

**Protocol: A Randomized Parallel-Group Study of Women After Hallux
Valgus Correction Surgery To Compare the Effects of “Core Foot System”
Training vs. Traditional Rehabilitation Methods**

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Purpose: The aim of this study is to compare the effects of Core Foot System muscle training vs. traditional rehabilitation methods in female patients after a hallux valgus correction surgery.

Methods: The project will involve 60 women who have undergone a Scarf osteotomy to correct the deformity; participants will be divided into a control and experimental group. The experimental group will follow the Core Foot System protocol, whereas the control group will perform standard lower-limb exercises. Outcome measures will be collected twice: before the intervention and after eight weeks. Gait will be assessed using the Zebris FDM-2 platform, which measures ground reaction forces during walking. **Results:** The effects of the exercises on the cross-sectional area of the abductor hallucis muscle and the flexor digitorum brevis muscle will be measured. Foot architecture and arch height will be measured using a podoscope. In addition, the participants will complete the Short Form Health Survey and the American Orthopaedic Foot and Ankle Society questionnaires.

Results: The study is expected to provide evidence of the effectiveness of foot muscle training using the protocol.

Conclusions: The findings may lead to an improved protocol of rehabilitation in patients after a correction surgery that may result in improved gait parameters and quality of daily life. In the future, an improved therapeutic method should make it possible to boost the effectiveness of physiotherapy in patients after a corrective surgery in the forefoot area. The study has been registered with clinicaltrials.org (NCT05210127; 13 January 2022).

Keywords: investigation, muscle, physiotherapy, forefoot, gait

1. Introduction

Hallux valgus (HV) is an orthopedic deformity that affects about 30% of the population and is more prevalent in women than in men [13]. A deviation of the hallux is recognized as a public health problem and a condition that impairs the quality of daily life [34], [8], [5]. HV is characterized by the subluxation and valgus angulation of the first metatarsophalangeal (MTP) joint combined with the pronation of the proximal phalanx. **Scientific reports highlight the complexity of static hallux valgus pathologies, indicating that this is a complex, progressive, multiplanar deformation of the entire foot [10], [33].** The deformity alters muscle tone, lowers the arches of the foot, and causes a supination of the forefoot in relation to the hindfoot. Consequently, the foot does not rotate over the first metatarsal head in the pre-swing and active propulsive phase [14], [7], [26].

Numerous surgical procedures exist for the treatment of HV, with the choice depending on such factors the degree of the deformity and the quality of the articular cartilage in the operated joint [43]. Regardless of the procedure chosen, the surgical intervention results in changes in foot biomechanics. After the surgical procedure, the patient should wear an orthosis for at least six weeks. Stiffness of the MTP joint and the medial arch of the foot disturbs the weight transfer and causes reduced power generation in the push-off phase. In the literature, there is no consensus among authors on the impact of the surgical correction of HV on gait function [19], [30], [4], [20], [39], [35]. The discrepancies could be due to differences in the time between the surgical procedure and the study, or due to the absence of a standardized therapeutic program.

Traditionally used methods of rehabilitating the muscles of the foot and the ankle joint include balance exercises and exercises strengthening such multi-joint muscles as the tibialis anterior (TA), the tibialis posterior (TP), the peroneus longus (PL), and the peroneus brevis (FB). It has been demonstrated that the action of muscles should be considered in groups (systems). In the literature there are 5 systems responsible for the shape of the foot and the alignment of the toes: “tendon stirrup”(system I); muscles complementary to the tendon stirrup (system II); “foot lever” (system III); muscles complementary to system III (system IV); “reins of hallux” (system V). The proper function of the muscular systems that shape the arches of the foot is essential for the alignment and function of the muscles directly responsible for the big toe (hallux) and the other toes. The correct arch architecture of the foot is primarily stabilized by the extrinsic muscle systems, which play a significant role in determining how the intrinsic muscle systems of the foot function [9], [11], [12].

