

STUDY PROTOCOL

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The effect of osteotomy technique (flat-cut vs wedge-cut Weil) on pain relief and complication incidence following surgical treatment for metatarsalgia in a private metropolitan clinic: protocol for a randomised controlled trial

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Abstract

Background: Weil osteotomies are performed to surgically treat metatarsalgia, by shortening the metatarsal via either a single distal oblique cut with translation of the metatarsal head (flat-cut) or through the removal of a slice of bone (wedge-cut). The wedge-cut technique purportedly has functional and mechanical advantages over the flat-cut procedure; however, in vivo data and quality of evidence are currently lacking. This study aims to investigate whether wedge-cut Weil osteotomy compared to traditional flat-cut Weil is associated with increased pain relief and fewer complications up to 12 months postoperatively.

Methods: Patient, surgical and clinical data will be collected for 80 consecutive consenting patients electing to undergo surgical treatment of propulsive metatarsalgia in a randomised control trial, embedded within a clinical registry. The primary outcome is patient-reported pain as assessed by the Foot and Ankle Outcome Score (FAOS) - Pain subscale, and the secondary outcome is the incidence of procedure-specific complications at up to 12 months postoperatively. The groups will be randomised using a central computer-based simple randomisation system, with a 1:1 allocation without blocking and allocation concealment. A mixed-effects analysis of covariance will be used to assess the primary outcome, with confounders factored into the model. A binary logistic regression will be used to assess the secondary outcome in a multivariable model containing the same confounders.

Discussion: To the best of the authors' knowledge, the trial will be the first to examine the clinical efficacy of the wedge-cut Weil osteotomy compared to the flat-cut technique with a prospective, randomised control design.

Trial registration: Australian New Zealand Clinical Trials Registry ACTRN12620001251910. Registered on 23 November 2020.

Keywords: Metatarsalgia, Weil osteotomy, Pain, Complication, Surgery

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Administrative information

Note: The numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see <http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/>).

Title {1}	The effect of osteotomy technique (flat-cut vs wedge-cut Weil) on pain relief and complication incidence following surgical treatment for metatarsalgia in a private metropolitan clinic
Trial registration {2a and 2b}	Australian New Zealand Clinical Trials Registry, ACTRN12620001251910. Registered on 23 November 2020.
Protocol version {3}	V1; 2 Oct 2020
Funding {4}	This study is funded in part by a grant from the Australian Orthopaedic Association Research Fund, awarded to Dr Michael Symes (Award Number 594).
Author details {5a}	[1] EBM Analytics [2] Sydney Orthopaedic Trauma and Reconstructive Surgery [3] North Sydney Orthopaedic and Sports Medicine Centre
Name and contact information for the trial sponsor {5b}	Dr Andrew Wines The Mater Clinic Suite 2, 25 Rocklands Road, Wolstonecraft, NSW 2065, Australia
Role of sponsor {5c}	Andrew Wines and Michael Symes are the investigator-sponsors for the trial and will be jointly responsible for its funding and governance.

Introduction

Background and rationale {6a}

Propulsive metatarsalgia is defined as pain under one or more metatarsal heads during the “third rocker” phase (30 to 60%) of the gait cycle, from heel lift-off to the end of propulsion by the great toe [1]. Weil osteotomy is a reliable distal oblique osteotomy procedure performed to treat lesser metatarsal deformities and alleviate metatarsalgia, by shortening the metatarsal in the transverse plane. The osteotomy is performed with or without adjunct procedures for toe correction, which may include proximal interphalangeal arthrodesis [2], fusion/arthrodesis of the first metatarsophalangeal (MTP) joint [3] or hallux valgus correction [4]. While Weil osteotomies are commonly performed, complications include floating toe, joint stiffness, avascular necrosis, transfer of metatarsalgia to subsequent toes and plantar flexion of the metatarsal [1, 5, 6].

Traditional flat-cut Weil osteotomies involve a single distal oblique incision in the dorsal aspect of the

metatarsal head, with translation of the head by 5–10 mm. Wedge-cut osteotomy is a modification of the flat-cut Weil procedure and includes a second incision to remove a slice of bone [1]. A wedge is created either with parallel sides or with an apex on the plantar aspect of the metatarsal, and the procedure is purported to reduce plantar translation of the metatarsal head, maintain the MTP centre of rotation and improve intrinsic muscle function as demonstrated on sawbone models [7]. However, there is limited in vivo data for the clinical efficacy of this technique, and the quality of evidence is lacking [7, 8].

The proposed study has therefore been designed to investigate whether the modified wedge-cut Weil osteotomy compared to the flat-cut technique, with or without required adjunct procedures, is associated with increased pain relief and fewer complications at up to 12 months postoperatively in patients presenting with propulsive metatarsalgia.

Objectives {7}

The primary objective of this study is to determine, in patients electing to undergo surgical intervention for propulsive metatarsalgia, whether wedge-cut osteotomy compared to flat-cut Weil (with or without adjunct procedures) is associated with increased pain relief during activities of daily living up to 12 months postoperatively. The secondary objective of this study is to determine whether a lower incidence of procedure-specific complications (floating toe or stiffness) at up to 12 months of follow-up is associated with the wedge-cut procedure, compared to the flat-cut Weil.

Trial design {8}

The proposed study is designed as a randomised controlled superiority trial with two parallel groups comprising 1:1 allocation.

Methods: participants, interventions and outcomes

Study setting {9}

Patient recruitment and data collection will be performed at the private hospitals and consulting clinics for the participating surgeons (New South Wales, Australia). Recruitment is expected to be complete by April 2023. Patients will be randomly allocated to either intervention using a central computer-based allocation randomisation system prior to surgery. The trial is embedded in a clinical registry with patient, surgical and clinical data captured as part of routine clinical care. Figure 1 outlines the schedule of study activities, and Fig. 2 outlines the study design for the trial described above.

The trial is scheduled to commence in January 2021 and is due to be completed by June 2023. The study

TRIAL	STUDY PERIOD				
	Recruitment	Allocation	Surgery	Post surgery	
Timepoint	-t ₂	-t ₁	0	Up to ~6 weeks	t ₁ =12 months
Enrolment					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
Interventions					
Group A (control intervention)			X		
Group B (experimental intervention)			X		
Assessments					
Patient demographic and clinical data	X				
Intraoperative data			X		
Serious adverse event assessment				X	
FAOS - Pain					X
Complications data					X

Fig. 1 Schedule of enrollment, interventions and assessment for the trial

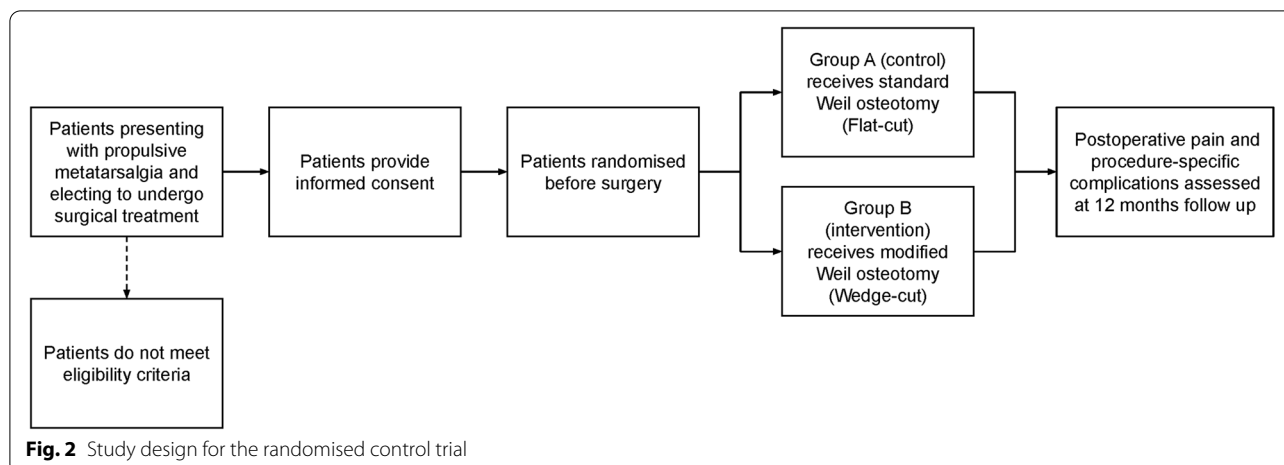
has been registered on an online registry for clinical trials (Australia New Zealand Clinical Trial Registry (ANZCTR)), where the study site and sponsor details are listed (ACTRN12620001251910). The study will be reported as per the CONSORT guidelines [7, 8].

Eligibility criteria {10}

Patients presenting to the participating surgeons for treatment of propulsive metatarsalgia who are over 18

years of age and eligible for surgical intervention (having failed a minimum of six months of conservative interventions) will be eligible for recruitment. Patients will need to be registered in the SOFARI registry and provide additional written informed consent for participation in the present randomised controlled trial.

Patients who have declined or revoked consent for use of clinical data for research (for the SOFARI registry or the current trial) or are unable to provide informed



consent will be excluded. Patients will additionally be excluded if they have had recent (< 6 months) prior surgery to the affected forefoot, if they require additional procedures involving the soft tissues of the foot-ankle complex, have had their surgery booking cancelled with the participating surgeon or have been judged by the participating surgeons as incapable to complete patient reported outcome measures (PROMs) as required for the study due to psychological impairment or insufficient English language capacity (Fig. 3).

Who will take informed consent? {26a}

The participating surgeons will discuss the study with prospective participants and obtain written informed consent prior to the participant undergoing surgery.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

Potential uses of the datasets generated and/or analysed during the trial may include subsequent analysis of sub-groups for investigation of surgical/management and patient-centred outcomes for internal clinic purposes.

The research data may form the basis of potential future studies, including additional research sites within allied health networks or collaborations with other research groups for the biomechanical evaluation of patients. Where appropriate, open-access principles will be followed to enable collaborative works with aligned groups, where the interest is academic and not for commercial uses, under appropriate licencing arrangements of de-identified data. Any future studies requesting the use of this data will seek appropriate amendment of the relevant ethical approval, and further consent will be obtained or waived on application to the HREC, as appropriate.

Interventions

Explanation for the choice of comparators {6b}

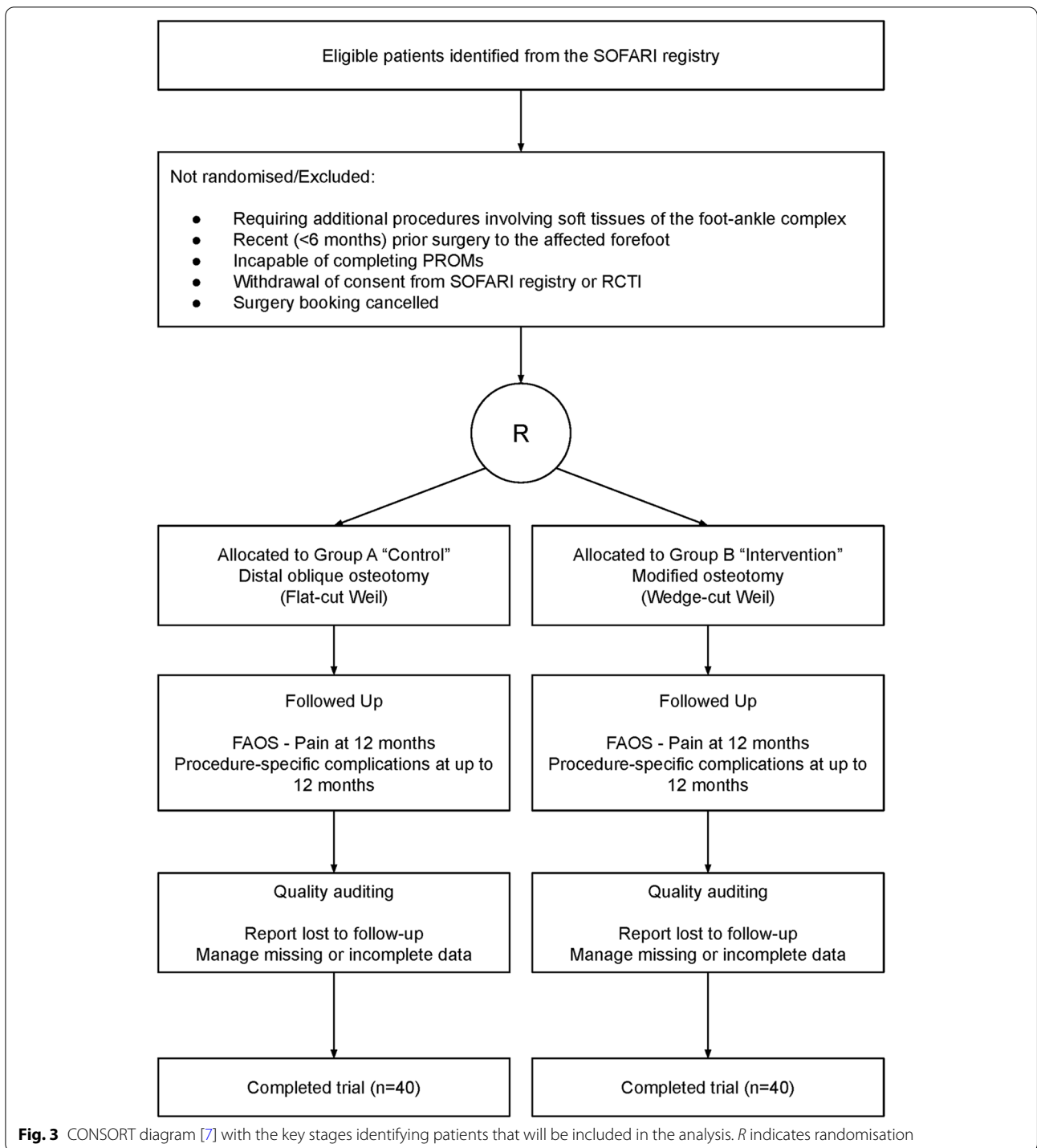
The two interventions are used by the participating surgeons for the surgical management of metatarsalgia.

