

## Prospective Clinical Study to Assess the Novel Technique of Collagen Application Over Meshed Split Thickness Graft for Wound Coverage

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Received: 06-11-2021 / Revised: 29-11-2021 / Accepted: 19-12-2021

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Conflict of interest: Nil

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### Abstract

**Aim:** A Novel Technique of Collagen Application over Meshed Split Thickness Graft for Wound Coverage.

**Methods:** This prospective study conducted in the Department of surgery, Anugrah Narayan Magadh Medical College and Hospital, Gaya, Bihar, India for 1 year. All cases with a raw area of 5-20% of total body surface area with the need for STSG for wound coverage, irrespective of the sex of patients, were included in the study. Children < 10 yrs and adults > 70 yrs were not part of the study.

**Results:** Causes for wounding requiring STSG included trauma (8 cases), burns (5 cases) and its sequelae contracture (4 cases), diabetic ulcer foot (3 cases) and a case of Melaney's gangrene. The lower extremity (10 cases) was the most common area requiring skin grafting in this study, followed by the trunk (7 cases) and upper extremity (3 cases). A total of 10 patients had co-morbidities. 2 patients were on treatment for diabetes mellitus, hypertension and congestive heart disease. Out of the other 8 patients, 5 typed II DM on oral hypoglycemic, 2 were on anti-hypertensives, and 1 was on treatment for hypothyroidism. All patients were adequately prepared for surgery. The majority of the patients were discharged after 2nd dressing between 5-11 days. Characteristics of grafted area: Vancouver scar scale (VSS) was used to determine the outcome of the grafted area. A score of more than 4 was considered a hypertrophic scar. The mean score of 20 patients at the end of 2 weeks, 1, 2, 4 and 6 months was 0.13, 0.25, 0.54, 1.07 and 1.48. Since the scoring used to determine the outcome of this technique did not take into account patient satisfaction, the same was individually determined.

**Conclusion:** As observed in the results, this technique has produced a very favourable outcome. However, it requires evaluation of procedure in a large cohort.

**Keywords:** Vancouver scar scale, Meshed Split Thickness Graft, Etiology

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## Introduction

A split-thickness skin graft (STSG), by definition, refers to a graft that contains the epidermis and a portion of the dermis, which is in contrast to a full-thickness skin graft (FTSG) which consists of the epidermis and entire dermis. Unlike flaps, skin grafts do not have their own blood supply, so they must rely on a well-vascularized wound bed for graft in-growth. Split-thickness skin grafts are obtainable from multiple sources (autograft, homograft, allograft, or xenograft), multiple anatomical locations, and in various thicknesses. Split-thickness skin grafts classify according to their thickness into thin STSGs (0.15 to 0.3mm), intermediate STSGs (0.3 to 0.45mm), and thick STSGs (0.45 to 0.6mm).[1,2] Split-thickness skin grafts contain the epidermis and a portion of the dermis. The epidermis is the outermost layer of skin, comprised primarily of keratinocytes. The epidermis is a thin, semitransparent layer that provides a significant barrier function. The dermis is the fibrous layer below the epidermis composed of collagen, glycosaminoglycans, and elastin. Split-thickness skin grafts play an integral part of the reconstructive ladder. They are indicated when simpler methods of wound closure will not suffice, such as healing by secondary intention, primary closure, or negative pressure wound therapy.[3]

To minimize scar formation and to accelerate healing time, different techniques of skin substitution have been introduced in the last decades.[4] Currently, bilayer concept of wound coverage in which both epidermal and dermal analogs are used is widely accepted.[5] In case of insufficient donor skin, after harvesting, STSG may be meshed to expand the graft up to 9 times the donor site surface area depending on the mesher. Meshing a graft enables it to conform to convoluted wound surfaces. It also allows the drainage of fluid through

the windows. However, meshed grafts carry some disadvantages: Widely expanded meshed grafts are more fragile. Expansion slits or windows have to heal by re-epithelialization, leading to significant contraction and poor cosmesis. Larger expansions have delayed epithelialisation.[6]

Collagen sheets are produced from bovine tissues comprising mostly type I and III collagen, which have been found important for wound healing. Previously, collagens were thought to function only as structural support. Nevertheless, current concepts with the advance in molecular mechanics, it has been found that collagen holds the key to control many cellular functions, including cell shape and differentiation, migration, and synthesis of several proteins.[7]

## Material and methods

This prospective study conducted in the Department of surgery, Anugrah Narayan Magadh Medical College and Hospital, Gaya, Bihar, India for 1 year.

