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# Management Strategies and Clinical Outcomes of Wound Complications after Polyetheretherketone Cranioplasty: A Real-World Single-Center Cohort Study

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**Title**

Management Strategies and Clinical Outcomes of Wound Complications after Polyetheretherketone Cranioplasty: A Real-World Single-Center Cohort Study

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# Management Strategies and Clinical Outcomes of Wound Complications after Polyetheretherketone Cranioplasty: A Real-World Single-Center Cohort Study


## Abstract

**Background:** Polyetheretherketone (PEEK) cranioplasty is increasingly used for skull defect repair, yet the optimal management of postoperative wound complications remains poorly defined. We aimed to characterize the management strategies and clinical outcomes of wound complications after PEEK cranioplasty in a real-world single-center cohort. **Methods:** This single-center retrospective cohort included 580 adults who underwent delayed PEEK cranioplasty. Treatment failure was defined as implant removal or death. Predictors of treatment failure were identified by multivariable logistic regression; outcomes across four management strategies (conservative care, debridement, flap coverage, removal) were compared with propensity score matching (PSM). **Results:** Wound complications occurred in 138 patients (23.8%). Success rates were 46.9% (conservative), 71.4% (debridement), 83.3% (flap), and 0% (removal); median healing times were 57, 40, and 30 days (log-rank $p < 0.001$). After PSM (33 matched pairs), active management achieved higher success (75.8% vs 39.4%, McNemar $p = 0.010$) and shorter healing time (36 vs 60 days, Wilcoxon $p < 0.001$) than conservative care. Dual antiplatelet therapy (OR 1.97, 95% CI 1.04-3.50), tracheostomy (OR 2.21, 95% CI 1.12-3.96), postoperative fever (OR 2.53, 95% CI 1.41-4.47), and immunosuppression (OR 3.95, 95% CI 1.27-9.37) independently predicted treatment failure; vacuum drainage was protective (OR 0.47, 95% CI 0.27-0.77; bootstrap C-index 0.74). A nomogram integrating seven readily available variables was constructed. **Conclusions:** Active management of PEEK cranioplasty wound complications achieved higher material preservation and faster healing than conservative care; the proposed nomogram may assist individualized strategy selection.

**Keywords:** polyetheretherketone; cranioplasty; wound complication; healing time; real-world study

**Contributions to the literature**

1. Skull reconstruction after brain swelling is a common operation, and losing the implant to a wound that will not heal is costly and largely avoidable.
2. Advice on managing these wounds rests mostly on small studies and expert opinion, not on measured outcomes.
3. This study uses routine records of 580 patients to compare how often each treatment worked and how long healing took.
4. It identifies a few bedside details that predict failure, offering a simple way to flag patients needing closer follow-up.
5. The findings support structured wound checks after discharge and may reduce avoidable removal of implants and repeat surgery.

## Background

Skull defect repair (cranioplasty) is one of the most frequently performed neurosurgical procedures and carries important implications for neurological recovery, cerebral protection, and patient quality of life[1,2]. Among the materials available, autologous bone remains the traditional first choice, but it is associated with high rates of resorption, infection, and irregular contouring, particularly after decompressive craniectomy[3]. Synthetic materials have therefore gained attention, with titanium mesh and PEEK being the two most widely used. Compared with titanium, PEEK offers superior radiological translucency (free of artifact on CT/MRI), patient-specific customization, biocompatibility, and a lower thermal conductivity profile[4]. Recent systematic reviews and a large German registry analysis have suggested that PEEK has lower overall and reoperation complication rates than titanium mesh, supporting its increasing adoption[3,5].

Nevertheless, wound complications after cranioplasty remain clinically relevant, with literature-reported overall rates of 10%-25%[6-8]. These include skin breakdown, subgaleal effusion/cerebrospinal fluid (CSF) leak, surgical site infection, and implant exposure. The latter, in particular, is associated with material loss, prolonged hospitalization, and a substantial psychological and economic burde[9]. Existing studies on PEEK cranioplasty have predominantly focused on the incidence and risk factors of complications[5,10,11]; in contrast, the management of these complications and the comparative effectiveness of different treatment strategies remain poorly characterized.

Existing evidence on management comes largely from small retrospective series or expert consensus[2,11]. Expert consensus on cranioplasty[12] recommends conservative measures (pressure dressing, aspiration) for subgaleal effusion, early surgical debridement for superficial infection, and implant removal for material exposure, deep infection, or intractable effusion with flap necrosis. However, no comparative outcome data underpin these recommendations, and the differential efficacy of conservative care versus active surgical strategies has not been systematically quantified. Moreover, healing time, arguably the most patient-centered outcome, has rarely been reported as a primary endpoint in the cranioplasty literature. A prolonged healing course not only delays rehabilitation and return to normal life but also expands the window for secondary infection, implant exposure, and material loss, making healing time a clinically meaningful and policy-relevant endpoint[13].

Against this background, the present real world single-center cohort study aimed to (1) describe the spectrum and predictors of wound complications after PEEK cranioplasty; (2) comparatively evaluate the clinical outcomes (success rate, healing time) of four management strategies with PSM-based adjustment; and (3) construct a bedside-applicable nomogram to support individualized strategy selection. The hypothesis was that active surgical management (debridement or flap coverage) would be associated with higher material-preservation success and shorter healing time than conservative care, after adjustment for selection bias using PSM.

## Methods

## 1. Study design and setting

This was a single-center, retrospective, observational cohort study conducted at the Department of Neurosurgery, Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology. The study is reported in accordance with the STROBE statement[14]. Ethical approval was obtained from the institutional review board, and the requirement for informed consent was waived owing to the retrospective design and use of de-identified data.

## 2. Study population

Consecutive adult patients who underwent delayed PEEK cranioplasty at our institution between 1 May 2024 (when PEEK was introduced following Hubei provincial volume-based procurement) and 31 January 2026 were screened. Inclusion criteria were as follows: (1) age ≥18 years; (2) history of decompressive craniectomy with clear aetiology (trauma, intracranial hemorrhage, ischemic stroke, or post-tumor resection); (3) skull defect repair with conventional surface-smooth PEEK (Xi'an Kangtuo Medical Technology; PEEK-OPTIMA-LT1; compliant with YY/T 0660), including standard components and customized implants; (4) complete pre-operative imaging; and (5) postoperative follow-up of at least 3 months. Pre-operative consciousness: For patients without tracheostomy, GCS ≥13 was required. For tracheostomized patients, in whom the verbal component is fixed at 1 and the conventional GCS is artificially lowered, the "eye + motor" sub-score (GCS-E+M ≥10, or corrected GCS ≥13) was adopted for inclusion; tracheostomy was retained as a covariate for subgroup analysis. Exclusion criteria were: (1) mixed-material cranioplasty (combined with titanium mesh or autologous bone); (2) emergency/primary repair performed simultaneously with hematoma evacuation; (3) revision cranioplasty; (4) combined complex procedures (e.g., tumour resection, vascular bypass, CSF leak repair); (5) pre-operative active infection; and (6) insufficient documentation or loss to follow-up without any wound-complication event before 3 months. The co-primary endpoint was treatment success (healed with material preserved). Variable definitions are provided in the footnotes to the relevant tables.

## 3. Data collection and quality control

Data were extracted by two independent reviewers from the institutional clinical research data platform and the electronic medical record[15], with disagreement resolved by a senior investigator. Variables were defined a priori in a data dictionary (CRF) and entered in a standardized electronic form. Logical consistency checks were performed (e.g., complication-timing consistency, success-outcome consistency, exposure nested within breakdown). Continuous variables were inspected for implausible values and duplicate-density artifacts, and categorical variables for coding errors. Missing data were minimal by design; variables with >20% missingness were to be excluded, and complete-case analysis was used otherwise. A random 10% of records was re-abstracted to audit inter-reviewer agreement (target $\kappa \geq 0.80$). Data were collected between 1 May 2024, when PEEK cranioplasty was introduced at our institution following the Hubei provincial volume-based procurement, and 31 January 2026, when the de-identified database was locked. Statistical analysis was performed between February and April 2026.

**4. Statistical analysis**

Continuous variables are presented as median (interquartile range, IQR) and compared with the Mann-Whitney U test. Categorical variables are presented as n (%) and compared with the $\chi^2$ or Fisher's exact test. The spectrum of wound complications is tabulated with absolute counts and proportions. The Kaplan-Meier method with the log-rank test was used to compare healing time across the four management strategies.

For the comparison of active (debridement or flap) versus conservative management, PSM was performed to reduce selection bias. A logistic regression model was fitted to estimate the propensity score using the following covariates: diabetes, dual antiplatelet, tracheostomy, ASA (American Society of Anesthesiologists) ≥III, hypoalbuminemia, scalp thickness, vacuum drainage, skin breakdown, and infection. Nearest-neighbour 1:1 matching with a caliper of 0.2 on the propensity score (matching from the highest to the lowest score, without replacement) was applied. Post-matching balance was evaluated using standardized mean differences (SMDs); a priori, SMD < 0.1 indicated adequate balance.

Multivariable logistic regression was used to identify independent predictors of treatment failure. Variables with $p < 0.10$ on univariable analysis or with strong clinical

relevance were entered into the multivariable model. Results are reported as odds ratios (OR) with 95% CI. To accommodate the number of treatment-failure events (n = 71) relative to the nine candidate covariates (event-per-variable ≈ 7.9), L2-regularized logistic regression was used and bootstrap resampling (1,000 iterations) was performed to obtain robust CIs and to assess model discrimination. The model's C-index and its bootstrap distribution are reported.

A bedside nomogram was constructed by refitting a parsimonious multivariable logistic model incorporating seven readily available variables (diabetes, dual antiplatelet therapy, tracheostomy, postoperative fever, immunosuppression, prior radiotherapy, and scalp thickness) to enable individualized risk prediction. Unadjusted RCS regression with four knots (at the 25th, 50th, 75th, and 95th percentiles of scalp thickness) was used to explore the nonlinear association of scalp thickness with treatment failure; overall significance was tested with a joint Wald test of the linear and nonlinear spline terms (chi-squared with 2 degrees of freedom), and the nonlinear component was tested with a Wald test of the spline term alone.

Three sensitivity analyses were pre-specified. (1) Restriction to patients with ≥ 6 months of follow-up: follow-up duration was defined as the time from cranioplasty to healing, implant removal, death, or the last documented clinical contact, and patients with < 180 days of follow-up and no in-hospital event were excluded (yielding 491 patients with 68 failure events). (2) Exclusion of perioperative deaths (n = 577, with 68 failure events). (3) Redefinition of the outcome as implant exposure only (n = 15 events), with the remaining patients classified as non-events regardless of removal status. All sensitivity analyses used the same nine covariates as the primary multivariable model; results are reported as adjusted odds ratios with bootstrap 95% CIs.

All tests were two-sided, with $p < 0.05$ considered statistically significant. Analyses were performed in Python 3.13 (lifelines 0.30, scikit-learn 1.9, statsmodels 0.14) and R 4.6.1 (cmprsk for Fine-Gray competing-risk regression). Generative artificial intelligence tools were used for language editing and manuscript formatting only; no data, analyses, or scientific content were generated by these tools. Study design, data

collection, statistical analysis, interpretation, and all conclusions were produced and verified by the authors, who take full responsibility for the content of this article.

## Results

### 1. Patient flow and characteristics

A total of 583 patients who underwent PEEK cranioplasty during the study window were screened. After excluding 3 patients with follow-up < 3 months and no recorded events, 580 patients (57.8% male; median age 51 years, IQR 40-59) were included in the analysis (**Figure 1**). Wound complications occurred in 138 patients (23.8%), and 442 (76.2%) had an uneventful course (**eTable 1**).

Baseline characteristics stratified by complication status are presented in **Table 1**. Patients with wound complications were older (median 54 vs 49 years, $p = 0.002$) and more likely to have diabetes mellitus (20.3% vs 9.7%, $p = 0.002$), dual antiplatelet therapy (22.5% vs 12.2%, $p = 0.005$), ASA grade ≥ III (32.6% vs 21.9%, $p = 0.015$), a history of poor wound healing (17.4% vs 10.4%, $p = 0.040$), immunosuppression (5.1% vs 1.1%, $p = 0.013$), and postoperative fever (29.7% vs 10.9%, $p < 0.001$); they were correspondingly less likely to have received vacuum drainage (28.3% vs 43.9%, $p = 0.002$). Age, sex, BMI (Body mass index), defect area, scalp thickness, incision site, flap type, tracheostomy, and drainage-free status were otherwise comparable between the two groups.

### 2. Spectrum of wound complications

Among the 580 patients, 138 (23.8%) experienced at least one wound complication, constituting the composite endpoint. Within the four events defining this endpoint, subgaleal effusion/CSF leak (n = 55, 9.5%) and skin breakdown (n = 54, 9.3%) were the most frequent, followed by wound infection (n = 40, 6.9%) and implant exposure (n = 15, 2.6%). Other events recorded across the cohort included postoperative fever (n = 89, 15.3%), subdural/epidural effusion (n = 59, 10.2%), postoperative seizure (n = 45, 7.8%), pneumocephalus (n = 34, 5.9%), and postoperative hematoma (n = 29, 5.0%); of these, postoperative fever was the single most frequent event overall. Because individual events were not mutually exclusive, the sum of event counts exceeds the 138 patients with any wound complication (**Table 2**).

### 3. Outcomes by management strategy

Among the 138 patients with wound complications, conservative care was the most common initial strategy (n = 96, 69.6%), followed by surgical debridement (n = 21, 15.2%), flap coverage (n = 12, 8.7%), and implant removal (n = 9, 6.5%) (**Table 3A**). Treatment success rates were 46.9% (conservative), 71.4% (debridement), 83.3% (flap), and 0% (removal). Median healing time decreased progressively from conservative care (57 days, range 25-90) to debridement (40 days, range 21-56) to flap coverage (30 days, range 18-42). The log-rank test confirmed a significant difference across the four strategies ($p < 0.001$; **Figure 2**).

### 4. Propensity-score-matched comparison

After 1:1 nearest-neighbour PSM (caliper 0.2, matching from the highest to the lowest propensity score without replacement), 33 matched pairs of active versus conservative care were formed. Covariate balance improved substantially after matching: 6 of 9 covariates achieved a SMD < 0.1, whereas residual imbalance persisted for dual antiplatelet therapy (SMD 0.209), ASA grade ≥ III (SMD 0.368), and scalp thickness (SMD 0.111) (**Table 3B**). In the matched cohort, active management was associated with a significantly higher success rate than conservative care (75.8% vs 39.4%, paired McNemar $p = 0.010$) and a significantly shorter median healing time (36 vs 60 days, paired Wilcoxon $p < 0.001$).

### 5. Predictors of treatment failure

On univariable analysis, postoperative fever (OR 2.72, 95% CI 1.54-4.82, $p = 0.001$), tracheostomy (OR 2.46, 95% CI 1.30-4.66, $p = 0.006$), immunosuppression (OR 5.43, 95% CI 1.68-17.61, $p = 0.005$), prior radiotherapy (OR 2.89, 95% CI 1.00-8.37, $p = 0.050$), dual antiplatelet therapy (OR 2.04, 95% CI 1.12-3.73, $p = 0.020$), and diabetes mellitus (OR 1.95, 95% CI 1.02-3.72, $p = 0.043$) were associated with treatment failure, whereas vacuum drainage was protective (OR 0.46, 95% CI 0.26-0.82, $p = 0.008$). After multivariable adjustment, four independent predictors of treatment failure remained: dual antiplatelet therapy (adjusted OR 1.97, 95% CI 1.04-3.50, $p = 0.029$), tracheostomy (adjusted OR 2.21, 95% CI 1.12-3.96, $p = 0.015$), postoperative fever (adjusted OR 2.53, 95% CI 1.41-4.47, $p < 0.001$), and immunosuppression (adjusted OR 3.95, 95% CI 1.27-9.37, $p = 0.007$); vacuum drainage remained independently

protective (adjusted OR 0.47, 95% CI 0.27-0.77, $p = 0.005$; **Table 4** and **Figure 3**). The L2-regularized model demonstrated moderate-to-good discrimination, with a C-index of 0.716 and a bootstrap-validated C-index of 0.735 (95% CI 0.672-0.794). Unadjusted RCS analysis did not identify a significant nonlinear association between scalp thickness and treatment failure (P-overall = 0.747, P-nonlinear = 0.489; **Figure 4**), suggesting that the relationship, if any, is approximately linear.

**6. Clinical nomogram**

A bedside-applicable nomogram was constructed by refitting a parsimonious multivariable logistic model that incorporated seven readily available variables (diabetes, dual antiplatelet therapy, tracheostomy, postoperative fever, immunosuppression, prior radiotherapy, and scalp thickness; **Figure 5**). The total-points axis (0-200) maps to the predicted probability of treatment failure (0.01-0.40), allowing individualized risk estimation at the bedside.

**7. Sensitivity analyses**

Three pre-specified sensitivity analyses yielded two distinct patterns (**eTable 2**). (i) Excluding perioperative deaths (n = 577, 68 failure events) and (ii) restricting to patients with ≥ 6 months of follow-up (n = 491, 68 failure events) both preserved the direction and significance of all main predictors: dual antiplatelet therapy, tracheostomy, postoperative fever, and immunosuppression remained independent risk factors, and vacuum drainage remained independently protective, with effect estimates consistent with the primary analysis. (iii) When the outcome was redefined as implant exposure only (n = 15 events), the predictor pattern differed qualitatively: prior radiotherapy (OR 5.68, 95% CI 1.50-15.63, $p = 0.004$) and diabetes mellitus (OR 3.19, 95% CI 0.96-7.93, $p = 0.040$) emerged as the dominant predictors, whereas tracheostomy (OR 0.47, 95% CI 0.35-0.64, $p < 0.001$) and immunosuppression (OR 0.74, 95% CI 0.56-0.93, $p = 0.023$) were no longer positively associated with exposure, and the direction of the tracheostomy estimate was reversed. This mechanism-specific pattern suggests that implant exposure and implant removal may reflect distinct failure pathways (tissue-quality-related versus infectious/airway-related), although the small number of exposure events (n = 15) and the resulting imprecision warrant cautious interpretation. In the formal Fine-Gray competing-risk analysis (R cmprsk; **eTable 3**),

active management was associated with a substantially higher subdistribution hazard of wound healing among complicated cases (sHR 6.44, 95% CI 3.37-12.32, $p < 0.001$). In the full cohort, with implant removal as the event of interest, tracheostomy (sHR 2.65, 95% CI 1.46-4.78, $p = 0.001$), postoperative fever (sHR 2.30, 95% CI 1.37-3.87, $p = 0.002$), immunosuppression (sHR 5.03, 95% CI 2.11-11.95, $p < 0.001$), and prior radiotherapy (sHR 2.83, 95% CI 1.17-6.83, $p = 0.021$) each increased the subdistribution hazard of implant removal. The nomogram calibration and decision-curve analyses (**eFigure 1**), the temporal profile of complications (**eFigure 2**), and the drainage-stratified analyses (**eFigure 3**) are provided in the Additional files (Additional file 1 and Additional file 2).

### 8. Temporal profile and drainage-stratified outcomes

The cumulative-incidence analysis (**eFigure 2**) revealed that the majority of wound complications manifested within the first 2-4 postoperative weeks, with subgaleal effusion appearing earliest and implant exposure emerging latest, consistent with the sequential pathophysiology of effusion → breakdown → exposure. In the drainage-stratified analysis (**eFigure 3**), vacuum drainage was associated with a lower wound complication rate than conventional drainage (16.7% vs 28.4%), and, among complicated cases, with a shorter median healing time; the difference between vacuum and conventional drainage was most pronounced for subgaleal effusion (4.7% vs 12.0%), supporting the biological rationale that active suction removes the fluid collection that would otherwise impair soft-tissue apposition. Patients without any drainage constituted a small minority (n = 30), precluding robust comparative inference for this subgroup.

## Discussion

### 1. Main findings

In this large real-world cohort of 580 consecutive PEEK cranioplasties, wound complications affected nearly one in four patients (23.8%), and 11.7% of all patients ultimately required implant removal, a substantial burden of complicated wound healing that underscores the need for proactive complication management. Beyond describing the spectrum and outcomes of these complications, the present study offers

a head-to-head comparison of the four management strategies with healing time as a patient-centered endpoint, an area for which comparative effectiveness data remain scarce; PSM was applied to mitigate the selection bias inherent in observational comparisons of management decisions. Multivariable analysis further identified four independent predictors of treatment failure: dual antiplatelet therapy, tracheostomy, postoperative fever, and immunosuppression with vacuum drainage as a protective factor. These predictors underpin a bedside nomogram that translates the findings into a quantifiable risk-stratification tool for individualized decision-making.

**2. PEEK cranioplasty outcomes in context**

The 23.8% composite wound complication rate observed here is consistent with the 10%-25% range reported for PEEK in prior meta-analyses[3,5] and with the 19.7% reported in a 211-patient comparative study from China[8]. Notably, the implant exposure rate of 2.6% lies at the lower end of the 2%-10% range reported in the literature, and the perioperative mortality of 0.5% is well within the 0.5%-3% reported for elective cranioplasty in large registries[16]. The spectrum of complications also mirrors published series: subgaleal effusion and skin breakdown were the most frequent events, whereas deep infection requiring implant removal remained uncommon[6,17]. These figures suggest that the institutional learning curve and standardized peri-operative management protocol were effective, providing a credible denominator against which the management-strategy findings can be interpreted.

**3. Management strategy comparison**

The most clinically actionable finding is that active surgical management (debridement or flap coverage) achieved higher material-preservation success and shorter healing time than conservative care, with the difference remaining significant after PSM (75.8% vs 39.4%, paired McNemar $p = 0.010$; healing time 36 vs 60 days, paired Wilcoxon $p < 0.001$). The log-rank test confirmed that conservative care was associated with the longest healing tail (up to 90 days), whereas flap coverage achieved complete healing in a median of 30 days. These findings empirically validate the 2025 Chinese expert consensus recommendation that material exposure, deep infection, or intractable subgaleal effusion with flap necrosis warrants active surgical intervention[18].

Importantly, the PSM-adjusted comparison, which adjusted for nine covariates (diabetes, dual antiplatelet therapy, tracheostomy, ASA grade, hypoalbuminemia, scalp thickness, vacuum drainage, skin breakdown, and wound infection), supports the causal interpretation that active management is genuinely superior rather than merely reserved for less severe cases. Nevertheless, residual unmeasured confounding (e.g., family support for home wound care, compliance with dressing regimens) cannot be excluded, and the conservative-first strategy remains reasonable for mild, non-exposed complications.

**4. Airway- and host-related predictors of treatment failure**

Tracheostomy was independently associated with treatment failure (adjusted OR 2.21, 95% CI 1.12-3.96), as were immunosuppression, postoperative fever, and dual antiplatelet therapy (**Table 4**). Several mechanisms plausibly underlie the tracheostomy association. Tracheostomized patients are typically more severely ill at baseline, with prolonged immobility, impaired cough reflex, and higher rates of multidrug-resistant colonization, all established risk factors for poor wound healing[6,19]. In addition, the tracheostomy tube constitutes a continuous bacterial reservoir, and its proximity to the cranioplasty incision in the temporal region provides a near-constant source of bacterial seeding. Notably, tracheostomized patients accounted for 11.2% of our cohort, reflecting the high burden of severe traumatic brain injury (TBI) and hemorrhagic stroke in our referral population[3]. The persistence of the association after multivariable adjustment, bootstrap validation, and formal competing-risk analysis underscores its robustness and supports intensified peri-operative wound surveillance in this subgroup. The independent associations of immunosuppression and postoperative fever further emphasize that host immune status and early signs of infection, rather than anatomy or material alone, are key determinants of material survival after complicated wound healing.

**5. Other risk factors and nonlinearity**

Consistent with previous reports[3,17], univariable analysis identified diabetes, dual antiplatelet therapy, tracheostomy, postoperative fever, immunosuppression, and prior radiotherapy as candidate risk factors for poor outcomes, with vacuum drainage emerging as protective. In the multivariable model, dual antiplatelet therapy,

tracheostomy, postoperative fever, and immunosuppression remained independently significant, whereas diabetes, radiotherapy, and ASA grade did not, suggesting partial collinearity with overall patient frailty. Postoperative fever, strongly associated with the composite endpoint (29.7% vs 10.9%, $p < 0.001$), likely reflects an early manifestation of infection rather than an independent upstream cause, consistent with its clinical role as a sentinel sign that should trigger wound inspection and imaging. Unadjusted RCS analysis did not identify a significant nonlinear association between scalp thickness and treatment failure (P-overall = 0.747, P-nonlinear = 0.489), supporting the linearity assumption implicit in the multivariable model. The previously hypothesized "thin-scalp–fragile-skin" mechanism[4,20] was not statistically supported, possibly because the scalp-thickness range in the study population (4.5-12.5 mm) was too narrow to detect a threshold effect, or because scalp thickness is a weaker determinant than microvascular status and inflammatory burden.

**6. Economic and quality-of-life implications**

Wound complications impose a substantial economic and quality-of-life burden that is often underappreciated. In our cohort, the median healing time was 51 days among complicated cases, and the 11.7% of patients who ultimately underwent implant removal required re-operation and a second cranioplasty, with attendant costs of materials, anesthesia, and prolonged rehabilitation. Conservative care, although inexpensive per episode, was associated with the longest healing tail (up to 90 days), which translates into repeated outpatient visits, wound-care supplies, and lost productivity. From a health-system perspective, the incremental cost of early debridement or flap coverage, procedures that are reimbursed and brief, may be outweighed by shorter healing times and higher material-preservation rates. Beyond direct costs, the psychological toll of a chronic non-healing scalp wound, including anxiety, social isolation, and delayed return to work, should not be underestimated, and the accelerated healing achieved by active management may confer meaningful intangible benefits. Prospective cost-effectiveness modeling, informed by the healing-time distributions reported here, would be a valuable next step.

**7. Methodological strengths and the 4D PEEK perspective**

Several methodological features strengthen confidence in these findings. The real-world design captured the full spectrum of clinician-driven management decisions rather than protocol-directed care. PSM with paired statistical tests (McNemar, Wilcoxon) appropriate to the matched design, and with SMDs explicitly reported (six of nine covariates balanced at SMD <0.1, residual imbalance acknowledged), mitigated the selection bias inherent in observational comparisons of management strategies. The bootstrap-validated C-index (0.735, 95% CI 0.672-0.794) provided quantified, honest discrimination, and the pre-specified sensitivity analyses together with the formal Fine-Gray competing-risk analysis (**eTable 3**) supported the stability of the findings.

The present conventional-smooth-surface PEEK cohort also serves as a historical control for the next generation of implants: a recently introduced "4D-printed" PEEK implant with a micro-sand surface designed to promote soft-tissue ingrowth and reduce exposure risk[21]. Our cohort provides the baseline against which the new material's performance, including healing time and material-preservation rates, can be benchmarked; the null association between scalp thickness and failure may inform its design rationale, and prospective evaluation of the 4D implant using the same endpoints will be the definitive test.

## 8. Limitations

Several limitations merit consideration. First, the retrospective, single-center design limits external generalizability, and our high-volume tertiary referral pattern may overrepresent severe cases. Second, although 71 treatment-failure events permitted adjustment for nine covariates (event-per-variable ≈ 7.9) under L2 regularization, residual confounding by unmeasured factors (e.g., nutritional status, home-care quality) cannot be excluded. Third, PSM balanced only measured confounders; residual imbalance persisted for three covariates, and the 33 matched pairs limited the precision of the active-versus-conservative comparison. Fourth, healing time was subject to follow-up schedule variability despite censoring adjustment, and the minimum 3-month follow-up may have missed late recurrences, although the sensitivity analysis restricted to ≥ 6-month follow-up yielded consistent results. Finally, whether complication management should be tailored by material also remains to be determined, as direct comparison with titanium mesh was outside the scope of this study.

## 9. Implications for clinical practice

These findings translate into a workable clinical rule. When a PEEK cranioplasty wound fails to settle with conservative measures, the threshold for debridement or flap coverage should be low: in the propensity-score-matched comparison, active management preserved the implant in 75.8% of patients versus 39.4% with conservative care, and shortened median healing time by 24 days (36 vs 60 days). The same analysis identifies who warrants the closest surveillance from the outset. Tracheostomized patients, patients receiving dual antiplatelet therapy, patients with postoperative fever, and immunosuppressed patients carried the highest risk of treatment failure; in this group vacuum drainage was protective where technically feasible, and fever should prompt immediate wound inspection and imaging rather than expectant observation. The nomogram reported here allows that risk to be quantified at the bedside and recorded in the clinical notes, and the conventional smooth-surface PEEK cohort provides a benchmark against which the surface-engineered implants now entering practice can be evaluated in prospective studies using the same endpoints.

## Conclusions

In this real-world cohort, wound complications complicated the course of nearly one in four PEEK cranioplasties and frequently necessitated implant removal. Active surgical management, debridement or flap coverage, achieved higher material-preservation success and faster healing than conservative care, a benefit that persisted after PSM. Dual antiplatelet therapy, tracheostomy, postoperative fever, and immunosuppression independently predicted treatment failure, with vacuum drainage as a protective factor. The bedside nomogram offers an accessible tool for individualized risk stratification and warrants prospective validation; the cohort simultaneously provides a historical benchmark against which next-generation surface-engineered PEEK implants can be evaluated.

## Abbreviations

| Abbreviation | Full term |
|---|---|
| ASA | American Society of Anesthesiologists |
| BMI | Body mass index |

| | |
|---|---|
| CDC | Centers for Disease Control and Prevention |
| CI | Confidence interval |
| CSF | Cerebrospinal fluid |
| CT | Computed tomography |
| DCA | Decision curve analysis |
| EPV | Events per variable |
| GCS | Glasgow Coma Scale |
| GOS | Glasgow Outcome Scale |
| IQR | Interquartile range |
| KM | Kaplan–Meier |
| MDR | Multidrug-resistant |
| MRI | Magnetic resonance imaging |
| mRS | Modified Rankin Scale |
| OR | Odds ratio |
| PEEK | Polyetheretherketone |
| PSM | Propensity score matching |
| RCS | Restricted cubic spline |
| sHR | Subdistribution hazard ratio |
| SMD | Standardized mean difference |
| STROBE | Strengthening the Reporting of Observational Studies in Epidemiology |
| TBI | Traumatic brain injury |
| VPS | Ventriculoperitoneal shunt |
| YY/T 0660 | Chinese medical device industry standard for implantable PEEK materials |

*Abbreviations are listed alphabetically; the full term is provided at first mention in the manuscript.*

## Ethics approval and informed consent

This retrospective study was conducted in accordance with the Declaration of Helsinki and was approved by the Medical Ethics Committee of Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology (approval number: TJ-IRB202408044). Because the study used only de-identified data from routine medical records, without any additional intervention or contact with patients, the requirement for informed consent was waived by the ethics committee. All patient data were anonymised before analysis, and no individually identifiable information is reported in this manuscript.

## Consent for publication

Not applicable.

## Clinical trial registration

Not applicable.

## Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available due to the sensitive nature of the clinical data and the restrictions imposed by the ethics committee and the institutional data governance policy, but de-identified data are available from the corresponding author on reasonable request and with the approval of the Institutional Review Board of Tongji Hospital.

## Competing interests

The authors report there are no competing interests to declare.


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## Authors' contributions

L.Z., Y.W., X.M., and X.L. contributed equally to this work: they performed data curation, formal analysis, and wrote the original draft of the manuscript. L.Z. also designed the methodology, conducted the statistical analyses and model validation, and prepared all figures and tables. Y.Z. and J.H. contributed to data collection, resource acquisition, and data curation. R.C. and J.Y. conceptualized and supervised the study, acquired funding, administered the project, and critically revised the manuscript for important intellectual content. All authors reviewed and approved the final version of the manuscript. CRediT roles will be provided for all authors in the submission portal.

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## Additional files

**Additional file 1: eTables 1-3.** Complete baseline characteristics of the study cohort (n = 580); sensitivity analyses for predictors of treatment failure; and Fine-Gray competing-risk regression.

**Additional file 2: eFigures 1-3.** Nomogram calibration and decision-curve analysis; temporal profile of wound complications; and drainage-stratified outcomes.

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## Table captions:

**Table 1.** Baseline characteristics of patients with and without wound complications

**Table 2.** Spectrum of wound complications after PEEK cranioplasty (n = 580)

**Table 3.** Outcomes of management strategies for wound complications and propensity-score-matched comparison

**Table 4.** Univariable and multivariable logistic regression for treatment failure (implant removal or death)

**eTable 1.** Complete baseline characteristics of the study cohort (n = 580)

**eTable 2.** Sensitivity analyses for predictors of treatment failure

**eTable 3.** Fine-Gray competing-risk regression (R cmprsk)

**Table 1. Baseline characteristics of patients with and without wound complications**

| Characteristic | No complication (n = 442) | Complication (n = 138) | P value |
|---|---|---|---|
| Age, years | 49 (39-58) | 54 (44-65) | 0.002 |
| BMI, kg/m² | 25.1 (22.0-28.3) | 25.1 (21.6-28.7) | 0.980 |
| Decompression-to-cranioplasty interval, months | 6 (4-8) | 6 (5-9) | 0.402 |
| Admission GCS | 14 (13-15) | 14 (13-15) | 0.458 |
| Bone defect area, cm² | 83.5 (58.1-106.7) | 86.5 (65.9-109.8) | 0.279 |
| Scalp thickness, mm | 8.3 (6.6-10.5) | 8.4 (6.1-9.9) | 0.339 |
| Operation duration, min | 170 (141-198) | 169 (137-195) | 0.399 |
| Blood loss, mL | 295.5 (194.3-393.5) | 326.5 (213.3-418.8) | 0.175 |
| Male sex | 260 (58.8) | 75 (54.3) | 0.406 |
| Hypertension | 178 (40.3) | 69 (50.0) | 0.055 |

| | | | |
|---|---|---|---|
| Diabetes mellitus | 43 (9.7) | 28 (20.3) | 0.002 |
| Smoking | 95 (21.5) | 29 (21.0) | 0.999 |
| Alcohol use | 84 (19.0) | 25 (18.1) | 0.914 |
| Prior radiotherapy | 10 (2.3) | 8 (5.8) | 0.070 |
| Dual antiplatelet | 54 (12.2) | 31 (22.5) | 0.005 |
| Tracheostomy | 47 (10.6) | 18 (13.0) | 0.529 |
| ASA grade ≥ III | 97 (21.9) | 45 (32.6) | 0.015 |
| History of poor wound healing | 46 (10.4) | 24 (17.4) | 0.040 |
| Immunosuppression | 5 (1.1) | 7 (5.1) | 0.013 |
| MDR colonization | 24 (5.4) | 7 (5.1) | 1.000 |
| Hypoalbuminemia (< 35 g/L) | 45 (10.2) | 21 (15.2) | 0.141 |
| Skull deformity (bulging) | 53 (12.0) | 28 (20.3) | 0.021 |
| VPS history | 56 (12.7) | 11 (8.0) | 0.175 |
| New hydrocephalus | 32 (7.2) | 4 (2.9) | 0.100 |
| Early cranioplasty (≤ 90 d) | 63 (14.3) | 17 (12.3) | 0.664 |
| Temporal/multiple incision | 237 (53.6) | 84 (60.9) | 0.162 |
| Enlarged/new flap | 113 (25.6) | 29 (21.0) | 0.331 |
| Dural breach/CSF leak | 44 (10.0) | 19 (13.8) | 0.271 |
| Vacuum drainage | 194 (43.9) | 39 (28.3) | 0.002 |
| Postoperative fever (≥ 38.5℃) | 48 (10.9) | 41 (29.7) | < 0.001 |
| Postoperative seizure | 37 (8.4) | 8 (5.8) | 0.421 |

***Data are presented as median (IQR) for continuous variables and n (%) for categorical variables. P values: Mann-Whitney U test for continuous, chi-square test for categorical.***

***Variable definitions:*** *antiplatelet/anticoagulant use was categorized as none, monotherapy (single agent), or dual therapy (aspirin plus clopidogrel); ASA grade ≥III indicates severe systemic disease; hypoalbuminemia was defined as serum albumin <35 g/L; immunosuppression included chronic corticosteroid therapy (≥20 mg/d prednisone equivalent for ≥4 weeks), chemotherapy within 3 months, or autoimmune disease on immunosuppressive agents; MDR colonization was identified by preoperative screening cultures; craniectomy-to-cranioplasty interval was categorized as early (≤90 d) or late (>90 d); skull deformity was defined as bulging of the scalp over the defect; drainage type was classified as none, conventional (open passive drain), or vacuum (closed-suction drain); temporal/multiple incision included any incision involving the temporal region or multiple incisions.*

***Abbreviations:*** *ASA, American Society of Anesthesiologists; BMI, body mass index; CSF, cerebrospinal fluid; GCS, Glasgow Coma Scale; IQR, interquartile range; MDR, multidrug-resistant; VPS, ventriculoperitoneal shunt.*

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**Table 2. Spectrum of wound complications after PEEK cranioplasty (n = 580)**

| Complication | n | Rate (%) |
|---|---|---|
| Skin breakdown | 54 | 9.3 |
| Implant exposure | 15 | 2.6 |
| Wound infection (superficial/deep) | 40 | 6.9 |
| Subgaleal effusion/CSF leak | 55 | 9.5 |

| | | |
|---|---|---|
| Subdural/epidural effusion | 59 | 10.2 |
| Pneumocephalus | 34 | 5.9 |
| Postoperative hematoma | 29 | 5.0 |
| Postoperative fever (≥ 38.5°C) | 89 | 15.3 |
| Postoperative seizure | 45 | 7.8 |

***Complication definitions:*** *skin breakdown, dehiscence or necrosis of the surgical incision without implant visibility; implant exposure, visible PEEK implant through a skin defect without intact epithelial coverage; wound infection classified as superficial or deep per CDC criteria; subgaleal effusion/CSF leak, symptomatic fluid collection at the operative site requiring aspiration or intervention; subdural/epidural effusion, postoperative fluid collection in the subdural or epidural space; pneumocephalus, intracranial air on postoperative imaging; postoperative hematoma, epidural or subdural hematoma requiring observation or evacuation; postoperative fever, body temperature ≥ 38.5 °C within 72 h after surgery; postoperative seizure, any clinical seizure within 30 days after surgery.*

***Abbreviations:*** *CDC, Centers for Disease Control and Prevention; CSF, cerebrospinal fluid.*

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**Table 3. Outcomes of management strategies for wound complications and propensity-score-matched comparison**

**(A) Outcomes by management strategy**

| Strategy | n (%) | Success (%) | Healing time, median (range), d | Reoperation (%) |
|---|---|---|---|---|
| Conservative wound care | 96 (69.6) | 46.9 | 57 (25-90) | 53.1 |
| Surgical debridement | 21 (15.2) | 71.4 | 40 (21-56) | 28.6 |
| Flap coverage | 12 (8.7) | 83.3 | 30 (18-42) | 16.7 |
| Implant removal | 9 (6.5) | 0.0 | — | 100.0 |

**(B) Covariate balance before versus after PSM (SMD)**

| Covariate | SMD before matching | SMD after matching |
|---|---|---|
| **Diabetes** | **0.312** | **0.000** |
| Dual antiplatelet | 0.016 | 0.209 * |
| Tracheostomy | 0.223 | 0.000 |
| ASA ≥ III | 0.087 | 0.368 * |
| Hypoalbuminemia | 0.041 | 0.088 |
| Scalp thickness | 0.405 | 0.111 * |
| Vacuum drainage | 0.224 | 0.064 |
| Skin breakdown | 0.641 | 0.062 |
| Wound infection | 0.374 | 0.076 |

***PSM analysis:*** *1:1 nearest-neighbour matching (caliper 0.2 on the propensity score, matching from highest to lowest score, without replacement), 33 matched pairs (active vs conservative care). Success rate: active 75.8% vs conservative 39.4% (p = 0.010); median healing time: active 36 vs conservative 60 days (paired Wilcoxon p < 0.001). After matching, 6 of 9 covariates achieved SMD <0.1; residual imbalance persisted for dual antiplatelet therapy (SMD 0.209), ASA ≥ III (SMD 0.368), and scalp thickness (SMD 0.111), denoted by asterisks; these were considered in sensitivity analyses and the discussion.*

*Management strategy definitions: conservative wound care, local wound care including pressure dressing, aspiration, and/or antibiotics; surgical debridement, operative debridement with primary closure without flap rotation; flap coverage, local or regional flap transfer to cover the defect; implant removal, complete PEEK explantation. Treatment success was defined as healed with material preserved; wound healing time was defined as days from the initial operation to complete epithelialization without discharge (− not applicable for implant removal). Paired McNemar test was used for success and paired Wilcoxon signed-rank test for healing time.*

***Abbreviations:*** *PSM, propensity score matching.*

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**Table 4. Univariable and multivariable logistic regression for treatment failure (implant removal or death)**

| Variable | Univariable OR (95% CI) | P | Multivariable OR (95% CI) | P |
|---|---|---|---|---|
| Diabetes | 1.95 (1.02-3.72) | 0.043 | 1.55 (0.71-2.94) | 0.226 |
| Dual antiplatelet | 2.04 (1.12-3.73) | 0.020 | 1.97 (1.04-3.50) | 0.029 |
| Tracheostomy | 2.46 (1.30-4.66) | 0.006 | 2.21 (1.12-3.96) | 0.015 |
| ASA ≥ III | 1.46 (0.85-2.51) | 0.176 | 1.08 (0.58-1.87) | 0.788 |
| Postoperative fever | 2.72 (1.54-4.82) | 0.001 | 2.53 (1.41-4.47) | < 0.001 |
| Scalp thickness | 1.02 (0.91-1.13) | 0.754 | 0.99 (0.89-1.12) | 0.897 |
| Vacuum drainage | 0.46 (0.26-0.82) | 0.008 | 0.47 (0.27-0.77) | 0.005 |
| Prior radiotherapy | 2.89 (1.00-8.37) | 0.050 | 2.42 (0.84-5.64) | 0.068 |
| Immunosuppression | 5.43 (1.68-17.61) | 0.005 | 3.95 (1.27-9.37) | 0.007 |

*C-index: 0.716; bootstrap 1,000: 0.735 (0.672-0.794). Multivariable model adjusted for 9 variables (event-per-variable = 71/9 ≈ 7.9). OR = odds ratio; CI = confidence interval.*

*Treatment failure was defined as implant removal or death during follow-up (n =71 events: 68 implant removals, 3 deaths). The multivariable model included six pre-specified core variables (diabetes, dual antiplatelet therapy, tracheostomy, ASA ≥III, postoperative fever, scalp thickness) plus variables with p < 0.10 on univariable analysis (vacuum drainage, prior radiotherapy, immunosuppression), fitted with L2-regularized logistic regression; adjusted ORs and CIs were obtained from 1,000 bootstrap resamples.*

**eTable 1. Complete baseline characteristics of the study cohort (n = 580)**

| Variable | All (n = 580) | Missing n (%) |
|---|---|---|
| Age, years | 51 (IQR 40-59) | 0 (0.0) |
| Male sex | Yes: 335 (57.8%) | 0 (0.0) |
| BMI, kg/m² | 25.1 (IQR 21.9-28.4) | 0 (0.0) |
| Hypertension | Yes: 247 (42.6%) | 0 (0.0) |
| Diabetes mellitus | Yes: 71 (12.2%) | 0 (0.0) |
| Smoking | Yes: 124 (21.4%) | 0 (0.0) |
| Alcohol use | Yes: 109 (18.8%) | 0 (0.0) |
| Prior radiotherapy | Yes: 18 (3.1%) | 0 (0.0) |
| Antiplatelet/anticoagulant use | 0: 364 (62.8%); 1: 131 (22.6%); 2: 85 (14.7%) | 0 (0.0) |
| Primary disease | 1: 236 (40.7%); 2: 118 (20.3%); 3: 79 (13.6%); 4: 68 (11.7%); 5: 49 (8.4%); 6: 30 (5.2%) | 0 (0.0) |
| Craniectomy-to-cranioplasty interval, months | 6 (IQR 4-9) | 0 (0.0) |
| Admission GCS | 14 (IQR 13-15) | 0 (0.0) |
| Tracheostomy | Yes: 65 (11.2%) | 0 (0.0) |
| ASA grade | 1: 123 (21.2%); 2: 315 (54.3%); 3: 127 (21.9%); 4: 15 (2.6%) | 0 (0.0) |
| History of poor wound healing | Yes: 70 (12.1%) | 0 (0.0) |
| Immunosuppression | Yes: 12 (2.1%) | 0 (0.0) |
| MDR colonization | Yes: 31 (5.3%) | 0 (0.0) |
| Hypoalbuminemia (< 35 g/L) | Yes: 66 (11.4%) | 0 (0.0) |
| Skull deformity | 0: 453 (78.1%); 1: 81 (14.0%); 2: 46 (7.9%) | 0 (0.0) |
| VPS history | 0: 513 (88.4%); 1: 39 (6.7%); 2: 13 (2.2%); 3: 15 (2.6%) | 0 (0.0) |
| New hydrocephalus | Yes: 36 (6.2%) | 0 (0.0) |
| Cranioplasty timing | 1: 80 (13.8%); 2: 500 (86.2%) | 0 (0.0) |
| Incision site | 1: 103 (17.8%); 2: 164 (28.3%); 3: 106 (18.3%); 4: 50 (8.6%); 5: 157 (27.1%) | 0 (0.0) |
| Flap type | Yes: 142 (24.5%) | 0 (0.0) |
| Intraoperative dural breach/CSF leak | Yes: 63 (10.9%) | 0 (0.0) |
| Bone defect area, cm² | 83.9 (IQR 58.7-107.8) | 0 (0.0) |
| Scalp thickness, mm | 8.4 (IQR 6.5-10.5) | 0 (0.0) |
| Reinforced galea suture | Yes: 217 (37.4%) | 0 (0.0) |
| Operation duration, min | 170 (IQR 140-197) | 0 (0.0) |
| Blood loss, mL | 304.5 (IQR 199.8-400.3) | 0 (0.0) |

| | | |
|---|---|---|
| Drainage type | 0: 30 (5.2%); 1: 317 (54.7%); 2: 233 (40.2%) | 0 (0.0) |
| Skin breakdown | Yes: 54 (9.3%) | 0 (0.0) |
| Implant exposure | Yes: 15 (2.6%) | 0 (0.0) |
| Wound infection | Yes: 40 (6.9%) | 0 (0.0) |
| Subgaleal effusion/CSF leak | Yes: 55 (9.5%) | 0 (0.0) |
| Subdural/epidural effusion | 0: 521 (89.8%); 1: 20 (3.4%); 2: 39 (6.7%) | 0 (0.0) |
| Pneumocephalus | Yes: 34 (5.9%) | 0 (0.0) |
| Postoperative hematoma | 0: 551 (95.0%); 1: 12 (2.1%); 2: 17 (2.9%) | 0 (0.0) |
| Postoperative fever (≥ 38.5°C) | Yes: 89 (15.3%) | 0 (0.0) |
| Postoperative seizure | Yes: 45 (7.8%) | 0 (0.0) |
| Healing grade (1/2/3) | 1: 452 (77.9%); 2: 91 (15.7%); 3: 37 (6.4%) | 0 (0.0) |
| Complication onset time, days | 13 (IQR 8-19) | 442 (76.2) |
| Management strategy | 0: 442 (76.2%); 1: 96 (16.6%); 2: 21 (3.6%); 3: 12 (2.1%); 4: 9 (1.6%) | 0 (0.0) |
| Wound healing time, days | 12 (IQR 9-18) | 9 (1.6) |
| Treatment success | Yes: 509 (87.8%) | 0 (0.0) |
| Reoperation | Yes: 68 (11.7%) | 0 (0.0) |
| Final outcome | 1: 509 (87.8%); 2: 68 (11.7%); 3: 3 (0.5%) | 0 (0.0) |
| mRS at 6 months | 0: 197 (34.0%); 1: 122 (21.0%); 2: 102 (17.6%); 3: 58 (10.0%); 4: 49 (8.4%); 5: 24 (4.1%); 6: 28 (4.8%) | 0 (0.0) |
| GOS at 6 months | 1: 28 (4.8%); 2: 24 (4.1%); 3: 49 (8.4%); 4: 160 (27.6%); 5: 319 (55.0%) | 0 (0.0) |
| Follow-up duration, days | 240 (IQR 180-270) | 0 (0.0) |

*Continuous variables are presented as median (IQR); binary variables as Yes: n (%). Antiplatelet/anticoagulant use: none (0), monotherapy (1), dual therapy (2). Primary disease: 1 trauma, 2 hemorrhage, 3 tumor, 4 ischemia, 5 aSAH, 6 other. ASA grade 1-4. Cranioplasty timing: 1 early (≤ 90 d), 2 late (> 90 d). Incision site: 1 frontal, 2 temporal, 3 parietal, 4 occipital, 5 multiple. Flap type: 0 original incision, 1 enlarged/new flap. Drainage type: 0 none, 1 conventional, 2 vacuum. Healing grade: 1 primary, 2 secondary, 3 poor. Management strategy: 0 none, 1 conservative, 2 debridement, 3 flap coverage, 4 implant removal. Final outcome: 1 healed, 2 implant removal, 3 death. mRS 0-6; GOS 1-5. Complication onset time and healing time are missing in patients without wound complications; follow-up duration was defined as the time from cranioplasty to healing, implant removal, death, or last clinical contact.* ***Abbreviations:*** *ASA, American Society of Anesthesiologists; BMI, body mass index; CSF, cerebrospinal fluid; GCS, Glasgow Coma Scale; GOS, Glasgow Outcome Scale; IQR, interquartile range; MDR, multidrug-resistant; mRS, modified Rankin Scale; VPS, ventriculoperitoneal shunt.*

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**eTable 2. Sensitivity analyses for predictors of treatment failure**

| Sensitivity analysis | Variable | OR (95% CI) | P |
|---|---|---|---|

| | | | |
|---|---|---|---|
| **A. Excluding perioperative deaths (n = 577)** | Diabetes | 1.64 (0.85-3.18) | 0.137 |
| | Dual antiplatelet | 2.09 (1.11-3.50) | 0.014 |
| | Tracheostomy | 2.35 (1.19-4.30) | 0.010 |
| | ASA ≥ III | 1.05 (0.56-1.85) | 0.870 |
| | Postoperative fever | 2.49 (1.42-4.53) | 0.003 |
| | Scalp thickness | 1.00 (0.89-1.11) | 0.988 |
| | Vacuum drainage | 0.47 (0.26-0.78) | 0.006 |
| | Prior radiotherapy | 2.52 (0.79-5.42) | 0.064 |
| | Immunosuppression | 4.08 (1.17-9.08) | 0.009 |
| **B. Outcome = implant exposure only (n = 15 events)** | Diabetes | 3.19 (0.96-7.93) | 0.040 |
| | Dual antiplatelet | 1.84 (0.62-4.15) | 0.210 |
| | Tracheostomy | 0.47 (0.35-0.64) | < 0.001 |
| | ASA ≥ III | 0.50 (0.21-1.18) | 0.136 |
| | Postoperative fever | 0.64 (0.32-1.30) | 0.243 |
| | Scalp thickness | 0.83 (0.59-1.11) | 0.247 |
| | Vacuum drainage | 0.74 (0.29-1.66) | 0.503 |
| | Prior radiotherapy | 5.68 (1.50-15.63) | 0.004 |
| | Immunosuppression | 0.74 (0.56-0.93) | 0.023 |
| **C. Restricted to ≥6 months of follow-up (n = 491)** | Diabetes | 1.75 (0.69-3.35) | 0.153 |
| | Dual antiplatelet | 2.13 (1.12-3.69) | 0.010 |
| | Tracheostomy | 2.25 (1.13-4.36) | 0.016 |
| | ASA ≥ III | 0.96 (0.49-1.69) | 0.900 |
| | Postoperative fever | 2.28 (1.19-4.23) | 0.009 |
| | Scalp thickness | 1.00 (0.90-1.12) | 0.986 |
| | Vacuum drainage | 0.45 (0.24-0.72) | 0.005 |
| | Prior radiotherapy | 2.48 (0.81-6.25) | 0.077 |
| | Immunosuppression | 3.87 (1.17-9.82) | 0.012 |

*All analyses used the same nine covariates as the primary multivariable model. ORs and 95% CIs from L2-regularized logistic regression with 500 bootstrap resamples. The exposure-only analysis (B) included only 15 events; results should be interpreted with caution. Follow-up duration was defined as the time from cranioplasty to healing, implant removal, death, or last clinical contact.*

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**eTable 3. Fine-Gray competing-risk regression (R cmprsk)**

***Analysis A: patients with wound complications (n = 138); event = wound healing; competing event = implant removal***

| Variable | sHR (95% CI) | P |
|---|---|---|
| Diabetes | 1.28 (0.68-2.40) | 0.44 |
| Dual antiplatelet | 1.04 (0.60-1.83) | 0.88 |
| Tracheostomy | 0.09 (0.02-0.39) | 0.001 |
| ASA grade ≥ III | 1.55 (0.95-2.53) | 0.079 |

| | | |
|---|---|---|
| Postoperative fever | 1.30 (0.78-2.16) | 0.32 |
| Scalp thickness | 0.95 (0.85-1.06) | 0.34 |
| Active management | 6.44 (3.37-12.32) | < 0.001 |

| ***Analysis B: full cohort (N = 580); event = implant removal; competing event = healing*** | | |
|---|---|---|
| **Variable** | **sHR (95% CI)** | **P** |
| Tracheostomy | 2.65 (1.46-4.78) | 0.001 |
| Postoperative fever | 2.30 (1.37-3.87) | 0.002 |
| Immunosuppression | 5.03 (2.11-11.95) | < 0.001 |
| Prior radiotherapy | 2.83 (1.17-6.83) | 0.021 |

*sHR = subdistribution hazard ratio. Analyses performed with R cmprsk (R 4.6.1); death coded as censored. Analysis A (n = 138 complicated cases): event = wound healing; competing event = implant removal; covariates: diabetes, dual antiplatelet therapy, tracheostomy, ASA ≥ III, postoperative fever, scalp thickness, and active management (debridement or flap coverage vs conservative care). Analysis B (full cohort, n = 580): event = implant removal; competing event = healing; covariates: tracheostomy, postoperative fever, immunosuppression, prior radiotherapy.*

## Legends of Figure 1-5:

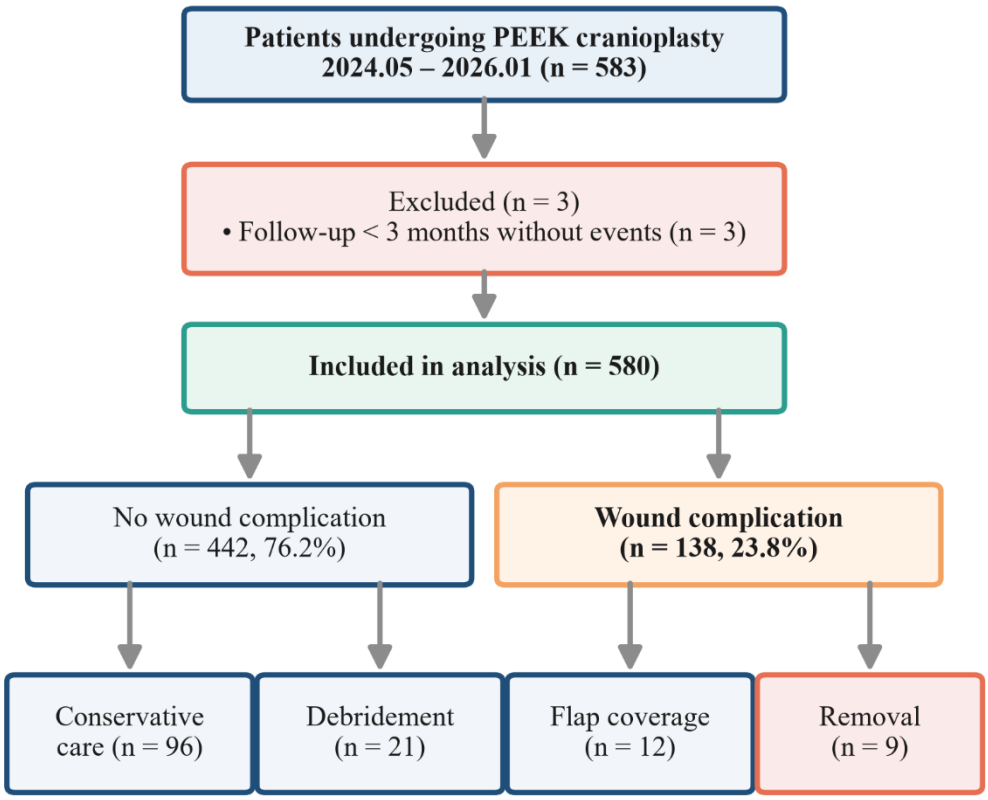



**Figure 1.** STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) patient flow diagram. Of 583 patients screened, 3 were excluded (follow-up < 3 months without a recorded wound-complication event), yielding 580 patients. Wound complications occurred in 138 (23.8%); 442 (76.2%) had an uneventful

course.