Intervention description {11a}

Eligible patients will be randomised in equal proportions between those receiving the flat-cut Weil osteotomy (the “control” intervention, group A) and the wedge-cut Weil osteotomy (the “experimental” intervention, group B).

Group A will receive an active control intervention. Preoperative planning will be undertaken to determine the amount of metatarsal shortening required to restore the parabola of the affected metatarsal. The amount of shortening will be determined by recreating the Maestro criteria for metatarsal parabola [9]. At the time of surgery, the patient will be prepared in the standard fashion, placed supine on the operating table with the operated limb prepared and draped to create a sterile area. General intravenous sedation will be administered in addition to prophylactic antibiotics, and an ipsilateral ankle tourniquet is applied and inflated prior to the first incision. A semi-elliptical transverse incision will be used to expose each metatarsophalangeal joint to be operated, spanning between the tendons of the extensor muscles without cutting or lengthening the tendons. Additional care will be taken to avoid release of other soft tissues such as the medial and lateral collateral ligaments.

The metatarsal and phalangeal joint surfaces will be inspected and additional resection performed to remove plantar capsule adhesions where required [10]. The metatarsal bone will be dissected, retracting other soft tissues, including the joint capsule to aid in visualisation and access to the metatarsal neck. A rasp will be used to remove the soft tissue on either side of the



osteotomy location. The dorsal zone of cartilage inferior to the metatarsal head will be identified and used as a landmark for the osteotomy. Neurovascular bundles in the intertarsal space will be retracted and a micro-sagittal motorised saw held parallel to the weight-bearing surface of the foot moved from the dorsal to plantar

cortices of the metatarsal to dissect the head from the neck in preparation for repositioning. The plantar plate will be inspected and repaired as required and the metatarsal head shifted proximally to achieve the desired shortening, avoiding medial or lateral shifting.

The osteotomy will be stabilised with a Kirschner wire placed across the osteotomy (along the metatarsal shaft) to guide screw fixation. Once the screw is fully engaged, the K-wire will be removed. The overhanging bone ledge will be resected with a bone saw or rasp, followed by releasing of the soft tissues under retraction closure of the joint capsule. The remaining soft tissues will be closed in layers and dressed with strips and bandages. The patient will be moved to recovery and discharged as per normal.

The preparation of the patient and surgery site for group B will be as described for group A (the control intervention). The surgical procedure will be modified by adding a second osteotomy proximally to remove a rectangular wedge of bone for the purposes of shortening the metatarsal and repositioning the floating segment of the metatarsal head proximally to the metatarsal neck [11].

Postoperative management for both groups will include elevation of the foot for the initial 72 h after surgery and stitches removed in 10–14 days. Analgesics and antibiotics will be prescribed for the first 14 days after surgery, with weight bearing as tolerated.

Criteria for discontinuing or modifying allocated interventions {11b}

If the participant requests a particular intervention, they will be unenrolled from the trial, and their data will not be included in later analyses.

Strategies to improve adherence to interventions {11c}

Adherence to the randomised intervention allocation will be assessed by comparing the patient osteotomy group allocation as identified in the operation report, to the trial master sheet with the allocation information. Follow-up and PROM compliance will be encouraged through follow-up reminders, as part of the SOFARI registry processes. The primary outcome will be collected electronically, with controls in place to prevent partial completion of the questionnaire.

Relevant concomitant care permitted or prohibited during the trial {11d}

If required, the osteotomies (both control and interventional) are performed with adjunct procedures for toe correction, based on the individual case and patient's anatomy:

- Proximal interphalangeal arthrodesis, which involves the longitudinal insertion of a Kirschner wire or pin to fuse the most proximal joint of the lesser toe [2]
- Fusion/arthrodesis of the first MTP joint, which involves the longitudinal insertion of a Kirschner

wire or pin to fuse the most proximal joint of the first ray [3]

- Hallux valgus correction, which is a correcting osteotomy performed to realign the first ray in the presence of first tarsometatarsal joint hypermobility [4]

No specific postoperative prohibitions above the standard of care will be communicated to participants during the trial.

Provisions for post-trial care {30}

Patients enrolled in the study are covered by indemnity for negligent harm through standard medical indemnity insurance. The intervention is routine and well-practised, and the insurance covers non-negligent harm associated with the protocol. This includes cover for additional health care and compensation or damages, whether awarded voluntarily or by claims pursued through the courts. Incidences judged to arise from negligence (including those due to major protocol violations) will not be covered by study insurance policies.

