Post traumatic distraction osteogenesis of the lower limb

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The purpose of this study was:1) to assess the postoperative complications and fracture healing in patients after posttraumatic distraction osteogenesis.2) to assess the degree of the degree of function of the lower extremity upon distraction...

Ethical review	Approved WMO
Status	Pending
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Observational non invasive

Summary

ID

NL-OMON30678

Source
ToetsingOnline

Brief title
Leg lengthening

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
- Bone and joint therapeutic procedures

Synonym
leg length discrepancy, malunion, segmental bone defect

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Onderzoek zelf wordt niet gefinancierd;mogelijk worden reiskosten van de patiënten vergoed door een fabrikant van

externe fixateurs.

Intervention

Keyword: distraction osteogenesis, leg length discrepancy, segmental bone loss

Outcome measures

Primary outcome

Degree of leg extension, duration of treatment, Healing Index (months/cm) and

postoperative complications, Lower Extremity Functional Scale, range of motion

of hip, knee and ankle of the affected limb.

Varus valgus measurement after X-ray of the entire affected lower extremity.

Secondary outcome

N.A.

Study description

Background summary

Complications following fractures of the femur and tibia include segmental bone loss and leg length discrepancy. Fracture consolidation may result in limb shortening due to malunion, collapse of comminuted fractures or premature closure of the diaphyse in children. A segmental bone defect is usually a result of high energy trauma or debridement for osteomyelitis. These complications may have severe negative impact on patient*s live and present complex treatment challenges.
Ilizarov was one of the first who treated these patients with a modular-ring fixator and transosseous wires to stabilize the bone fragments. He used this method to generate new bone between the osseous surfaces that were gradually pulled apart. This technique is called distraction osteogenesis.

Study objective

The purpose of this study was:
1) to assess the postoperative complications and fracture healing in patients after posttraumatic distraction osteogenesis.
2) to assess the degree of the degree of function of the lower extremity upon

distraction osteogenesis.

Study design

A retrospective analysis of the patient*s notes was performed to determine the duration of treatment and healing index. The healing index is defined by the total duration of treatment divided by the number of centimetres of new bone formation (months/cm). Furthermore, complications such as pin-track infections and secondary operations were recorded.
All patients are invited for a personal physical examination to asses their long term functional outcome. The functional outcome is based on the Lower Extremity Functional Scale (LEFS) and the range of motion (ROM) of the hip, knee and ankle joints. The LEFS is a 20-item self-report measure of physical function. Each item is rated on a five point scale (0-4), with lower scores representing greater difficulty. Total scores can range from 0 to 80. The ROM*s were measured and listed according the American Medical Association guides to the evaluation of permanent impairment.
In addtion, an X-ray of the operated lower limb (from hip to ankle) will be made.

Study burden and risks

One additional X-Ray.

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 that had undergone distraction osteogenesis surgery due to posttraumatic bone defect or malunion

Exclusion criteria

Age below 18
Cognitive impairment

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2007
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO Date:	05-07-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL16081.078.07