## Inclusion and exclusion criteria

All cases with a raw area of 5-20% of total body surface area with the need for STSG for wound coverage, irrespective of the sex of patients, were included in the study.

Children < 10 yrs and adults > 70 yrs were not part of the study. Pregnant women, cancer and immunocompromised patients, patients with coagulopathy, those on steroids and anticoagulant therapy were excluded.

## Methodology

Patients with connective tissue disorders, including collagen vascular disease, were excluded from the study. Systemic diseases, if any, such as hypertension, diabetes mellitus, were adequately treated before surgery. Patients with beta-haemolytic streptococcal infection were properly treated, and only after subsequent

negative culture was included in the study. Patients were informed about the potential risks and benefits of the procedure, and signed consent was obtained from each of them. Patients underwent surgical procedures either under general or spinal.

### Results

The majority of patients in the study were in 3rd, 4th and 5th decades. The youngest patient was 16 yr old, and the eldest was 70 yr old. 15 patients in the study group were males and 5 females. Causes for wounding requiring STSG included trauma (8 cases), burns (5 cases) and its sequelae contracture (4 cases), diabetic ulcer foot (3 cases) and a case of Meleney's gangrene. The lower extremity (10 cases) was the most common area requiring skin grafting in this study, followed by the trunk (7 cases) and upper extremity (3 cases). The Head and neck region was not included in the study. In this study, since only patients requiring STSGs for raw areas of 5 – 20% of total body surface area, the same ranging from 500 – 3500 cm<sup>2</sup> were considered. The largest STSG harvested in a single case was 1150 cm<sup>2</sup> to cover a wound surface of 3100 cm<sup>2</sup>, which expanded to almost thrice the size after meshing. A total of 10 patients had co-morbidities. 2 patient was on treatment for diabetes mellitus, hypertension and congestive heart disease. Out

of the other 8 patients, 5 typed II DM on oral hypoglycemic, 2 were on Antihypertensives, and 1 was on treatment for hypothyroidism. All patients were adequately prepared for surgery.

A numeric rating scale (NRS-11) was used to score pain. The recipient site pain scoring was independent of the donor site, which was not accounted for in the study. However, patients complaining of pain of donor site were less, since we used collagen dressing for donor site too. Patients were administered analgesics, Inj. Diclofenac, only on request. None of the patients needed analgesics after 2nd postoperative day (POD). (Table 2)

The majority of the patients were discharged after 2nd dressing between 5-11days. Characteristics of grafted area: Vancouver scar scale (VSS) was used to determine the outcome of the grafted area. A score of more than 4 was considered a hypertrophic scar. The mean score of 20 patients at the end of 2 weeks, 1, 2, 4 and 6 months was 0.13, 0.25, 0.54, 1.07 and 1.48. Since the scoring used to determine the outcome of this technique did not take into account patient satisfaction, the same was individually determined. At the end of the study stipulated 6 weeks, most of the patients were satisfied with the outcome. 3 patients, however, had poor satisfaction. (Table 3)

**Table 1 Vancouver Scar Scale.**

Vancouver Scar Scale		
Scar Characteristics		Score
Vascularity	Normal	0
	Pink	1
	Red	2
	Purple	3
Pigmentation	Normal	0
	Hypopigmentation	1
	Hyperpigmentation	2
Pliability	Normal	0
	Supple	1

	Yielding	2
	Firm	3
	Ropes	4
	Contracture	5
Height	Flat	0
	<2 mm	1
	2 – 5 mm	2
	>5 mm	3
Highest Score		13

Table 2 Pain Score

Pain Score	No. of Patients				
	Immediate Post-Op	1st POD	2nd POD	4th POD	7th POD
<b>0 (No Pain)</b>	14	15	17	18	20
<b>1 – 3 (Mild Pain)</b>	5	2	3	2	-
<b>4 – 6 (Moderate Pain)</b>	1	3	-	-	-
<b>7 – 10 (Severe Pain)</b>	-	-	-	-	-

Table 3 Patient satisfaction

	2nd Week	1st Month	2nd Month	4th Month	6th Month
Excellent	0	0	1	1	3
Good	6	6	8	12	10
Satisfactory	10	10	8	6	5
Poor	4	4	3	1	2

