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C0166 - LONG-TERM SAFETY AND PERFORMANCE OF A POLYMERIC CLAMP-LIKE CRANIAL FIXATION SYSTEM

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Resumen

Objectives: After a craniotomy procedure to access the brain, neurosurgeons have several options to fix the bone flap to the skull. The aim of this study was to assess if a polymeric clamp-like fixation system (Cranial LOOP) is a safe and reliable system that maintains over time an appropriate alignment of the bone flap.

Methods: This is an observational, retrospective, case-series study of 60 patients that underwent a craniotomy and were subject to cranial bone flap fixation with the Cranial LOOP fixation system. Baseline clinical parameters, surgical variables, medical records and all the post-operative medical images available were reviewed to assess the bone flap alignment and potential adverse events.

Results: A total of 182 Cranial LOOPS were implanted in the 60 patients (56.01 ± 20.21 years, 55.0% women) included in the study. The cranial fixation system maintained a good bone flap alignment in 95% of the patients studied immediately after surgery, and in up to 96.7% of them at the end of follow-up. No intraoperative complications were reported. An ulcer potentially related with a device was detected, which was solved without the need of device removal. No artifacts were observed in any of the 219 medical images analysed.

Conclusions: Cranial LOOP is a safe and reliable postoperative long-term cranial bone flap fixation system. The devices can fix the bone flap after a wide range of craniotomy procedures, performed in multiple locations, and they provide a good bone flap alignment. Cranial LOOP does not interfere in patient follow-up through medical imaging.