Transparent vs Padded vs Topical Skin Adhesive for Pediatric Surgical Wounds — A Multicenter, Randomized Controlled Study

Executive Summary

The study will compare wound outcomes, pain and psychological impacts, caregiver satisfaction, and health economic metrics across three strategies: (1) transparent non-padded dressing (TNPD), (2) non-transparent padded dressing (NTPD), and (3) topical skin adhesive (TSA).

Background & Rationale

Optimal post-operative wound coverage in pediatrics balances infection prevention, secure wound edge approximation, patient comfort, parental satisfaction, and cost. Transparent film dressings facilitate inspection but offer minimal padding, while padded dressings provide protection at the expense of visibility. Topical skin adhesives (TSAs) can seal the epidermis, serve as a microbial barrier, and eliminate dressing changes in selected cases. Evidence across pediatric surgical specialties suggests variable practice with no consensus standard. This trial seeks to generate high-quality comparative data across these three common strategies.

The outcomes of this trial have the potential to:

- Improve clinical decision-making in pediatric surgery by identifying the most effective and patient-friendly wound coverage method.
- Enhance patient and caregiver experience, reducing anxiety and discomfort associated with post-operative care.
- Support health economics and policy, offering data to inform procurement strategies and insurance coverage decisions.
- Advance surgical nursing practices, particularly in wound care and post-operative monitoring.
- Contribute to pediatric anesthesiology and pain management, through insights into pain trajectories and anxiety reduction.
- Inform medical education and training, by integrating evidence-based wound care protocols into pediatric surgical curricula.

This study will benefit professionals across pediatric surgery, nursing, hospital administration, health economics, and clinical research, and may influence national and regional standards for post-operative care in children.

This study provides the first high-quality, multicenter randomized controlled evidence directly comparing transparent dressings, padded dressings, and topical skin adhesives for

pediatric surgical wound coverage. By integrating clinical outcomes, patient-reported experiences, and economic evaluation, it addresses a long-standing gap in standardized post-operative care for children. The trial's rigorous design and comprehensive scope offer a benchmark for evidence-based wound management, potentially guiding global best practices and harmonizing care across pediatric surgical specialties.

Objectives

Primary Objective:

To determine whether TSA reduces 60-day incisional wound morbidity compared with NTPD, and TNPD in pediatric surgical patients with primarily closed wounds.

Secondary Objectives:

- Compare pain trajectories, patient/parent anxiety, comfort, and caregiver satisfaction across arms.
- Compare surgical site infection (SSI) rates, dehiscence, seroma/hematoma requiring intervention.
- Evaluate resource use (dressing changes, clinic/ED visits) and direct material costs.
- Explore cosmetic outcomes at 60 days using a validated scar scale.

Study Design

- **Design:** Prospective, multicenter, parallel-group, three-arm randomized controlled trial (1:1:1).
- **Centers:** Four tertiary pediatric surgical centers (Al-Basheer, QRCH, JUH, KAUH).
- **Randomization & Allocation:** Centralized web-based randomization list with permuted blocks, stratified by site (center) was generated using Microsoft Copilot. Randomization parameters were as follows:

Center	Seed	BlockSizesUsed	TopUpArm	TotalAssignments
Center 1	20251206	12,15,15,3,3,15,15,9,12,9,3,15,6,6,15,6,3,12,9,15,15,12,15,9	TSA	250
Center 2	20251206	15,9,3,6,6,15,6,3,3,12,9,3,15,12,6,6,15,12,9,3,15,9,9,3,3,6,12,6,6,6,3,3	TNPD	250
Center 3	20251206	15,9,15,12,12,6,15,9,9,9,6,6,9,9,15,3,9,15,6,6,9,9,6,12,9,9	NTPD	250
Center 4	20251206	6,3,3,12,15,3,9,3,6,12,6,6,6,9,3,9,9,6,12,15,12,15,15,6,15,9,15,3,3,3	TSA	250

  Allocation is to be sequential upon the already prepared list for each center.
- **Blinded Data Analysis:** To minimize analytical bias, the statistical analysis of trial outcomes will be conducted in a blinded manner. Treatment groups will be coded as Group A, B, and C in the dataset, without revealing the actual intervention assignments to the trial statistician during the primary analysis phase. Unblinding will occur only after the completion of all prespecified analyses. This approach ensures objectivity in interpreting the results and aligns with best practices for randomized controlled trials.
- **RCT Standards:** This study is designed and conducted in accordance with internationally recognized standards for randomized controlled trials, including the CONSORT (Consolidated Standards of Reporting Trials) and SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines. These

frameworks ensure methodological rigor, transparency, and reproducibility in trial design, conduct, analysis, and reporting.

Participants

Inclusion Criteria:

- Age 3–14 years.
- Undergoing clean/clean-contaminated surgery with primary skin closure with absorbable/non-absorbable sutures, either interrupted or subcuticular.
- Surgical category (head and neck, chest, abdomen, back, genitalia, and extremities).
- Anticipated need for immediate post-operative wound coverage (dressing or TSA).
- Informed consent from parent/guardian.

Exclusion Criteria:

- Known allergy/sensitivity to cyanoacrylates, adhesive tapes, or dressing components.
- Presence of surgical drains exiting through the primary incision.
- Contaminated/dirty wounds.
- Immunocompromised states where protocol interventions are contraindicated.

Interventions (Standardized Application)

Arm A — Transparent Non-Padded Dressing (TNPD): sterile transparent film sized to cover incision plus 2–3 cm margin. Dressing removal per protocol on POD 3–5 unless soiled/detached.
Arm B — Non-Transparent Padded Dressing (NTPD): sterile non-transparent pad with adhesive borders. Dressing removal per protocol on POD 3–5 unless soiled/detached.
Arm C — Topical Skin Adhesive (TSA) cyanoacrylate-based (Glubran® Tiss 2 0.25ml): applied in two thin layers along approximated incision; allowed to polymerize fully; no additional dressing unless clinically indicated.

Outcomes

Primary Outcome (Day 60):

Incisional wound morbidity: any of..

a) superficial/deep incisional SSI per CDC criteria
b) wound dehiscence
c) seroma/hematoma requiring intervention

Secondary Outcomes:

- Pain scores using (Wong–Baker FACES) scale at 24–48 h.
- Dressing-related satisfaction in parents.
- Dressing-related complications (skin blistering, maceration, dermatitis).
- Resource use: number/duration of dressing changes, unplanned readmissions.

- Length of stay.
- Relation to usage of antibiotics (prophylactic vs therapeutic, IV vs oral).
- Cost.

Follow-up & Assessments

In-hospital daily assessment until discharge; outpatient follow-up at Day 7 (±2), and Day 60 (±7). Data captured in Microsoft Forms and linked Excel sheets.

Sample Size

The sample size for this multicenter randomized controlled trial was calculated to ensure adequate power for the primary comparison between topical skin adhesive (TSA) and non-transparent padded dressing (NTPD). Based on prior literature and clinical experience, we anticipate a 60-day incisional wound morbidity rate of 25% in the NTPD group and 15% in the TSA group, representing a clinically meaningful absolute reduction of 10%. Using a two-sided alpha of 0.025 (Bonferroni correction for two primary pairwise comparisons) and a desired power of 80%, the required sample size is 300 patients per group. To account for potential attrition (estimated at 10%), we will enroll 330 patients per arm. This yields a total sample size of 990 participants across three arms, which balances statistical rigor with feasibility across the four participating centers. While the trial will be underpowered for the secondary comparison between TNPD and NTPD unless the true difference exceeds 7–10%, sensitivity analyses will be conducted to explore effect sizes and confidence intervals across all comparisons.

Statistical Analysis Plan (SAP)

Primary Analysis

The primary analysis will adhere to the intention-to-treat (ITT) principle, ensuring that all randomized participants are analyzed in the groups to which they were assigned, regardless of protocol adherence.

- Binary outcomes (e.g., wound morbidity) will be analyzed using mixed-effects logistic regression, with:
    - Treatment group as a fixed effect.
    - Study site included as a random intercept to account for center-level variability.
    - Results will be reported as odds ratios (ORs) with 95% confidence intervals (CIs).

- Time-to-event outcomes (if applicable) will be evaluated using Cox proportional hazards models with robust variance estimation to account for clustering.

Primary Comparisons
Two pairwise comparisons will be conducted for the primary endpoint:

1. TSA vs NTPD vs TNPD (primary hypothesis)

To control for family-wise error rate, a Bonferroni correction will be applied, setting the significance level at $\alpha = 0.025$ for each comparison.

Exploratory Comparison
- These results will be interpreted descriptively, focusing on effect sizes and 95% CIs.
- P-values will not be reported for exploratory analyses to avoid misinterpretation as confirmatory findings.
- This approach aligns with CONSORT guidelines for reporting secondary and exploratory outcomes and ensures transparency in interpretation.

Handling Missing Data
- If >5% of data are missing, and the missingness is assumed to be at random, multiple imputation techniques will be employed to preserve statistical power and reduce bias.

Subgroup Analyses
Prespecified subgroup analyses will be conducted based on:

- Age bands: 3–6 years, 7-10 years and 11–14 years.
- Surgical category: head/neck, chest, abdomen, back, genitalia, and extremities.

Interaction effects will be tested using a significance level of $\alpha = 0.10$, appropriate for exploratory subgroup evaluation.

Economic Evaluation
In addition to direct cost comparisons, the study will explore the feasibility of conducting:

- Cost-effectiveness analysis (CEA) or
- Cost-utility analysis (CUA)

If sufficient data are available on resource utilization, clinical outcomes, and patient-reported quality of life, incremental cost-effectiveness ratios (ICERs) will be calculated to compare TSA, TNPD, and NTPD. This analysis will help determine whether higher upfront costs (e.g., TSA) are justified by improved outcomes or reduced downstream healthcare utilization. The inclusion of economic evaluation will support evidence-based decision-making and inform policy and procurement strategies in pediatric surgical care.

Data Management & Quality Assurance

Data captured in Microsoft Forms with linked Excel sheets. Regular monitoring visits (remote/on-site) verify consent, eligibility, outcomes, and SAE reporting.

Ethics & Regulatory

Conduct per the Declaration of Helsinki and relevant pediatric research regulations. Written informed consent from parents/guardians. Adverse events, including skin reactions and unplanned re-interventions, will be recorded and reported per center policy.

Glubran® Tiss 2 (0.25 ml) is used in this study solely for clinical and research purposes. The investigators have no financial relationship, sponsorship, or funding from the manufacturer or distributor of this product. No commercial entity has influenced the study design, conduct, data analysis, or reporting. The inclusion of Glubran® Tiss 2 does not imply endorsement, and its use was based on clinical availability and suitability for the study objectives.

Trial Registration

This clinical trial will be registered with the ISRCTN registry (International Standard Randomised Controlled Trial Number), a WHO-recognized primary registry that ensures transparency and accessibility of trial information. Registration will occur prior to the enrollment of the first participant. The ISRCTN record will include key protocol details, eligibility criteria, outcome measures, and contact information. This step aligns with international ethical standards and facilitates dissemination, peer review, and compliance with journal publication requirements.

Data Sharing Statement

To promote transparency and support future research, we plan to make the anonymized individual participant data (IPD) and associated metadata available upon reasonable request following publication of the primary results. Access will be granted to qualified researchers for non-commercial academic purposes, subject to approval by the trial steering committee and in accordance with applicable data protection regulations. A data sharing agreement will be required to ensure appropriate use and confidentiality.

Team Roles & Responsibilities

- Principal Investigator (overall lead, protocol fidelity).
- Site Principal Investigators (local oversight, recruitment, safety).
- Trial Statistician (SAP, randomization lists, analyses).

• Data Manager (eCRF build, data quality, exports).
• Research Coordinators (screening, consent, follow-up, data entry).

Anticipated Costs (12–18 months)

Materials:

- TSA (16 JDs/0.25ml vial)
- TNPD (average 0.5 JD/5x5cm patch) and NTPD (average 2 JDs/5x5cm patch). TNPD and NTPD are covered by all kind of medical insurances in Jordan.

Total rough order estimate= (4 centers, 990 patients of which only 330 will have TSA applied: 5280 JDs) + (extra 100 vials for cases with multiple wounds: 1600 JDs) = 6880 JDs

Timeline

• Start-up (IRB approvals, contracts, eCRF build): 3–4 months.
• Enrollment: 12 months (average ~20 patients/center/month across 4 centers).
• Follow-up completion: +3 months.
• Data clean & analysis: 2 months.
• Manuscript & dissemination: 2 months.

Related Studies

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[2] M. Kuddushi, A. A. Shah, C. Ayranci, and X. Zhang, "Recent Advances in Novel Materials and Techniques for Developing Transparent Wound Dressings," J. Mater. Chem. B, vol. 11, no. 27, 2023. [Online]. Available: https://pubs.rsc.org/en/content/articlelanding/2023/tb/d3tb00639e
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