Outcomes {12}

Primary outcome measures

The primary outcome of this trial will be the Foot and Ankle Outcome Score (FAOS) - Pain subscale, collected at up to 12 monthly postoperatively. The FAOS was developed as a foot and ankle-specific PROM assessment analogous to the Knee injury and Osteoarthritis Outcome Score (KOOS), with content validity confirmed with 213 patients with ankle instability [12]. The FAOS consists of 5 subscales: pain, other symptoms, function in daily living (ADL), function in sport and recreation (Sport(Rec)), and foot- and ankle-related quality of life (QOL). Patients rate the questions on a 5-point Likert scale, with 0 representing no symptoms/problems and 4 representing extreme symptoms. The FAOS has been used in patients with lateral ankle instability, Achilles tendonitis and plantar fasciitis, with reliability confirmed in instability patients [12] and responsiveness confirmed in patients with Achilles tendinosis [13] and hallux rigidus [14]. Given the interventions performed in this trial are to treat metatarsalgia, a condition characterised by pain during weight-bearing activity, particularly noticeable during the push-off phase of the gait cycle, the pain subscale of the FAOS Questionnaire was selected as the most clinically relevant patient-reported measure for the purposes of measuring the primary outcome of this trial. One study reported an MCID of 15.3 points (95% confidence interval 10–20.6) [15], with a difference between groups equal to half this (7.7) deemed sufficient to guide

future decision-making with respect to technique selection. For analysis purposes, a mixed-effects model will be used, which will aggregate scores from all responders and report mean and standard deviation (SD) associated with different combinations of model predictors, such as intervention group, sex and adjunct procedures.

Secondary outcome measures

The secondary outcome of this trial will be the incidence of procedure-specific complications at up to 12 months postoperatively. The most commonly reported complication of the Weil osteotomy is a floating toe, with an overall occurrence of 36% [6]. A floating toe is defined as a toe that is not in contact with the floor under weight-bearing conditions [16]. It will be recorded using a weight-bearing coronal view static photograph and manually rated. Recurrence is reported in 15% of the cases, followed by transfer metatarsalgia (7%) and delayed union, non-union and malunion collectively reported in 3% of the cases [6]. Metatarsal osteotomy union will be defined using cortical continuity [17], with patients failing to show any healing (nonunion) and insufficient cortical continuity (delayed) by the 12-month review, identified in the trial data.

Participant timeline {13}

The time schedule for participant recruitment, interventions and assessment in this trial will follow the standard clinical pathway embedded within the SOFARI registry (Fig. 3). The recruitment, allocation, surgery and 12 months follow-up time points relevant to the current trial are described in Fig. 1.

Sample size {14}

The sample size required for the primary outcome was established to provide adequate power to detect half an MCID difference (15.3/2) in the FAOS Pain score between the control flat-cut Weil and experimental wedge-cut groups, with an average estimated baseline standard deviation of 20.8. The MCID and baseline SD were derived from a previous study [15], and 0.5MCID was determined to be a clinically important effect that would influence future clinical decision-making regarding technique selection. A mixed-effects model (analysis of covariance (ANCOVA)) was selected as the most appropriate to answer the question posed, with power (β) at 0.9 and α of 0.05, with an allowance for a dropout rate of 10%. The required sample size was determined using GPower [18] to be $N = 80$ patients, with patient age at surgery, sex, body mass index, single/multiple procedures and adjunct procedures included as model covariates.

The sample size required for the secondary outcome was established to provide adequate power to detect a 15% reduction in complication incidence from a baseline

of 60% incidence. The reduction in incidence was deemed to be the minimal amount of improvement that would influence future decision-making regarding technique selection in this patient population. A one-sided test within a logistic regression model was selected within GPower, with the R^2 for other predictors in the model (patient age at surgery, sex, body mass index, single/multiple procedures and adjunct procedures) set to 0.1. The required sample size was determined to be $N = 123$ procedures.

Recruitment {15}

The principal investigator for the study performed a total of 127 Weil osteotomies in 87 patients over the 12 months preceding the study. To meet the required sample size of $N = 80$ patients with $N = 123$ procedures to assess the primary and secondary outcomes, respectively, the expected recruitment period will extend over 12 months. All prospective patients eligible for recruitment will be approached to participate in the study.

Assignment of interventions: allocation

Sequence generation {16a}

Participants will be randomly assigned to receive either a flat-cut Weil osteotomy (control, group A) or wedge-cut osteotomy (experimental, group B) procedure using a central computer-based simple randomisation system, with a 1:1 allocation without blocking. The random allocation sequence will be embedded within the clinical registry via a randomisation algorithm (Matlab 2018b, Mathworks Inc., USA). The allocation will be communicated electronically to the treating surgeon via an allocation code comprising nondescript terminology, whereby the allocation cannot be inferred from the label to other study personnel.

Concealment mechanism {16b}

The system will not release the allocation code to the treating surgeon until the patient has been recruited into the trial (on the day of scheduled surgery) to maintain allocation concealment.

Implementation {16c}

The senior data engineer will be responsible for generating the allocation sequence and assigning interventions.

Assignment of interventions: blinding

Who will be blinded {17a}

Blinding is not feasible for the treating surgeon or the senior data engineer responsible for coding the randomisation sequence, who will have access to the allocation code and allocation code key. The senior data engineer

will not have further involvement in the study beyond the allocation and data coding.

Trial participants will be blinded to the intervention assignment and will be counselled at the time of recruitment regarding both surgical techniques, supplementing the information provided on the participant information sheet and consent form (PISCF). Surgical assistants, practice staff, clinical outcome assessors members of the research team and study statisticians involved in the data analysis will be blinded to the allocation, with access to only the allocation code which will comprise a label where grouping is not able to be inferred.

Postoperative clinical evaluations and assessment of serious adverse events will be conducted by a surgical fellow that is hosted within the clinic on a rotating basis for 6 months. In cases where the surgical fellow assisting with surgery also performs the postoperative evaluation, masking will occur through access to only the allocation coding described above. While the treatment evaluator will have access to postoperative radiographs of the operated structures within the foot, it is expected the intervention allocation cannot be derived from these images. Patients returning for evaluation at the 12-month follow-up will be assessed by a fellow not involved in the surgery.

Procedure for unblinding if needed {17b}

In situations where an adverse event or complication has occurred such that reoperation or other invasive intervention is deemed necessary, it may be necessary to unmask the intervention allocation to plan appropriate treatment. Requests to unmask will be made electronically via the treating surgeon and logged within the study masterlist. Requests will be managed by the senior engineer with access to the allocation key.

Data collection and management

Plans for assessment and collection of outcomes {18a}

Patient personal and medical data is routinely collected and stored in the participating surgeons' practice management systems (Bluechip, MedicalDirector, Australia and Genie, Genie Solutions, Australia). Patient demographic data, comorbidities and full patient history relating to the history and onset of the foot and ankle condition will be recorded in the practice management system during patient consultation. Radiological reports collected routinely as part of diagnosis, surgical planning and postoperative follow-up, full description of diagnosis, mode of treatment and details of nonoperative and surgical interventions, and timing of treatments will also be recorded in the practice management system during patient

consultation. Intraoperative data, patient-reported outcomes data and findings from clinical examination will be electronically entered into the SOFARI registry via web-based forms (Google Suite, Google, USA) by the clinical research nurse, research team, surgeon or the patient.