Nevertheless, the rationale behind the use of this type of exercise has started to be questioned [29], [3], [37]. McKeon et al. [29] found that the stiffness caused by increased multi-joint muscle tension shifts the body’s center of mass laterally and deactivates the muscles of the foot during rollover. Biz et al. [3] found that in 31% of HV patients who performed foot exercises postoperatively by strengthening multi-joint muscles, the range of motion of the first MTP joint decreased, and so did the loading applied to the first ray during gait. Similar results were obtained by Schuh et al. [37], who demonstrated that exercises activating the PL muscle failed to improve kinetic parameters, in particular the loading applied to the head of the first metatarsal bone and the entire first ray of the foot during gait.

The Core Foot System (CFS) concept, which involves activating and training the foot muscles, has been used for training in chronic ankle instability [23]. Its authors have reported significant improvements in dynamic balance and foot function during gait in the experimental

group compared to the control group. A larger cross-sectional area (CSA) of the short muscles of the foot correlates with reduced pain levels, improved quality of life, increased stability of the joints in the foot, and the proper load applied to parts of the foot during standing and walking [40], [25], [1], [16]. The findings demonstrate the need for more exercises of the foot muscles and highlight their crucial role for the rollover function during gait. Based on the findings presented, it appears that a structured program and more precise activation of certain smaller groups of foot muscles will enhance the effectiveness of rehabilitation in patients after HV correction. However, there are no studies examining the use of CFS in patients after a surgical procedure in the forefoot area. Deficits in this group of patients resulting from foot deformity are consistent with the goals of the CFS concept.

The purpose of this study will be to investigate the effects of CFS foot muscle training on anthropometric, spatiotemporal, and kinetic gait parameters and on the CSA of foot muscles in female patients after HV correction surgery, as compared to those undergoing traditional rehabilitation methods including balance exercises and exercises strengthening multi-joint muscles.

2. Material and methods

This study is designed as a prospective randomized controlled study with pre-intervention and post-intervention assessment. All participants consecutively enrolled in the study who meet the inclusion criteria will be sequentially assigned, by MB, alternately to the control or experimental group. The protocol has been developed in keeping with the guidelines and checklists for the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [6]. Results will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) Statement [38]. The study will be conducted at the Faculty of Rehabilitation, Józef Piłsudski University of Physical Education in Warsaw, Poland, which is also the source of all funding for the study. The study has been registered with clinicaltrials.org (NCT05210127; 13 January 2022) and is in compliance with the latest version of the Helsinki Declaration [42]. The study was approved by the Ethics Committee of the Józef Piłsudski University of Physical Education in Warsaw, Poland (SKE 01-42/2021). All subjects will be informed about the purpose of the study and will provide written informed consent.

2.1 Participants

The 60 participants will be recruited from patients who have undergone a Scarf osteotomy exclusively at a chosen medical facility in the period between January 2023 and May

2025. Inclusion criteria will include: hallux deformity, a surgical procedure, an X-ray before and six weeks after the procedure, the attending doctor's permission to bear weight on the foot, the patient's consent to the study (obtained by one of the authors of this trial protocol), females aged 25–55 years. Women who had other procedures in the operated foot or in the ankle joint, who will be prevented by pain from performing a full gait cycle, or who underwent fewer than half of the planned rehabilitation sessions in a period of eight weeks will be excluded from the study. All participants undergo eight-week rehabilitation period between examinations. The total number of meeting included from 20 to 24 rehabilitation sessions. The software G*POWER was used to determine that the total number of participants should be $n = 44$ for $\alpha = 0.05$; $1 - \beta = 0.90$, and $\eta^2 = 0.06$.

For reasons related to possible dropouts, having equal groups of 20–30 participants each should ensure that the study will have 80% power to detect the average effect size. We aim for 60 participants in order to ensure that this objective is met.

