ISRCTN13631918 https://doi.org/10.1186/ISRCTN13631918

Randomized control trial about two diferent approaches of the Scarf technique to treat hallux valgus: the classical open and the minimally invasive

Submission date
14/11/2020

Recruitment status
No longer recruiting

Registration date
20/11/2020

Overall study status
Completed

Last Edited
02/12/2020

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Hallux valgus is a common deformity that affects the first toe of the foot. The Scarf osteotomy is one of the surgical procedures to address the deformity and has shown excellent results. It was originally described as a first metatarsal osteotomy, with an open approach. To date, any of the Scarf variations have always involved open surgery and no minimally invasive (MI) adaptation has been described to the best of our knowledge. MI procedures have the theoretical advantages of faster recovery, reduced pain levels, less soft-tissue damage and reduced morbidity. We developed the minimally invasive technique to perform the Scarf procedure.
There are currently no available studies that report outcomes for MI Scarf osteotomy nor any comparison with open Scarf. The purpose of this prospective randomized study was to describe the MI scarf osteotomy and to evaluate its outcomes in comparison with the open Scarf osteotomy.

Who can participate?
All patients who will undergo hallux valgus surgery are eligible to participate in this study. There are some exceptions related to systemic diseases like infection or vascular ischemia.

What does the study involve?
All the patients have a symptomatic hallux valgus that requires a surgery. The chosen surgical procedure is a Scarf osteotomy as we perform in our hospital following our protocol. There are two different approaches that we use daily: open and minimally invasive. In a preliminary review we did not observe differences about results. If a patient participates in this study, will be randomised in two groups: open approach and minimally invasive approach. The postoperative controls will be as usual, and we will not perform extra x-ray explorations.

What are the possible benefits and risks of participating?
There are no benefits of participating. About the possible risks: both approaches have been used in our hospital for more than 10 years, we have not observed extra risks for using these two techniques.

Where is the study run from?
The study is run from the orthopaedics department of the Hospital universitari Mutua Terrassa

When is the study starting and how long is it expected to run for?
January 2017 to September 2019

Who is funding the study?
The Hospital Universitari Mutua Terrassa (Spain)

Who is the main contact?
Josep Torrent M.D. jtorrent@mutuaterrassa.es

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRB number 10.04.2017

Study information

Scientific Title

Open versus minimally invasive Scarf osteotomy for hallux valgus correction. A randomized controlled study

Study objectives
The minimally invasive scarf technique provides a clinically and radiologically equivalent outcome to open scarf for the treatment of hallux valgus deformity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/10/2017, Ethics Comitee Hospital Universitari Mútua de Terrassa (Dr Robert St number 5, 08772, Terrassa (Barcelona), Spain; +34 937365050; ceim@mutuaterrassa.cat), ref: 10.04.2017

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hallux valgus

Interventions
Procedure A: Open Scarf Osteotomy
Procedure B: Minimally invasive scarf Osteotomy

All patients had initially undergone a 6-month period of conservative treatment that included shoe wear modification, interdigital orthosis, physiotherapy and non-steroidal anti-inflammatory drugs. Only after failing conservative treatment for at least 6 months, the patient was proposed for surgical intervention. Patients were then randomized into two groups using a system with envelopes that were selected at random from a box. The first group underwent minimally invasive scarf osteotomy (MI group), and the second open scarf osteotomy (open group). Patients were assigned to minimally invasive or open group by random selection.

The mean follow-up was 21 (range, 12 to 23) months.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The angle among the 1st and the 2nd metatarsal bone of the foot measured using the digital sotware RaimJava® at 3-6-12 months.

Key secondary outcome(s))
Surgery duration measured using a stopwatch during the surgical procedure

Completion date
01/09/2019

Eligibility

Key inclusion criteria
Patients undergoing hallux valgus surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
58

Key exclusion criteria
1. Intermetatarsal angle >20º
2. Previous hallux valgus surgery
3. Metatarsalgia of the lesser rays that requires an osteotomy during the surgical procedure
4. 1st cuneometatarsal instability
5. Infection
6. Vascular ischemia
7. Neuropathy

Date of first enrolment
10/10/2017

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitari Mutua de Terrassa
Dr Robert St, 5

Terrassa
Spain
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Sponsor information

Organisation
University Hospital Mútua de Terrassa

ROR
https://ror.org/011335j04

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Mútua de Terrassa

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. All the data will be destroyed after the final follow-up of 5 years. The data will be analysed by the main investigator and shared to the statistical department of the hospital. We will not use the initials of the patient in the statistical study to preserve the anonymity. We obtained the consent of all the patients.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		18/11/2020	02/12/2020	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes