Wrist repair in severe trauma (WRIST) study

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Bone and joint injuries
Study type	Interventional

Summary

ID

NL-OMON43869

Source
ToetsingOnline

Brief title
WRIST study

Condition

- Bone and joint injuries
- Joint disorders
- Bone and joint therapeutic procedures

Synonym
post traumatic wrist osteo-arthritis, wear and tear of wrist after injury

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: functional outcome, interposition arthroplasty, post-traumatic arthritis, wrist

Outcome measures

Primary outcome

The objective of this study is to investigate whether reconstruction of the radiocarpal joint by implantation of a tailor-made and patient specific 3D printed interpositional arthroplasty made out of Bionate® II 80A PCU (DSM®) is feasible as a therapy in patients with severe posttraumatic radiocarpal osteoarthritis.

The feasibility will be measured in by evaluation of the position, aspect, degree of wear and tear and eventual (dis)location of the Bionate® II interpositional arthroplasty. The evaluation will be done by magnetic resonance imaging (MRI) of the wrist at different time points in follow-up after implantation.

Eventual negative side-effects of implantation of a Bionate® II PCU sheet in the radiocarpal joint will be registered.

Secondary outcome

Next to radiological evaluation of the feasibility, clinical and functional outcomes will be assessed as well. We will investigate the effect of the Bionate® II interpositional arthroplasty on functionallity of the radiocarpal joints, measured as range of motion and grip strength of the affected wrist compared to baseline. We will assess the functional outcome and pain as measured with the PRWHE, SF36 and EQ5D questionnaires. We will determine the functional outcome at four different time points in follow-up after

implantation, compared to the situation prior to surgery. Eventually we want to investigate whether the Bionate® II interpositional arthroplasty can serve as a better alternative for severe posttraumatic degenerative wrist conditions than excisional arthroplasty or wrist arthrodesis.

Study description

Background summary

Posttraumatic osteo-arthritis of the wrist, especially the radiocarpal joint, is a possible consequence of severe wrist trauma and can lead to serious functional impairment and pain. Clinical results of presently available surgical techniques for treatment of posttraumatic radiocarpal osteo-arthritis are disappointing.
A possible solution might be performing an interpositional arthroplasty. In the past, both autologous tissues and artificial materials have been used for the construction of interpositional arthroplasties. Interpositional arthroplasty using silicon rubber implants in
the wrist joint has been performed since decades and short-term results are excellent. Long-term results however are disappointing, most likely due to limited tensile and tear strength of the available silicone implants.
Recently, a more suitable material for these indications, called Bionate® II Polycarbonate-urethane (PCU) (DSM®), has been developed. Preliminary results for this material in orthopedic surgery are very encouraging.

Study objective

The objective of this study is to investigate whether reconstruction of the radiocarpal joint by implantation of a tailor-made and patient specific 3D printed interpositional arthroplasty made out of Bionate® II 80A PCU (DSM®) is feasible as a therapy to reduce pain and preserve mobility of the wrist joints in patients with severe posttraumatic radiocarpal osteoarthritis.

Study design

This study is an observational prospective single center clinical pilot study to investigate of the feasibility of the Bionate® II interpositional arthroplasty for posttraumatic osteoarthritis of the radiocarpal joint.

Intervention

An interpositional artroplasty is performed by inserting a small Bionate® II PCU sheet in the radiocarpal joint via a limited dorsal wrist arthrotomy. This procedure will be performed under general or regional anesthesia.

Study burden and risks

Patients will be submitted to physical examination at 6, 12, 24 and 52 weeks after surgery. Physical examination consists of determination of range of motion of the wrist joint and grip strength. Radiological evaluation will be done by performing magnetic resonance imaging (MRI) scans of the wrist at 24 and 52 weeks after surgery. Next to physical and radiological investigation, patients are requested to fill out 3 questionnaires preoperatively and at 6, 12, 24 and 52 weeks after surgery: The Patient Rated Wrist and Hand Evaluation (PRWHE) questionnaire, the Short Form 36 (SF36) questionnaire and the Euroqol 5D (EQ5D) questionnaire.

Bionate® II has a long history of successful use in (joint) surgery with FDA approval for several indications. For this study, only the form and placement of the implant differs from Bionate® II inserts already available for and used in clinical practice. Therefore risks associated with the implanted material are limited.
Moreover, we expect an improved functional outcome and less surgery related complications than presently available surgical techniques for treatment of severe posttraumatic osteo-arthritis of the wrist joint. (like excisional arthroplasty, total wrist arthroplasty or total wrist artrodesis)

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 over 18 years of age with severe post traumatic radio carpal osteo-arthritis with an indication for excision arthroplasty, arthrodesis or wrist arthroplasty will be eligible for inclusion

Exclusion criteria

Exclusion criteria are previous surgery for severe post traumatic radiocarpal conditions, especially salvage procedures (such as excisional artroplasty, arthrodesis) and general objections for surgery, determined after anaesthesiological assessment.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start

Enrollment:	12
Type:	Anticipated

Medical products/devices used

Generic name:	Bionate® II 80A thermoplastic polycarbonate-urethane
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-03-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL52867.068.15