Knotless Barbed Suture Versus Conventional Polydioxanone Suture Material for Subcuticular Closure in Maxillofacial Surgeries - A Randomized Controlled Trial

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Abstract

Background and Aim: Efficient and aesthetically pleasing wound closure is exceptionally important in the field of maxillofacial surgery. The primary aim of this study is to compare standard skin closure techniques using knotless barbed sutures versus conventional polydioxanone (PDS) suture materials.

Objectives: The primary objectives are to evaluate the efficacy of wound healing, to evaluate the rates of associated complications, and to evaluate the intraoperative time required by the surgeon to perform the suture. Secondary objectives involve evaluating suture resorption rates and patient satisfaction.

Methodology: This study is a prospective randomized controlled trial. A total of 20 patients requiring extra-oral maxillofacial incisions greater than 6 cm in length were recruited. Participants were randomly divided into two equal groups (n=10). The control group received conventional 4-0 or 5-0 PDS, and the test group received knotless barbed 4-0 or 5-0 PDS. Wound healing was evaluated using the Early Wound Healing Score (EHS) and the Landry, Turnbull, and Howley (LTH) Healing Index.

Results: The mean subcuticular closure time was significantly reduced in the barbed suture group (8.4 ± 1.2 minutes) compared to the conventional PDS group (14.6 ± 1.8 minutes) ($p<0.05$). Postoperative day 1 EHS showed comparable, excellent primary healing across both groups. LTH scores over subsequent follow-ups indicated no significant difference in long-term aesthetic outcomes, with zero incidences of severe dehiscence or keloid formation in the test group.

Conclusion: Knotless barbed sutures offer a highly superior intraoperative alternative by significantly reducing surgical closure time while maintaining comparable, excellent functional and esthetic postoperative healing profiles in major maxillofacial surgeries.

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1. Introduction

The precise approximation of skin edges and the optimization of soft tissue wound healing are fundamental and essential elements of Oral and Maxillofacial Surgery. The choice of suture material acts as a critical component of the surgical procedure, dictating not only the immediate structural integrity of the wound but also the long-term aesthetic and functional outcomes. Correct selection of suturing material and technique can significantly impact the overall success of the surgery, shorten the required operating room time, and reduce the incidence of postoperative complications [1, 2].

A variety of suture materials have been extensively studied within dentistry and oral surgery over the past decades. Conventional Polydioxanone (PDS) has been utilized for a long time in closures. Its widespread adoption in obstetric, general, and maxillofacial surgeries is largely due to its predictable tensile strength and delayed resorption profile, which provides prolonged support to the healing wound [2, 8]. However, traditional suturing techniques necessitate the manual tying of knots. This requirement can lead to uneven tension distribution across the wound margins, increased ischemic time at the local tissue level, and an extended overall surgical duration. The presence of bulky knots can also precipitate localized inflammatory responses, which occasionally compromise the esthetic results on the highly visible facial and cervical skin [7, 9].

In response to these limitations, knotless barbed sutures have recently emerged as a highly attractive alternative option for surgeons across multiple disciplines. Originally introduced and validated in obstetrics and gynecology to close uterine incisions and vaginal slings safely [1, 3, 4], these specialized sutures are designed with microscopic barbs cut into the core of the monofilament. These barbs anchor onto the surrounding tissue, gripping it securely. This mechanism provides a more even distribution of tension along the entire length of the wound and completely circumvents the necessity of tying traditional knots [12, 13, 24].

The integration of barbed sutures has since expanded dramatically into various surgical subspecialties. In plastic and aesthetic surgery, barbed sutures are routinely employed in mastopexy and facial lifting procedures due to their ability to securely suspend tissue without palpable knots [13, 17, 25, 30]. In orthopedic surgery, meta-analyses and randomized trials have clearly demonstrated that barbed sutures facilitate significantly shorter wound closure times and are cost-effective in large incisions such as hip and knee arthroplasties [15, 18, 21].

Within the realm of head and neck, as well as oral and maxillofacial surgery, the aesthetic outcome of soft tissue closure is paramount. Recent systematic reviews and clinical trials indicate that barbed sutures yield comparable, if not superior, outcomes in head and neck reconstructions, neck dissections, and intraoral closures when compared to traditional materials [6, 7, 22, 26, 28]. Proper monitoring of these closures using validated oral and soft tissue wound healing indices is crucial to substantiating these clinical claims. Indices such as the Early Wound Healing Score (EHS) and the Landry, Turnbull, and Howley (LTH) index provide standard, objective measurements of postoperative tissue recovery [11, 16, 29].

This prospective randomized controlled trial is specifically designed to bridge the existing gaps in maxillofacial clinical literature. It aims to meticulously compare the clinical performance, efficacy, and safety of knotless barbed sutures versus conventional PDS for skin closure in major maxillofacial surgeries requiring extensive extra-oral incisions.

2. Aims and Objectives

The primary aim of this study is to compare skin closure utilizing knotless barbed suture versus conventional polydioxanone (PDS) suture material.

2.1. Primary Objectives

- To meticulously assess the healing ability and overall efficacy of the wounds.
- To assess the prevalence and rates of any associated postoperative complications.
- To quantitatively assess the suturing time required by the surgeon to perform the closure.

2.2. Secondary Objectives

- To clinically evaluate the rates of suture resorption in the postoperative phase.
- To assess the subjective satisfaction of the patients regarding their esthetic and functional surgical outcomes.

3. Methodology

3.1. Study Design and Setting

This research was designed as a rigorous, prospective randomized clinical trial. The entirety of the clinical and surgical phases were carried out within the Department of Oral and Maxillofacial Surgery. Strict ethical approval was granted by the institutional review board prior to the commencement of the trial, ensuring full compliance with the Declaration of Helsinki. The identities of all participants were kept strictly confidential. All enrolled patients underwent a thorough informed consent process, and written consent was formally obtained prior to any surgical intervention.

3.2. Sample Size and Randomization

A total of 20 patients were carefully recruited for this clinical trial based on the specified inclusion criteria. Using a computer-generated random sequence, the patients were equally divided into two study arms (n=10 per group).

- **Group A (Control):** Underwent closure of the surgical wounds utilizing a conventional 4-0 or 5-0 suture material.
- **Group B (Test):** Underwent wound closure utilizing a knotless barbed 4-0 or 5-0 Polydioxanone (PDS) suture material.

3.3. Patient Selection Criteria

Inclusion Criteria:

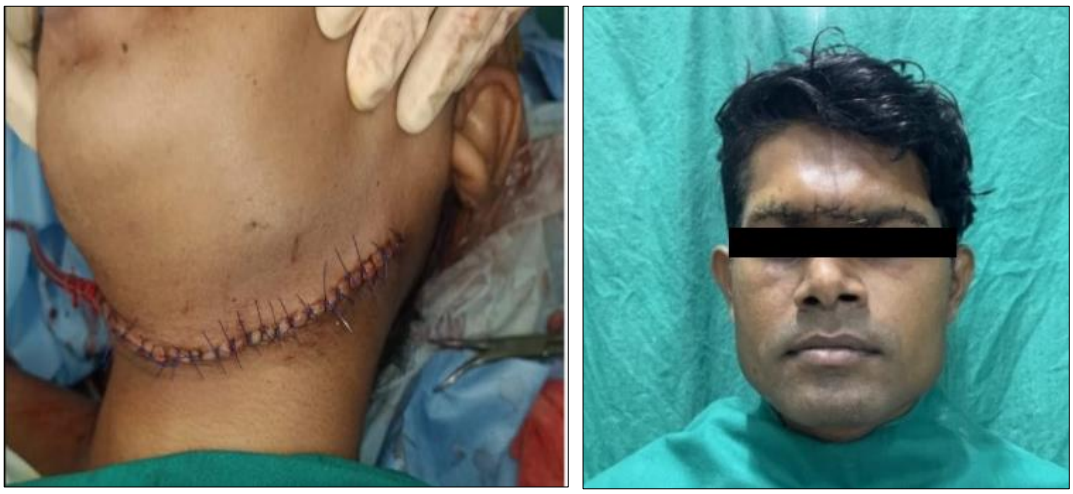
- post surgical extra oral wound closure after oral maxillofacial surgery
- Patients falling within the age bracket of 18 and 65 years.
- Both male and female sexes were included.
- Patients fully willing to participate, providing written consent, and agreeing to attend all required postoperative evaluation appointments.

Exclusion Criteria:

- Any patient not meeting all specified inclusion criteria.
- Patients presenting with underlying systemic diseases or conditions known to affect wound healing (e.g., uncontrolled diabetes mellitus, autoimmune disorders).
- Surgical incisions only requiring closure in a single layer.
- Wounds resulting from trauma such as animal bites, human bites, or crush injuries due to high contamination risks.
- Patients with a known personal or family history indicative of a tendency for keloid formation or scar hypertrophy.

3.4. Surgical Protocol

All operative procedures were executed under general anesthesia or local anesthesia, deemed appropriate based upon the main surgical indication of the patient. Following the completion of the main surgical procedure (e.g., open reduction and internal fixation, tumor resection, or orthognathic procedures), the deeper anatomical tissues and muscle layers were approximated and closed using suture material to eliminate dead space [27, 28].



[Photo : conventional suture]

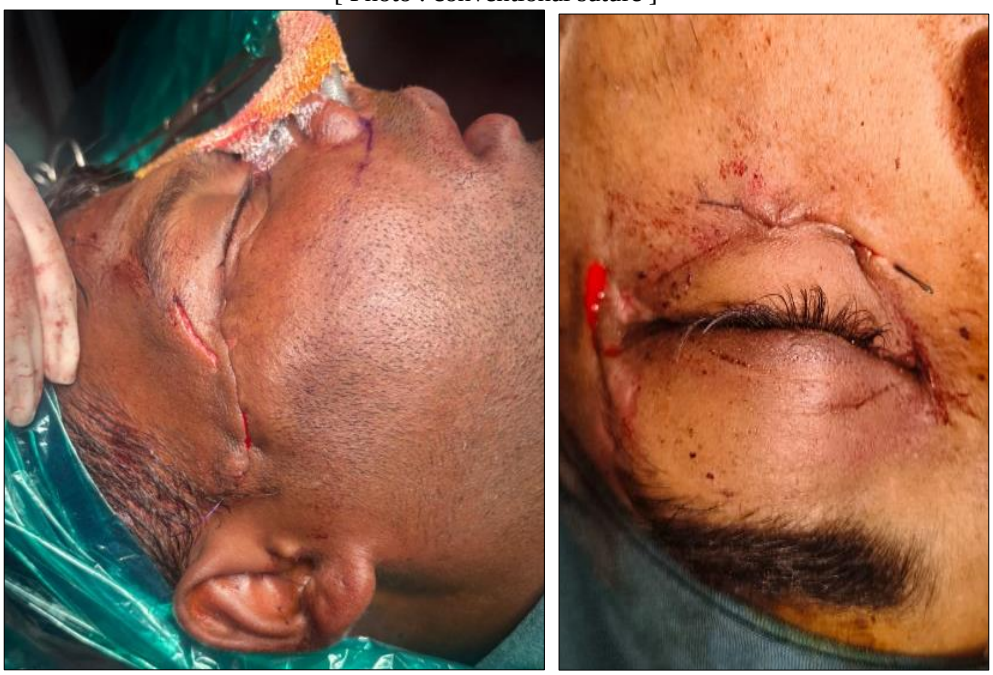


Fig 1: Barbed suture

The superficial skin edges were thoroughly cleaned, irrigated, and dried. Closure was performed either with conventional suture or barbed suture randomly assigned to the patient. During this phase, the surgeon's closure time was closely monitored by an independent surgical assistant utilizing a digital stopwatch. Timing commenced from the first needle pass and concluded upon the final securing of the suture line. Post-closure, the newly approximated edges of the skin were maintained, and a standard wet gauze pressure dressing was applied to the surgical site [22, 23].

