Original Article

DOI: 10.7860/IJARS/2022/51192.2776

Surgery Section

Collagen Dressing Versus Conventional Vaseline Gauze Dressing in Reducing Pain and Infection at the Donor Area for Skin Grafting: A Prospective Interventional Study

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ABSTRACT

Introduction: The harvest of a split thickness skin graft causes a partial thickness injury and an outflow of blood and protein rich exudate from the donor site wound. Conventionally, closed dressings are employed using petroleum jelly impregnated gauge which are permeable to bacteria and wound exudate soaks through. This may lead to pain and infection of the donor site. Biological dressings create the most physiological interface between the wound surfaces and the environment and also dressings are natural, non immunogenic, non pyrogenic and hypo allergenic. Collagen sheet is one such dressing material used.

Aim: To compare the conventional dressing using petroleum jelly impregnated gauze versus biological dressing with collagen sheets in terms of pain, infection and healing at skin graft site.

Materials and Methods: It was a prospective interventional study conducted in Department of Surgery, SSG Hospital and Medical College, Baroda, Gujarat, India, over a period of November 2012 to November 2017 on 220 participants. Randomisation was done by choosing an envelope containing cards marked 'A' or 'B'. The group A (110) was a study group with collagen sheet dressing while group B (110) was the control group with conventional vaseline gauze dressing. Both group patients were examined at six hours postoperatively and then two times a day at 8:00 am and 8:00 pm daily. They were evaluated for pain with Visual Analogue Scale (VAS) score, infection, haematoma formation, healing at donor site and allergic reaction to collagen.

Results: Mean VAS score for pain showed that it decreased over a period of time in both the groups. The group with collagen sheet dressing shows decreasing mean VAS score from 4.34 on 1st day to 0.29 on 3rd day ($p<0.0001$). Similarly, the vaseline gauze dressing shows decreasing mean VAS score from 5.64 on 1st day to 1.39 on 3rd day ($p<0.0001$).

Conclusion: Collagen sheet dressing are easy to apply, with advantage of less pain at donor site and lower infection rate. Also healing time required is less than the vaseline gauze dressing. collagen sheet dressing is clinically more efficient overall.

Keywords: Collagen sheet, Donor site infection, Donor site wound, Skin graft

INTRODUCTION

Human skin is a uniquely engineered organ that permits terrestrial life by regulating heat and water loss from the body whilst preventing the ingress of noxious chemicals or microorganisms. The technique of skin grafting is more or less standardised and the treatment of the donor site differs greatly and has been a topic of debate. The harvest of a split thickness skin graft causes a partial thickness injury and an outflow of blood and protein rich exudate from the donor site wound [1]. Petroleum jelly impregnated gauge were commonly used conventionally, which are permeable to bacteria and wound exudate soaks through. This leads to pain and infection of the donor site and when it is removed the growing epithelium is dislodged [1,2].

The most physiological way of covering the wound surface is biological dressings. They make interface between the wound surface and the environment and permit the bodies reparative and immune system to function most efficiently. Biological dressings are natural, non immunogenic, non pyrogenic and hypo allergenic. Collagen sheet is one such dressing material used. Collagen displays ability to support cellular growth and minimal bio degradation [3]. In a previous study, it was found that it has various benefits like pain relief, effective barrier against infection, breathes like skin, preserves local heat, moderates fluid flux from the wound, promotes epithelialisation by acting as a scaffolding, and protects regenerating epithelium, stimulates healthy granulation and accelerates tissue remodeling [4,5]. There were several studies that found that compares the reduction in pain after use of petroleum jelly versus collagen sheets [6,7]. In the present study, it was intended to study infection rate and healing rate at the graft site along with reduction in pain in both the type of the management. Also, there was no any study found in mid Gujarat area that compares dressing by the petroleum jelly and collagen sheets. The present study was done to compare the conventional dressing using petroleum jelly impregnated gauge versus biological dressing with collagen sheets in terms of pain, infection and healing at skin graft site.

MATERIALS AND METHODS

The present study was a prospective interventional study, conducted in Department of Surgery, SSG Hospital and Medical College, Baroda, Gujarat, India, from November 2012 to November 2017. Human Research Ethics Committee permission was taken prior to starting the study. The patients included in the study were those who needed split thickness skin grafting with following inclusion and exclusion criteria.

Inclusion criteria: All patients with age >18 years of any gender, with post-traumatic or post-infective raw area and surgically created defect were included in this study.

Exclusion criteria: All patients below 18 years of age, patients with burns whose analgesic requirement were more and difficult to compare with the study proposed, immunocompromised patients where wound healing may be affected, mentally ill patients and any condition which influences pain recording. Treatment with systemic corticosteroids within 30 days prior to surgery were excluded in this study.

