Official title :

Ambispective, Multicentre, Open-label Study Evaluating the Clinical Outcomes of Foot Surgery Using SERF Medical Devices

NCT number : NCT05672069

Document date : 10/11/2022

Title	Ambispective, Multicentre, Open-label Study Evaluating the Clinical Outcomes of Foot Surgery Using SERF Medical Devices
Sponsor	**SERF** 85 avenue des bruyères 69150 Décines Charpieu France
Rational (or justification)	The aim of the study is to follow patients with foot pathology. These patients undergo foot surgery with the aim of reducing their pain and restoring their ability to walk. This study will monitor changes in the patient's quality of life before and after the operation. The products under investigation are CE marked under Directive 93/42/EEC with clinical data based on equivalent devices. Regulation 2017/745 requires the collection of clinical data specific to each device. Consequently, this study will collect clinical data on the performance and safety of the devices, making it possible to confirm the favourable benefit/risk profile for the patient.
Implants studies	The devices studied in this clinical trial are as follows: - FAST plates (CE marked since 2018) - FAST screws (CE marked since 2016) - Toe FAST (CE marked since 2021) - VEOFIX screws (CE marked since 2019) The devices in the FAST screws, FAST plates, Toe FAST and VEOFIX screws ranges have been designed to be implanted in patients requiring repair or stabilization of elements of the foot, up to and including stabilization and fixation of the bones between them.
Population concerned	The target population for this study was any adult patient implanted with FAST screws, FAST plates, Toe FAST and VEOFIX screws between november 2021 and october 2022.
Subject population	For each Extremity product, the number of inclusions was set at 80, giving a total of 320 subjects for this study. The following selection criteria were used. <u>Inclusion criteria:</u> - Male or female subject of legal age at the date of implantation; - Subject implanted with one or more implants: FAST Screw, FAST Plate, Toe FAST and VEOFIX Screw between November 2021 and October 2022; - Subject able to understand the information and instructions given by the investigator; - Subject with a social security affiliation. <u>Exclusion criteria:</u> - Vulnerable persons - People with contraindications (including pregnant women) <u>Non-inclusion criteria:</u>

	As the series is observational and involves an additional procedure that is neither burdensome nor invasive, all implanted patients will be considered. However, the following patients will not be included: Subjects who have not expressed their consent to the collection of their data and participation in the study.
Methodology	Post-marketing clinical follow-up study performed according to standard care with an additional, non-burdensome, non-invasive procedure (Case 4.1) ambispective, multicentre, open-label, non-comparative. Only a quality-of-life questionnaire (AOFAS Score) and patient satisfaction will be requested in addition to standard care.
Objectives	Primary objective: - To evaluate the reduction in patient pain and the restoration of walking. Secondary objectives: - To collect performance and safety data to assess the subject's outcomes and functional status.
Endpoints	Primary endpoints: American Orthopaedic Foot and Ankle Society (AOFAS) score >80 points at 12 months. This score is assessed using a questionnaire measuring the patient's pain, function and mobility of the foot. It incorporates both subjective and objective information. Patients report their pain and the doctor assesses bone alignment. The scores range from 0, the worst, to 100, the best. There are different AOFAS scores depending on the location of the implant: - AOFAS Forefoot - Hallux - AOFAS Midfoot - AOFAS Ankle/Hindfoot Secondary endpoints: - Survival rate of each implants, at 12 months, to determine the Kaplan-Meier type survival curve, with any revision, whatever the cause, as the endpoint. Each inflection point will correspond to a revision surgery involving the removal or replacement of a component of the implant in question, whatever the cause of the revision. Patients who died or were lost to follow-up will be included in the analysis. - Bone consolidation rate of the cohort, the evaluation of bone consolidation at 12 months is assessed by the investigator via the following question: 'On radiographic reading, is bone consolidation satisfactory? 4 answers are proposed: 'total / partial / none / no information'. - Overall patient satisfaction will be assessed at 12 months using the following question: 'Given your expectations, are you satisfied with your operation? 4 answers are proposed: 'I am completely satisfied with the results of my operation / My condition has not improved as much as I had hoped, but I would be prepared to undergo the same operation for the same result / The operation has improved my condition, but I would not be prepared to undergo the same operation for the same result / My condition is the same or even worse than before my operation'. - Complications / effects and adverse events during and after the operation at all follow-up visits.

Data collected	The data collected for this study are: demographics, surgery details, clinical scores (AOFAS score, patient satisfaction), possible adverse events related or not to the implant.
Indirectly nominative nature of the data	Data is collected and stored in a pseudo-anonymized format that does not allow any patient to be identified through the data collected. Under no circumstances will patient names be transmitted or communicated to SERF.
Ethical consideration	CIP and associated procedures obtained an EC approbation on 18/11/2022 (CPP Nord Ouest III), prior to investigation initiation on 07/12/2022. As per its design, the investigation is submitted to an ethic committee and is reported to a Competent Authority (ANSM). This study was registered on clinicaltrials.gov public database.
Data quality assurance	A sponsor's clinical staff member will monitor collected clinical data through source data verification and source data review. A report will then be prepared.
Study-related treatment(s) / procedure(s)	Only a quality-of-life questionnaire and patient satisfaction (an additional procedure that is non-burdensome and non-invasive) are required for participation in this CI, compared with the standard care provided as part of the routine follow-up to foot surgery at each centre.
Study schedule	Study preparation: January-June 2022 Inclusion: as soon as regulatory approvals are obtained, estimated for November 2022 End of monitoring: 10/2023 CI report: Q3 2024
Study duration	The total duration of the study (inclusion + follow-up) is 2 years.
Statistical analysis	No statistical tests are planned for this CI. Only a descriptive analysis of the data is planned.