

Fusion surgery for bunions gives improvement in pain and function

Submission date 29/01/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/04/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 04/11/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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

Contact name

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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

ClinicalTrials.gov (NCT)

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