All the patients who gave written informed consent were enrolled in the study. Total 220 patients were included. All the participants were asked a detailed history and a detailed clinical examination was

done to diagnose the clinical condition. They were investigated for blood investigations, X-ray, Electrocardiogram (ECG), and special investigations for associated disease or disorder. Randomisation was done by choosing an envelope containing cards marked 'A' or 'B' and so accordingly grouped as A or B. The group A was a study group with collagen sheet dressing while group B was the control group with conventional vaseline gauze dressing.

Study Procedure

The donor site was prepared for five minutes with povidone iodine scrub on previous night and early in the morning on the day of surgery. Split thickness grafts were harvested from thigh following which pressure was applied to donor site with saline soaked gauze pieces to achieve haemostasis. In group A (study group), a collagen sheet of the required dimension was selected and washed in normal saline to remove the preserving medium. It was then applied to the donor site after ensuring that, proper haemostasis was achieved and all the entrapped air was removed. Oozing of blood immediately after application could be seen but the blood could easily be removed by cautious pressure over the sheet. A light dressing was given over a non adherent padding. In group B (control group) after achieving proper haemostasis vaseline soaked gauze piece was applied over donor site. A light padded dressing was applied over it.

Patients in both the groups were given prophylactic antibiotic in the form of injection ampicillin 500 mg intravenous stat and analgesic in the form of injection diclofenac 75 mg intramuscular stat postoperatively for one dose. After that all the patients were given capsule ampicillin 500 mg four times a day and tablet diclofenac 50 mg two times a day.

Both group patients were examined at six hours postoperatively and then two times a day at 8:00 am and 8:00 pm daily. They were evaluated for pain with VAS score [8], infection, haematoma formation, healing at donor site and allergic reaction to collagen.

Group A: Light pressure dressing over the collagen sheet was removed in the morning of 2nd postoperative day and evaluated for pain with VAS score, infection, haematoma formation and any allergic reaction to collagen. If haematoma was found beneath the collagen sheet, it was removed by making slit opening in collagen sheet. If large haematoma was found beneath the collagen sheet, collagen sheet was removed by making it wet with normal saline, haematoma was removed and new collagen sheet was applied in sterile condition. If purulent collection was found beneath collagen sheet, patient was excluded from the study. All the patients in group A were examined twice daily for pain, healing, haematoma formation, infection and any new complaint or adverse reaction of the patients. 'The collagen sheet peels off itself as healing takes place'. Complete peeling off of collagen sheet from donor site was noted and it was considered as a complete epithelialisation or complete healing. The day on which the collagen sheet completely peeled off was recorded.

Group B: All the patients were given vaseline gauze dressing with padded dressing over it at donor site during surgery. Dressing was kept over donor site until complete epithelialisation occurred. Patients were examined at six hour postoperatively and then after two times daily for pain at donor site, tenderness, foul smelling discharge, dressing soakage, and any other morbidity the patients felt. Pain was recorded on VAS scale as in study group A. If primary dressing was found soaked without foul smell and tenderness, second dressing with sterile pad was applied over primary dressing without removing it. If primary dressing was found soaked with foul smell or tenderness at local site, primary dressing was removed and donor site was examined for infection. Swab was taken from the donor site and sent for culture and sensitivity report. Then alternate day dressing with vaseline gauze was given and systemic antibiotics were started according to culture and sensitivity report until complete healing occurred. In all patients loosening of primary dressing was considered as a complete healing and primary dressing was removed and donor site was examined for complete epithelialisation. The day on which complete epithelialisation occurred was recorded.

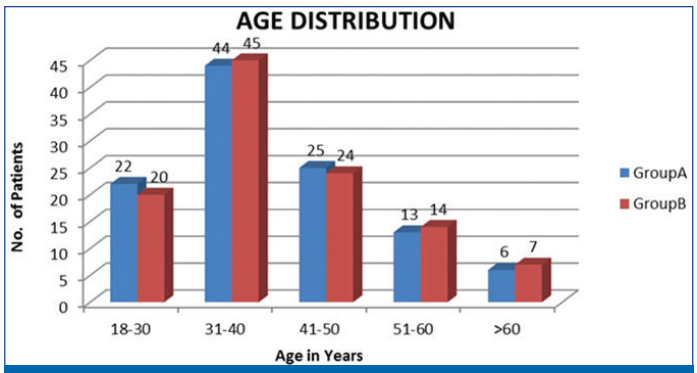
All the patients were given regular analgesic in form of tablet diclofenac 50 mg two times a day at 11:00 am and 11:00 pm and evaluated for pain at 8:00 am and 8:00 pm. VAS score more than 5 was considered as significant and all the patients with VAS score more than 5 were given additional analgesic in the form of tablet tramadol 50 mg stat. Number of patients required additional analgesic were recorded in both the groups and compared. In both groups A and B, the results were compared in form of VAS score for pain for three days, local tenderness, additional analgesic requirement, infection rate, haematoma formation and days taken was complete epithelialisation at donor site.