Intraoperative (surgical technique), patient-reported (FAOS-Pain) and clinical outcome (complications) data collected during this trial will additionally be linked to the SOFARI registry via the same modes of data entry. Data collection will continue until the minimum sample size requirements for the study are met with complete records established.

Plans to promote participant retention and complete follow-up {18b}

Once a participant is enrolled in the study, they will be contacted at 3, 6 and 12 months postoperatively for PROMs follow-up data collection as per the existing SOFARI registry procedures. The routine contact will facilitate participant retention up until the 12-month follow-up. Follow-up reminders will be administered from the clinic, and the electronic questionnaires can be completed remotely at the patient's convenience. There is an additional opportunity to collect PROM data when the patient visits the clinic for their 12-month follow-up, if they have not completed the electronic forms.

In cases where the intervention protocol is not followed, the participant will be removed from the trial and the randomisation slot filled by the next participant recruited into the trial.

Data management {19}

Data sources Patient personal and medical data is routinely collected at the consulting clinics and entered into the practice management systems (Bluechip, MedicalDirector, Australia and Genie, Genie Solutions, Australia). The data is collated with PROMs and organised into the Sydney Orthopaedic Foot and Ankle Research Institute (SOFARI) Registry established within the surgeon's practice (ACTRN12620000331932), and will form the primary source for patient, clinical, intraoperative and postoperative data for the current trial. Ethical approval for use of the practice registry for research was provided by the New South Wales/Victoria branch of the Ramsay Health Care HREC (HREC approval number 2020-007). Registry data is hosted in a secure, HIPAA-compliant cloud-based database (Google Suite, Google, USA).

Data entry All data collected in this trial will be entered electronically via web-based forms (Google Suite, Google, USA) by either the investigators, research team or participants. The research team will be responsible for the organisation of the data within a HIPAA-compliant database environment (Google Suite, Google, USA) and performing quality assurance checks on the consolidated dataset.

Clinic data management Identifiable data (collected only as necessary for treatment and management of the health services) will be stored permanently on the practice management software, as is standard clinical practice. The data will be stored on a secure server within the consulting rooms, with restricted access.

Data linkage processes Identifiable personal and medical information collected from patients will be stored and kept indefinitely within the database to link patient records to patient information from other sources (e.g. electronic medical records within the practice management systems, clinic notes or radiology records). The research team will access the practice management software in order to conduct quality assurance audits which will involve access to identifiable data, within the environment of the password-protected server.

Web-based forms will be provided to patients to capture validated PROMs using identifiers to link the form responses to the rest of the registry dataset. No identifiable information (name, date of birth, address, contact information) will be included or requested of patients in the forms. Standard operating procedures for data entry will be available to individuals who will require access to the database via a web browser interface to streamline and control data-entry processes. All members with access to the data will have signed a non-disclosure agreement.

Access to the trial data will be password protected. Data will be stored in a HIPAA-compliant environment (Google Suite, Google, USA) prior to further processing locally by the research team. The research team will retain access to the data for the duration of the trial. At the termination of the trial, any study-relevant data will be transferred to the clinic servers and deleted from the research team's environment. The data gathered will be retained on the existing password-protected servers of the clinic for future reference, publications and potential future studies.

Supplementary information within clinical notes in external databases, such as those at the hospitals where the treatment or surgery is performed or radiology services, will not be integrated directly with the study database. This data will be requested from these systems on an as-needed basis by the surgeons or practice managers, matching patients by name, date of birth and treatment and will be manually transcribed into the practice management system and subsequently into the database.

Confidentiality {27}

Confidentiality and privacy of patient information in the trial will be protected through the execution of nondisclosure agreements between all involved parties, prohibiting them from sharing identifiable information externally.

Identifiable trial data is kept electronically on a secure server at the study clinic sites, and de-identified study data will be stored in a secure, HIPAA-compliant online database with access restricted to individual staff members responsible for handling the data.

No identifiable data from the study will be externally shared without consent from the patients. All identifying information such as name, date of birth, email or phone will be removed from any data prior to the transfer of this data to sites not listed in the document. Patient identification numbers will be used as a substitute for identifiable data, and only the investigators will be able to re-identify patients. Patients will not be identified in any publication or presentation resulting from the trial.

All investigators will have unrestricted access to the cleaned data sets. Study data sets will be housed and secured as per the data management procedures outlined in this protocol.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Not applicable; no biological specimens will be collected during this study.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

Principles

An analyst blinded to treatment allocation will perform the primary and secondary analyses, by comparing the intervention group to the control group. Data will be analysed following intention-to-treat principles (i.e. participants will be analysed in the group to which they were

randomised to). Data normality of baseline characteristics and process measures will be evaluated by visual inspection of histograms. Continuous variables will be presented as means and standard deviations for normally distributed variables; median, minimum, maximum and interquartile range for non-normally distributed variables. Frequencies and percentages will be used to summarise categorical variables. Percentages will be calculated using the number of participants for whom data are available as the denominator. Alpha will be set at 0.05 and effect sizes as described in the sample size calculation will be considered of interest.

Data integrity

All data points for the study core dataset will be retrieved electronically, so comparing to original paper records will not be necessary. Data integrity will be defined in the context of this study as completeness, consistency and validity. An error rate of < 3% will be considered acceptable across the total of fields assessed.

Patients who are otherwise lost to follow-up will be included in the analysis under an intention-to-treat framework. Where appropriate, imputation will be used to provide estimates of outcomes for patients lost to

