Patient-Reported Outcomes Following Application of Intraoral Sutures: A Split-Mouth Randomized Controlled Trial

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Title

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1. Background and Rationale

Primary wound closure is essential for the successful healing of surgical sites in periodontal and oral surgery, ensuring stabilization of soft tissues, hemostasis, and protection against mechanical and microbial insults.(1,2) Sutures remain the primary method for intraoral closure and can significantly influence clinical outcomes and patient comfort based on their composition and behavior in tissue (Selvig et al., 1998; Lilly et al., 1968a).(3)

The ideal suture should maintain adequate tensile strength, be biocompatible, resist microbial colonization, and be comfortable for the patient during healing (Leknes et al., 2005).(4) However, suture materials differ widely in their structure (monofilament vs. multifilament/braided), size (diameter), origin (natural vs. synthetic), and absorption characteristics (absorbable vs. non-absorbable), all of which affect wound healing dynamics and tissue response (Dragovic et al., 2020; Lilly et al., 1969).(2)

Silk, a braided natural suture, is known for its excellent handling and knot security, but it is also associated with enhanced bacterial adhesion and a more pronounced inflammatory response due to its organic and braided structure.(5) In contrast, synthetic monofilament materials like nylon and Monocryl demonstrate lower microbial retention, reduced plaque accumulation, and minimal tissue reactivity (Dragovic et al., 2020; Selvig et al., 1998).(2,3)

While numerous studies have addressed microbial adherence and tissue-level outcomes of different suture types, there is limited literature assessing patient-reported outcomes specifically in response to suture material in intraoral sites. Most existing patient experience data comes from broader surgical or periodontal interventions where sutures were only one of many variables.

Pain and discomfort following periodontal or surgical dental procedures typically peak in the first 48–72 hours and resolve by Day 7, with symptoms influenced by the extent of surgical trauma and tissue manipulation.(6) Yet, studies that isolate sutures and/or suture material as a variable influencing pain, speech interference, or awareness are lacking.

Spatial tactile sensitivity within the oral cavity varies by anatomical site. Studies using monofilament and two-point discrimination testing have shown that the gingiva has the lowest tactile sensitivity among the tested oral tissues (8.06 g/mm^2), followed by the

buccal mucosa (4.77 g/mm²). In comparison, the palate demonstrates higher sensitivity (3.60 g/mm²), and the tongue tip has the highest (2.26 g/mm²) (Trulsson & Essick, 2010).(7) Additionally, grating orientation tasks—a reliable measure of tactile spatial resolution—have demonstrated thresholds of ~0.51 mm on lips, ~0.58 mm on the tongue, and ~0.94 mm on the finger, underscoring high oral acuity. Although the gingiva and palate were not included in these grating orientation studies, these results guide expectations for spatial sensitivity in adjacent mucosa (Van Boven & Johnson, 1994).(8) More recently, Miles et al. (2022) examined tactile acuity in various oral tissues, emphasizing both the challenges and importance of developing accurate stimuli for assessing spatial resolution within the oral cavity.(9)

These sensory differences may influence how patients perceive suture awareness and irritation, depending on the site of suture placement.

Given this gap, a well-controlled clinical study using validated patient-reported outcome measures—such as the Visual Analog Scale (VAS) (10)and the Oral Health Impact Profile (OHIP-14) (11)—is necessary to evaluate the effect of suture type on patient experience.

This approach is supported by earlier findings from Selvig et al. (1998), who highlighted the differing tissue responses to various suture types in the oral mucosa, and from Lilly et al. (1968b, 1969), who provided foundational histological evidence of differential healing patterns linked to suture composition. Leknes et al. (2005) further demonstrated how monofilament sutures induce less inflammation and promote more favorable healing than multifilament braided alternatives. Additionally, Dragovic et al. (2020) outlined the methodological utility of split-mouth designs in suture research and emphasized the clinical relevance of evaluating both subjective and objective healing outcomes in a controlled intraoral setting.

This randomized, within-person controlled trial is designed to compare four commonly used suture materials—silk, polyamide, polyglactin 910, and Poliglecaprone —placed in standardized intraoral sites. This design allows for direct comparison across material classes (braided vs. monofilament, absorbable vs. non-absorbable) within the same patient, minimizing variability and enhancing the interpretability of both subjective (PROMs) and objective healing outcomes.

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2. Objectives and Hypotheses

Primary Aim: To compare patient-reported outcomes (pain, awareness, irritation, and satisfaction) associated with four commonly used suture materials placed at intraoral sites (palate vs. buccal gingiva).

Null Hypothesis: Suture material and location have no effect on patient-reported outcomes.

Alternative Hypothesis: Suture material, location, or their interaction significantly affect patient-reported outcomes.

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3. Materials Studied

All sutures will be a **4-0 size** and have a **reverse cutting 19mm needle** with a **3/8 circle curvature**(12). The specific suture materials that will be included are:

- **Silk** (natural fiber, braided, non-absorbable)
    - **SILK-SEIDE** USP 4-0, 3/8 circle reverse cutting 19 mm needle, Medipac SA, Stavrochori (Kilkis), Greece.
- **polyglactin 910** (synthetic, braided, absorbable)
    - **Neosorb (PGLA) or PGA** USP 4-0, 3/8 circle reverse cutting 19 mm needle, Medipac SA, Stavrochori (Kilkis), Greece. (both are coated)
- **Poliglecaprone** (synthetic, monofilament, absorbable)
    - **Assucryl® monorapid** , Assut Medical Sàrl Assut Medical Sàrl, Pully-Lausanne (specifically Avenue de Rochettaz 57, Pully, canton of Vaud), Switzerland.
- **Polyamide** (synthetic, monofilament, non-absorbable)
    - Nylon USP 4-0, 3/8 circle reverse cutting 19 mm needle, Atramat®, Internacional Farmacéutica S.A. de C.V., Mexico City, Mexico.

All sutures will have dark colors if possible.

Each suture material will be placed using a **horizontal mattress** technique.

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4. Study Design

A randomized within-person clinical trial. Each participant will receive all four suture types, placed in the same randomly selected maxillary quadrant at distinct anatomical sites: two buccal and two palatal.

Buccal Sites: - Located in the attached gingiva, **1 mm coronal to the mucogingival junction**, unless width of keratinized tissue is less than 2mm then **1 mm apical to a line connecting the mid-buccal gingival margins**. - Site 1: between canine and first premolar (C–P1). - Site 2: between P2 and M1, or adjusted accordingly if P1 is missing.

Palatal Sites: - Located **2 mm apical to a line connecting the mid-palatal gingival margins** - Site 1: between C–P1 - Site 2: between P2–M1. If P1 is extracted, alternate positions (C–P2) will be used.

Randomization will be performed via block-randomization, and allocation concealed using sequentially numbered opaque envelopes. Each suture material will be randomly assigned to one of the four predefined sites.

The study will include **4 clinic visits**: a) One **screening visit** (consent & records); b) One procedure visit (**Study Day 0**; placement of sutures), and 2 postoperative visits: one at 7 days (**Study Day 7**: assessment, completion of questionnaires, and suture removal) and one at 14 days (**Study Day 14**: follow-up assessment of suture wounds one-week post-removal, questionnaires). In addition, participants will be asked to complete an online questionnaire at day-3 after suture placement (Study Day 3).

Assessments will include questionnaires (see below) and clinical photos that will be judged by a blinded panel of periodontists for healing according to **Landry Healing Index (1988)** for suture entry and exit points as well as any adverse effects that may arise.

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5. Sample Size Calculation

Based on a repeated-measures ANOVA design, with 4 suture conditions (within-subjects), a medium effect size (f = 0.25), alpha = 0.05, and power = 0.8, the minimum required sample is 48. Allowing for 20% attrition, the final target enrollment is **60 participants**.

Reference: Faul F et al., G*Power 3, Behav Res Methods 2007.

The sample size was calculated based on the findings of Balakrishna et al. (2022). Assuming a clinically meaningful difference of 1.0 point on the 1-10 VAS for pain, a within-subject standard deviation of 2.07 (derived from reported standard deviations and an assumed inter-measurement correlation of 0.5), a paired-sample calculation using G*Power indicated that 37 participants are required to achieve 80% power at an alpha level of 0.05. Allowing for an anticipated dropout rate of 20%, a total of 46 participants will be recruited to ensure adequate study power.

Reference:

Balakrishna R, Poojay D, Arvind R, Sali S, Moharana AK, Deepak Ts. Single blind, randomized study comparing clinical equivalence of Trusilk and Mersilk silk sutures for mucosal closure following surgical removal of mesioangular impacted mandibular third molar. F1000Res 2022;21:689.

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6. Intervention Protocol

First Visit: - Patients will be screened for eligibility based on inclusion/exclusion criteria. - After consent, demographics will be recorded (age, gender, previous Experience, smocking states).

Surgical Technique: - Following establishment of anesthesia (Posterior Superior Alveolar Nerve block and Greater Palatine Nerve block with Articaine 1:100,000), sutures will be placed in the randomly chosen maxillary quadrant using a standardized **horizontal mattress** technique by one trained surgeon using Castroviejo Needle Holders. - Positioning will follow predefined anatomical sites (two buccal, two palatal). – bleeding points will be placed in the predetermined suture sites. - Bite width will be standardized to 5 mm (bleeding points will provide needle entry and exit points). Entry and exit points will be marked using a thin sharp straight dental explorer (LIKE #11-12 OR SIMILAR ;). Once entry and exit points have been marked (bleeding points visible), then the surgeon will place the sutures. The order of suture placement should always be the same (1-distal palatal, 2-mesial palatal, 3-distal buccal, 4-mesial buccal).

Knotting Protocol: - **Silk**: Surgeon's knot, 4 throws - **polyglactin 910**: Surgeon's knot, 4 throws - **Poliglecaprone**: Surgeon's knot, 5 throws - **Polyamide**: Surgeon's knot, 5 throws (13)- All knots positioned **mid-span of suture line** and tail length trimmed to 3mm(14).

Postoperative protocol: the subjects will be given a printed postoperative instruction: AVOID BRUSHING the suture area, not to manipulate the sutures, and to not trying to stretch the lips to see the sutures so they move the tissues, also the subjects will be advised to take ANY over the counter analgesics (e.g., paracetamol 500mg 2 tablets per need).

Suture Removal: All sutures will be removed at Day 7 ; - Removal follows aseptic technique: - Clean site with saline - Lift knot with Adson forceps - Cut closest to tissue on coronal side - Pull gently in direction of suture path using Curved suture scissors, 12 cm, sharp/sharp tips - Avoid dragging external suture through tissue(15).

Clinical photos: will be taken in the screening visit and after suture placement, suture removal and at the follow up visit, they will be used to document the intervention as well as for the panel to judge the healing of the suture entry and exit points and any adverse reaction (ulcer, abscess, etc.).

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7. Outcome Measures

Primary Outcomes (Patient-reported via Google Form): - Pain (VAS) – ANALGESIC MEDICATION USE (# OF PILLS PER DAY).

Secondary Outcomes: -Awareness (VAS) - Cheek/tongue irritation (VAS) - Speech interference (VAS) - Esthetic assessment (when smiling or when speaking) (QUESTIONNAIRE). Overall preference and ranking. - Pain during suture removal (VAS) -

Objective healing (photographs and clinical index) - Tissue reaction at suture entry/exit points: redness, edema, exudate, ulceration

Healing Assessment Tool: - **Landry Healing Index (1988)** used at Days 7 and 14, primarily for suture entry and exit points and if/when any adverse reaction occur (ulcer, abscess, etc.).

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8. Data Collection Timeline - **Day 1**: Patient screening for inclusion/exclusion criteria, consent, photos, Sutures will be placed and photos after suture placement. - Days 1 (suture placement visit), 3 (over the phone), 7(the suture removal visit), 14 (in person visit): VAS forms - Day 7: Suture removal, first assessment, photos - Day 14: Final assessment, photos. If any adverse effect arises at any moment it will be dealt with even if it requires more follow up visits after day 14.

