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Study on pelvis stabilization with the PERLA® TL System

Submission date
03/11/2025

Recruitment status
Recruiting

Registration date
12/11/2025

Overall study status
Ongoing

Last Edited
06/11/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The PERLA® TL system is a CE-marked device, intended to provide immobilization and stabilization of spinal segments in patients requiring spino-pelvic fixation. The sacropelvic region is a complex anatomical junction subject to high biomechanical stress, and extension of the construct is often indicated in cases of complex deformities, high-grade spondylolisthesis, or complex fractures. Despite advances in fixation techniques, challenges such as pseudoarthrosis and fixation failures remain. Techniques using iliac screws and S2-alar-iliac (S2AI) screws have shown improved outcomes, although no consensus exists in the literature regarding the superiority of one technique over another. This study aims to confirm the clinical performance and safety of the PERLA® TL system for spino-pelvic stabilization through a post-market clinical investigation combining retrospective and prospective data.

Who can participate?
Patients who received the PERLA TL system to immobilize and stabilize the spino-pelvic segments and were followed for at least 22 months after their surgery.

What does the study involve?
All the data will be collected per the sites' standard of care and based on their availability as real-world evidence for the retrospective visits (Pre-operative, Surgery, Immediate Post-operative, 1st Follow-up visits). This includes preoperative data, surgical details, and immediate to interim postoperative follow-up information.
The final postoperative follow-up is a prospective mandatory visit, and depending on the investigational site, may or may not be part of the site's routine care. In the latter case, the associated procedures (questionnaire, full spine X-ray or EOS) are considered non-invasive and non-burdensome additions to standard care.
Patient safety will be closely monitored, especially the revision rate of the pelvic fixation levels.

What are the possible benefits and risks of participating?
There are no anticipated benefits for the patients participating in the study. The surgery benefit will be the same whether the patients participate in the study or not. The additional visits and questionnaires are without risk to the patient. Depending on the site's standard of care, there is a slight increase in potential risks: if the EOS/full spine x-ray to assess the spinopelvic

parameters is performed out of the site's standard of care, the ionization risk is slightly increased.

Where is the study run from?
It is a French multicentric trial coordinated by Spineart SA (Switzerland)

When is the study starting and how long is it expected to run for?
From July 2025 to August 2027.
First SIV in January 2026
Close out visit in February 2027

Who is funding the study?
Spineart SA (Switzerland)

Who is the main contact?
clinic@spineart.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
P79_CLD004, IDRCB 2025-A02269-40

Study information

Scientific Title
Clinical investigation on spino-pelvic stabilization using PERLA® TL system in adult patients

Acronym

Perla TL Pelvic Fixation Study

Study objectives
The PERLA® TL system is CE marked device, intended to provide immobilization and stabilization of spinal segments in patients requiring spino-pelvic fixation. Between 2021 and the end of 2024, a total of 375,461 units were placed on the market, including 186,008 units sold in the European Economic Area (EEA), Turkey, and Northern Ireland. Globally, this corresponds to approximately 134,890 screws and 41,620 rods, with an estimated 17,020 surgeries performed.
This study aims to confirm the clinical performance and safety of the PERLA® TL system for spino-pelvic stabilization through a post-market clinical investigation combining retrospective and prospective data. This approach is part of Spineart's ongoing Post-Market Surveillance (PMS) activities and is considered sufficient to support the long-term clinical evidence required for the device's intended use.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted, Ethics committee name not provided (Address not provided, City not provided, Zip/postal code not provided; Telephone number not provided; not@available.com), ref: Reference number not provided

Study design
Restrospective and prospective French single-arm multicentric post-marketing clinical follow-up study

Primary study design
Interventional

Study type(s)
Safety

Health condition(s) or problem(s) studied
The Perla® TL system is indicated in skeletally mature patients in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine, spondylolisthesis, spinal stenosis, tumor, trauma, and deformities.

