Evaluation of a new postoperative dressing after hallux valgus surgery

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Research legislation:	Ordinance on human research (HRO) [1].
Type of Research Project:	Research project involving human subjects
Risk Categorisation:	Risk category A acc. to ordinance HRO Art.7
Project leader:	[redacted]
Sponsor:	[redacted]

PROTOCOL SIGNATURE FORM

Study Title	Evaluation of a new postoperative dressing after hallux valgus surgery

The project leader has approved the protocol version 1 30.04.2025 and confirms hereby to conduct the project according to the protocol, the [redacted] legal requirements [1, 2], current version of the World Medical Association Declaration of Helsinki [3] and the principles and procedures for integrity in scientific research involving human beings.

The project leader has received the ICF and consider it appropriate for use.

Project leader:

Site [redacted]

Name: [redacted]

Date: October 15th, 2025 _____ Signature: _____

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GLOSSARY OF ABBREVATIONS

BASEC	*Business Administration System for Ethical Committees*
CRF	*Case report form*
FOPH	*Federal Office of Public Health*
HRA	*Human Research Act*
HRO	*Ordinance on Human*

1 BACKGROUND AND PROJECT RATIONALE

After hallux valgus surgical correction, a spacer is applied between the first and the second in order to maintain the alignment during the soft tissue healing period.[1] Serval methods exist such as a soft gauze folded between the first and second toe, a spica dressing or a tongue depressor wrapped around the medial side of the hallux. [2] These methods often lack reliability because they are not tailored to the specific anatomy of the patient. As a result, they can misalign the lesser toes—pushing them laterally—instead of properly maintaining the hallux in alignment with the foot. Additionally, these techniques are time-consuming and may cause discomfort, which can negatively affect patient compliance.

The goal of the project is to assess the tolerance of a custom-made 3D-printed spacer (3D spacer) designed to maintain the alignment of the hallux following surgical correction. Additionally, the study aims to evaluate the resulting position of the hallux and the lesser toes.

Risk Category (according to Art. 7 HRO): A

Rationale:
This research project falls under Category A because the custom-made spacer is not implanted into the body but applied externally to the foot, in a manner similar to orthotic devices.

The spacer will never be in direct contact with the surgical wound, which is systematically covered with a sterile postoperative dressing maintained in place until the wound has fully healed. This ensures protection of the surgical site and eliminates any risk of wound contamination from the device.

The spacer is manufactured using thermoplastic polyurethane (TPU), a material that is commonly used in orthotic applications and that complies with ISO 10993 standards for biocompatibility. Custom-made spacer are manufactured using the HP Jet Fusion 5200 Series printer, a state-of-the-art industrial technology widely adopted in the medical field, particularly for the production of custom orthoses and prostheses. It is based on the Powder Bed Fusion process, which ensures high precision, consistent reproducibility, and excellent mechanical properties of the printed parts.

Hewlett-Packard officially recommends this technology for orthopedic applications.

Given its external application and the use of biocompatible, well-established materials, the intervention is associated with minimal risks and participant burden.

2 PROJECT OBJECTIVES AND DESIGN

2.1 Hypothesis and primary objective

Hypothesis:
The use of a custom-made 3D-printed spacer following surgical correction of the hallux will be well tolerated by patients and will better maintain the alignment of the hallux and lesser toes compared to conventional methods (e.g., folded gauze).

Primary Objective:
To evaluate the tolerance of a custom-made 3D-printed spacer used postoperatively to maintain hallux alignment.

Secondary Objectives:

To assess the postoperative alignment of the hallux and the lesser toes using radiographic or photographic evaluation.

To document any complications or adverse events related to the use of the custom-made spacer.

2.2 Primary and secondary endpoints

Primary Endpoint:

The variable of primary interest is the tolerance of the custom-made 3D-printed spacer. Tolerance will be evaluated at 1 week, 3 weeks, and 5 weeks postoperatively, based on patient-reported outcomes (e.g., comfort, pain, willingness to continue use) and clinical assessment (e.g., skin irritation, redness, pressure marks, or ulceration).

