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Fusion surgery for bunions gives improvement in pain and function

Submission date
29/01/2025

Recruitment status
No longer recruiting

Registration date
28/04/2025

Overall study status
Completed

Last Edited
04/11/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims:
Hallux valgus (HV) is a painful deformity of the big toe/forefoot, also known as a bunion. There are multiple surgical options for its management, including fusing the joint at the base of the big toe (first metatarsophalangeal joint [MTPJ] arthrodesis). In our institution, this procedure is preferred over corrective osteotomy for patients with severe HV. This study aimed to investigate the outcomes of patients undergoing first MTPJ arthrodesis for HV.

Who can participate?
Patients aged over 16 years undergoing arthrodesis for HV between 2016 and 2021 in NHS Tayside

What does the study involve?
Participants complete questionnaires about their health and function before surgery and at 26, 52 and 104 weeks after surgery.

What are the possible benefits and risks of participating?
The study will identify whether first metatarsophalangeal joint fusion is a safe and effective treatment for hallux valgus.

Where is the study run from?
NHS Tayside (UK)

When is the study starting and how long is it expected to run for?
January 2021 to June 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Miss Rebecca Lewis, rebecca.lewis71@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
First metatarsophalangeal joint arthrodesis for hallux valgus gives satisfactory patient-reported outcomes: a retrospective case series

Study objectives
Arthrodesis for hallux valgus in the absence of radiological evidence of degenerative joint disease results in improvements in patient-reported outcome measures.

Ethics approval required
Ethics approval not required

Ethics approval(s)
Ethical approval was not sought for this study because it was a retrospective evaluation of local clinical practice and, therefore, not deemed to require ethics committee approval. Caldicott permission was sought and granted.

Study design
Single-centre observational case series

Primary study design

Observational

Study type(s)
Efficacy, Treatment

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

Interventions
The researchers will conduct a single-centre case series design with prospectively collected Patient Reported Outcome Measures data and retrospective case note review. Data will be requested from the local Foot and Ankle database. For each patient, the primary pathology of HV will be confirmed using preoperative radiographs and first MTPJ arthrodesis will be confirmed using the operative notes. After confirming these details, all patients who have completed preoperative PROMs and had their operations between January 2016 and July 2021 will be included. Patients will be excluded based on inadequate operative information, in cases where arthrodesis cannot be confirmed, and patients whose primary pathology is degenerative disease, apparent on preoperative radiographs. Some patients will have undergone simultaneous bilateral arthrodesis or additional concurrent procedures involving the first ray or lesser metatarsals; to reflect clinical practice, these patients will be included. Finally, patients will not be excluded because of rheumatoid arthritis if HV is still considered the primary pathology. Instead, patients with rheumatoid and diabetes mellitus will be considered during analysis.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Pain is measured using the Manchester-Oxford foot questionnaire (MOxFQ) and the EQ-5D-5L questionnaire at baseline, 26, 52 and 104 weeks postoperatively
2. Walking-standing ability is measured using the Manchester-Oxford foot questionnaire (MOxFQ) at baseline, 26, 52 and 104 weeks postoperatively
3. Social interaction is measured using the Manchester-Oxford foot questionnaire (MOxFQ) at baseline, 26, 52 and 104 weeks postoperatively
4. Overall health is measured using the EQ-5D-5L visual analogue score (VAS) at baseline, 26, 52 and 104 weeks postoperatively

Key secondary outcome(s))
Complication rates, including non-union, pain, reoperation, infection and delayed wound healing. This data will be collected at the end of the study period.

Completion date
30/06/2022

Eligibility

Key inclusion criteria
1. Aged over 16 years
2. Undergone first MTPJ arthrodesis for hallux valgus between January 2016 and July 2021

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Total final enrolment
62

Key exclusion criteria
Patients with inadequate operative information.

Date of first enrolment
22/01/2016

Date of final enrolment
10/06/2021

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
NHS Tayside
Ninewells Hospital
Dundee
United Kingdom
DD3 8EA

Sponsor information

Organisation
NHS Tayside

ROR
https://ror.org/000ywep40

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to data protection & patient confidentiality.

IPD sharing plan summary
Not expected to be made available