

Comparison of outcomes of knotless barbed sutures and non-barbed sutures used as wound closure materials for subcuticular suturing at the nasolabial donor site in patients undergoing surgical rehabilitation for oral submucous fibrosis - A Study Protocol.

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Abstract

Background: Oral submucous fibrosis (OSF) is a chronic, precancerous condition causing severe scarring and limited mouth opening, with advanced cases often requiring surgical reconstruction using nasolabial flaps. This process depends heavily on effective wound closure to prevent complications. Barbed sutures, a self-retaining type of suture, simplify closure by eliminating knots and reducing tension. A study aims to evaluate the use of barbed versus non-barbed sutures in oral surgeries, specifically focusing on how they impact complications and aesthetic outcomes, addressing the challenges posed by dynamic facial muscles in maxillofacial procedures.

Objective: The primary objective of this study is to evaluate and compare the time required for closure of nasolabial donor site with Barbed (Knotless Suture) and Non-Barbed suture techniques in Oral submucous fibrosis. The secondary objectives include comparing the time required for closure of the nasolabial donor site, wound healing, and post-operative aesthetic outcomes between barbed (Knotless Suture) and non-barbed Vicryl sutures.

Methods: This prospective observational study takes place at the department of oral and maxillofacial surgery, SGM cancer hospital, in collaboration with the Sharad Pawar Dental College Maharashtra, India, from April 2025 to January 2026. Patients clinically diagnosed with grade III or grade IV oral submucous fibrosis (OSMF) will undergo a series of preoperative procedures. A Pre-Anaesthetic checkup (PAC) will also be conducted to assess their fitness for surgery. Once the patients meet all inclusion criteria they will be scheduled for the surgical procedure. Group A will receive 3-0 polyglyconate barbed suture and group B will receive 3-0 poliglecaprone vicryl suture. Patients will be assessed based on wound closure timing, measurement of wound healing using "REEDA SCALE" and assessment of scar using "MANCHESTER SCAR SCALE(MSS)". The outcome measures will be statistically analysed and appropriate tests applied to each outcome measures. The p-value <0.05 will be considered significant.

Results: As of April 2025, institutional ethical clearance has been obtained, and patient recruitment is ongoing. Recruitment began after IEC approval and is ongoing, with 5 patients enrolled as of April 2025. Data collection is expected to be completed by December 2025, and results will be published in mid-2026.

Conclusions: This study is designed to compare 3-0 polyglyconate knotless barbed sutures with conventional 3-0 poliglecaprone (Vicryl) subcuticular sutures for closure of the nasolabial donor site in patients undergoing nasolabial flap reconstruction for advanced oral submucous fibrosis. By measuring subcuticular closure time (primary outcome) and early wound healing (REEDA) and scar quality (Manchester Scar Scale) at predefined intervals, the protocol will assess both efficiency and patient-centred aesthetic outcomes in a clinically relevant maxillofacial setting where dynamic facial musculature complicates closure. Clinical Trial: CTRI NO (CTRI/2025/06/089139)

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“Comparison of outcomes of knotless barbed sutures and non-barbed sutures used as wound closure materials for subcuticular suturing at the nasolabial donor site in patients undergoing surgical rehabilitation for oral submucous fibrosis”- A Study Protocol.

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ABSTRACT

Introduction:

Oral submucous fibrosis (OSF) is a chronic, precancerous condition causing severe scarring and limited mouth opening, with advanced cases often requiring surgical reconstruction using nasolabial flaps. This process depends heavily on effective wound closure to prevent complications. Barbed sutures, a self-retaining type of suture, simplify closure by eliminating knots and reducing tension. A study aims to evaluate the use of barbed versus non-barbed sutures in oral surgeries, specifically focusing on how they impact complications and aesthetic outcomes, addressing the challenges posed by dynamic facial muscles in maxillofacial procedures.

Need for study:

Patients undergoing nasolabial flap in OSMF reconstruction require better aesthetic and rapid wound healing, which can be achieved using barbed and non-barbed sutures.

Aim:

To evaluate and compare Knotless Barbed suture with Non-Barbed Vicryl Suture used as wound closure material for subcuticular suturing at the nasolabial donor site in patients undergoing surgical rehabilitation of Oral Submucous Fibrosis.