2.2 Sampling

Participants meeting the inclusion criteria will be assigned alternately to one of two groups: experimental and control (convenience sampling). The study manager will assign participants alternately to groups to maintain an equal number of participants in both groups. Both groups of participants will be blinded, and the examinations performed at the Central University Laboratory will be identical for both groups. In order for the study to be conducted properly, ensuring that the participants follow the exercise program, it is not possible to blind the therapist.

2.3 Intervention protocol

Each participant will take part in 20 rehabilitation sessions over a period of eight weeks. Permission for weight-bearing on the limb, confirmed by an X-ray and a visit to a specialist medical doctor, will be required before commencement of the rehabilitation, six weeks after the surgical procedure. The therapy will then continue for eight weeks (ending 14 weeks after the surgical procedure). The eight-week duration of the rehabilitation has been chosen based on the experience of doctors and the current state of medical science. Foot muscle training of at least four weeks has been shown to improve foot function, increase the height of the longitudinal arch, measured using the position of the navicular bone, improves stability in balance tests, and increases the CSA of the abductor hallucis (AbH) muscle [32], [17], [27], [35]. During each rehabilitation session, each group will undergo manual therapy for the joints in the hallux, the

post-surgical scar, and soft tissues in the foot and in the ankle joint. The exercises will last a total of about 30 minutes in each group, performed during rehabilitation meetings and on days off from rehabilitation. Participants in the control group will undergo traditional rehabilitation protocol consisting of the following elements: gait re-education, correction of the rollover movement of the foot, exercises activating multi-joint muscles such as the tibialis anterior (TA), the fibularis longus (FL), the gastrocnemius (Ga), and the soleus (S). Multi-joint muscle exercises will be performed using resistance bands (Thera Band), and gait training will be conducted on a stable surface and on balance discs. The participants will perform balance exercises standing on both legs, on one leg, and on an uneven surface [36], [24]. In the experimental group, the participants will perform exercises according to Protocol P1 [29].

Protocol P1: CFS method

1. Short foot – the patient stands on both feet and transfers the load to the foot being exercised. The task involves tensing the muscles of the foot so that the foot shortens along its length and the longitudinal arch becomes elevated. The exercise is performed incorrectly if the participant lifts the foot off the floor or curls the toes. The exercise is repeated 20 times. During the exercise, load is applied to the first metatarsal head and hallux abduction. It activates the flexor hallucis brevis (FHB) and AbH muscles.
2. Hallux lift, other toes kept on the floor – in a sitting position, the participant performs the short foot exercise and then lifts the hallux up and lowers it back down 20 times. During the exercise, load is applied to the first metatarsal head, the hallux is extended for the rollover movement of the foot, and the longitudinal arch of the foot increases. This activates the FHB muscle.
3. Toe lifts without the hallux – in a sitting position, the participant performs the short foot exercise and then lifts toes 2–5 20 times while the hallux remains pressed to the floor. During the exercise, load is applied to metatarsal heads 2–5, activating the longitudinal and transverse arches, extending the toes for the pre-swing phase. This activates the quadratus plantae (QP) muscle.
4. Heel raises with the front of the foot on an elevation – the exercise is performed in a sitting position with the front of the foot on an elevation, the participant raises and lowers the heels. The exercise is repeated 20 times. It activates the longitudinal arch, results in load being applied on the first metatarsal head, supinates the heel, and abducts the hallux. This activates the FHB, flexor digitorum brevis (FDB) muscle, QP, and AbH muscles.
5. Toe curls in a sitting position – the foot rests on the floor. The participant performs the short foot exercise and then curls all toes, holding the position for six seconds. The exercise is

repeated 10 times. It exercise shortens the longitudinal and transverse arches. This activates the FHB and FDB muscles.

6. Toe spreading – the participant attempts to spread the toes. The foot rests on the floor. The exercise is repeated 15 times a day. The exercises generates a load on the first and fifth metatarsal heads and supinates the heel. This activates the AbH and QP muscles.
7. FHB stretch in a standing position – the patient presses rests the toes on an elevation or presses them against a wall as much as possible. She stretches the FHB muscle using the post-isometric relaxation technique in six sets of 30 seconds each. The exercise shortens the longitudinal arch.

Participants will not undergo any other post-surgical rehabilitation for the duration of the trial. Either intervention (control or experimental) may be discontinued at participant’s request and/or on a physician’s recommendation.

2.4 Outcome measures

Outcome measures will be collected at baseline and immediately after the intervention. Table below shows the distribution of various measures across the timepoints during the study. Table 1. Distribution of outcome measures across timepoints.

	Before intervention	Intervention	After intervention
TIMEPOINT	6 weeks	2nd and 3rd months (8 weeks)	14th week
INTERVENTIONS			
Traditional rehabilitation program in the control group and CFS in the experimental group.		X	
ASSESSMENTS			
Demographic data	X		X
Weight	X		X
Height	X		X
Lower limb length	X		
AOFAS Score	X		X

Short Form Health Survey Score (SF-36)	X		X
Gait assessment (spatiotemporal and kinetic parameters)	X		X
Foot dimensions (Clarke's angle, the Wejsflog Index)	X		X
CSA of FHB and AbH muscles	X		X

Legend: CFS- Core Foot System; AOFAS- American Othopaedic Foot & Ankle Society; CSA- Cross Sectional Area; FHB- Flexor Hallucis Brevis muscle; AbH- Abductor Hallucis muscle

2.4.1 Data handling

Demographic data collected will include age, height, weight, and lower limb length. This demographic data, the personal data of participants, and the data from interventions and exams will be securely retained in a secure personal computer at the Central University Laboratory of the Józef Piłsudski University of Physical Education in Warsaw, Poland. Only the investigators listed as authors of this protocol will have access to these datasets.

2.4.2. Primary outcomes

2.4.2.1 Function and pain evaluation

In the assessment of function, the American Orthopaedic Foot and Ankle Society (AOFAS) score will be used for the first MTP joint. The score is used to assesses pain, the range of motion in the hallux joints, hallux alignment, and the function of the first ray [2].

2.4.2.2 Gait assessment

Gait performance will be measured on a 304 cm long, 56 cm wide electronic walkway (Zebris Medical System, Tübingen, Germany). Intervention data will be sampled at 120 Hz and stored in a personal computer at the Central University Laboratory, which calculates spatiotemporal parameters and foot pressure distribution parameters using the Zebris software. As described in detail in the study of Kaczmarczyk et. Al. [18] twenty-two spatiotemporal parameters were collected: left and right step length (% of leg length), left and right foot rotation (degrees), left and right step time (s), left and right stance phase (% of gait cycle (GC)), left and right loading response (%GC), left and right single support (%GC), left and right pre-swing (%GC), left and right swing phase (%GC), total double support (%GC), stride length (% leg length), stride time (s), step width (cm), cadence (strides/min), speed (km/h). The foot pressure

distribution parameters will be: left and right gait line length (mm), left and right single support line (mm), ant/post position (mm), lateral symmetry (mm).

2.4.2.3 Foot dimensions

The assessment will be performed using a CQ Elektronik System podoscope. During the assessment, the following parameters will be calculated from the collected data: foot pressure distribution, foot width and length, Clarke's angle, and the Wejsflog index. Clarke's angle is a method of evaluating the longitudinal arches of the foot based on the footprint obtained on a podoscope. The angle is determined between the line of the medial edge of the foot and the internal tangent lying on the medial recess of the foot. Based on the angular value, 4 types of foot are defined: flat foot (0-29.9 degrees); moderate flat foot (30-34.9 degrees); normal foot (35-42 degrees); high arched/shod foot (>42 degrees) [22]. The Wejsflog index, in turn, measures the ratio between the length and width of the foot. The physiological norm is a ratio of 3:1, whereas values tending towards 2:1 are indicative of a lowering of the transverse arch [27].

