Randomised Controlled Trial for investigation of the timing to allow weight bearing walking after soft tissue hallux valgus correction

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Abstract
Many patients with Hallux Valgus feel that the restriction of weight bearing immediately after surgery an obstacle to their activities of daily living and one of the chief determining factors to undergo surgery or not. There has been no trial to investigate the optimal timing to allow weight bearing walking after distal soft tissue reconstruction for hallux valgus. The objective of the randomized controlled trial is to investigate whether early partial weight bearing will improve the outcomes of patients undergoing Endoscopic Assisted Distal Soft Tissue Procedure (EDSTP).

This is an open-label randomized controlled trial. Fifty adult (>18 yrs) patients who undergo hallux valgus by the EDSTP will be recruited and randomly assigned to trial group and control group. Subjects in the control group follow the existing rehabilitation protocol of non-weight bearing walking for 6 weeks followed by heel walking for 6 weeks, followed by the resumption of normal full weight-bearing walking in normal shoes at 12 weeks post-operation. Subjects in the trial group begin heel walking when the bulky dressing and sutures are removed at 2 weeks post-operation and resume full weight bearing walking in normal shoes at 12 weeks post-operation. The primary outcome is radiological changes including hallux valgus angle (HVA), intermetatarsal angle (IMA), and tibial sesamoid position by weight bearing feet X-Rays at 12, 18, and 26 weeks post-surgery. Other outcomes include pain, range of motion, and foot function.

Introduction
Although Hallux Valgus is a common problem presenting to the foot and ankle surgeon, many aspects of this disease entity are still poorly understood. Surgical procedures are plenty, and can be very broadly classified into those that correct the deformity via soft tissue reconstruction and those that correct through osteotomies. There is currently no gold standard surgical procedure that is proven to be the most superior and lots of exciting research is being undertaken globally. The commonest distal soft tissue procedure is the Mcbride operation where the tight lateral tissues such as the adductor hallucis and lateral capsule are released while the lax medial capsule is plicated and a bunionectomy is performed. Upon this theoretical background, multiple modifications of the original procedure have been proposed, from double skin incisions to endoscopic variants.

Many patients feel that the restriction of weight bearing immediately after surgery an obstacle to their activities of daily living (ADL) and one of the chief determining factors to undergo surgery or not. Rehabilitation plans vary even amongst pure distal soft-tissue procedures, with some units allowing immediate post-operative weight bearing, while others having a 12-week

period of post-operative non-weight bearing walking. Not critical evidence is available to account for the discrepancies but a prolonged period of non-weight bearing is usually employed in the fear that the construct will fail and early recurrence will occur if stressed too early.

To the best of our knowledge, there has been no trial to investigate the optimal timing to allow weight bearing walking after distal soft tissue reconstruction for hallux valgus. This article will investigate if early weight bearing will affect the outcomes for patients whom have underwent Endoscopic Assisted Distal Soft Tissue Procedure (EDSTP). This procedure is chosen because the it is a minimally invasive modification of the Mcbride procedure and has one of the longest publishing track records. It is the default procedure of choice in the investigators' institution; with the current post-operative protocol requiring the patient to undergo a 6-week period of non-weight bearing walking before initiating heel walking at 6 weeks.

Hypothesis and study objectives

The objective of the randomized controlled trial is to investigate whether early partial weight bearing will improve the outcomes of patients undergoing EDSTP.

We hypothesize that compared with standard 6-week non-weight bearing, early partial weight bearing walking at 2 weeks post-surgery improves the patient's quality of life, allows faster rehabilitation with better 1MTPJ range of motion and faster decrease in generalized swelling. This early weight bearing rehabilitation program will not negatively affect the stability of the surgical reconstruction correction and maintains a good radiological outcome as well as the traditional rehabilitation protocol where weight earing begins at 6 weeks.

Patients and Methods

Patients

This is an open-label randomized controlled trial. We aim to recruit 50 adult (>18 yrs) patients who undergo hallux valgus by the EDSTP will be recruited. Exclusion criteria are those whom have disabilities (both physical and mental) which may impair the adherence of the rehabilitation and those who have undergone additional procedures such as concomitant 2nd toe deformity correction.

Randomization will be performed after the end of the EDSTP surgery to ensure the there is no bias during the surgical procedure. Parallel groups will be allocated at 1:1 ratio via a computer generated random number, with 25 patients at each group.

In the control group, the subjects will follow the existing rehabilitation protocol of non-weight bearing walking for 6 weeks followed by heel walking for 6 weeks, followed by the resumption of normal full weight-bearing walking in normal shoes at 12 weeks post-operation. In the trial group, the subjects will begin heel walking when the bulky dressing and sutures are removed at 2 weeks post-operation and resume full weight bearing walking in normal shoes at 12 weeks post-operation. All subjects will be followed-up at 2 weeks, 6 weeks, 12 weeks, 18 weeks and 26 weeks post-operatively.

This study will be performed in the North District Hospital in Hong Kong. The study protocol will be approved by the Joint Chinese University of Hong Kong – North Territories East Cluster Clinical Research Ethics Committee and all participant will provide written informed consent. The study procedure will be conducted in compliance with Declaration of Helsinki and Good Clinical Practice (GCP) Guidelines.

Study outcomes

The primary outcomes are:

- Radiological changes including hallux valgus angle (HVA), intermetatarsal angle (IMA), and tibial sesamoid position by weight bearing feet X-Rays will be measured at 12, 18, and 26 weeks post-surgery.

Secondary Outcomes are:

- Pain at the bunion, the first metatarsophalangeal joint (1MTPJ) and transfer metatarsalgia using the visual analogue scale will be measured at 2, 6, 12, 18, and 26 weeks post-surgery.
- Range of Motion (ROM) at 1MTPJ will be measured at 2, 6, 12, 18, and 26 weeks post-surgery.
- Foot function measured by the American Orthopaedic Foot and Ankle, Score hallux score, which ranges from 0 to 100, will be conducted at 12, 18, and 26 weeks post-surgery.
- Foot function by the self-reported Foot and Ankle Outcome Score (FAOS) questionnaire will be measured at 12, 18, and 26 weeks post-surgery. FAOS consists of 5 subscales: pain, other Symptoms, function in ADL, function in sport and recreation, and foot and ankle-related Quality of Life. The previous week is taken into consideration when answering the questionnaire. Standardized answer options are given (% Likert boxes) and each question gets a score from 0 to 4. A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) is calculated for each subscale.

Statistical analysis

All analyses will be performed in IBM SPSS Statistics, Version 20.0 (SPSS Inc, Chicago, IL, USA). Results are shown as mean±SD, median (interquartile range) or number (frequency) depending on the type and distribution of data. Between-group comparisons will be conducted by one-way analysis of variance (continuous normal distributed data), Mann-Whiteney U test (continuous non-normally distributed data), or chi-square test (categorical data) depending on the type and distribution of data. All hypotheses are two-tailed, and p values<0.05 are considered statistically significant.

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