Rationale for Selection:

Tolerance is the primary endpoint because the spacer represents a novel, patient-specific medical device. Before further evaluating its efficacy, it is essential to confirm that the device is well tolerated and does not cause discomfort or adverse effects during the postoperative period. This will inform its feasibility for broader clinical use.

Secondary Endpoints:

Alignment of the hallux, assessed:

Clinically at 5 weeks (e.g., visual inspection, standardized photographs)

Radiographically on a weight-bearing foot radiograph at 5 weeks

Alignment of the lesser toes, assessed:

Clinically at 5 weeks (e.g., signs of toe drift, or lateral deviation)

Radiographically at 5 weeks, focusing on toes orientation

2.3 Project design

Study Design and Justification:
This project is a prospective, single-center, exploratory cohort study involving patients who undergo surgical correction for hallux valgus. The study aims to assess the tolerance of a custom-made 3D-printed spacer and evaluate hallux and lesser toe alignment postoperatively.

The exploratory design is appropriate, as this is a preliminary investigation into the use of a novel, patient-specific device. The main goal is to evaluate feasibility and early clinical outcomes, particularly tolerance, before conducting larger-scale or comparative trials.

The project is conducted at a single center, which ensures standardized surgical techniques, consistent postoperative care, and uniform assessment procedures. This setting minimizes variability and improves the reliability of the findings for early-stage evaluation.

In addition to evaluating outcomes in patients using the 3D-printed spacer, we will perform a matched comparison with a prospective cohort of patients who will be treated using the traditional spacer (e.g., folded gauze). Participants will be allocated to one of the two study groups by a simple randomisation procedure using sealed opaque envelopes prepared in advance to ensure allocation concealment. This comparative element adds value by contextualizing the performance of the new device against standard care, while still maintaining the exploratory nature of the project.

3 PROJECT POPULATION AND STUDY PROCEDURES

3.1 Project population, inclusion and exclusion criteria

Project Population and Sample Size:
The project will include a total of 20 patients undergoing surgical correction for hallux valgus at a single center. These patients will receive a custom-made 3D-printed spacer postoperatively.

No additional cost will be charged during the study for the custom-made spacer.

In addition, a prospective control group of 20 patients will be formed. These patients will receive the traditional spacer method (e.g., folded gauze) postoperatively. Matching will be based on age, gender, and severity of the deformity, ensuring comparability between the two groups regarding key variables influencing alignment outcomes.

Participant Selection and Representation:
All patients eligible for surgical correction of hallux valgus will be considered for inclusion, without restriction based on age or gender, provided they meet the inclusion and exclusion criteria.

At our institution, approximately 80% of patients undergoing hallux valgus surgery are women, with a female-to-male ratio of 8:1. We will aim to maintain this natural distribution in our study population to ensure representativeness and avoid introducing sex-based selection bias. The underrepresentation of men reflects the actual patient population affected by the condition and not a result of intentional exclusion.

Despite the gender imbalance, the findings will remain scientifically valid as they reflect the real-world demographic of patients undergoing this procedure.

Recruitment Strategy:
Participants will be recruited consecutively from patients scheduled for hallux valgus surgery. They will be informed about the study and invited to participate during their preoperative consultation. Recruitment will continue until the target number of participants (n=20) is reached.

Inclusion Criteria:

- Signed informed consent

- Diagnosis of hallux valgus with indication for surgical correction
- Undergoing one of the standard hallux valgus surgical procedures at the study center
- Age ≥18 years

Exclusion Criteria:

- Inability to provide informed consent
- Inability to follow study procedures (e.g. due to cognitive impairment or logistical reasons)
- Insufficient knowledge of the project language
- Bilateral surgery
- Kown allergy to TPU

3.2 Recruitment, screening and informed consent procedure

The project leader explains to each participant the nature of the research project, its purpose, the procedures involved, the expected duration, the potential risks and any discomfort it may entail. Each participant is informed that the participation in the research project is voluntary and that he/she may withdraw from the research project at any time and that withdrawal of consent will not affect his/her subsequent medical assistance and treatment. The participants are informed that he/she can ask any question. Enough time is given to the participant.