2.4.3. Secondary outcomes

2.4.3.1 Muscle CSA

A Esaote MyLabSeven ultrasound system will be used to evaluate changes in the CSA of AbH and FHB muscles. The examination will be performed twice (before and after the rehabilitation) by the same specialist. Ultrasound imaging will be used to determine the thickest part of FHB and AbH muscles, at the midpoint of the muscle belly and at the beginning and at the end of the muscle belly [21]. The patient will be in the supine position with the foot in the neutral position.

2.4.3.2 Quality of life evaluation

Subjective assessment of the quality of life and health of participants will be made using the Short Form Health Survey Score (SF-36) [41].

2.5 Statistical analysis

Data (analyzed with STATISTICA version 13, PL.iso) will be expressed as mean standard deviation. The Shapiro–Wilk test will be applied to assess if the collected parameters exhibit a normal distribution. The ANOVA for repeated measures (the fixed factor GROUP and the repeated factor PRE-POST) will be used to evaluate the interaction effect. Post-hoc comparisons will be done using the Tukey test. In the case of a deviation from a normal distribution, the Mann–Whitney *U* test comparing increments in the tested groups will be used

to examine the interaction. Post-hoc comparisons will be done using the Wilcoxon matched pairs test with Bonferroni correction. Statistical significance will be set at $\alpha = 0.05$.

2.6 Safety conditions

All measurements will be performed in a place that will ensure patient safety. Enrollment in the study will require the attending doctor's prior permission for the participants to bear weight on the lower limb. The exercises performed by the patients will not pose a risk of destabilizing the osteotomy site. Any adverse or other unintended effects of the trial interventions identified by Laboratory staff or spontaneously reported by participants will be reported to MB (who would be responsible for deciding to terminate an intervention or the trial as a whole).

2.7 Data security

All patient data and test results will be saved on a computer, and the access will be password protected. Only the test administrator will have access to the sensitive data of patients and the test results.

3. Discussion

The purpose of the study will be to examine the effectiveness of the CFS method and its advantages over previously used rehabilitation methods. The use of the CFS concept is justified, as it involves activating foot muscles (FHB, AbH, FDB, and QP muscles) and affects the alignment of the arches of the foot. Proper functioning of intrinsic muscle is possible with proper alignment of the arches of the foot, which is the case with functional muscles of systems first and seconds [11]. The force generated by the intrinsic plantar foot muscles supports the maintenance of the longitudinal arch [12] and controls movements in the foot joints, including the subtalar joint, during the stance phase of gait [15]. A decrease in the height of the navicular bone and the medial longitudinal arch has been shown to result from fatigue or dysfunction of the aforementioned muscles, which confirms their role in the alignment of foot arches. Insufficient strength of these muscles or their abnormal recruitment are predisposing factors in foot pathologies, including HV [31]. Therefore, the patients in the CFS experimental group are expected show a greater improvement in the area of the foot's arches, stability of the foot joints, and loading of the sesamoid bones, which will reduce forefoot supination in relation to the hindfoot and improve the spatiotemporal and kinetic parameters of gait, particularly the change in foot rollover during gait [14], [7], [26]. In addition, the improvement of gait pattern in the

patients from the CFS group is expected to lead to a greater improvement in the quality of life than in the patients receiving traditional rehabilitation. The use of an experimental design will make it possible to control the possible impact of confounding variables as equal in both groups and therefore to identify the direct impact of the experimental method on the effects of the rehabilitation process. We plan to develop and disseminate methodological materials on the proposed CFS method in the rehabilitation of patients after HV surgery among rehabilitation and orthopedic specialists.

4. Authors' contribution

MB- Conceptualization, Methodology Investigation ,Writing–Original Draft Preparation; PK- Methodology, Investigation; KK Conceptualization, Methodology Writing–Review & Editing

5. Competing interests

All authors declare that they have no competing interests that might bear upon their involvement in this study.

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