## Discussion

Wound healing is a highly complex process involving timely expression of promoters (growth factors) and diminution of hinderers (matrix metalloproteinases) of healing occurring at molecular level. Extensive and complex wound coverage is the greatest challenge confronting a plastic surgeon. This problem is confounded by limited options available for tissue transfer. Though wound closure is the primary objective, ultimate aim is to allow the patient to return to normal life. In Indian setting, due to unavailability of skin banks for procurement of skin, surgeon has to resort to patients' own tissue for wound coverage. Since, the description of

meshing of skin graft for expansion by Tanner in 1964,[8] the technique has been used to solve the paucity of skin, to a certain extent but carries its own baggage of drawbacks. Mesh grafted areas are dogged by problems of slow healing, pain due to raw areas in skin windows which are persistently in contact with dressing, uneven surface, cobble- stone/snake skin appearance, pigmentation disorders, unsightly scarring and contractures. Collagen sheet is non-inflammatory, non-toxic and has low antigenicity. It is elastic, soft, and supple with good tear strength and has enough strength to be peeled off the wound. It facilitates migration of fibroblasts and microvascular cells, helps in the

synthesis of neodermal collagen matrices and has minimal biodegradation.[9] Also it has advantages of being impermeable to bacterial migration, modulates fluid flux from the wound and also helps in minimizing scarring. This clinical study was undertaken to evaluate the novel technique of combined use of autologous meshed split thickness skin graft and collagen dressing to exploit the aforementioned benefits of collagen sheet. Also wide availability, relatively low cost, ease of use, no antigenicity, tissue compatibility, lack of contaminants like lipids, elastin & other immunogenic proteins and pain relief encouraged to devise this technique.

In our study, all types of wounds, fulfilling the inclusion criteria were considered irrespective of pathology. The study included 20 patients, conducted over duration of 12 months, with patients being followed for a minimum of 6 months. Those patients included in the study but lost during follow up were excluded during analysis. There were 4 such cases. In analyzing study data, wound demographics were also accounted. The study group was mainly distributed in 3rd, 4th and 5th decades of life. Both the sexes were considered for study, with no gender bias.

Since this is our indigenously devised technique, with no availability of any known medical literature employing this method to the best of our knowledge, all wounds amenable for meshed STSGs were considered for the study, irrespective of pathology without any prejudice. Wounds due to trauma, acute burns, post burn contracture reconstruction, diabetic foot ulcers and a case of Meleney's synergistic gangrene were included in the study. All of these went same procedural upon treating / controlling their primary etiology.

The largest wound treated in our study was 3100 cm<sup>2</sup> in area and the smallest was 720

cm<sup>2</sup>. The largest STSG harvested for wound coverage of the largest wound was 1150 cm<sup>2</sup>. With meshing, expansion of the harvested graft increased the surface area nearly to 3 times. The expansion of the graft not only increases the size of the harvested STSG but also limits the morbidity of the donor site by reducing the size of the graft required to cover the wound. Nearer the slits and larger the slit size, larger is the expansion of the graft. We used Brennen skin graft mesher of 3:1 ratio in our study. Numerous pain assessment scales are being used such as Wong-Baker FACES pain rating scale, Numeric pain rating scale (NRS 11) and Pain quality assessment scale (PQAS).[10] In our study, post-operative pain was assessed independent of the donor site pain. Patients were administered Inj. Diclofenac only on request. Usually, in case of meshed STSG being used patients complain more incidence and severity of pain than in non meshed cases. This is due to the exposure of nerve endings in wound surface through the expansion slits which is in constant contact with the dressing and its shearing effect. This also leads to release of inflammatory factors from the wound surface which hinders wound healing and subsequent Unfavourable scar. Use of collagen to cover these slits protects the wound from these effects and effectively reduces pain. Along with this, another aspect is re epithelialization. Expansion slits or windows have to heal by re-epithelialization and this leads to significant contraction and poor cosmesis. The larger the size of the windows, slower is the process of re epithelialization. In this study, it has been noticed that use of collagen to cover the meshed STSG helps in incorporation of collagen in the wound surface of these slits. Since collagen is highly bioactive and, cell conducive, it supports towards enhancing tissue generation. It provides a framework in the wound surface, and promotes regeneration of blood vessels

