ISRCTN43431378 https://doi.org/10.1186/ISRCTN43431378

Long-term outcomes of keyhole bunion surgery (Minimally Invasive Chevron Akin)

Submission date
02/07/2023

Recruitment status
No longer recruiting

Registration date
13/10/2023

Overall study status
Ongoing

Last Edited
20/06/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Hallux valgus (bunion) is the most common deformity of the forefoot, affecting 23% of 18- to 65-year-olds and 35% of adults over 65 years old. The main symptoms of bunions are hard lumps on the side of the feet near the toes, and the big toe might also point towards the other toes.
Over 100 surgical procedures have been used to treat hallux valgus, broadly classified into open (large incisions 3 - 10 cm) and minimally invasive (small incisions 2 - 5 mm). Minimally invasive surgery for hallux valgus has evolved over three generations since 1986. The third generation (with screw fixation) started in 2008, with one technique being MICA.
MICA (minimally invasive chevron and akin osteotomies) is a surgical technique to correct hallux valgus by using 3-5 mm incisions to allow specialist small instruments (burrs) to create osteotomies (bone cuts). This is in contrast to the large incisions required to accommodate a sagittal saw in open procedures.
This study aims to answer the question: 'Is minimally invasive hallux valgus correction using the MICA technique, safe and effective over the mid and long term?'

Who can participate?
Patients 16 years of age and older who underwent primary minimally invasive bunion correction using the MICA technique (of any deformity severity)

What does the study involve?
Questionnaires will be sent by email and non-responders will be telephoned. Data will be collected at 5 years (then every 2.5 years) and compared to previously collected data (including pre-op and 2-year post-op data). X-rays will be collected at 5 years post-op (then every 5 years) and compared to previously collected data (including pre-op and 6-week post-op data). There will be a drop-in service for radiographs at a local Spire Hospital or The London Clinic.

What are the possible benefits and risks of participating?
By participating in the study, participants will receive access to high-quality healthcare related to their bunion surgery. The study may also identify this emerging technique as improving the effectiveness and safety of minimally invasive bunion surgery, which can benefit future patients. Participants may gain a better understanding of their bunion surgery and the potential risks and benefits associated with it. This can help them make informed decisions about their healthcare

in the future.
This study involves specialized healthcare providers with expertise in minimally invasive bunion surgery. Participants will have access to these specialized providers, who may offer additional support and guidance beyond what is typically available in routine care.
By participating in the study, participants have the opportunity to contribute to scientific knowledge about minimally invasive bunion surgery. The results of the study may help to advance understanding of the safety and effectiveness of this procedure, leading to improvements in patient care in the future.
Participants may experience a sense of personal satisfaction by contributing to medical research that may ultimately benefit patients with similar conditions.
The two x-ray views of the operated foot/feet will involve ionising radiation. This protocol is standardised to minimise exposure to ionising radiation. The use of ionising radiation for foot x-rays can be justified in the context of the study based on its benefits in providing accurate information to evaluate the technique in terms of healing, deformity correction, complications and recurrence. The effective dose is relatively low and the risk of adverse effects is minimal. The benefits of accurate information to evaluate the technique outweigh the potential risks associated with ionising radiation exposure. There is a very small possibility that the x-rays may show a delay in bone healing or a complication (such as loosening or displacement of a screw) which is asymptomatic (e.g. not causing symptoms or pain). If any X-rays or questionnaires demonstrate something that has gone wrong with a patient's treatment or has the potential to cause harm or distress, the Chief Investigator and lead surgeon responsible for the patient's care will be informed so that an open and honest consultation can take place with the patient and/or people in their care.

Where is the study run from?
The London Clinic and Spire Healthcare Hospitals (UK)

When is the study starting and how long is it expected to run for?
July 2022 to July 2042

Who is funding the study?
Apio Implants Ltd (UK)

Who is the main contact?
David Gordon, research@davidgordonortho.com

Contact information

Type(s)
Scientific

Contact name
Dr David Gordon

ORCID ID
https://orcid.org/0000-0003-2188-7766

Contact details
20 Devonshire Place
London
United Kingdom

W1G 6BW
+44 (0)2079932373
research@davidgordonortho.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
326721

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 326721

Study information

Scientific Title
Patient-reported and radiological outcomes of 333 feet following hallux valgus correction using minimally invasive chevron and akin osteotomy after 5 years postoperatively and beyond

Acronym
MICA Long Term Follow Up

Study objectives
After 5 years (and beyond) following surgery for hallux valgus using minimally invasive chevron and akin osteotomy (MICA), patient-reported and radiological outcomes will improve compared with preoperative scores and recurrence rates will be low.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/06/2024, London - Fulham Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8084; fulham.rec@hra.nhs.uk), ref: 23/LO/0881

Study design
Case series/case note review

Primary study design
Observational

Study type(s)
Quality of life, Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied

Hallux valgus (bunions)

Interventions
Minimally invasive surgery for hallux valgus (bunions) using the minimally invasive chevron akin (MICA) technique

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. How foot problems impair health-related quality of life, assessed using the Manchester-Oxford Foot Questionnaire (MOXFQ)
2. Health state for mobility, self-care, usual activities, pain/discomfort and anxiety/depression, assessed using the EuroQol-5 Dimensions-5 Level (EQ-5D-5L) Index
3. Global assessment of health assessed using the EuroQol-visual analogue scale (EQ-VAS)
4. Pain intensity measured using Visual Analogue Score (VAS)for pain (VAS-pain)

Patient-reported outcomes measures will be collected using questionnaires at pre-op, 2 years and 5 yearly

Key secondary outcome(s))
Radiographic measures of the pre-operative deformity and the post-operative correction and its endurance over time will be measured on standing foot X-rays using digital integrated measurement software at pre-op, 6 weeks and 5 yearly. These will include the distal and proximal intermetatarsal angle (degrees), hallux valgus angle (degrees), sesamoid position (grades 0-3), round sing (presence or absence) and percentage of metatarsal head translation (percentage).

Completion date
01/07/2042

Eligibility

Key inclusion criteria
1. Adult >16 years
2. Primary hallux valgus operation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex

All

Key exclusion criteria
Unable to attend for radiographs

Date of first enrolment
01/08/2023

Date of final enrolment
01/08/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The London Clinic
20 Devonshire Place
United Kingdom
W1G 6BW

Study participating centre
Spire Group of Hospitals (head office)
3 Dorset Rise
United Kingdom
EC4Y 8EN

Sponsor information

Organisation
Apio Implants Ltd

Funder(s)

Funder type
Industry

Funder Name
Apio Implants Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from David Gordon (research@davidgordonortho.com). Only anonymised data will be shared. Consent from participants is required and will be obtained.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes