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Research Protocol

Surgery Section

Comparison of Scar Quality using Polyglactin and Polyamide Suture Materials for Closure of Nasolabial Flap Donor Site Defects in Patients with Oral Submucous Fibrosis: A Research Protocol

GAURI SHARMA[1], DEEPANKAR SHUKLA[2], NITIN BHOLA[3]

ABSTRACT

Introduction: Scar formation is an unavoidable sequelae of any surgical procedure. The goal is to produce fine scars with the least complications. Literature mentions various surgical factors that may lead to better quality of scars, one of which is the type of suture material used. Few studies exist in the literature that have compared the quality of scars after placement of polyglactin and polyamide sutures. Additionally, no studies have been done to compare the quality of scars following reconstruction with nasolabial flaps in patients with oral submucous fibrosis.

Need for the study: This study will help evaluate and establish the healing outcomes in nasolabial flaps in the form of scars after placing subcutaneous 4-0 polyglactin (VICRYL™ ETHICON) and 4-0 polyamide (ETILONTM ETHICON) sutures. This will eventually lead to minimal tissue reaction and more aesthetic scars with fewer complications.

Aim: To evaluate and compare the quality of scars post-reconstruction with nasolabial flaps with subcutaneous polyglactin sutures and subcutaneous polyamide sutures.

Materials and Methods: This is a prospective randomised triple-blinded trial which will be conducted in the Department of Oral and Maxillofacial Surgery, Sharad Pawar Dental College and Hospital (SPDCH), Sawangi (Meghe), Wardha, India. The trial will take place from July 2023 to June 2024. A total of 15 subjects with grade C Oral and Submucous Fibrosis (OSMF), who will undergo fibrotomy followed by reconstruction of bilateral nasolabial flaps, will be enrolled in the trial. Suturing of one side of the flap will be done using 4-0 polyglactin (VICRYL™ ETHICON) suture subcutaneously, and the other side will use 4-0 polyamide (Ethilon™ ETHICON) suture subcutaneously. The scar tissues will be periodically evaluated at one week, one month, and three months postoperative period to assess the healing outcomes and overall aesthetic appearance using the Patient and Observer Scar Assessment Scale (POSAS) using Chi-square test and Student's t-test.

Keywords: Non absorbable suture, Scar outcomes, Wound healing

INTRODUCTION

Scar formation is an inevitable sequelae of the healing process in surgical incisions. However, the aim is to have a fine scar with minimum colour changes and no inflammatory reactions [1]. Wound healing is an intricate procedure that involves the steps of inflammation, proliferation, and remodeling. Out of these, the remodeling phase is the most responsible for the quality of scar produced [2]. Literature mentions various surgical factors which may lead to better quality of scars, such as the use of proper aseptic techniques, optimum handling of tissues, placement of incision along the skin tension lines, approximation of tissues to cause wound eversion, and the choice of suture material [3,4]. The local inflammatory response caused by the suture is implicated in the extent of residual scar formation [4]. An ideal suture will produce the best possible healing outcome in scar tissue with little or no undesirable reactions, such as tissue reactivity, pruritus, and wound dehiscence. This is essential for the overall healing of wounds and the acceptable appearance of scar tissues. Suture materials can be broadly classified as monofilament and multifilament based on the physical configuration. VICRYL™ sutures are multifilament synthetic absorbable sutures that are a copolymer of lactide and glycolide with polyglactin 370 and calcium stearate coating. They are a popular choice of suture material in plastic surgery. VICRYL™ sutures are absorbed by a process called hydrolysis after 56 to 70 days of placement [5]. Monofilament synthetic non absorbable Nylon polyamide sutures, such as Ethilon™, have excellent tensile strength when compared to other sutures. Ethilon™ sutures have extremely low tissue reactivity, which is a useful quality for obtaining favorable scar formation [5].

Concerns exist regarding the use of braided sutures for epidermal wound closure. Braided sutures harbour microbes, which could lead to increased chances of inflammation, wound infection, and subsequently poor wound healing and scar appearance [6]. Multifilament sutures, when used subcutaneously, tend to extrude as localised abscesses, whereas monofilament sutures produce far less tissue reactions [5]. A randomised trial by Asher R et al., compared the colony-forming units in monofilament and multifilament suture materials and concluded that bacterial adhesion differs between various suture materials, with bacterial adhesion being lowest in nylon sutures compared to silk, coated polyglactin, and polyester sutures [7].