and supports biologic cell migration and thence, relatively faster re epithelialization. According to study by Donaghue et al., collagen type 1 accelerates tissue remodeling without causing irritation and basically reduces post-treatment care requirements compared to regular dressings.[11] Collagen sheet maintain a physiologically moist microenvironment that promotes cell generation and migration. Healing of windows in meshed STSG requires the development of a vascularized granular tissue bed, followed by dermal regeneration, and restoration of a continuous epidermal keratinocyte layer. Our finding is complemented by several experimental results suggesting that collagen type 1 is an ideal material for tissue regeneration compared to other non-biological wound healing materials. Also when expanded graft has to heal in-between the expansion slits by epithelialization, the underlying wound may contract significantly. Using collagen prevents this contraction of wound appreciably with considerable pain relief, enhanced wound recuperation and need for lesser number of wound dressings, hospital stay duration is reduced. Majority of the patients were discharged within 2 weeks. Advice for immobilization, elevation of extremities, and hygiene were given to patients. Regular follow up thereafter was done at regular intervals as per requisite.

Common complications of STSG such as seroma and haematoma formation, and infections were not noticed in our study. Graft loss of <5% was noticed in 2 patients, which healed spontaneously with only dressings. Collagen plays a vital role in all phases of wound healing. It absorbs 40-60 times its weight in fluid and is an excellent hemostatic agent. This effect has been noticed when used in donor site dressing. Thence no seroma or haematoma formation was noticed in our study cases. Chung J et al., have researched on the

ability of collagen in stopping bleeding, thence, no incidence of haematoma formation in our study can be attributed to this.[12] Also, Healicoll forms an impermeable barrier to bacteria and prevents infections. Protection from the shearing forces of dressing and prevention of evaporation of fluids protects the meshed autologous skin graft from desiccation. Collagen is semi-translucent and hence easier for observation of healing underneath without need for disturbance. Only wound areas with no STSG covering (windows in meshed graft) will interact with collagen. Collagen over skin bridges of the graft remains intact and can be rinsed away with saline irrigation after its purpose is served. Thence, removal of the dressings does not interface with healing granulation tissue, nor does it cause pain to the patient.

Scar assessments can be objective and subjective. Subjective assessments are observer dependant, but objective assessment provides a quantitative measurement of the scar. Semi quantitative methods make subjective assessments objective to a certain extent. Ideally, scar measuring devices for objective assessment should be non-invasive, easy to use, accurate and reproducible. Currently available devices assess scar parameters such as colour (chromameter, derma spectrometer, mexameter and tristimulus colorimeter), thickness (tissue ultrasound palpation system), perfusion (laser Doppler perfusion imaging), firmness (durometer), pliability (pneumatometer and cutometer) and 3D topography. Presently, 5 scar scales are commonly used for scar assessment. The Vancouver Scar Scale (VSS), Manchester Scar Scale (MSS), Patient and Observer Scar Assessment Scar (POSAS), Visual Analog Scale (VAS) and Stony Brook Scar Evaluation Scale (SBSES).[13] The final scar outcome in our study was assessed by means of the Vancouver Scar Scale (VSS),

which takes into account vascularity, pigmentation, pliability and height of the scar. The VSS was first described by Sullivan in 1990 and is the most widely used post-burn scar assessment method.[14] However, this scale does not tab patient satisfaction in means of appearance, pruritus among others. To circumvent this drawback, we analyzed patients, satisfaction separately. The assessment was done regularly at predetermined intervals of 2 weeks, 1 month, 2 months, 4 months and 6 months. 0 is the lowest, and 13 is the highest score awarded. A score of more than 4 was considered as a scar to be hypertrophic. The highest score obtained was 3 in two patients.[15] The overall scoring was favourable for this technique. It is to be noted that at the end of 6 months, the pliability of the skin was the most common Unfavourable outcome of the scar. Cloning this was pigmentation and scar height disorders. Only hyper pigmentation was noted in pigmentation disorders. Collagen reduces scar formation by depositing oriented and organized collagen fibres and regulating the amount of collagenase expressed by keratinocytes, thus bettering the overall cosmetic outcome of the grafted area scar.

### Conclusion

Our novel technique of using collagen sheet over meshed STSG is unique in that it comprises the use of autologous skin and biological dressing in the same procedure. As observed in the results, this technique has produced a very favourable outcome. However, it requires evaluation of procedure in a large cohort.

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