Evaluating the utility of bone grafts in open wedge corrective osteotomy and plate fixation in patients with malunited distal radius fractures (WOPPeR trial)

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Primary objectives are:1. Are there differences in complication rates between patients treated with harvesting of bone from the iliac crest and patients not treated with bone grafting during open wedge corrective osteotomy and plate fixation of the…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON56098

Source
ToetsingOnline

Brief title
The utility of bone grafts in corrective osteotomy of the distal radius

Condition

- Fractures

Synonym
malunion, malunited distal radius fractures

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: ZonMw Doelmatigheidsonderzoek

Intervention

Keyword: Bone grafting, Corrective osteotomy, Malunited distal radius fractures, Quality of life

Outcome measures

Primary outcome

The primary study outcomes are:

• Complications (number and severity) during and after the operation with a

follow-up period of at least one year

• Quality of life using the EQ-5D-5L questionnaire

• Time to complete bone healing, defined as the time between the corrective

osteotomy and bridging of the fracture site by bone or callus

Secondary outcome

The secondary study outcomes are:

• Subjective functional outcomes: Patient-Rated Wrist Evaluation (PRWE) and

Disability of the Arm, Shoulder and Hand (DASH) questionnaire

• Objective functional outcomes: active range of motion and grip strength

• Cost effectiveness (including costs, medical consumption using iMCQ,

productivity loss using iPCQ)

Age, gender, hand dominance, comorbidities, smoking, body mass index,

indication for operation, hobbies, sporting activities, usage of all

medications and vitamin supplements, occupation and resumption of work.

Study description

Background summary

Malunion is the most common complication of distal radius fractures and is associated with increased pain, weakness, decreased range of motion, and/or neurologic symptoms. These symptoms can have a great impact in daily activities. Many surgical techniques have been described for the correction of the radial deformity, but open wedge osteotomy with plate fixation and bone grafting from the iliac crest is considered as the standard procedure. This technique effectively restores the length of the radius, but it also creates a void. A variety of bone grafts and substitutes are available for filling that void, but the harvesting of bone from the iliac crest is the gold standard as it allows easy access to corticocancellous bone of a desirable quality and quantity. The idea behind bone grafting is to provide optimal bone formation and structural stability, which is crucial for bone healing. Biomedical studies, however, have shown that the current design of the plate and screws provides good structural stability in itself. Further, the harvesting and use of bone from the iliac crest come with the risk of complications, with reported complication rates between 2.8% and 39%. The following complications are reported: delayed union; size mismatch between the graft and the osteotomy defect; longer operation times; donor site morbidity, including nerve, arterial, and ureteral injury; herniation of abdominal contents; sacroiliac joint instability; pelvic fractures; hematoma; and infection. Up to 49% of patients complain of pain around the iliac crest, which can persist for several years. This pain is often reported as more severe than the pain at the primary surgical site. The complications associated with harvesting bone from the iliac crest can adversely affect patients* quality of life, leading to more reinterventions, longer hospital stays and greater reliance on pain medication.

To date, there is no consensus in literature on the harvest and use of bone from the iliac crest during corrective osteotomy and plate fixation of the distal radius. We are not aware of any randomized, controlled studies comparing the standard treatment with the intervention. The standard treatment is extensively described in literature. However, several retrospective studies have evaluated various outcomes after open wedge corrective osteotomy and plate fixation without bone grafting. These studies showed no relevant differences in incidence of bone healing problems compared to studies which used the standard treatment. These studies evaluated bone healing using standard radiographs with limited resolution, meaning the bone healing process could not be followed in detail. A CT scanner enables more precise detection of early fracture healing than radiographs. There is no data available regarding to cost-effectiveness.

As the disadvantages of bone grafting can have a major impact on patients*

everyday lives, research is needed on whether bone grafting is genuinely necessary during corrective osteotomy and plate fixation of the distal radius. If there is no difference in bone healing and functional outcomes between the standard treatment and the intervention, there is no reason to subject patients to harvesting bone from the iliac crest and they will be no longer exposed to the associated complications. This will result in reducing costs by avoiding the complications associated with the harvest and use of bone from the iliac crest. The findings will also be relevant for corrective osteotomy in other metaphyseal bone areas, where bone grafting from the iliac crest is also the standard treatment, yet no consensus exists on whether it is necessary.

Study objective

Primary objectives are:
1. Are there differences in complication rates between patients treated with harvesting of bone from the iliac crest and patients not treated with bone grafting during open wedge corrective osteotomy and plate fixation of the distal radius?

2. Will patients not treated with bone grafting have a better quality of life compared to patients treated with harvesting of bone from the iliac crest during open wedge corrective osteotomy and plate fixation of the distal radius?

3. Are there differences in time to complete bone healing between patients treated with harvesting of bone from the iliac crest and patients not treated with bone grafting during open wedge corrective osteotomy and plate fixation of the distal radius?

Secondary objectives are:
1. Are there differences in subjective and objective functional outcomes between patients treated with harvesting of bone from the iliac crest and patients not treated with bone grafting during open wedge corrective osteotomy and plate fixation of the distal radius?

2. Is open wedge corrective osteotomy and plate fixation without bone grafting cost effective compared to the standard treatment with harvesting of bone from the iliac crest in patients with malunited distal radius fractures?

Study design

This is a prospective, randomized, controlled multicenter study involving the following hospitals: Maastricht University Medical Centre (MUMC+), Academic Medical Centre (AMC), VieCuri Medical Centre, Zuyderland Medical Centre,Elkerliek Hospital, Erasmus Medical Centre and Amphia Hospital. The follow-up period is at least 1 year and includes 5 postoperative visits. During the visits, the patients will undergo several examinations: filling out

questionnaires, undergoing physical examination and making radiographs and CT scans. This study will take at least 4 years taking into account that approximately 35 patients will be operated per year.

Intervention

All included patients will undergo an open wedge osteotomy and plate fixation according to the standard surgical techniques. In one group, the bone defect will be filled with bone graft of the iliac crest after open wedge osteotomy according the standard procedure. The other group includes patients who will not receive any bone grafts. All participating hospitals have extensive experience with both treatments. The postoperative care and rehabilitation protocol will be the same for both groups.

Study burden and risks

All included patients have to fill out questionnaires and undergo physical examination of their wrists. Also extra radiographs and CT scans will be made. The extra radiation exposure in this study will be maximal ~1,01 mSv (CT scans: 5x0,2 mSv = 1 mSv and radiographs: 1x7 µSv = 0,007 mSv). When the osteotomies in patients show complete bony union on the radiographic imaging, no more CT-scans will be made in these patients during the follow-up. The radiation exposure in the standard care is ~0,04 mSv (radiographs: 6x7 µSv). Each visit at the hospital will take 60 minutes. By participating in this study, patients will be more intensively monitored and they contributed to better health care. Also, the patients will have more insight in how scientific research works.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients of either sex from the age of 18 years or above
- Symptomatic extra-articular malunion of the distal radius
- Eligible for open wedge osteotomy and plate fixation with or without bone grafting
- Patients are able to undergo postoperative follow-up of at least 12 months

Exclusion criteria

- Patients with known systemic or metabolic disorders leading to progressive bone deterioration
- Chronic use of glucocorticoids
- Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-05-2019
Enrollment:	95
Type:	Actual

Ethics review

Approved WMO Date:	27-03-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-12-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-02-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-05-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	30-12-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	20-01-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-10-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-12-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	30-06-2023
Application type:	Amendment
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	NL68126.068.18
Other	NTR-7597