All participants are given an information document and a consent form describing the research project. The formal consent of a participant, using the approved consent form, is obtained before the participant is enrolled in the research project.

The participant should read, understand, and voluntarily agree before signing and dating the informed consent form, and is given a copy of the signed document. The consent form is signed and dated by the participant and the project leader (or her/his designee). The signed consent form it is retained as part of the investigation records.

Screening and recruitment:

Recruitment Location and Procedures:

Participant recruitment will take place at Centre Assal SA, where all surgical procedures and follow-up visits will also be conducted.

Recruitment Process:

All patients scheduled to undergo surgical correction of hallux valgus at Centre Assal SA will be screened for eligibility. Recruitment will be prospective and consecutive, meaning every eligible patient will be informed about the project as part of the standard preoperative consultation. This approach ensures an unbiased and representative selection of participants.

Informed Consent Process:

Patients will receive oral and written information about the study during their preoperative visit. They will be given ample time to consider participation. Patients will be encouraged to ask questions and will have the opportunity to clarify any aspects of the project with the clinical or research team.

Only after ensuring full understanding and voluntary agreement will written informed consent be obtained, in accordance with legal and ethical guidelines.

Representation of Relevant Population – Age, Sex, and Gender Considerations:

The recruitment strategy is designed to ensure appropriate representation of the population typically affected by hallux valgus. At our center, approximately 80% of patients treated surgically for hallux valgus are women, reflecting the epidemiology of the condition. We aim to maintain this natural distribution within the study to ensure scientific validity and real-world relevance. Men undergoing the same surgical procedure will be included whenever available, to avoid unjustified exclusion of any gender group.
Patients of all adult age groups will be considered, and no upper age limit is imposed, as long as the patient meets the inclusion criteria and can participate in follow-up visits.

3.3 Study procedures

The overall project duration is approximately six months, including patient recruitment, intervention, and follow-up assessments. The recruitment period is expected to last three to four months, continuing until 20 participants undergoing hallux valgus surgery are enrolled. Each participant will be involved in the study for five weeks postoperatively, with evaluations conducted at scheduled intervals to assess spacer tolerance and alignment outcomes.

Before surgery, participants provide informed consent during their preoperative consultation. Baseline data, including demographic information and preoperative hallux alignment, are collected. The custom 3D-printed spacer is fabricated based on individual foot measurements obtained through a 3D photograph of the foot and applied immediately after surgical correction. A matched retrospective control group, treated with traditional folded gauze spacers, is used for comparison, with patients selected based on age, sex, and deformity severity.

To ensure balanced allocation between the two study groups, a simple randomisation process will be implemented.
A total of 40 opaque sealed envelopes will be prepared in advance, containing 20 assignments labeled “PSMT 3D” and 20 labeled “Spacer standard.”

When a patient’s date of surgery is confirmed, the secretary in charge of operating-room planning will draw one sealed envelope at random and record the group allocation.
The envelope will then be opened to determine whether the participant belongs to the PSMT 3D or Spacer standard (control) group.

This procedure ensures allocation concealment and prevents any influence from the investigators on group assignment.
Randomisation will continue until all 40 envelopes have been used.

Follow-up visits occur at one week, three weeks, and five weeks post-surgery. During the first visit, clinical inspection evaluates spacer fit, skin condition, and initial tolerance, assessed through patient-reported comfort and pain levels. The three-week visit repeats these assessments to monitor ongoing tolerance. The final visit at five weeks includes a comprehensive evaluation: both clinical and radiographic assessments are performed. 3D photographs document foot alignment, while weight-bearing X-rays measure hallux and lesser toe positioning.

