges will be worn during the scanning process.

The radiation protection aprons, thyroid shields and gonad shields have been specifically purchased for this study and will only be used for the purposes of this study.

Dr. Neal Chen or [redacted] or one on the research fellows which is approved by IRB as a study staff will have carefully screened prospective subjects for possible contraindications at the initial evaluation. These contraindications include pregnancy and breast feeding women. Subjects with these contraindications will be excluded from the study.

Adverse events will be reported promptly to the IRB according to Partners Human Research Committee guidelines.

VII. Potential benefits

We do not expect any direct benefit to any subjects in this study. However, we hope that this study contributes important information for the development of joint kinematics analysis technique. An improved knowledge of carpal kinematics can inform future patients and surgeons and help optimize surgical techniques.

VIII. Monitoring and Quality Assurance

The Principal Investigator, Dr. Chen, has overall responsibility for monitoring and assuring the validity and integrity of the data and adherence to the IRB-approved protocol. All data acquired as specified by this protocol will be maintained and monitored by Dr. Chen and [redacted] at Bioengineering Laboratory. An IRB approved study staff will be responsible for collecting the signed consent forms and subject questionnaires. [redacted] will maintain the subject consent forms and questionnaires and review the forms for completeness. All electronic data and subject information will be secured on non-networking password protected computers; all paperwork will be secured in locked filing cabinets.

The Principal Investigator, Dr. Chen, has overall responsibility for data and safety monitoring. A credentialed, Massachusetts licensed physician or a licensed radiological technologist will be operating fluoroscopes for this study. Subjects are monitored by Dr. Chen (or research fellows, approved as study staff) during the time of fluoroscopic image acquisition. Other study representatives will also be on hand to assist the subject. Participants will be supervised by the clinical technicians of the MGH Imaging Department during the MR acquisition. Any discomfort during fluoroscopy or MRI will lead to termination of the procedure and excluding the participants from the study.

The study staff will update the treating physicians on the imaging procedures. The treating physicians will decide whether the subject is eligible to continue his or her participation in the study.

The principal investigator will review, analyze, and report to the IRB any adverse events according to the guidelines set forth by MGH/Partners.

All participants are given a participation number/code at the time of enrollment. This code is kept on all data sheets instead of the subject name. Subject information is only accessible by Partners authorized investigators and will not be shared with outside entities.

Questionnaires and self-reported responses will not become part of the subject's medical record and will not contain medical record numbers or names. Hardcopies of study related data and forms will be stored in a lockable file cabinet. Subject information

will remain confidential by keeping identifying information (name, medical record number, and subject number) in a separate locked file cabinet. Only the investigators and study staff specified on the consent form will have access to this information.