Interventions
As the primary function, the PERLA® TL system is intended to provide immobilization and stabilization of spinal segments. Sacropelvic is a complex junctional area owing to the complex regional anatomy and higher biomechanical stress. However, extension of the construct is indicated in cases with complex deformities, high-grade spondylolisthesis, and complex fractures. The challenges remain, which include pseudoarthrosis and fixation failures. The fixation techniques have constantly evolved, with better results with iliac screws and S2-alar-iliac (S2AI) screws. There is currently no consensus in the literature on which technique carries more favorable clinical outcomes.

To confirm the safety of the PERLA® TL System, the rate of the surgical revision/reintervention due to device failure or pain at the pelvic fixation level will be collected within the study follow-up period.

All other devices, instruments or surgery-related events will also be collected.

The performance of spino-pelvic stabilization based on radiographic parameters, as well as the clinical benefits based on Patient Reported Outcomes, will be collected.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Perla® TL System

Primary outcome(s)
Revision/reintervention rate due to device failure or pain, measured using data collected from the patient's medical record within the post-operative follow-up

Key secondary outcome(s))
The performance of spino-pelvic stabilization with the PERLA® TL System will be evaluated with the measurements of the following radiographic parameters on full spine x-ray or electro-optical system (EOS) x-ray, defined as below:
1. The correction of the sagittal lumbar lordosis (L1-S1) between the preoperative and postoperative follow-up visits
2. Pelvic incidence (PI) at the preoperative and postoperative follow-up visit
3. Pelvic tilt (PT) at the preoperative and postoperative follow-up visit
4. Sacral slope at the preoperative and postoperative follow-up visit
5. Sagittal vertical axis (SVA) at the preoperative and postoperative follow-up visit
6. Thoracic kyphosis (T4-T12) at the preoperative and postoperative follow-up visit
7. Coronal Cobb angle correction (in case of deformity) between the preoperative and postoperative follow-up visit
8. Interbody fusion at the level treated, as applicable (if interbody device implanted), at postoperative follow-up visit
9. Pelvic incidence - lombar lordosis (PI-LL) Mismatch at the preoperative and postoperative follow-up visit

The clinical benefits of spino-pelvic stabilization with the PERLA® TL System were evaluated using Patient Reported Outcomes (PRO) with the following endpoints:
1. Pain reduction was measured using the Visual Analog Scale (VAS back and leg) self-reported questionnaire at the postoperative visits compared to the preoperative visit (as applicable)
2. Functional capacity improvement was measured using the Oswestry Disability Index (ODI) self-reported questionnaire at the postoperative visits compared to the preoperative visit (as applicable)

Completion date
01/08/2027

Eligibility

Key inclusion criteria

Patients who meet all inclusion criteria will be enrolled:
1. Patients who received PERLA® TL system to immobilize and stabilize the spino-pelvic segments.
2. Informed Consent Form signed.
3. Patients followed for at least 22 months after their surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Key exclusion criteria
Patients who meet at least one exclusion criterion will be excluded:
1. Patient under 18 years old
2. Patient who had been deprived of their freedom by administrative or legal decision or who is under guardianship
3. Patient who does not speak/understand French

Date of first enrolment
15/01/2026

Date of final enrolment
15/02/2027

Locations

Countries of recruitment
France

Study participating centre
Hôpital Privé Saint-Martin
Allée des Tulipes
Pessac
France
33600

Study participating centre
Hôpital Privé de Provence
235 allée Nicolas de Staël
CS40 620
AIX EN PROVENCE CEDEX 3
France
13595

Study participating centre
Polyclinique Jean Villar
Avenue Maryse Bastié
BP 61
Bruges Cedex
France
33523

Sponsor information

Organisation
Spineart (Switzerland)

ROR
https://ror.org/05sz2c652

Funder(s)

Funder type
Industry

Funder Name
Spineart (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

The dataset generated and analysed during the current study will be available upon request from clinic@spineart.com. The type of data that will be shared: clinical data of the study. Participants will be required to provide consent. All subjects' data are pseudo-anonymized. There are no ethical or legal restrictions.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes