

## Introduction

Rigid cranial flap fixation is essential for ensuring neurological protection and maintaining cranial integrity following craniotomy. Titanium plates and screws, the current gold standard, offer reliable mechanical fixation but are associated with limitations including imaging artifact, hardware palpability, potential long-term complications, particularly in younger or medically complex populations, and unfavorable cosmesis at bony prominences or in cases where multiple fragments require reapproximation, as often encountered in skull base surgery. Bioresorbable alternatives have emerged to address these concerns, with recent attention focused on a novel mineral-organic bone adhesive currently under clinical evaluation (NCT06780852). This material is designed to provide immediate fixation of the flap while supporting bone remodeling and eliminating the need for permanent hardware.

## Methods and Materials

We present an intra-patient comparative case of a 44-year-old female undergoing staged bilateral middle fossa craniotomies for skull base repair and meningoencephaloceles. The first procedure utilized the novel bone adhesive for flap fixation, while the second, performed six months later, employed conventional titanium plates and screws. This unique sequential approach allows direct qualitative and radiographic comparison of fixation outcomes within the same anatomical and physiological environment.

This is a unique patient who was part of a larger cohort in an ongoing prospective pilot clinical trial of a novel mineral-organic bone adhesive (NCT06780852). This study is assessing the safety and preliminary efficacy of this bioresorbable adhesive in cranial flap fixation. The primary endpoint is the rate of serious device- or procedure-related adverse events within 6 months postoperatively. Secondary outcomes include radiographic assessment of radiolucency at flap margins, flap immobility, patient-reported outcome measures, and cosmetic satisfaction at multiple time points.

## Results

In this intra-patient case, the adhesive-fixed flap demonstrated excellent intraoperative handling and immediate mechanical stability. At six months, CT imaging showed no evidence of radiolucency or displacement, per Table 2. Cosmetic contour was subjectively superior on the adhesive-fixed side, with no complications reported. These findings are concordant with preliminary results from NCT06780852, which so far indicate a favorable safety profile and promising radiographic outcomes.

## Discussion

Published literature on bioresorbable fixation systems supports these observations. Studies evaluating polymeric clamps, absorbable plates, and mineral-organic adhesives in both clinical and preclinical models report high fixation strength, low complication rates, and improved imaging compatibility. For example, Foley et al. demonstrated enhanced bone integration and mechanical resistance in an ovine model, while Smith et al. showed improved alignment and CSF leak resistance using a mineral-organic adhesive in cadaveric studies. Across these studies, absorbable systems consistently show stable fixation with minimal adverse events and improved patient satisfaction metrics.

Table 1

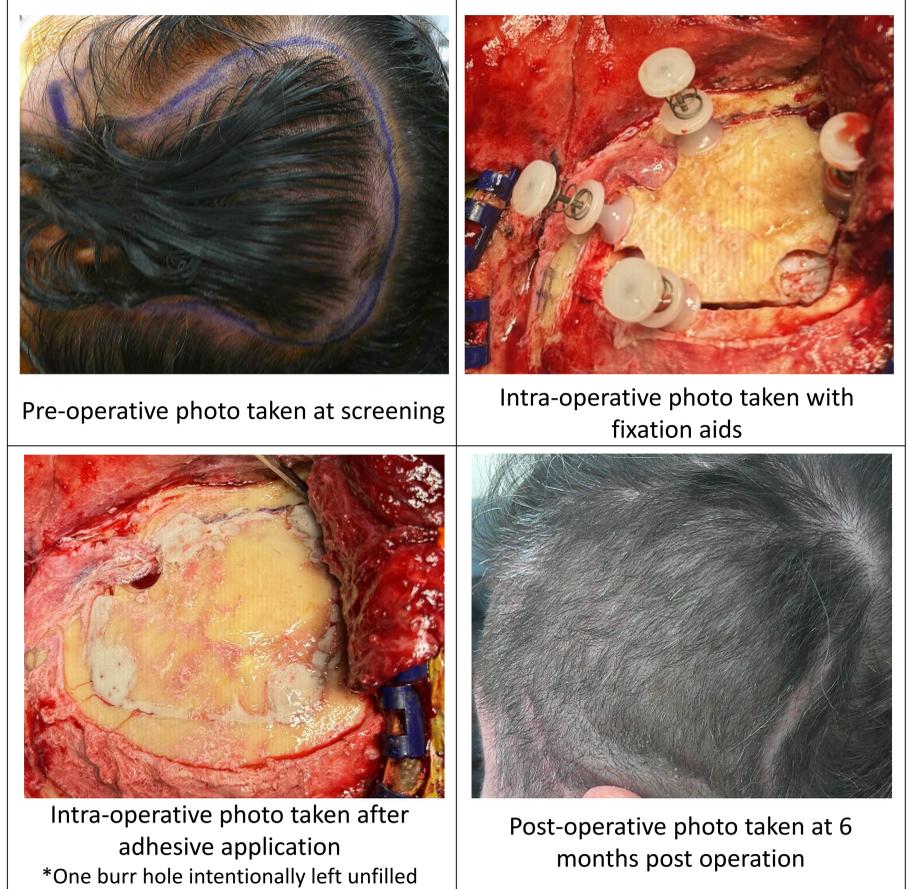
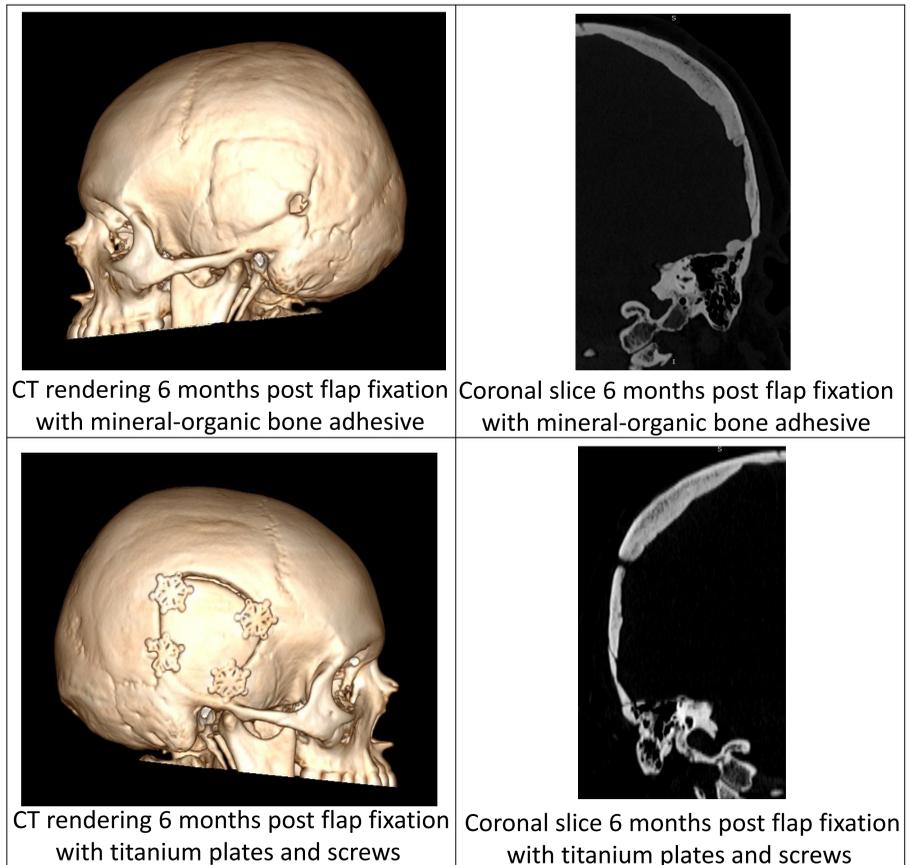


Table 2



## Conclusions

This intra-patient comparison adds to the growing body of evidence supporting the clinical feasibility of a bioresorbable bone adhesive for cranial flap fixation. Early findings from an ongoing clinical trial (NCT06780852) reinforce the material's safety, radiographic integration, and cosmetic acceptability. While longer-term and larger-scale studies are needed, these initial results suggest that such adhesives may represent a meaningful advancement in cranial reconstruction by eliminating permanent hardware and enhancing postoperative outcomes.

## Contact

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