Material and Method:

This prospective observational study takes place at the department of oral and maxillofacial surgery, SGM cancer hospital, in collaboration with the Sharad Pawar Dental College Maharashtra, India, from April 2025 to January 2026. Patients clinically diagnosed with grade III or grade IV oral submucous fibrosis (OSMF) will undergo a series of preoperative procedures. A Pre-Anaesthetic checkup (PAC) will also be conducted to assess their fitness for surgery. Once the patients meet all inclusion criteria they will be scheduled for the surgical procedure. Group A will receive 3-0 polyglyconate barbed suture and group B will receive 3-0 poliglecaprone vicryl suture. Patients will be assessed based on wound closure timing, measurement of wound healing using "REEDA SCALE" and assessment of scar using "MANCHESTER SCAR SCALE(MSS)". The outcome measures will be statistically analysed and appropriate tests applied to each outcome measures. The p-value <0.05 will be considered significant.

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As of April 2025, institutional ethical clearance has been obtained, and patient recruitment is ongoing. Recruitment began after IEC approval and is ongoing, with 5 patients enrolled as of April 2025. Data collection is expected to be completed by December 2025, and results will be published in mid-2026.

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This study is designed to compare 3-0 polyglyconate knotless barbed sutures with conventional 3-0 poliglecaprone (Vicryl) subcuticular sutures for closure of the nasolabial donor site in patients undergoing nasolabial flap reconstruction for advanced oral submucous fibrosis. By measuring subcuticular closure time (primary outcome) and early wound healing (REEDA) and scar quality (Manchester Scar Scale) at predefined intervals, the protocol will assess both efficiency and patient-centred aesthetic outcomes in a clinically relevant maxillofacial setting where dynamic facial musculature complicates closure.

Key Words:

Knotless Barbed suture, Oral Submucous Fibrosis, Nasolabial flap.

INTRODUCTION-

Oral submucous fibrosis (OSF) is a chronic condition that causes scarring, tissue fibrosis, and precancerous lesions. It frequently occurs in the buccal mucosa. Patients with OSF experience a severe burning sensation in the mouth after ingesting spicy foods. Other symptoms of OSF include dry mouth, pain, taste disorders, restricted tongue mobility, trismus, dysphagia, and altered speech. [1]

Management of OSF includes traditional therapies such as steroids and antioxidants, as well as novel modalities like pentoxifylline and collagenase, which have demonstrated efficacy in reducing fibrosis and improving symptoms. Surgical techniques such as tongue flaps and free tissue transfer have gained interest in the treatment of advanced OSF cases. The nasolabial flap has shown favorable results in restoring normal mouth opening and addressing functional limitations associated with OSF. It has been found to be a versatile and well-established option for reconstructing moderate facial deformities, including intraoral defects caused by OSF. The flap's strong vascular supply contributes to its high survival rate and versatility in reconstructing moderate facial deformities.[2]

The nasolabial flap can be based superiorly or inferiorly, depending on the vascularity required, and is suitable for reconstructing defects in the cheek, nose, lips, and intraoral region.

Meticulous wound closure following any surgical procedure is critical, as it directly influences the occurrence of postoperative complications such as wound dehiscence, hematoma formation, and infection. These complications can lead to prolonged hospitalization, delayed initiation of adjuvant treatments, and adversely affect overall patient outcomes. A common complication associated with nasolabial flap procedures is the widening of scars and gapping. These issues can be mitigated through proper closure of the subcutaneous layer. Consequently, suturing techniques have evolved over time, with conventional sutures remaining the standard approach for wound closure.

Constant efforts are made to enhance aesthetic outcomes through the use of interventions such as corticosteroids, triamcinolone acetonide, and platelet-rich plasma. Among these, corticosteroids are the most commonly employed method in clinical practice for effectively reducing scar formation and volume. However, these approaches are post-operative modalities, and addressing scar widening

intraoperatively would be more beneficial than managing it later. In this context, the use of barbed sutures can help prevent scar formation.

The introduction of barbed sutures has significantly advanced the field of surgical wound closure. Barbed sutures, also known as self-retaining or knotless sutures, are an innovative type of surgical suture featuring unidirectional or bidirectional barbs. These barbs facilitate anchoring and distribute tension more effectively during the closure process. [3]

The knotless barbed suture was introduced and patented in 1964 by John H. Alcamo. This suture is considered self-securing, eliminating the need for additional adhesives to secure the suture. More recently, knotless barbed sutures have been increasingly applied in a wide range of medical fields, such as cosmetic surgery, urology, general surgery, orthopedics, obstetrics, gynecology, and other surgical disciplines.

Barbed sutures are available in both absorbable and non-absorbable monofilament materials [4]. A barbed suture is a specifically designed monofilament suture with barbs oriented in the opposite direction to the needle. Complications associated with conventional knot tying are well recognized, as it requires time and skill to perform, and the knots may easily break or extrude. Infections related to knots are also commonly observed. In contrast, the novel barbs on the ligature allow the suture to grasp the tissue, preventing it from sliding back. Knotless sutures offer the advantage of saving time during the procedure. Additionally, studies in plastic surgery have shown that the safety and efficacy of barbed sutures are comparable to non-barbed sutures.

In the maxillofacial region, barbed sutures have been utilized in aesthetic procedures such as brow lifts, facelifts, and neck lifts. The dynamic nature of facial musculature, however, presents challenges in achieving uniform and stable wound closure, further underscoring the need for innovative techniques. While knotless sutures have a strong track record in other surgical specialties, reports on their use in extraoral applications within maxillofacial surgery remain limited. Given the scarcity of literature comparing barbed and non-barbed sutures for wound closure in the oral region, the present study aims to evaluate both barbed and non-barbed suture materials, focusing on postoperative complications and aesthetic outcomes.

Methods:

Study Objectives

- The **primary objective** of this study is to evaluate and compare the time required for closure of nasolabial donor site with Barbed (Knotless Suture) and Non-Barbed suture techniques in Oral submucous fibrosis.
- The **secondary objectives** include comparing the time required for closure of the nasolabial donor site, wound healing, and post-operative aesthetic outcomes between barbed (Knotless Suture) and non-barbed Vicryl sutures.

Ethical Considerations

This clinical study involves human participants and complies with the ethical principles outlined in the Declaration of Helsinki (latest revised version). The study protocol and related documents were reviewed and approved by the Institutional Ethics Committee (IEC) of Datta Meghe Institute of Higher Education and Research, with approval reference number DMIHER(DU)/IEC/2025/659, granted in April 2025.

The study has been registered prospectively with the Clinical Trials Registry of India (CTRI) under registration. Before the initiation of recruitment, administrative and regulatory clearances were obtained from the institutional authorities, and agreements were established with participating departments for clinical coordination and data sharing.

The controller and processor of the study data is the Department of Oral and Maxillofacial Surgery, Sharad Pawar Dental College, which will manage all patient-related data in accordance with the Indian Information Technology Act, 2000, and amendments thereto, including the Personal Data Protection Bill, as well as international standards of data confidentiality and Good Clinical Practice (GCP) guidelines.

All participants will be provided with detailed oral and written information about the objectives, methodology, expected risks and benefits, and confidentiality safeguards of the study. Written

informed consent will be obtained from all participants prior to any study-related procedures. Each participant will be assigned a unique identification number, and all collected data will be pseudonymized to maintain confidentiality. Access to identifiable personal data will be restricted to authorized study personnel only.

All investigators and clinical staff involved in the. Data collection, entry, storage, and analysis will be conducted under strict adherence to standard operating procedures, and periodic audits will be performed to ensure compliance with ethical and regulatory standards.

No financial inducements will be offered. However, participants will be compensated for their time and travel as per the norms approved by the Ethics Committee. Any incidental findings or complications during the study will be addressed appropriately, and standard of care will be maintained throughout.

Eligibility Criteria

Inclusion criteria

- Patients diagnosed with grade III/grade IV OSF requiring surgical intervention and reconstruction with nasolabial flap.

Exclusion criteria

- Patient underwent previous facial surgery.
- Patients with known allergic history to the contents in the suture material.
- Patients who had undergone radiotherapy.
- Patients with other than ASA Group I.

Pre-operative assessment

Patients clinically diagnosed with Grade III or Grade IV Oral Submucous Fibrosis (OSF) will undergo a series of preoperative procedures, including history taking, clinical evaluation, histopathological examination, and MRI/CECT of the head and neck. Additionally, patients will receive counselling, written informed consent, and undergo preliminary clinical investigations. A pre-anaesthetic checkup (PAC) will also be conducted to assess their fitness for surgery. Once the patients meet all inclusion criteria and obtain PAC clearance, they will be scheduled for the surgical procedure.

Materials used in the study:

3-0 polyglyconate barbed suture [COVIDIENV-LOC 180][®]

3-0 poliglecaprone 25 [ETHICON MONOCRYL][®]

Sample Size Calculation:

Krejcie Morgan formula for sample size estimation:

Formula for determining sample size

$$s = \frac{X^2 NP(1-P)}{d^2(N-1)} + X^2 P(1-P)$$

s = required sample size.

X^2 = the table value of chi-square for 1 degree of freedom at the desired confidence level (3.841).

N = the population size.

P = the population proportion (assumed to be 50 since this would provide the maximum sample size).

d = the degree of accuracy expressed as a proportion (05).

(Source: Krejcie & Morgan, 1970)

N = Total number of patients undergoing nasolabial flap reconstruction at AVBRH, Sawangi(M), Wardha
= 10

$$\begin{aligned} \text{Sample Size } n &= \frac{3.84 * 18 * 0.50 * 0.50}{(0.05^2 * 18) + (3.84 * 0.5 * 0.5)} \\ &= 19.23 \\ &= 20 \text{ patients needed in study } (10 * 2 = 20) \end{aligned}$$

Study Reference : No of patients at AVBRH

Formula Reference: Krejcie and Morgan(1970)

Statistical Methods : Student's t test, one way ANOVA.

Software Used : SPSS 27.0 version

Study Design : Comparative study design

Interventions

The clinical study will be conducted at the Department of Oral and Maxillofacial Surgery, Siddharth Gupta Memorial Cancer Hospital, Sawangi, Wardha, Maharashtra. Following approval from the IEC, DMIHER (DU), and after explaining the detailed treatment protocol to the patients, the procedure will be performed on those diagnosed with Grade III or Grade IV Oral Submucous Fibrosis (OSF) who require surgical correction and reconstruction using a nasolabial flap.

Patients who meet the study's inclusion criteria will undergo assessment and surgery. A detailed history will be taken, and the pre-treatment clinical condition of the patient will be evaluated through clinical, radiological, and histopathological data. Records will be maintained for the evaluation of various parameters.

All patients will undergo a pre-surgical workup, which includes:

- PAC fitness assessment
- Thorough explanation of the procedure, followed by written and signed informed consent
- Pre-operative photographs
- Intra-operative photographs
- Anesthesia induction

The study will be divided into two groups:

- Group A: The knotless suture group, where one side of the nasolabial flap will be closed using knotless sutures.

- Group B: The conventional suture group, where the other side of the nasolabial flap will be closed using non barbed suture.

Methodology

Under the AAP and SPP protocols, patient sedation will be achieved using Midazolam and Propofol. Nasoendotracheal intubation will be performed, and general anesthesia (GA) will be induced. The patient will be maintained on a combination of O₂, N₂O, and Sevoflurane throughout the procedure. All necessary armamentarium for the surgery will be prepared prior to the procedure's commencement.

Bilateral fibrotomy and coronoidotomy will be performed to release the fibrous bands and achieve a mouth opening of 35-40 mm. The surgical area for nasolabial flap harvesting will be prepared under standard aseptic conditions by painting the perioral region with a 10% w/v povidone-iodine solution. Standard markings for the nasolabial flap will be made bilaterally, and a mixture of saline and adrenaline will be infiltrated into the area.

An incision will be made through the skin, subcutaneous tissue, and fat to harvest the nasolabial flap. The flap will then be sutured over the intraoral defect, after which hemostasis will be achieved. Closure of the extraoral nasolabial wound site will be performed in two layers. The muscles on both sides will be sutured with 3-0 vicryl sutures.

In the study group (Group A), skin closure will be done using 3-0 polyglyconate barbed sutures using a continuous sub-cuticular suturing technique. In the control group (Group B), skin closure will be performed with 3-0 poliglecaprone 25 (conventional sutures) using the same continuous sub-cuticular technique.

Post-operatively, all patients will be prescribed antibiotics and analgesics, along with proper dressing of the surgical site as per standard surgical protocol.

ASSESSMENT METHOD

1. Wound Closure Timing

Suturing time would be recorded from the start of suturing till the time the final surgical knot will be secured or till the activation of knotless suture by an independent observer using digital clock in seconds.

2. Measurement of Wound Healing

Wound healing will be measured by “REEDA scale” on the 7th and 15th post-operative days. The wound healing would be assessed based on redness, oedema, ecchymosis, discharge and approximation. The scores are ranged from 0 to 3.

POINTS	REDNESS	EDEMA	ECCHYMOSIS	DISCHARGE	APPROXIMATION
0	None	None	None	None	Close
1	Within 0.25cm of the incision bilaterally	Less than 1cm from the incision	Within 0.25cm bilaterally or 0.5cm unilaterally	Serum	Skin separates 3mm or less
2	Within 0.5cm of the incision bilaterally	Between 1 to 2 cm from the incision	Between 0.25cm to 1 cm bilaterally or between 0.5 to 2 cm unilaterally	Sero-sanguinous	Skin and subcutaneous fat separation
3	Beyond 0.5cm of the incision bilaterally	Greater than 2cm from incision	Greater than 1cm bilaterally or 2cm unilaterally	Bloody, purulent	Skin, subcutaneous fat and fascial layer separation
SCORE					
					TOTAL =

3. Assessment of Scar

Scar will be assessed on MANCHESTER SCAR SCALE (MSS) colour, shine, counter and distortion which will be observed on post op day 1st and 2nd month.

<u>Parameters</u>	<u>Scar category</u>	<u>points</u>
Colour	Perfect	1
	Slight mismatch	2
	Obvious mismatch	3
	Gross mismatch	4
Shine	Matte	1
	Shiny	2
Contour	Flush with surrounding skin	1
	Slightly proud/indented	2
	Hypertrophic	3
	Keloid	4
Distortion	None	1
	Mild	2
	Moderate	3
	Severe	4
Best outcome (lowest score)		4

Discussion

This study protocol outlines a prospective, randomized clinical trial designed to compare and evaluate the time required for closure of the nasolabial donor site, wound healing and post-operative aesthetic outcomes between barbed and non-barbed Vicryl sutures. It is anticipated that the findings will provide meaningful insights into closure time, wound healing and post-operative aesthetic outcomes between barbed and non-barbed Vicryl sutures. Based on previous literature and clinical observations, it is said that barbed sutures (knotless) are used in various procedures such as donor leg wounds in coronary artery bypass grafting, breast surgery, laparoscopic hysterectomy, and myomectomy[6].

Many studies have been conducted earlier, which have suggested that knotless barbed sutures are

effective in wound closure and are used rarely due to their cost. The effectiveness of the barbed suture lies in its design as it has barbs over the suture surface, which get locked in the tissue due to which closure time gets reduced and working efficiency of the surgeon's increases[7]. Many studies have reported that knotless barbed suture takes less time with better wound healing.

The uniqueness of this protocol lies in its focus on donor site closure and the evaluation of scar formation in relation to improved wound healing. Previous studies mainly addressed wound healing and the time required for closure, often with smaller sample sizes. Moreover, barbed sutures in those studies were typically used intraorally. This study, however, aims to enhance the understanding of knotless barbed sutures by using them extraorally for donor site closure, potentially improving both clinical outcomes and aesthetic results.

Conclusion

This is a prospective, paired comparative protocol that will rigorously evaluate whether 3-0 polyglyconate knotless barbed sutures offer measurable advantages over conventional 3-0 poliglecaprone subcuticular sutures at the nasolabial donor site in patients undergoing nasolabial flap reconstruction for advanced oral submucous fibrosis.

By measuring operative subcuticular closure time (primary outcome) and wound-healing (REEDA) and scar quality (Manchester Scar Scale) at predefined time points, the study is designed to provide objective, clinically relevant evidence about efficiency, early healing, and aesthetic outcomes. If knotless barbed sutures reduce closure time without compromising wound healing or scar appearance, their adoption could streamline procedures and improve patient-centred aesthetic results in maxillofacial reconstruction.

The study is ethically approved, prospectively registered, and methodologically powered for the planned comparisons; findings will therefore add high-value data to inform suture selection in extraoral maxillofacial wounds and guide future, larger trials where indicated.

IMPLICATIONS-

The finding of this study may provide evidence-based insights that optimizes suture selection and will enhance wound healing and aesthetic outcome.

LIMITATION

The study was conducted over a relatively short timeframe and involved a limited number of patients, with a follow-up period that may not have been sufficient to capture long-term outcomes. Due to these limitations, further comprehensive studies with larger patient populations and extended follow-up durations are necessary to thoroughly validate and confirm the findings presented.

Study status*

Not started yet.

Data availability*

Not applicable as this is a protocol.

Competing interests*

No competing interests.

Grant information*

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