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## P-001 - A MULTICENTRIC, RANDOMIZED CONTROLLED TRIAL TO ASSESS THE PERFORMANCE AND SAFETY OF TWO DIFFERENT BONE FLAP FIXATION SYSTEMS FOR CRANIOTOMY PROCEDURES

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### Resumen

**Introduction:** Titanium plates and screws (P&S) is the most widely used system to close a craniotomy after a neurosurgical procedure.

**Objectives:** The aim of this study was to compare the clinical safety and performance of a PEEK-based clamp-like system (Cranial LOOP, NEOS Surgery, S.L.) with the standard of care system for craniotomy closure: P&S.

**Methods:** International multi-center, prospective, two-arm, randomized controlled trial. Sixty patients that had a craniotomy procedure were randomized to clamp-like (CLOOP) or P&S bone flap fixation systems. Subjects were evaluated at screening (pre-operative visit), during surgery, immediately post-surgery and mid-term follow-up. Main study variables were: bone flap alignment (MR/TC assessment), easiness of use, and the presence of bulges or discomfort associated to the closure system. Potential adverse effects of both closure systems were also monitored during the trial.

**Results:** A total of 60 patients ( $54.5 \pm 16.2$  years, 60% women) were randomized to P&S ( $n = 32$ ) or CLOOP group ( $n = 28$ ). The implantation of both closure systems was rated as Easy or Very easy (96.4% CLOOP and 100% P&S), but the surgeons were more satisfied with the CLOOP system (96.4% satisfied or very satisfied) than with P&S (84.4% satisfied or very satisfied,  $p = 0.049$ ). After surgery, CLOOP achieved a perfect bone flap alignment in 89.3% of cases ( $n = 25$ ), while 3 cases showed a slight protrusion; P&S achieved a perfect bone flap alignment in 87.5% of cases, while 3 cases showed a slight depression and one a slight protrusion. One patient implanted with P&S reported some discomfort associated with the closure system, and another one, visible bulges. No serious adverse events or device deficiencies were associated to any of the two systems evaluated.

**Conclusions:** Despite the widespread use of P&S versus clamping systems, our data shows that PEEK-based clamp-like devices perform equally, or even better, than P&S for fixation of the cranial bone flap.