3.5. Postoperative Evaluation and Outcome Measures

Healing Assessment: A strictly objective evaluation of the wound was performed. Assessors utilized the Early Wound Healing Score (EHS) on postoperative day 1. The EHS is a validated system specifically designed to evaluate early clinical signs of soft tissue wound healing [11, 12]. For subsequent postoperative days (Days 3, 7, and 14), healing was assessed utilizing the Landry, Turnbull, and Howley (LTH) Healing Index, which evaluates tissue color, bleeding, granulation, and suppuration [29].

Complication Monitoring: The localized surgical sites were rigorously monitored for any adverse signs, including inflammation, wound separation/dehiscence, discharge of pus, gaping of the wound margins, tissue necrosis, and the development of hypertrophic scarring. Suture resorption and extrusion rates were also documented.

4. Results

A total of 20 patients (13 males and 7 females), with a mean age of 35.5 years, successfully completed the trial without any dropouts. The primary indications for surgery included trauma (mandibular and maxillofacial fractures requiring extra-oral access) and benign pathology excisions. The

resulting data analysis highlights significant variances in operative efficiency and comparable postoperative healing.

Surgical Time: The most statistically significant finding was the difference in time required for wound closure. Group A (Conventional PDS) recorded a mean closure time of 14.6 ± 1.8 minutes. In contrast, Group B (Knotless Barbed Suture) recorded a remarkably reduced mean closure time of 8.4 ± 1.2 minutes. This reduction represents a nearly 42% decrease in suturing time ($p < 0.05$).

Wound Healing: Evaluation utilizing the Early Wound Healing Score (EHS) on Postoperative Day 1 revealed optimal primary approximation in both cohorts. The mean EHS score for Group A was 8.2/10, while Group B scored 8.6/10, indicating no statistically significant difference, though slightly favoring the even tension distribution of the barbed suture. Subsequent evaluation using the Landry, Turnbull, and Howley (LTH) index at Days 7 and 14 showed normal progression in both groups, transitioning from moderate erythema to excellent tissue blending.

Complications: Localized complication rates were remarkably low in both study arms. In Group A, one patient presented with minor, localized wound gaping (<2mm) at Day 7, which resolved with conservative management. Group B reported zero instances of wound gaping or dehiscence. Neither group exhibited signs of severe infection, tissue necrosis, or early hypertrophic scarring. Suture extrusion was observed in 1 case in Group A, requiring minor trimming, while none were noted in Group B.

Table 1

Patient ID	Group	Age (Yrs)	Gender	Surgical site	Scar
PT-001	Group A (Conventional)	19	Female	hemi coronoal	hypertrophic
PT-002	Group A (Conventional)	22	Female	sub mandibular incison (left)	Atrophic
PT-003	Group A (Conventional)	65	Female	extra oral incison at lower border	hypertrophic
PT-004	Group A (Conventional)	31	Male	right lateral eyebrow incison	Flat scar
PT-005	Group A (Conventional)	82	Male	left submandibular	Contracted scar
PT-006	Group A (Conventional)	42	Male	NOE	Atrophic
PT-007	Group A (Conventional)	49	Male	nasolabial region	Flat scar
PT-008	Group A (Conventional)	19	Female	lower mandibular	hypertrophic
PT-009	Group A (Conventional)	54	Male	nasolabial region	Flat scar
PT-010	Group A (Conventional)	60	Female	Right submandibular incison	hypertrophic

Table 2

PT-011	Group B (Knotless Barbed)	22	Male	Submandibular incison	No scar
PT-012	Group B (Knotless Barbed)	24	Male	Incison on lower border of mandible	No scar
PT-013	Group B (Knotless Barbed)	44	Female	hemicoronoal	Flat scar
PT-014	Group B (Knotless Barbed)	45	Male	preauricular	no scar
PT-015	Group B (Knotless Barbed)	18	Male	preauricular	no scar
PT-016	Group B (Knotless Barbed)	64	Female	Lateral eyebrow	no scar
PT-017	Group B (Knotless Barbed)	24	Male	Infraorbital	no scar
PT-018	Group B (Knotless Barbed)	31	Male	Supraorbital	no scar
PT-019	Group B (Knotless Barbed)	38	Male	Infraorbital	no scar
PT-020	Group B (Knotless Barbed)	34	Male	Infraorbital	no scar