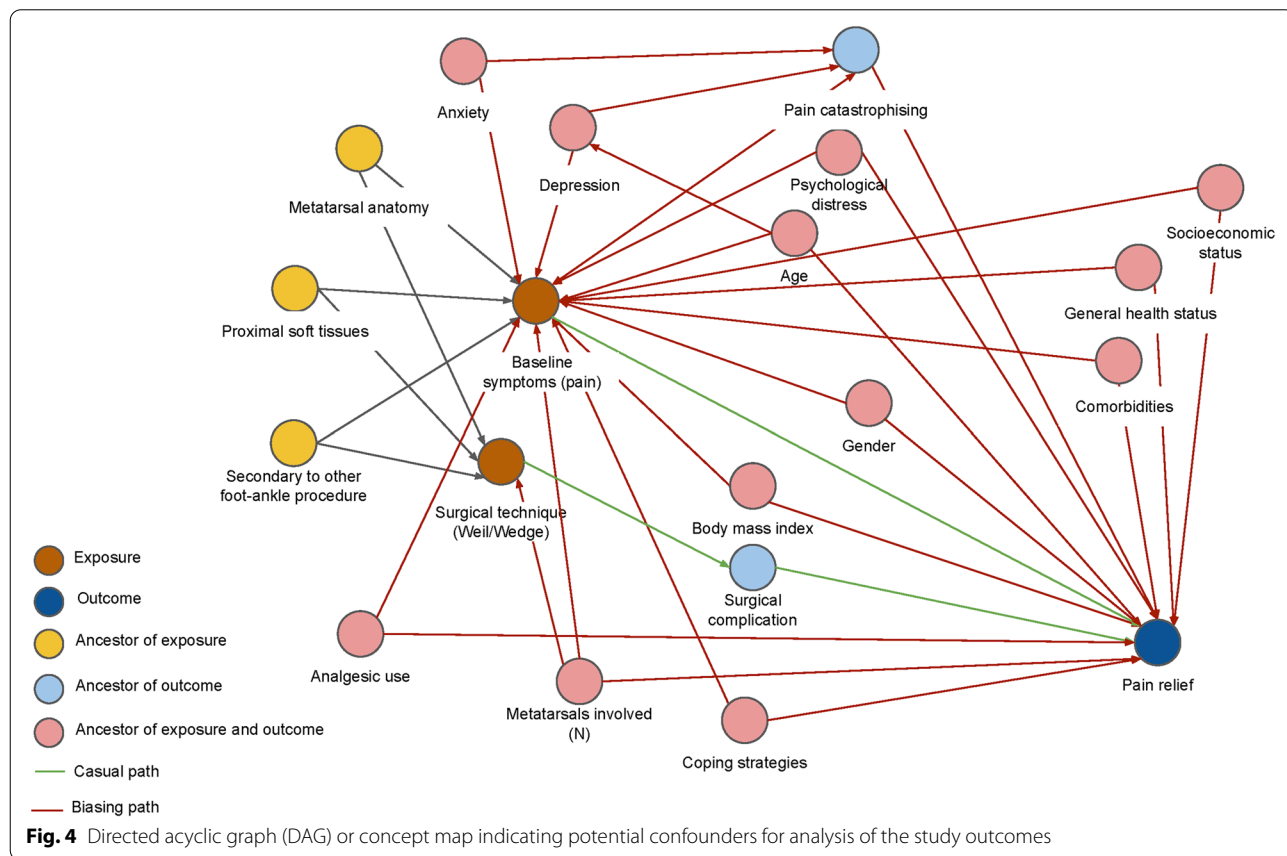
follow-up. To mitigate the effects of loss to follow-up on the analysis, the sample size factored in an estimated dropout rate of 10% to ensure adequate power for analyses requiring listwise deletion of missing data.

Evaluation of demographics and baseline characteristics

Baseline characteristics will be presented in a table stratified by treatment group. Hypothesis testing of baseline characteristics between the groups will not be performed in accordance with the recommendations of the CONSORT statement [7]. Figure 4 describes the prognostic factors which will be treated as potential confounders of the effect of the intervention and included in the models used to analyse primary and secondary outcomes. These confounders were selected based on the available literature on pain ratings in metatarsalgia [19–23].

Primary outcome analysis

The primary outcome of the trial is postoperative pain at 12 months follow-up represented by the pain subscale of the FAOS. A mixed-effects ANCOVA will be used to test for differences between the groups with the following factors and covariates included in the model:



- Patient ID (random factors)
- Baseline FAOS pain subscore (covariate)
- Age at surgery (covariate)
- Sex (covariate)
- Multiple procedures
- Adjunct procedures

The overall model fit will be assessed with partial η^2 and coefficients (β) with 95% confidence limits will describe the strength and direction of relationships between factors and the postoperative FAOS-Pain score. Post hoc comparisons with Dunnett tests (against control) will be used to compare osteotomy groups. Cohen's d will be used to report the effect size of differences between the groups. A Cohen's d exceeding 0.36 will be deemed clinically significant.

Secondary outcome analysis

The secondary outcome of the trial will be the incidence of procedure-specific complications by the end of the follow-up period (12 months). A binary logistic regression will be used to assess the effect of intervention allocation on complications incidence in a multivariable model containing confounders described above. Alpha will be set at 0.05 and partial η^2 used to assess model fit. Odds ratios with 95% confidence limits will describe the strength and direction of relationships between model predictors and the probability of having a complication compared to not having one.

Interim analyses {21b}

No interim analysis has been planned that would lead to early termination based on the results of the study. The study will be monitored for adverse events on a continual basis and reported regularly to the investigators, and an unacceptably high incidence in either treatment group (50% greater than reported in the equivalent literature) may be reviewed by the investigators and cause the trial to be terminated.

Methods for additional analyses (e.g. subgroup analyses) {20b}

Depending on the overall incidence of procedure-specific complications (assuming that the incidence is > 5% overall) a Cox regression will be employed to compare the groups for time to event (complication detected) between day 1 postoperatively to 12-month evaluation with right censoring for participants that complete the study follow-up with no complications reported. Hazard ratios with 95% confidence intervals will be used to describe the strength and direction of the relationship between intervention allocation and time to event.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

The nature of the dataset does not lend itself to multiple imputation in the first instance. If patients have not returned the form at follow-up, despite multiple reminders, a multiple imputation approach will be employed based on published guidelines for analysis of trial data [24]. Secondary outcomes are unlikely to have missing data due to the nature of clinical follow-up and the acute nature of procedure-specific complications (i.e. all patients are reviewed in person or by phone within the timeframe that complications would be observed). In the event that missing secondary outcomes are apparent, analyses will be performed to assess the *randomness* of the missing data and to determine whether complete case analysis is appropriate. In the event that the missing data does not conform to a random pattern, sensitivity analysis using worst-case, best-case scenarios for missing data will be constructed and reported [24].

Plans to give access to the full protocol, participant-level data and statistical code {31c}

There are no restrictions in the public dissemination of results within the current scope of this protocol. The results will primarily be communicated via peer-reviewed publications and abstracts. Planned publications include a manuscript summarising findings from the trial to be published at the conclusion of the study. Patients will not be identified in any publication or presentation that will be published as a result of the trial. Patients are able to request the results of the trial and any resulting publications by contacting the clinic.

