

Resection of the Distal Pole of the Scaphoid in Symptomatic Scaphotrapeziotrapezoid Osteoarthritis and Scaphoid Fracture Nonunion

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON37572

Source

ToetsingOnline

Brief title

Distal pole resection scaphoid in STT OA and scaphoid nonunion

Condition

- Bone and joint therapeutic procedures

Synonym

joint degeneration, nonunion

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: nonunion, osteoarthritis, resection, scaphoid

Outcome measures

Primary outcome

Pain is measured by a visual analogue scale. Wrist function will be evaluated by measuring grip and key pinch strength and range of motion (ROM) according to a standardized protocol and to the other hand. Limitations in daily life and patient satisfaction are measured by a standardised questionnaire (DASH, Michigan Hand Questionnaire, Mayo Clinical Scoring Chart). An X-ray will be made to detect possible DISI-deformity or other anatomical deformities.

Secondary outcome

N.A.

Study description

Background summary

Resection of the distal pole of the scaphoid is not a common used procedure and the long term outcomes and patient's benefits are unclear. It is also unclear which patients benefit most from this type of surgery. Currently, distal pole resection is performed as an isolated procedure for the following indications: osteoarthritis (OA) of the scaphotrapeziotrapzoid (STT) joint and nonunion of a scaphoid fracture and it is also used in combination with radioscapulunate fusion. The main goals of the operation are to relief pain and improve wrist function.

Study objective

Our aim is to assess the outcomes of distal pole resection of the scaphoid in patients with symptomatic OA of the STT joint or patients with a fracture nonunion of the scaphoid. Pain, functional outcome, and radiological outcome

will be described and related to pre- and postoperative deformities. Therefore, the outcomes will be compared with standardized measurements and the other hand, except from those patients who underwent this operation or another operation at the other hand.

Study design

Retrospective observational survey study.

Study burden and risks

Patient*s burden and risk are small. Patients are requested to pay a single visit (45 min) to the outpatient clinic in which a physical examination of the wrist function is conducted, an X-ray of the operated wrist is taken, and the patient is asked to fill in a questionnaire.

Radiation exposure (effective dose) of the wrist X-ray in one direction is <0.01 mSv. The physical examination is non-invasive. In addition, the questionnaires are not associated with discomfort. There is no benefit for the participant. Findings from this study will provide information about the results of a distal pole resection of the scaphoid in wrist function, pain and patient satisfaction. Findings can be compared to results of other surgical procedures which have been described in literature. Based on the findings new prospective studies will be initiated.

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

Patients with symptomatic STT OA or scaphoid fracture nonunion who have undergone a distal pole resection of the scaphoid between 2004 and 2011 in the VU University Hospital or The Hand Clinic Amsterdam.

Exclusion criteria

Patients with other pathologies or operations of the hand or wrist affecting the STT-joint
Patients who are unable to visit the hospital or fill in the questionnaires or undergo the physical tests and X-ray (eg pregnant women)

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 21-05-2012

Enrollment: 30

Type:

Actual

Ethics review

Approved WMO

Date:

03-12-2012

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

NL39692.029.12