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9. Inclusion and Exclusion Criteria

Inclusion Criteria:

- *Demographic:* Adults aged 20–30 years.
- *Systemic:*
    - Healthy adults (ASA I-II)
    - No history of allergy to study suture materials
- *Oral:*
    - Periodontally healthy, with no active oral lesions, including carious lesions.
    - All maxillary canine, second premolar and first molar teeth present, with minimal (≤0.5 mm) open contacts between the pairs of teeth that define the study sites.
        - Ideally, full maxillary dentition present from first molar to first molar, with minimal open contacts.
    - At least 2 mm of keratinized tissue width on buccal intervention sites.
- *Other:*
    - Willing and able to provide informed consent.
    - Willing and able to attend all study follow-up visits and complete study questionnaires.

Exclusion Criteria:

- *Systemic:*
    - ALLERGY TO ANY STUDY MATERIALS (E.G., SUTURE MATERIALS or ANESTHATICS) OR MEDICATIONS (PARACETAMOL).
    - Any systemic disease affecting wound healing (e.g., diabetes, immunosuppression)
    - Use of any medications
    - Pregnancy or lactation
- *Other:*
    - Unwillingness or inability to provide informed consent
    - Unwillingness or inability to comply with study protocol and follow-up visits.

Exit Criteria: -

- Participants may exit the study at any time if they wish to discontinue participation.
- Noncompliance with study protocol and visits.
- Development of conditions, e.g., infection, that require immediate care or that introduce exclusion criteria.

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10. Randomization and Blinding - Randomization: Computer-generated, sealed opaque envelopes - Patients: Partially blinded (identical needle/suture sizes) - Assessors: Fully blinded using de-identified photos - Operators: Not blinded, but follows strict standardization protocol, statistician fully blinded using coded data.

Randomization and Allocation Procedure

A centralized computer-generated randomization sequence will be created prior to recruitment using a reproducible random-seed method. Randomization will occur on two levels:

(1) Side Allocation (Right vs. Left):
Participants will be assigned to receive the intervention sutures on either the right or left maxillary side using **block randomization with a block size of 4** (two "Right" and two "Left" assignments per block) to ensure balanced distribution throughout enrollment.

(2) Within-Side Suture Material Allocation:
Four suture materials (Silk, Nylon, Vicryl, Monocryl) will be assigned to the four standardized intraoral sites (mesial-buccal, distal-buccal, mesial-palatal, distal-palatal). Allocation of materials will be performed using a **stratified permuted randomization**, ensuring each material appears an equal number of times in each site position across the total sample (i.e., 15 repetitions per material per site across 60 subjects), maintaining full stratified balance.

The allocation list will be exported into an **Excel-based Sequentially Numbered Opaque Sealed Envelope (SNOSE)** system. Each participant will be assigned the next available envelope in numerical order (ENV-001 to ENV-060). The envelope will contain:

- The assigned side (Right/Left)
- The suture material per site (MB, DB, MP, DP)
- A code for verification

The investigator placing the sutures will open the envelope only after confirming participant eligibility. Outcome assessors and data analysts will remain blinded to allocation.

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11. Statistical Analysis -descriptive statistics. -parametric and nonparametric analysis.

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12. Ethical Considerations - Ethical approval to be obtained from Jordan university review board - Informed consent will be obtained from all participants - Risks minimized through use of routine clinical materials and sterile technique

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13. CONSORT Compliance - Designated as a “within-person randomized clinical trial” - Follows CONSORT 2017 Extension for Within-Person Trials - Trial registration, flowchart, and reporting per checklist

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14. Funding and Resources - Study funded through institutional research grant - All suture materials provided by hospital procurement - Costs include suture packs, local anesthetic, gloves, surgical stents, MEDS GIVEN TO PARTICIPANTS, and software licenses for data analysis, participants compensation: gift cards or 20JD given as 5JD day 1 and 7, 10 JD day 14, as well as research assistant payroll.

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15. Sample Source - Participants will be drawn from **convenience sampling adults ageing 20-30 years old**.

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16. Appendices (Available Upon Request) - OHIP-14 Questionnaire (Arabic/English) - Landry Healing Index Score Sheet - Randomization Matrix - Surgical placement diagrams - VAS and suture feedback form - Data collection Google Form structure

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