The results from the study may also be informally shared by the investigators with peer networks in internal meetings, and be made available upon request to the ethics board and other health/regulatory authorities.

Supplementing this protocol manuscript, the statistical code used in the trial will be uploaded to GitHub (GitHub Inc, USA) to enable peer review where appropriate. The deidentified study dataset will be made available upon request, keeping in line with open access principles to enable collaboration, where the interest is academic and not for commercial uses. Only deidentified data will be shared if required, under the appropriate licencing arrangements.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

A governance and steering committee with the principal investigators and the research team will maintain the governance of the trial. This committee will meet on a quarterly basis to discuss trial progress.

Composition of the data monitoring committee, its role and reporting structure {21a}

The scope of the proposed protocol does not warrant a data monitoring committee due to the nature of the interventions and the outcomes selected for comparison between groups.

Adverse event reporting and harms {22}

An adverse event is defined as any deviation from the normal recovery trajectory requiring alteration to the patient's care or medical intervention. Adverse events will be collected after the subject has provided consent and enrolled in the trial. A serious adverse event (SAE) for this study is any untoward medical occurrence within the follow-up period of the study and results in any of the following: life-threatening condition, severe or permanent disability, prolonged hospitalisation or a significant hazard. Investigators will determine the relatedness of an event to the trial based on a temporal relationship to the intervention, as well as whether the event is unexpected or unexplained given the subject's clinical course, previous medical conditions and concomitant medications. A separate form will be set up for adverse reporting, to be completed by the evaluator or the trial monitoring team based on updated clinical notes for the patient within the practice management system and electronically linked to the study database.

Frequency and plans for auditing trial conduct {23}

Quality assurance of the trial will be maintained through auditing and reporting of data completeness, consistency and validity: completeness (all data fields required are filled in) will be monitored in real time and compared to the requirements outlined in the core dataset; consistency (data responses match the rules specified within the core dataset) will be examined by assessing continuous variables for outliers and categorical variables for consistency with pre-specified responses within the core dataset; validity (data is accurate and correct) will be assessed in a subsample of patients (10%) by spot-checking the information held in the study masterlist relative to the original source in the practice management system. Discrepancies will be investigated and rectified (where possible) by practice staff or the research team. Audit reporting will be provided to the registry steering committee and communicated to the principal investigators on a quarterly basis.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

Ethics approval for this study was provided through the NSW/VIC branch of the Ramsay Health Care Human

Research Ethics Committee (HREC approval number 2020-007). Any modifications to the protocol which may impact the conduct of the study, patient safety or significant administrative aspects (e.g. changes to study sponsorship) will require a formal amendment to the protocol. Such amendments will be agreed upon by the investigators and approved by the NSW/VIC Ramsay Health HREC prior to implementation. Modifications will also be reflected in the public trial registry record on the ANZCTR.

Dissemination plans {31a}

Trial results There are no restrictions in the public dissemination of results within the current scope of this protocol. The results will primarily be communicated via peer-reviewed publications and abstracts. Planned publications include a manuscript summarising findings from the trial to be published at the conclusion of the study. Patients will not be identified in any publication or presentation that will be published as a result of the trial. Patients are able to request the results of the trial and any resulting publications by contacting the clinic.

The results from the study may also be informally shared by the investigators with peer networks in internal meetings, and be made available upon request to the ethics board and other health/regulatory authorities.

Authorship For any resulting publications, authorship eligibility for anyone involved in the study design, management and conduct of the trial will be determined in accordance with the International Committee of Medical Journal Editors (ICMJE) authorship guidelines [25]. Anyone not meeting the requirements for authorship (minimum 10% contribution) will be listed in the acknowledgements section of the manuscript.

Discussion

The trial will provide clinical data pertaining to the efficacy of the modified wedge-cut Weil osteotomy procedure compared to the traditional flat-cut method. Flat-cut Weil osteotomy is a routinely performed procedure with complications frequently reported [1, 5, 6]. The wedge-cut modification purportedly has functional and mechanical advantages over the flat-cut technique; however, in vivo data and quality of evidence are currently lacking [11, 26].

A previous study reported satisfactory performance on the American Orthopaedic Foot and Ankle Society (AOFAS) forefoot score (with 65% of patients

reporting no pain and 23% reporting mild pain), but higher than expected complication rates for transfer metatarsalgia, floating toes, infection and wound healing complications in patients receiving segmental resection (wedge-cut) osteotomies [11, 26]. The study, however, was a retrospective case series, lacking baseline data and with a short (minimum 6 months) follow-up. To the best of the authors' knowledge, the current trial will be the first to directly examine the clinical efficacy of the wedge-cut Weil osteotomy within a randomised control design.

Quality assurance of the trial will be maintained through regular auditing and reporting on data completeness, consistency and validity. The trial has been designed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 guidelines, in order to enhance transparency and facilitate appraisal of its scientific merit, ethical considerations, and safety aspects [27].

Trial status

Protocol version: 1

Date: 02 October 2020

Recruitment start date: 12 April 2021

Anticipated recruitment end date: 12 April 2023

Abbreviations

FAOS: Foot and Ankle Outcome Score; ANZCTR: Australian New Zealand Clinical Trials Registry; ACTRN: Australian New Zealand Clinical Trials Registry Number; MTP: Metatarsophalangeal; CONSORT: Consolidated Standards of Reporting Trials; PROMs: Patient-reported outcome measures; SOFARI: Sydney Orthopaedic Foot and Ankle Research Institute registry; HREC: Human Research Ethics Committee; HIPAA: Health Insurance Portability and Accountability Act of 1996; KOOS: Knee injury and Osteoarthritis Outcome Score; ADL: Activities of daily living; QOL: Quality of life; MCID: Minimum clinically important difference; SD: Standard deviation; ANCOVA: Analysis of covariance; PISCF: Participant information statement and consent form; USA: United States of America; DAG: Directed acyclic graph; NSW: New South Wales, Australia; VIC: Victoria, Australia; ICMJE: International Committee of Medical Journal Editors; AOFAS: American Orthopaedic Foot and Ankle Society; SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials.

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13063-022-06591-4>.

Additional file 1. Participant Information Sheet and Consent Form.

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Authors' contributions (31b)

AW, MS and CS contributed to the conceptualisation of the study. CS, MF and NE contributed to the design of the study. MF and CS contributed to the drafting of the study protocol, with critical feedback provided by NE and clinical guidance provided by MS and AW. AW sponsored the study. All authors read and approved the final manuscript.