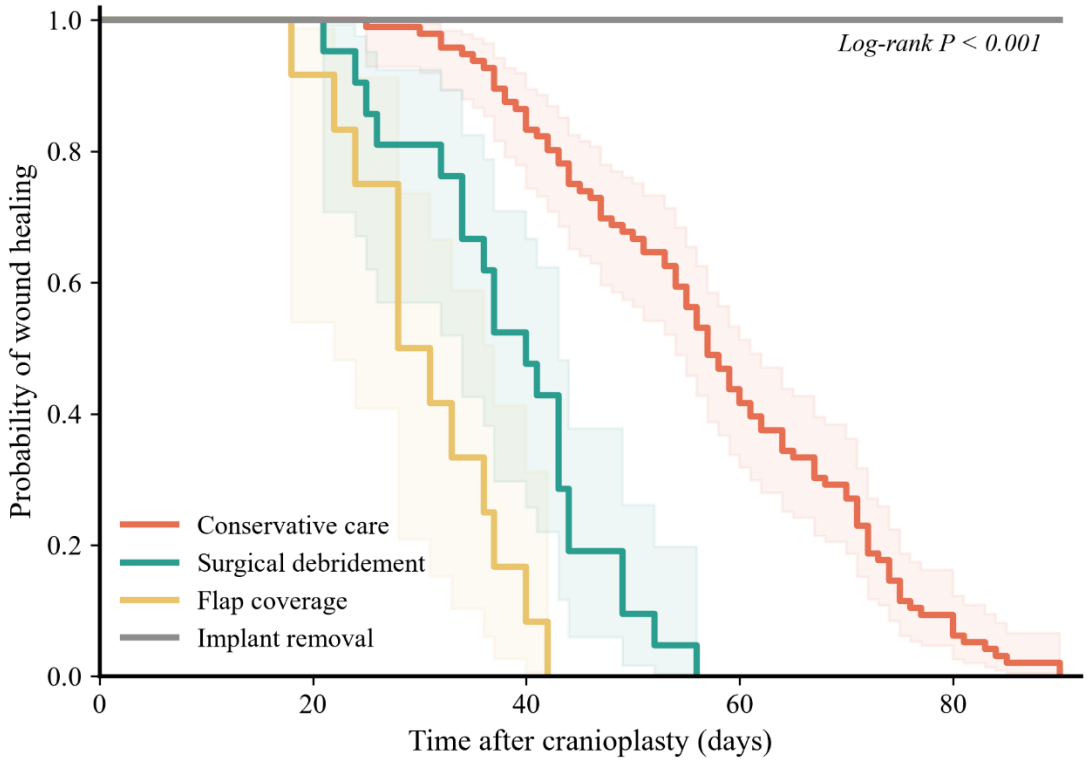



**Figure 2.** Kaplan-Meier curves for wound healing time by management strategy among 138 patients with wound complications (log-rank $p < 0.001$). Tick marks indicate censoring; numbers at risk are shown below the x-axis. Conservative care had the longest healing tail (up to 90 days), whereas flap coverage achieved the most rapid healing (median 30 days). Abbreviation: d, days.

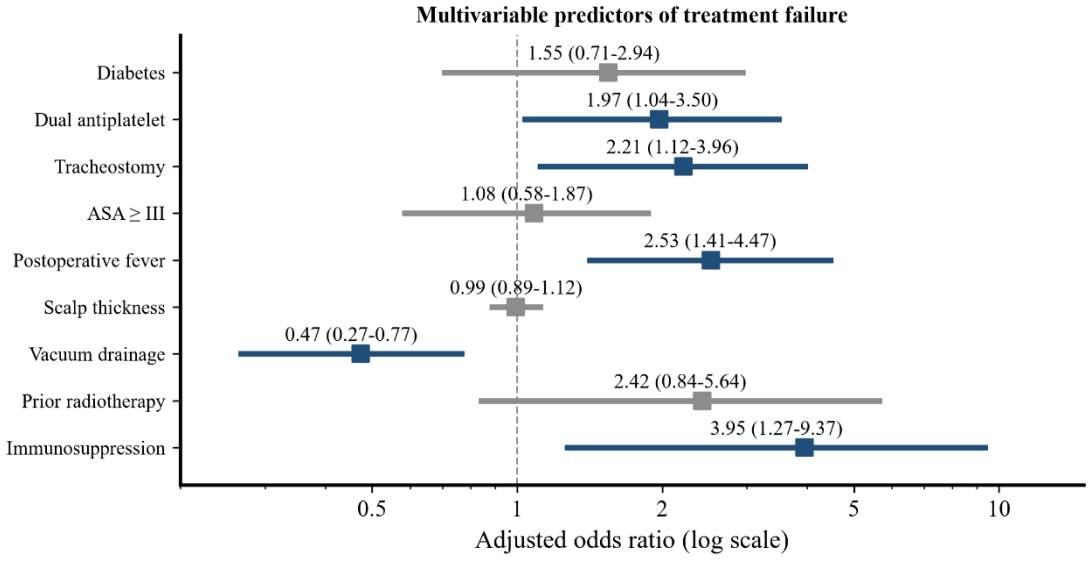



**Figure 3.** Multivariable forest plot of predictors of treatment failure. Squares indicate adjusted odds ratios (ORs) and horizontal lines 95% confidence intervals (CIs); the vertical dashed line marks OR = 1. Independent predictors were dual antiplatelet

therapy (OR 1.97, 95% CI 1.04-3.50), tracheostomy (2.21, 1.12-3.96), postoperative fever (2.53, 1.41-4.47), and immunosuppression (3.95, 1.27-9.37); vacuum drainage was independently protective (0.47, 0.27-0.77). Model discrimination: C-index 0.716; bootstrap-validated 0.735 (95% CI 0.672-0.794). Abbreviations: CI, confidence interval; OR, odds ratio.

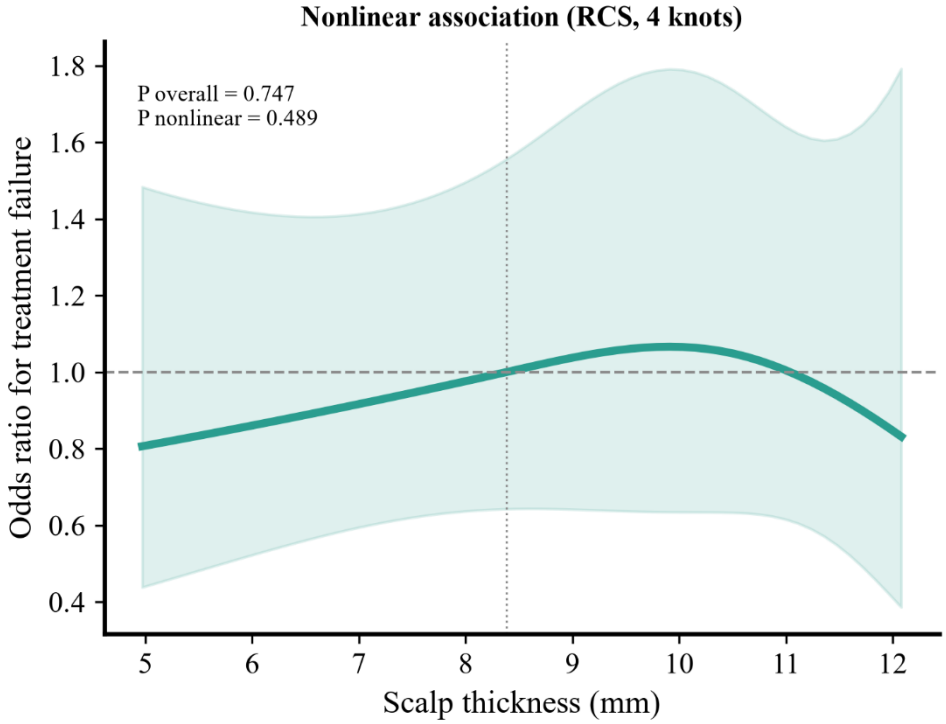



**Figure 4.** Unadjusted restricted cubic spline (RCS) analysis of the association between scalp thickness and treatment failure. The solid line represents the unadjusted log-odds of treatment failure with median scalp thickness as reference; the shaded band is the 95% confidence interval. Knots were placed at the 25th, 50th, 75th, and 95th percentiles. P-overall = 0.747 and P-nonlinear = 0.489 indicate no significant nonlinear association, supporting the linearity assumption of the multivariable model.

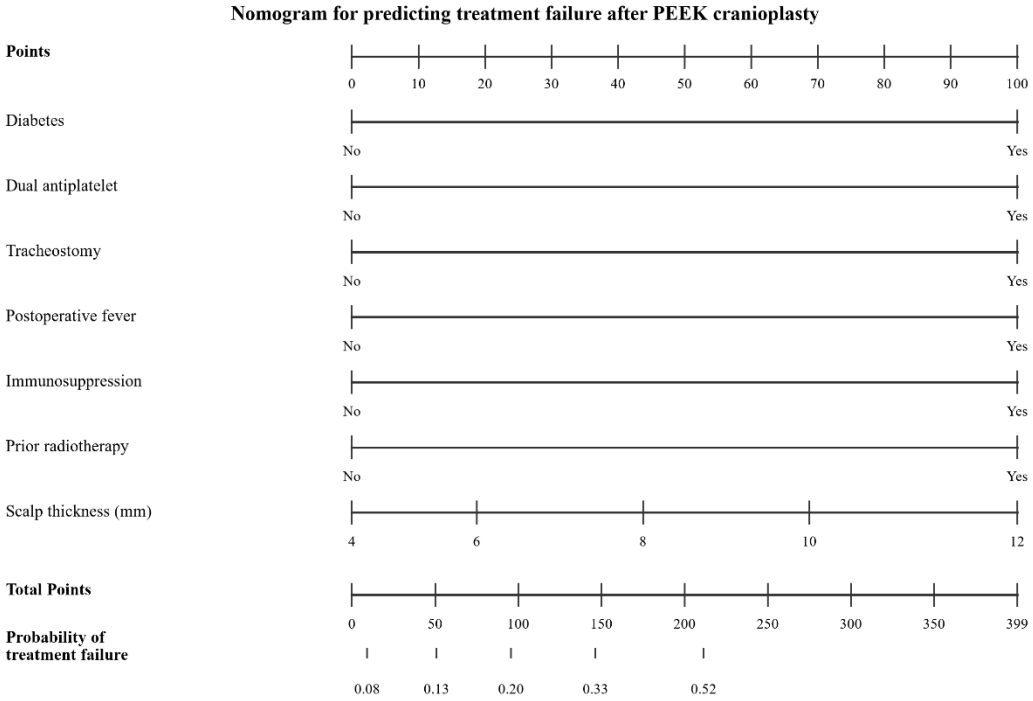
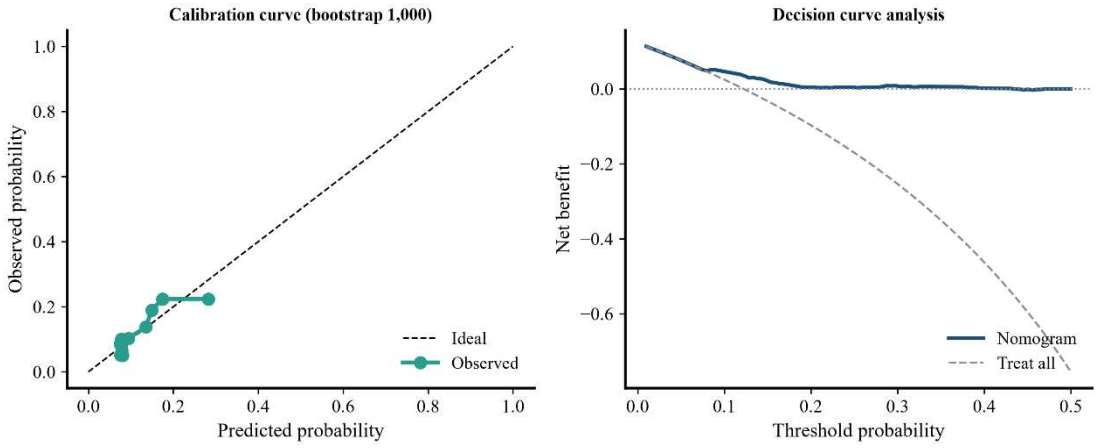


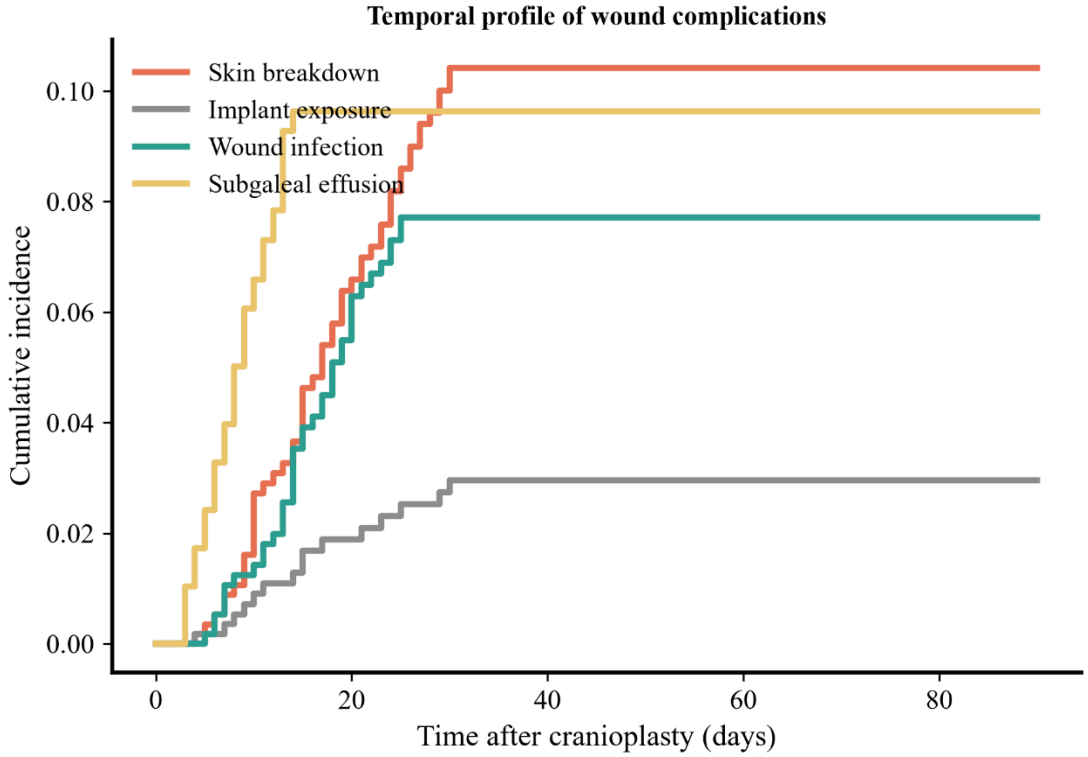

**Figure 5.** Bedside nomogram for predicting treatment failure after PEEK cranioplasty, constructed by refitting a parsimonious multivariable logistic model. Seven readily available variables are integrated: diabetes mellitus, dual antiplatelet therapy, tracheostomy, postoperative fever, immunosuppression, prior radiotherapy, and scalp thickness. Instructions for use: locate the value of each variable on its axis, draw a vertical line upward to the "Points" axis to obtain the points score, sum the points across all seven variables, and project the total score downward onto the "Total points" and "Probability" axes to obtain the predicted probability of treatment failure.

## Legends of eFigure 1-3：

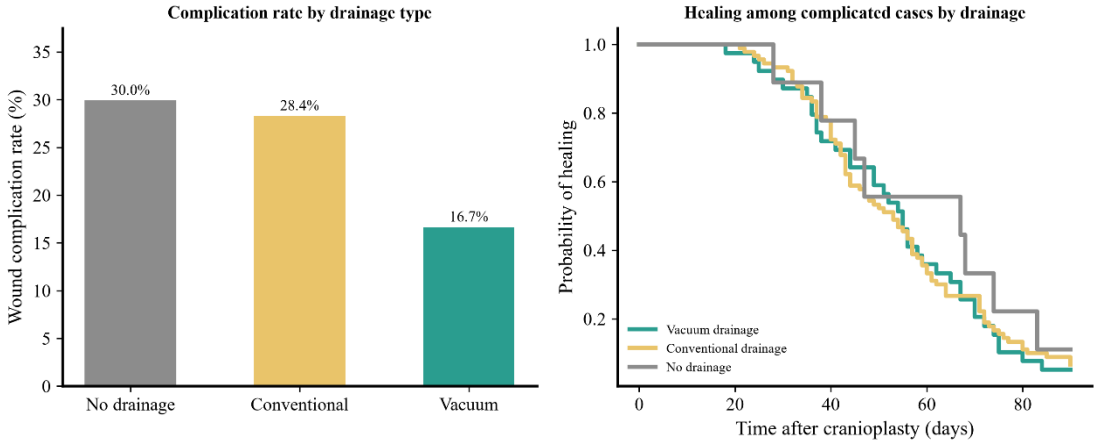



**eFigure 1.** Nomogram performance. **(A)** Calibration curve comparing bootstrap-corrected predicted versus observed probabilities of treatment failure (1,000 resamples); the dashed diagonal line indicates perfect calibration. **(B)** Decision curve analysis (DCA) showing the net benefit of the nomogram-guided strategy versus treat-all and

treat-none strategies across threshold probabilities; the nomogram strategy yielded positive net benefit across a clinically relevant range of thresholds. Abbreviation: DCA, decision curve analysis.




**eFigure 2.** Temporal profile of wound complications. Cumulative incidence of each complication subtype (subgaleal effusion, skin breakdown, wound infection, implant exposure) over the first 12 postoperative weeks. Subgaleal effusion appeared earliest and implant exposure latest, consistent with a sequential pathophysiology (effusion → breakdown → exposure).




**eFigure 3.** Drainage-stratified outcomes. **(A)** Wound complication rates by drainage type (none, conventional, vacuum); **(B)** Kaplan-Meier healing curves for complicated cases stratified by drainage type. Vacuum drainage was associated with lower overall complication (16.7% vs 28.4%) and subgaleal effusion rates (4.7% vs 12.0%) than

conventional drainage, supporting the rationale that active suction removes fluid collections that would otherwise impair soft-tissue apposition.