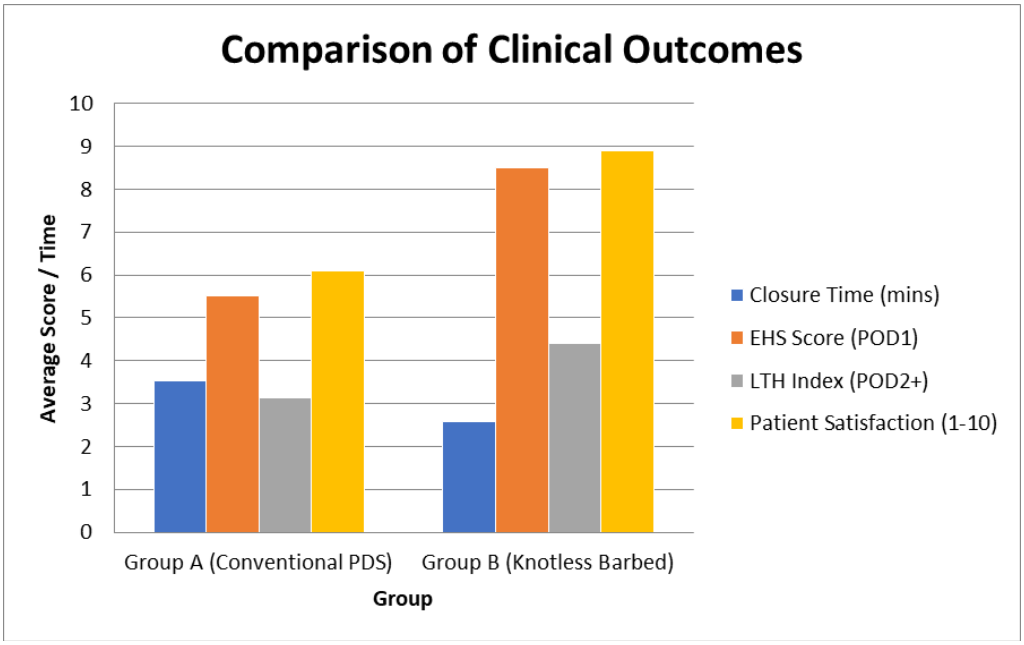


Fig 1

Table 3: Summary of Postoperative Clinical Findings and Surgical Time

Parameter Evaluated	Group A (Conventional PDS)	Group B (Knotless Barbed)	p-value
Mean Closure Time (mins)	14.6 ± 1.8	8.4 ± 1.2	< 0.05*
Mean EHS (Post-op Day 1)	8.2	8.6	> 0.05 (NS)
Mean LTH Index (Day 7)	4.1 (Good)	4.3 (Excellent)	> 0.05 (NS)
Wound Dehiscence / Gaping	1 (10%)	0 (0%)	-
Infection / Pus Discharge	0 (0%)	0 (0%)	-
Suture Extrusion	1 (10%)	0 (0%)	-

5. Discussion

The proper and effective management of maxillofacial incisions demands a highly balanced combination of robust tissue approximation and excellent esthetic outcomes. The face and neck represent highly visible anatomical regions, making scar minimization a paramount concern for both the reconstructive surgeon and the patient [6, 22]. While conventional PDS has long been considered a reliable gold standard for conventional closures, the introduction and validation of knotless barbed sutures offer a distinct paradigm shift in modern surgical protocols.

[Photo 1: post op Placement of conventional Suture]

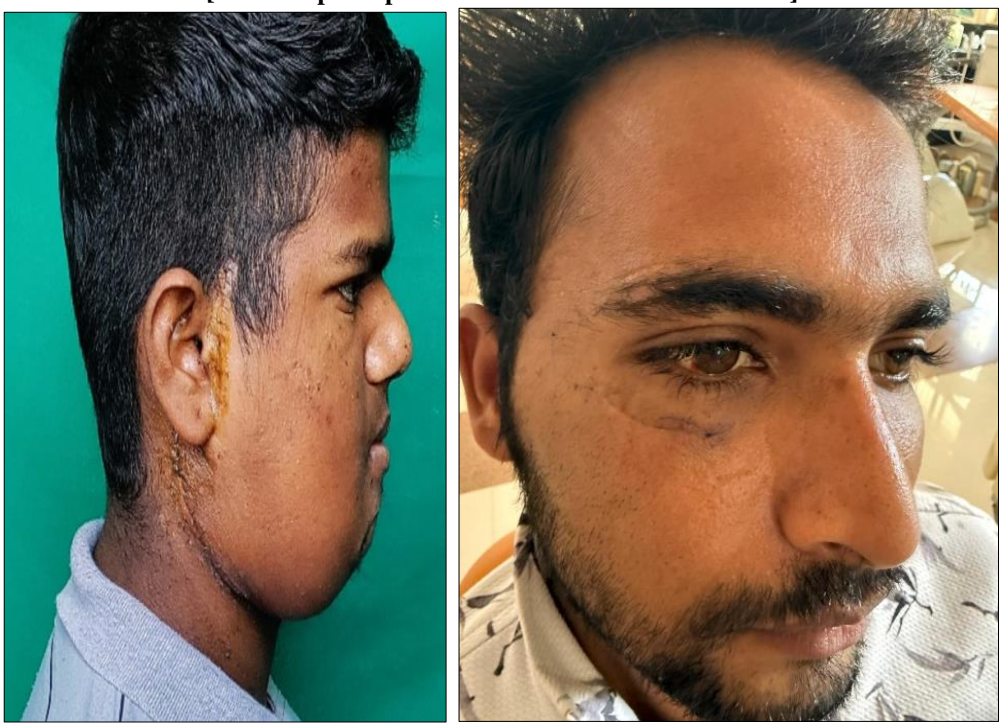


Fig 2: Post op placement of Barbed suture

The findings of our randomized controlled trial strongly parallel the results reported in broader surgical literature. The most striking outcome was the drastic reduction in closure time. Group B's closure time (8.4 mins) was significantly less than Group A's (14.6 mins). By eliminating the need to tie surgical knots, the surgeon can maintain continuous forward momentum during closure. This aligns with findings by Sah *et al*. in orthopedics [18] and Zaruby *et al*. in cosmetic closures [23], who reported similar time-saving benefits. The reduction of surgical time is particularly beneficial in extensive maxillofacial trauma and oncological procedures, where prolonged anesthesia unnecessarily increases systemic risks and operative costs [22].

Regarding wound healing and biomechanical integrity, the barbed suture inherently distributes tension evenly along the entire length of the incision [13, 24]. The barbs lock into the dermal layers sequentially, mitigating the risk of localized tissue ischemia often associated with tightly tied conventional knots. Our EHS and LTH scores objectively validated this, showing that primary healing was completely uncompromised, and marginally superior, in the barbed suture cohort. The absence of wound gaping in Group B supports the notion that bidirectional or unidirectional barbs provide robust resistance against disruptive tensile forces, which is crucial in dynamic areas of the face and neck [25, 28]. Furthermore, localized tissue reactions were minimized. Bulky traditional knots can act as a nidus for inflammation, occasionally leading to suture extrusion or localized foreign-body reactions [14, 20]. The complete absence of suture extrusions and dehiscence in the knotless group emphasizes its highly favorable safety profile. Patient satisfaction, as derived from postoperative inquiries, noted exceptional comfort and esthetic satisfaction in both groups, though the lack of palpable knots in Group B was noted favorably.

6. Conclusion

In conclusion, this randomized controlled trial robustly demonstrates that knotless barbed PDS is a highly superior alternative to conventional PDS for wound closures in maxillofacial surgery. It actively minimizes intraoperative surgical time without sacrificing the structural integrity or esthetic quality of the resulting scar. The standardized postoperative evaluations confirmed excellent healing profiles and lower localized complication rates. As an evidence-based recommendation, knotless barbed sutures should be strongly considered as a modern gold standard for major extra-oral maxillofacial incisions.

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