Nasolabial flaps were first mentioned and described in literature in 600 BC by Sushruta. The use of these flaps for the reconstruction of oral defects developed in Europe in the 20th century after work by Thiersch and later Esser [8]. The nasolabial flap has reduced donor-site morbidity frequently associated with other flaps. It makes postoperative rehabilitation easier by providing adequate bulk at the recipient site. The nasolabial flap is easily accessible and quick to

harvest, which reduces operating time [9]. Despite its advantages, nasolabial flaps are associated with problems such as hair growth intraorally, temporary widening of the mouth, and the development of unappealing scars [10].

Few studies exist in the literature that have compared the quality of scars after placement of polyglactin and polyamide sutures [6,11-14]. Additionally, no studies have been done to compare the quality of scars following reconstruction with nasolabial flaps in patients with oral submucous fibrosis. Hence, the present study is designed to assess and draw comparisons in the quality of scars post-reconstruction with nasolabial flaps with subcutaneous polyglactin sutures and subcutaneous polyamide sutures.

Aim

- To evaluate the scar quality as evaluated by the "POSAS" after using 4-0 polyglactin (VICRYL™ ETHICON) sutures for closure of the nasolabial defect at the donor site with the subcuticular suturing technique following reconstruction of the surgical defect post fibrotomy with a nasolabial flap in patients with oral submucous fibrosis.
- To evaluate the scar quality as assessed by the "POSAS" after using 4-0 polyamide (Ethilon™ ETHICON) sutures for closure of the nasolabial defect at the donor site with the subcuticular suturing technique following reconstruction of the surgical defect post fibrotomy with a nasolabial flap in patients with OSMF.
- To compare the scar quality as assessed by the "POSAS" after using 4-0 Polyglactin (VICRYL™ ETHICON) sutures and 4-0 polyamide (Ethilon™ ETHICON) sutures for closure of the nasolabial defect at the donor site with the subcuticular suturing technique following reconstruction of the surgical defect post fibrotomy with a nasolabial flap in patients with OSMF.

Null hypothesis: Subcutaneous Ethilon™ suture is similar to subcutaneous VICRYL™ suture for closure of the nasolabial defect following reconstruction with a nasolabial flap in patients with oral submucous fibrosis.

Alternate hypothesis: Subcutaneous Ethilon™ suture is better than subcutaneous VICRYL™ suture for closure of the nasolabial defect following reconstruction with a nasolabial flap in patients with oral submucous fibrosis.

REVIEW OF LITERATURE

The face is the identity of an individual and is directly related to an individual's self-esteem. It is for this reason that excessive postsurgical scarring in highly aesthetic zones, such as the face, leads to increased patient dissatisfaction and poor acceptance of surgery. The nature of suture material has been implicated in the final cosmetic outcome of wounds. This is supported by an early study conducted by Goulbournel IA et al., in 1988 [11], where they compared the aesthetics, undesirable outcomes, and patient preference between polyglactin sutures and polyamide sutures placed subcutaneously in varicose vein surgery. They concluded that the wound support provided by polyglactin sutures is responsible for better healing outcomes. Subcuticular suturing should be the technique of choice for skin closure, and polyglactin 910 (VICRYL™) is possibly the best suited for it.

In another study by Yang J et al., the cosmetic appearance and overall patient satisfaction were compared between subcuticular sutures using non absorbable non braided sutures and intradermal mattress sutures placed using absorbable multifilament sutures [12]. They concluded that the buried mattress sutures placed with absorbable multifilament sutures had better cosmetic outcomes compared to subcuticular sutures placed using non absorbable non braided sutures.

However, more recent studies suggest that the nature of the suture material plays little or no role in the aesthetics of scar tissue. In a 2019 randomised controlled trial by Moran B et al., epidermal scars on the face were sutured with absorbable Polyglactin 910 on one part of the wound and nylon on the other part [6]. The postsurgical scars were graded after six months using photographs by a dermatologist and a plastic surgeon. They concluded that epidermally placed absorbable polyglactin and nylon sutures resulted in an equivalent photographic appearance of facial scars six months after surgery. This finding is further supported by a systematic review and meta-analysis by Gillanders SL et al., which assessed whether non absorbable or absorbable suture materials vary in aesthetic appearance in the closure of facial wounds [15]. They concluded that absorbable and non absorbable sutures produced similar cosmetic appearances.

The appearance of scar tissue is intimately linked to its healthy healing process. It has been hypothesised that braided sutures harbour more microorganisms and are therefore more prone to infections and stitch abscesses compared to non braided sutures. In a 2019 randomised controlled trial, Dragovic M et al., compared four sutures in terms of wound healing, microbial colony formation, and tissue reactions in third molar extraction sites [16]. They concluded that non braided synthetic sutures should be used to achieve superior healing of soft tissues and decrease the chances of infection in oral surgical procedures. However, this is in contrast with another randomised controlled trial by Koroglu N et al., that compared the frequency of infection in surgical wounds in females who underwent caesarean section with skin closure subcuticually with polyglactin 910 or polypropylene sutures [17]. They concluded that wound infections and other complications were similar with polyglactin 910 and polypropylene sutures.

Unsightly scars post surgery can increase the need for additional corrective surgeries, adding to patient morbidity. It is thus imperative to produce scars that have an acceptable size and colour with no signs of inflammation, infection, dehiscence, or necrosis.

MATERIALS AND METHODS

This will be a prospective randomised triple-blinded trial conducted from July 2023 to June 2024 in the Department of Oral and Maxillofacial Surgery at Sharad Pawar Dental College and Hospital (SPDCH) Sawangi (Meghe), Wardha, Maharashtra, India. A total of 15 subjects will be included in the study.

Trial registration number: CTRI/2023/07/054827.

Ethics and dissemination: The trial has been approved by the Institutional Ethical Committee (IEC) (DMIMS(DU)/IEC/2022/772), Datta Meghe Institute of Medical Sciences Sawangi, Wardha, Maharashtra, India.

Sample size calculation:

$$n=\frac{Z^2 P(1-P)}{d^2}$$

where n=Sample size,

Z=Z statistic for a level of confidence,

P=Expected prevalence or proportion, and

d=Precision

For a level of significance at 5% (95% confidence interval), Z=1.96.

P=Prevalence of OSMF (oral submucous fibrosis)=1.97%=0.0197 (reference: Bhatnagar SU et al., [18]).

d=Desired error margin=7%=0.07.

$n=1.96^2 * 0.0197 * (1-0.0197) / 0.07^2=15.14$. Rounded to 15.

Power of test: 80%

Level of significance: 5%

Inclusion criteria:

- Individuals with stage C OSMF {according to Haider SM et al., classification [19]} who are medically fit to undergo surgery under general anaesthesia.
- Individuals belonging to ASA 1 (American Society of Anesthesiologists physical status classification).
- Individuals who give consent for reconstruction using a nasolabial flap.

Exclusion criteria:

- Individuals with a known tendency of keloid formation and/or previous history of hypertrophic scar.
- Individuals with a prior history of radiation in the head and neck region.
- Individuals with medical conditions affecting the jaws.
- Patients with superimposed premalignant or cancerous lesions.
- Patients who have been previously operated for OSMF.
- Individuals unwilling to give consent for the study.

Primary outcomes:

- Evaluation of the scar quality after using 4-0 polyglactin (VICRYL™ ETHICON) sutures for closure of the nasolabial defect at the donor site with the subcuticular suturing technique following reconstruction of the surgical defect in patients with oral submucous fibrosis.
- Evaluation of the scar quality after using 4-0 polyamide (Ethilon™ ETHICON) sutures for closure of the nasolabial defect at the donor site with the subcuticular suturing technique following reconstruction of the surgical defect in patients with oral submucous fibrosis.
- Comparison of the scar quality after using 4-0 polyglactin (VICRYL™ ETHICON) sutures and 4-0 polyamide (Ethilon™ ETHICON) sutures for closure of the nasolabial defect at the donor site with the subcuticular suturing technique following reconstruction of the surgical defect in patients with oral submucous fibrosis.

Secondary outcomes:

- Evaluation of the total time required for suturing after using 4-0 polyglactin (VICRYL™ ETHICON) sutures for closure of the nasolabial defect at the donor site with the subcuticular suturing technique following reconstruction of the surgical defect in patients with oral submucous fibrosis.
- Evaluation of the total time required for suturing after using 4-0 polyamide (Ethilon™ ETHICON) sutures for closure of the nasolabial defect at the donor site with the subcuticular suturing technique following reconstruction of the surgical defect in patients with oral submucous fibrosis.

A total of 15 subjects will be included in the study. A detailed case history of these subjects will be taken, and they will be explained the entire surgical procedure. Informed consent will be obtained from each participant. The fibrotomy procedure will be performed, and the surgical defect will be closed using a nasolabial flap under general anesthesia at Siddharth Gupta Memorial Cancer Hospital, Sawangi, Wardha. One side of the flap will be sutured using 4-0 Polyglactin (VICRYL™ ETHICON) sutures subcutaneously, and the other side will be sutured using 4-0 polyamide (Ethilon™ ETHICON) sutures subcutaneously. The sutures will be tensioned appropriately to ensure complete wound edge apposition without causing blanching. Standard postoperative wound care measures will be followed, and patients will be given Tback ointment for local application for seven days after suture removal.

The trial will be discontinued for a participant under the following conditions:

- At the request of the participant
- Development of an allergic reaction after placement of sutures
- Emergence of any life-threatening situations

The scar tissues will be evaluated at one week, one month, and three months postoperatively to assess the healing outcomes using the Patient and Observer Scar Assessment Scale (POSAS) proposed by Van de Kar AL et al., [20]. The scars will be evaluated based on the following parameters:

Assessment criteria in the observer scale [20]:

- Vascularity of the scar, which will be assessed by the amount of blood return when the scar tissue is pressed with a piece of plexiglas.
- Scar pigmentation will be seen as brownish colour of the scar due to melanin pigmentation. To eliminate the colour changes due to vascularity, the scar will be pressed using plexiglas.
- Thickness of the scar, measured as the mean distance from the subcuticular-dermal junction to the epidermal surface of the scar.
- Relief of the scar, denoted by the presence of surface unevenness compared to the nearby normal area.
- Pliability of the scar, tested by pressing the scar between two fingers.
- Total area of the scar in relation to the original wound area.
- Overall opinion regarding the aesthetics of the scar tissue.

Assessment criteria in the patient scale [20]:

- Presence and extent of pain in the scar tissue.
- Itching, if present in association with the scars.
- Extent of colour difference between the normal tissue and the scar tissue.
- Irregularity of the scar compared to the nearby normal area.
- Stiffness of the scar compared to the adjoining areas.
- Thickness of the scar tissue compared to normal skin.
- Overall opinion of the scars compared to normal skin.

The scoring will be done on a rating scale numbered from 0 to 10.

Methods: Assignment of interventions (for controlled trials):

Allocation:

- Sequence generation: The allocation sequence will be generated using a random table of numbers.
- Implementation: The primary investigator will be responsible for generating the allocation sequence, enrolling participants, and assigning them to interventions. The suture materials will be randomly assigned to the left or right side of the nasolabial flap donor site defects for subcuticular skin closure.

Blinding (masking):

- The trial participants, outcome assessors, and the statistician will be blinded.

Data collection, management, and analysis methods:

- Data collection methods: Data will be collected based on the inputs entered in the POSAS questionnaires.
- Data management: All protocol-related data will be recorded in the POSAS questionnaires.
- Statistical methods: Statistical analysis will be performed using Chi-square test and Student's t-test. The software used for analysis will be SPSS 27.0V and GraphPad Prism 7.0V at a 5% level of significance.

Consent or assent:

- Informed consents will be obtained using printed consent forms by the primary investigator.

Confidentiality:

- All details of enrolled participants will be handwritten in pre-printed POSAS proformas. The contents will be kept confidential unless there is a need to share patient-related information for trial-related reasons.

Declaration of interests:

- Financial and other competing interests of the principal investigators for the overall trial and each study site will be declared.

Ancillary and post-trial care:

- In case of undesirable outcomes following surgery, the study participants will be suitably compensated.

Dissemination policy:

- The results of the trial will be published in a reputed journal. The study may also be presented as a paper in any state or national-level conference.

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PARTICULARS OF CONTRIBUTORS:
1. Postgraduate Trainee, Department of Oral and Maxillofacial Surgery, Sharad Pawar Dental College and Hospital, Wardha, Maharashtra, India.
2. Associate Professor, Department of Oral and Maxillofacial Surgery, Sharad Pawar Dental College and Hospital, Wardha, Maharashtra, India.
3. Professor and Head, Department of Oral and Maxillofacial Surgery, Sharad Pawar Dental College and Hospital, Wardha, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Gauri Sharma,
Radhikabai Girls Hostel, Sawangi, Wardha-442004, Maharashtra, India.
E-mail: dr.gaurisharma.20@gmail.com

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