A clinical comparison of patient-specific 3D printed splints versus conservative splints in the treatment of distal radius fractures.

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The main objective of this study is to assess patient reported outcome measures of adult patients who are diagnosed with a distal radius fracture and treated with a patient-specific 3D- printed splints as compared to a control cohort.

Ethical review	Approved WMO
Status	Pending
Health condition type	Fractures
Study type	Observational non invasive

Summary

ID

NL-OMON51615

Source
ToetsingOnline

Brief title
3D-printed splints

Condition

- Fractures

Synonym
fraccture, injury

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

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

Intervention

Keyword: 3D-printing, Distal radius fractures, Splints

Outcome measures

Primary outcome

The main study parameters are patient reported outcome measures related to comfort and satisfaction of the medical aid. This will be measured qualitatively with a semi-structured interview (issues discussed: limitations daily life, cosmetic look, local complications) and quantitively using questionnaires.

Questionnaires:

• Patient Reported Wrist Evaluation (PRWE) - measure of patient rated pain and disability for wrist conditions.

•D-QUEST - instrument for measuring client satisfaction with a medical device. D-Quest is a Dutch version of the Quebec User Evaluation of Satisfaction with assistive Technology.

•CSD-OPUS - The orthotics and Prosthetics User*s Survey (OPUS) on the Satisfaction with Devices (CSD).

•EQ-5D VAS - Rates the overall health of a patient.

Secondary outcome

Clinical outcomes:

- Complications. The McKay checklist will be used for scoring the complications after a DRF.

- Union rate will be measured according to the current clinical standard. The

treatment will be considered sufficient if the bone is capable of undergoing

the tasks it was capable of before the fracture.

Safety outcomes:

- Reasons for withdrawal.

- Adverse events (production- and wearing of the 3D-printed splints).

Barriers to implementation:

- Acceptance by caregivers

- Technical problems related to hardware used in the 3D workflow

Study description

Background summary

The standard conservative treatment for distal radius fractures includes immobilization of the injured extremity using a conventional forearm cast. These casts do cause all sorts of discomfort during wear and impose life-style restrictions on the wearer. Examples are irritation and itching of the skin, pain from pressure points and inability to shower or swim without a protective sleeve. Patient specific 3D-printed splints may be a viable alternative to conventional casts. We hypothesize that personalized 3D-printed splints result in improved outcomes on patient reported outcome measures.

Study objective

The main objective of this study is to assess patient reported outcome measures of adult patients who are diagnosed with a distal radius fracture and treated with a patient-specific 3D- printed splints as compared to a control cohort.

Study design

A single centre cross-cohort study

Study burden and risks

Participants may benefit in the form of better ventilation, less perspiration,

less warmness and ability to perform water related activities such as showering and swimming compared to the standard of care. The results from the study will provide new insights into feasibility and effectivity of patient specific 3D-printed splints in the treatment of DRF*s. We would like to investigate whether the use of personalized 3D-printed splints leads to higher patient satisfaction compared to treatment with conventional forearm casts.

We expect none or only minimal adverse effects from the 3D-printed splint intervention. We assume that healing rates are similar. However, potential risks are breakage of the 3D-printed splint or allergic reaction the resin used. Besides the utmost care taken in the design and production process to prevent this, the potential risks could include damage of the underlying skin. Treatment can be continued with a conventional forearm cast. Therefore, we assume the risk is minimal.

Other burdens for participants associated with this study is related to measurements of endpoints. Patients need to fill in one questionnaire directly after immobilization one week post injury and five (short) questionnaires directly after the removal of the 3D splint. Filling out the questionnaire directly after immobilization will take approximately 5-10 minutes. The questionnaires will take approximately 25-30 minutes to fill out directly after removal of the 3D-printed splint. Moreover, after removal pictures of the affected forearm will be made and participants answer questions in a semi-structured interview. The interview will take an additional 10-15 minutes. Patients may be called by the investigator for further clarification when a questionnaire is incomplete. Patients are not required to visit the Radboudumc more than required for the standard of care DRF*s. Informed consent is needed to include patients for the study and get access to the medical files.

Outside the scope of this study: the use of patient-specific 3D-printed splints seems to result in a lot less waste products. This assumption will be investigated in different studies such as a life cycle assessment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

•Age 16 years or older
•Admitted to the emergency department or plaster room with a DRF
•Non-operative treatment with cast immobilisation
•Written informed consent
•Patients must be able to follow the study protocol

Exclusion criteria

•Operative treatment
•Open fractures
•History of surgically treated wrist fracture on the currently injured side
•Unable to wear conventional forearm cast or splint due to medical condition, known allergies or other reasons.
•(partially) paralysis of the affected limb
•DRF older than two weeks.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2023
Enrollment:	24
Type:	Anticipated

Medical products/devices used

Generic name:	PolyCast
Registration:	No

Ethics review

Approved WMO

Date:	04-04-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL83500.091.22