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Clinical Investigation Title	Occipitocervical spine stabilization using PERLA® posterior occipito-cervico-thoracic fixation. A post-market clinical follow-up study.
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Study design	This is a retrospective, multicenter, single-arm, post-market study on 15 patients having received treatment with the PERLA® Occipital plate of PERLA® posterior Occipito-Cervico-Thoracic (PERLA OCT) fixation system, to treat cranio-cervical instability. These patients had occipito-cervical fixation surgeries between March 2021 and March 2023 in 3 hospitals (one in Toulon, France, one in Bruck an der Mur, Austria and one in Donauwörth, Germany). The study duration went from March 2023 (1st inclusion) to January 2024 (last patient last visit). For the final analysis, the data entry cut was 03 July 2024.
Device and study purpose	The PERLA® OCT fixation system consists of a variety of rods, screws, hooks, rod connectors, and occipital plates which can be rigidly locked to the rods. PERLA® implants are made of titanium alloy; some rods are also available in cobalt chromium alloy. The implantable components of the system are delivered sterile. The Perla® OCT system is a class III (MDR) CE marked device. The occipital plate is categorized as a bone-screw internal spinal fixation system that allows the immobilization and stabilization of the craniocervical junction (CCJ) and of the atlantoaxial joints by occipitocervical fixation leading to fusion. Occipitocervical (O-C) fixation results in severe restriction of head movement after surgery creating stability and time for fusion of the segment. Addition of bone graft promotes the fusion. According to the state of the art, time to solid fusion is variable, but it is usually 6–12 months and can be up to 24 months. After 24 months, if the fusion has not occurred, it is generally considered that the fusion failed. In cases where bone graft is not added, the objective is stability, but not necessarily fusion. This study is focused on evaluating the Perla® Occipital Plate system. It has been demonstrated that occipitocervical fusion (OCF) is an established surgical technique for the treatment of CCJ instability. It is considered that the Perla® OCT system is a known technology with no significant novelty when compared to currently marketed systems with demonstrated clinical performance and safety data. Therefore, a post-market retrospective study to collect real-world evidence on existing post-operative follow-ups is deemed sufficient to confirm the clinical performance and safety of Perla® Occipital Plate for the treatment of cranio-cervical instabilities as part of the PMCF.
Results and conclusion	This report provides short- and long-term safety and performance data on the Perla® Occipital Plate when used to treat cranio-cervical junction instability. Clinical and safety data was collected retrospectively on 15 patients who received the Perla® Occipital Plate. The average follow-up period for all 15 patients was 8.7±6.3 months (ranging from 0 to 17.2 months). Four patients died following surgery or within the first weeks after surgery. These patients suffered from extremely serious underlying conditions (large trauma or tumors), which caused their cranio-cervical instability. Safety data was collected on all 15 patients. Performance data (which required at least one follow-up with radiological imaging) and clinical benefit data were collected on the remaining 11 patients. Data on these 11 patients was collected over an average follow-up of 11.9±3.9 months (6.4–17.2 months).

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Treatment levels

In total, 55 cranio-cervical spinal levels were treated:

- All 15 patients had occipital fixation using the PERLA® Occipital plate in C0.
- 40 cervical levels (C1–C7) were stabilized using PERLA® cervical screws, hooks, and rods.
- All cervical levels used lateral mass fixation (MAGERL technique).
- Most constructs extended from the occiput down to C4 (60%) or C3 (20%).
- No cages or anterior plates were used in addition to the PERLA® OCT system.

Safety Results (n = 15, mean follow-up 8.7 months)

A total of 17 adverse events occurred in 11 of the 15 patients.

The most common events were:

- Infection: 4 patients (26.7%)
- Difficulty swallowing (dysphagia): 2 patients (13.3%)
- Fractures: 2 patients (13.3%)

Among these 17 adverse events, 3 were related to the surgery or the device

- 1 infection was related to the surgery.
- 1 dysphagia was related to the device.
- 1 rod breakage occurred and was considered a serious adverse event related to both surgery and the device, requiring revision surgery.

The remaining 14 adverse events were not related to the device or the spine surgery. Five of these 14 events led to patient death (4 occurred following surgery or within the first weeks). Causes of death included:

- Massive hemoptysis during a CT-guided lung puncture
- Severe polytrauma with brain and spinal cord injury
- Postoperative asystole
- Asphyxia due to tracheostomy complications
- Dysphagia with vomiting and nausea

No device deficiencies that could have caused serious adverse device effects were reported.

Performance and Clinical Benefit (n = 11, mean follow-up 11.9 months)

<u>Spinal stability and fusion</u>

- 81.8% of patients maintained stable alignment of the operated spinal segment from immediately after surgery to their last follow-up.
- Out of 34 levels assessed:
    - 35.3% showed solid fusion
    - 14.7% showed ongoing fusion

50% of patients had full fusion or ongoing fusion across all treated levels.

No bone graft was placed at the occipital level at sites #1 or #2 (only cervical levels received graft).

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Adjacent Segment Degeneration (ASD)

- 4 patients (36.4%) developed ASD. None required surgical re-intervention.
  - 3 had bone spurs and degenerative arthritis of the facet joints
  - 1 of these 3 patients also had spondylolisthesis
  - The 4th had a herniated disc with stenosis.
- 2 other patients showed bones spurs and degenerative arthritis of the facet joints at other cervical levels than the adjacent treated levels.

All these events, the ASD or degeneration at another cervical/instrumented segment occurred in the same site.

Clinical symptoms and daily functioning

- Before surgery, most patients had high mJOA scores, meaning no or mild myleopathy:
  - 6 had no myelopathy
  - 3 had mild myelopathy
  - 1 had moderate
  - 1 had severe

  Over time, postoperative information was collected for 7 patients:
  - Most patients stayed stable (5 of 7)
  - Some improved (2 of 7)
  - None worsened
- 8 out of 9 patients, with clinical data and long follow-up, recovered their ability to perform daily activities, and their need for pain medication decreased significantly.

Conclusion

The study shows that the PERLA® OCT fixation system generally provides acceptable outcomes in terms of spinal stability, fusion, and clinical improvement. Because cranio-cervical instability is rare, most published studies involve small patient numbers. This PERLA OCC dataset alone cannot provide definitive conclusions due to its limited size, but it contributes valuable real-world evidence. These results can be combined with other existing studies in future literature reviews or meta-analyses.