Data collection relies on structured questionnaires for subjective tolerance feedback, clinical examinations for spacer performance, and imaging for objective alignment verification. Patient-reported outcomes focus on discomfort, ease of use, and willingness to continue spacer

application. Clinical assessments note any adverse effects, such as skin irritation or pressure marks. Radiographic analysis quantifies alignment changes.

Potential biases in the study are addressed through specific mitigation strategies. Selection bias, arising from the predominance of female participants, is minimized by matching control patients based on key demographic and clinical factors. Measurement bias is reduced by standardizing imaging protocols and, where feasible, employing blinded assessors for radiographic analysis. Recall bias is limited through frequent follow-ups, ensuring timely and accurate patient feedback. Attrition bias is managed by closely monitoring participants for complications, encouraging compliance, and addressing issues promptly to prevent dropouts.

3.4 Withdrawal and discontinuation

Participants may leave the study for several reasons: if they choose to withdraw their consent, if they experience significant discomfort from the 3D-printed spacer, if they miss follow-up visits, if new health problems arise, or if they don't follow study instructions.

If a participant stops the study early, the research team will conduct a final check-up if possible. This includes examining the foot, recording any issues with the spacer, and noting why they left the study. Collected data up to that point will still be used for analysis.

For participants who cannot tolerate the 3D-printed spacer, the study team will replace it with a traditional spacer (such as folded gauze) and continue monitoring their progress.

All personal information is carefully protected. Names and identifying details are removed from study records, and any stored materials (like scans or X-rays) are labeled with codes instead. If a participant withdraws and requests full data deletion, their information will be securely erased.

Even if participants leave the study early, their available data may still be analyzed to help researchers understand the spacer's performance. The study team documents all withdrawals to ensure transparency and minimize bias in the results.

4 STATISTICS AND METHODOLOGY

4.1. Statistical analysis plan

Objectives The primary objective of this study is to descriptively evaluate patient tolerance of the 3D-printed spacer in comparison to traditional methods.

Sample Size Justification Due to the exploratory nature of this study, a formal power calculation was not performed. Instead, the sample size of 20 participants was chosen based on feasibility, considering the expected number of eligible patients at the study center within a reasonable timeframe. This sample size allows for preliminary assessment of tolerance and alignment outcomes while maintaining practical recruitment constraints.

Analyses will be performed according to the randomised group assignment (“PSMT 3D” vs “Spacer standard”) as determined by the sealed-envelope procedure described in Section 3.3.

Statistical Methods for Primary Endpoint (Tolerance) Tolerance will be assessed using patient-reported outcomes (e.g., Likert scale ratings on comfort and pain). Descriptive statistics (mean, standard deviation, frequencies) will summarize these results. Given the exploratory aim and limited sample size of this study, tolerance results for the 3D-printed spacer will be reported descriptively without formal comparative statistical testing.

Secondary Endpoint (Alignment of Lesser Toes) Lateral deviation of the lesser toes will be measured radiographically. A two-sample t-test (or Wilcoxon rank-sum test for non-normal data) will compare alignment between groups. No adjustments for multiple testing are planned, as this is an exploratory study.

4.2. Handling of missing data

In this study, we do not expect much missing data because the follow-up period is short (only 5 weeks) and we are closely monitoring a small group of 20 patients. However, if some data is missing—for example, if a patient skips a follow-up visit or leaves the study early—we will clearly note the reason (such as discomfort or personal reasons) and report it in the final publication.

5 REGULATORY ASPECTS AND SAFETY

5.1 Local regulations / Declaration of Helsinki

This research project will be conducted in accordance with the protocol, the Declaration of Helsinki [3], the Human Research Act (HRA) and the Human Research Ordinance (HRO) [1] as well as other locally relevant regulations. The project leader acknowledges his responsibilities as both the project leader and the Sponsor.

5.2 Notification of safety and protective measures (HRA Art. 15, HRO Art. 20)

If, during the research project, circumstances arise which could jeopardise the safety or health of the participants or lead to a disproportionate relationship between the risks and burdens and the benefits, all the measures required to ensure protection are to be taken without delay.
The project leader is promptly notified (within 24 hours) if immediate safety and protective measures must be taken during the conduct of the research project. The Ethics Committee will be notified via BASEC of these measures and of the circumstances necessitating them within 7 days.

5.3 Serious events (HRO Art. 21)

If a serious event occurs, the research project will be interrupted and the Ethics Committee notified on the circumstances via BASEC within 7 days according to HRO Art. 21[1].

The project leader reports to the ethics committee on the connection between the event and the collection of health-related personal data. At the same time, the project leader submits proposals concerning the next steps to be taken.

[1] A serious event is defined as any adverse event where it cannot be excluded, that the event is attributable to the sampling of biological material or the collection of health-related personal data, and which:
a. requires inpatient treatment not envisaged in the protocol or extends a current hospital stay;
b. results in permanent or significant incapacity or disability; or
c. is life-threatening or results in death.

Any new relevant information and the outcome to the original Serious Event is reported to the ethics committee via BASEC.

5.4 Procedure for investigations involving radiation sources

The study includes standard postoperative X-rays at the 5-week follow-up to assess toe alignment. These X-rays are part of routine clinical care for hallux valgus surgery, meaning patients would receive them regardless of study participation. No additional radiation exposure is required for this study.

5.5 Amendments

Substantial changes to the project set-up, the protocol and relevant project documents will be submitted to the Ethics Committee for approval according to HRO Art. 18 before implementation. Exceptions are measures that have to be taken immediately in order to protect the participants.

The following are considered to be substantial changes:

a. changes affecting the participants' safety and health, or their rights and obligations;
b. changes to the protocol which concern the objectives of the research project;
c. a change of research site or conducting the research project at an additional site; or
d. a change of project leader or Sponsor.

5.6 End of project

Upon project completion or discontinuation, the Ethics Committee is notified within 90 days.

The completion of the research project is defined by the last collection of health-related personal data.

5.7 Insurance

In the event of project-related damage or injuries, the Sponsor will be liable. The liability coverage covers damage occurring up to 10 years after the completion of the research project

6 FURTHER ASPECTS

6.1 Overall ethical considerations

This study has scientific and social value by addressing an unmet need in postoperative care following hallux valgus correction. Existing spacer methods are not patient-specific, often uncomfortable, and can lead to suboptimal alignment. The development and assessment of a custom-made 3D-printed spacer aims to improve patient comfort, compliance, and clinical outcomes. Although the results will be descriptive due to the small sample size, they will contribute valuable preliminary data that may inform future, more robust clinical trials.

Justification of Study Design and Participant Burden

The study design is justified given the exploratory nature and low risk of the intervention. The 3D-printed spacer is externally applied and made from commonly used orthotic materials. It replaces the folded gauze currently used, without adding any invasive procedure. The burden on participants is minimal and limited to routine postoperative care, completion of a tolerance questionnaire, and potentially a photographic or radiographic assessment, which are standard in this setting. The estimated time commitment and discomfort are negligible.

Voluntary Participation and Informed Consent

Participation is entirely voluntary. Informed consent will be obtained from all participants, ensuring they understand the study's purpose, procedures, and their right to withdraw at any time without consequence.

Overall Ethical Balance

The study presents a fair balance between minimal risk and potential benefit. It offers participants the possibility of improved postoperative comfort and outcomes, without exposing them to additional burdens.

6.2 Risk-Benefit Assessment

This study poses minimal risk to participants. The 3D-printed spacer is externally applied and made from safe, commonly used orthotic materials. Potential risks include mild discomfort or pressure, which can be managed by adjusting or removing the spacer, and a minimal risk of allergic reaction. No invasive procedures are involved.

Data privacy risks are mitigated by coding participant data, storing identifiers separately, and using secure, password-protected systems. Only authorized personnel will have access.

While the study offers no direct medical benefit, participants may experience improved comfort and alignment. The findings may benefit future patients by informing better postoperative care practices in hallux valgus surgery.

7 QUALITY CONTROL AND DATA PROTECTION

7.1 Quality measures

Radiographic analysis will be conducted by the project leader or a fellowship trained foot and ankle surgeon. Statistical analysis will be performed by an independent individual who is not involved in the measurements or surgical treatment.

For quality assurance the Ethics Committee may visit the research sites. Direct access to the source data and all project related files and documents must be granted on such occasions.

The project leader has appropriate knowledge and skills in the areas of data security and data protection or is able to ensure compliance by calling in appropriate expertise (Art. 4 HRO).

7.2 Data recording and source data

Project data will be recorded using an Excel spreadsheet. Source data for the study will include medical records, radiological images, and questionnaire responses. Patients will complete the questionnaire at home or just after the routine follow-up visits. To ensure data privacy and reliability, the Excel file will be stored in a secure, password-protected swiss based cloud system (Infomaniak) with controlled access and user rights. The "Track Changes" feature will be enabled to monitor any modifications to the data. This approach ensures data traceability and maintains data integrity throughout the research project.

7.3 Confidentiality and coding

Project data will be handled with uttermost discretion and is only accessible to authorized personnel who require the data to fulfil their duties within the scope of the research project. On the CRFs and other project specific documents, participants are only identified by a unique participant number. Coding is done using a method based on the current state of the art that must be based on the current state of the art (Art. 26 HRO).

The project data will be stored in a coded format to ensure participant confidentiality. The participant identification list, which links the coded data to individual identities, will be securely stored on the project leader's password-protected computer. Both the data file and the identification list will be protected with password access to prevent unauthorized or accidental disclosure, alteration, deletion, copying, or theft.

To ensure data traceability and integrity, the Excel file will have the "Track Changes" feature enabled to maintain an audit trail of all modifications. Regular backups will be performed on secure storage media to prevent data loss or misuse. These measures are in place to ensure data security and traceability throughout the project.

7.4 Retention and destruction of project data and biological material

The project leader will retain all project data and documents, both electronic and hard copies, for a minimum period of 20 years following the completion or early termination of the study. Data will be stored securely to prevent unauthorized or accidental disclosure, alteration, deletion, or copying.

Electronic data will be stored in a password-protected Excel file with the "Track Changes" feature enabled to ensure traceability. The participant identification list will be stored separately on the project leader’s password-protected computer. Regular backups will be performed to prevent data loss.

No biological material will be collected or stored as part of this project.

Following the completion of the study and subsequent publication of the manuscript, files containing radiographic measurements will be deleted. The deletion process will be documented to confirm appropriate data disposal. All retained data will be handled in accordance with data protection regulations to ensure participant confidentiality.

9 FUNDING / PUBLICATION / DECLARATION OF INTEREST

This project has no specific funding sources. The results of the study will be submitted for publication in a peer-reviewed orthopedic journal. There are no conflicts of interest to declare. If any sex- or gender-related effects are observed during analysis, these findings will be reported in the final study report. Conversely, if no such effects are identified, this outcome will also be acknowledged in the publication.

10 REFERENCES

1. Ordinance on Human Research with the Exception of Clinical trials (HRO)

https://www.fedlex.admin.ch/eli/cc/2013/642/en

2. Human Research Act (HRA)
https://www.fedlex.admin.ch/eli/cc/2013/617/en

3. Declaration of Helsinki
(https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects)

4. STROBE statement (doi:10.1016/j.jclinepi.2007.11.008)

1. Coughlin MJ, Jones CP. Hallux valgus: demographics, etiology, and radiographic assessment. *Foot Ankle Int*. Jul 2007;28(7):759-77. doi:10.3113/fai.2007.0759
2. Lewis LK, Chen J, Johnson CS, Adams SB, Jr. Hallux Valgus Bunion Splint: Surgical Dressing Technique. *Foot Ankle Spec*. Feb 2024;17(1_suppl):53S-56S. doi:10.1177/19386400231169376