Funding (4)

This study is partly funded by an early career researcher grant awarded to Michael Symes by the Australian Orthopaedic Association Research Foundation (AOARF, grant number 594). The AOARF has no involvement in the design, conduct or reporting of the trial. The investigator-sponsors have been jointly responsible for funding the remainder of the trial.

Availability of data and materials (29)

De-identified data analysed during the current study and statistical code are available from the corresponding author on reasonable request, as is the full protocol.

Declarations

Ethics approval and consent to participate (24)

Ethics approval for this study was provided through the NSW/VIC branch of the Ramsay Health Care Human Research Ethics Committee (HREC approval number 2020-007). All participants will provide informed consent to participate in the trial.

Consent for publication (32)

Not applicable.

Competing interests (28)

AW declares institutional funding and fellowship payments from Zimmer Biomet and DePuy Synthes, for facilitating teaching workshops. AW and MS have employed EBM Analytics to assist with the trial conduct and management. CS is a shareholder and paid employee of EBM Analytics and in the last 3 years has received institutional payments from Exactech Inc., Stryker South Pacific, Headsafe Pty Ltd. and Naviswiss AG for work unrelated to this clinical trial or the primary investigators. CS is a past associate editor for the *Journal of Orthopaedic Surgery and Research*. MF and NE are paid employees of EBM Analytics.

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References

- Besse J-L. Metatarsalgia. *Orthop Traumatol Surg Res.* 2017;103:S29–39.
- Jay RM, Scot Malay D, Landsman AS, Jennato N, Huish J, Younger M. Dual-component intramedullary implant versus Kirschner wire for proximal interphalangeal joint fusion: a randomized controlled clinical trial. *J Foot Ankle Surg.* 2016;55:697–708.
- Donegan RJ, Blume PA. Functional results and patient satisfaction of first metatarsophalangeal joint arthrodesis using dual crossed screw fixation. *J Foot Ankle Surg.* 2017;56:291–7.
- Bia A, Guerra-Pinto F, Pereira BS, Corte-Real N, Oliva XM. Percutaneous osteotomies in hallux valgus: a systematic review. *J Foot Ankle Surg.* 2018;57:123–30.
- Lunz D, Cadden A, Negrine J, Walsh W. The Weil osteotomy: indications, surgical technique and fixation. *Orthop Proc.* 2010;92-B(Suppl 1):179.
- Highlander P, VonHerbulis E, Gonzalez A, Britt J, Buchman J. Complications of the Weil osteotomy. *Foot Ankle Spec.* 2011;4:165–70.
- Schulz KF, Altman DG, Moher D, CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMC Med.* 2010;340:c332.
- Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ.* 2010;340:c869.

9. Pascual Huerta J, Arcas Lorente C, García Carmona FJ. The Weil osteotomy: a comprehensive review. *Rev Española Podol.* 2017;28:e38–51.
10. DeCarbo WT, Dial D. The Weil osteotomy: a refresher. *Tech Foot Ankle Surg.* 2014;13:191.
11. Melamed EA, Schon LC, Myerson MS, Parks BG. Two modifications of the Weil osteotomy: analysis on sawbone models. *Foot Ankle Int.* 2002;23:400–5.
12. Roos EM, Brandsson S, Karlsson J. Validation of the foot and ankle outcome score for ankle ligament reconstruction. *Foot Ankle Int.* 2001;22:788–94.
13. Roos EM, Engström M, Lagerquist A, Söderberg B. Clinical improvement after 6 weeks of eccentric exercise in patients with mid-portion Achilles tendinopathy -- a randomized trial with 1-year follow-up. *Scand J Med Sci Sports.* 2004;14:286–95.
14. Hogan MV, Mani SB, Chan JY, Do H, Deland JT, Ellis SJ. Validation of the Foot and Ankle Outcome Score for hallux rigidus. *HSS J.* 2016;12:44–50.
15. Sierveelt IN, van Eekeren ICM, Haverkamp D, Reilingh ML, Terwee CB, Kerkhoffs GMMJ. Evaluation of the Dutch version of the Foot and Ankle Outcome Score (FAOS): responsiveness and minimally important change. *Knee Surg Sports Traumatol Arthrosc.* 2016;24:1339–47.
16. Miguez A, Slullitel G, Bilbao F, Carrasco M, Solari G. Floating-toe deformity as a complication of the Weil osteotomy. *Foot Ankle Int.* 2004;25:609–13.
17. DeSandis B, Ellis SJ, Levitsky M, O'Malley Q, Konin G, O'Malley MJ. Rate of union after segmental midshaft shortening osteotomy of the lesser metatarsals. *Foot Ankle Int.* 2015;36:1190–5.
18. Faul F, Erdfelder E, Lang A-G, Buchner A. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods.* 2007;39:175–91.
19. Khan RS, Ahmed K, Blakeway E, et al. Catastrophizing: a predictive factor for postoperative pain. *Am J Surg.* 2011;201:122–31.
20. Chou LB, Wagner D, Witten DM, Martinez-Diaz GJ, Brook NS, Toussaint M, et al. Postoperative pain following foot and ankle surgery: a prospective study. *Foot Ankle Int.* 2008;29:1063–8.
21. Lopez V, Slullitel G. Metatarsalgia: assessment algorithm and decision making. *Foot Ankle Clin.* 2019;24:561–9.
22. Park SJ, Lee R, Yoon DM, Yoon KB, Kim K, Kim SH. Factors associated with increased risk for pain catastrophizing in patients with chronic neck pain: a retrospective cross-sectional study. *Medicine.* 2016;95:e4698.
23. Hurn SE, Vicenzino BT, Smith MD. Correlates of foot pain severity in adults with hallux valgus: a cross-sectional study. *J Foot Ankle Res.* 2014;7:32.
24. Jakobsen JC, Gluud C, Wetterslev J, Winkel P. When and how should multiple imputation be used for handling missing data in randomised clinical trials - a practical guide with flowcharts. *BMC Med Res Methodol.* 2017;17:162.
25. ICMJE (2019) Defining the role of authors and contributors roles and responsibilities; in Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. <http://www.icmje.org/icmje-recommendations.pdf>. Accessed 10 Mar 2020
26. Garg R, Thordarson DB, Schrupf M, Castaneda D. Sliding oblique versus segmental resection osteotomies for lesser metatarsophalangeal joint pathology. *Foot Ankle Int.* 2008;29:1009–14.
27. Chan A-W, Tetzlaff JM, Gøtzsche PC, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ.* 2013;346:e7586.

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