STATISTICAL ANALYSIS

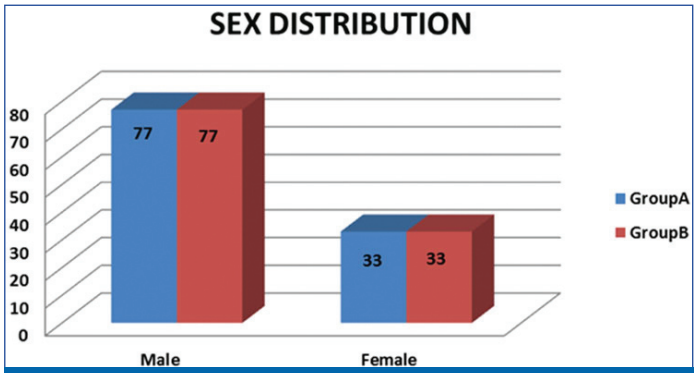
Statistical analysis was carried out using Statistical Package For The Social Sciences (SPSS) version 20. Student's t-test and chi-square test was performed to compare the groups. All results were considered to be significant at the 5% critical level $p<0.05$.

RESULTS

There was no significant difference in age and gender wise distribution of both the groups. The highest numbers of patients were from 31-40 years of age in both the groups [Table/Fig-1,2]. Indications for the skin grafting were trauma, infection, burns, after excision of swelling or tumours, Modified radical mastectomy, laparotomy wound gape etc. Among them infection (102) and trauma (92) were the highest indications for the grafting [Table/Fig-3].



[Table/Fig-1]: Age-wise distribution of all participants in group A and B.



[Table/Fig-2]: Gender-wise distribution of all participants in group A and B.

Indications	No. of patients		Total
	Group A	Group B	
Infection	55	47	102
Trauma	43	49	92
Burns	5	8	13
Others	7	6	13
Total	110	110	220

[Table/Fig-3]: Indications for skin grafting.
Others: After excision of swelling or tumours, Modified radical mastectomy, laparotomy wound gape etc.

As seen in [Table/Fig-4], mean VAS score for pain shows that it decreases over a period of time in both the groups. However, the mean VAS score was less in group A after six hours and after day 1, 2 and 3. The mean VAS score on the 3rd day of surgery was 0.29 in group A while 1.39 in group B. On applying "t-test" the calculated value was less than the table value at 95% confidence limit (p=0.05), so null hypothesis was rejected, so the data was statistically significant. Additional analgesic required for pain relief shows that mean requirement of analgesic was very less in group A while in group B the requirement was nearly three times [Table/Fig-5].

Postoperative time	M/E*	Group A (in cm)	Group B (in cm)	p-value
Six hours		4.34	5.64	<0.0001
Day 1	M	3.36	4.66	<0.0001
	E	2.78	4.13	<0.0001
Day 2	M	2.33	3.67	<0.0001
	E	2.01	3.13	<0.0001
Day 3	M	0.94	1.93	<0.0001
	E	0.29	1.39	<0.0001
p-value between 6 hours and day 3	Group A <0.0001		Group B <0.0001	

[Table/Fig-4]: Mean Visual Analogue Scale (VAS) score.
Paired t-test for intragroup p<0.05; Independent t-test for intergroup p<0.05; *M: Morning; E: Evening

Postoperative time	*M/E	Group A	Group B	p-value
Six hours		14-19	33-58	0.001
Day 1	M	9-12	24-42	0.006
	E	4-6	17-30	0.005
Day 2	M	3-4	15-26	0.006
	E	2-3	12-23	0.01
Day 3	M	1-1	8-14	0.039
	E	0	6-10	0.037
p-value between 6 hours and day 3	Group A <0.0001		Group B <0.0001	

[Table/Fig-5]: Additional analgesic required.
Paired t-test for intragroup p<0.05; Independent t-test p<0.05; *M: Morning; E: Evening

Eleven participants from group B got secondary infection at local graft site while no any participants from group A got infection at graft site [Table/Fig-6]. Mean time for healing was 11.72 (±1.88) days after graft for group A, while for group B the time for healing was 14.89 (±2.08) days [Table/Fig-7]. Statistical analysis showed that difference was statistical significant with p<0.005.

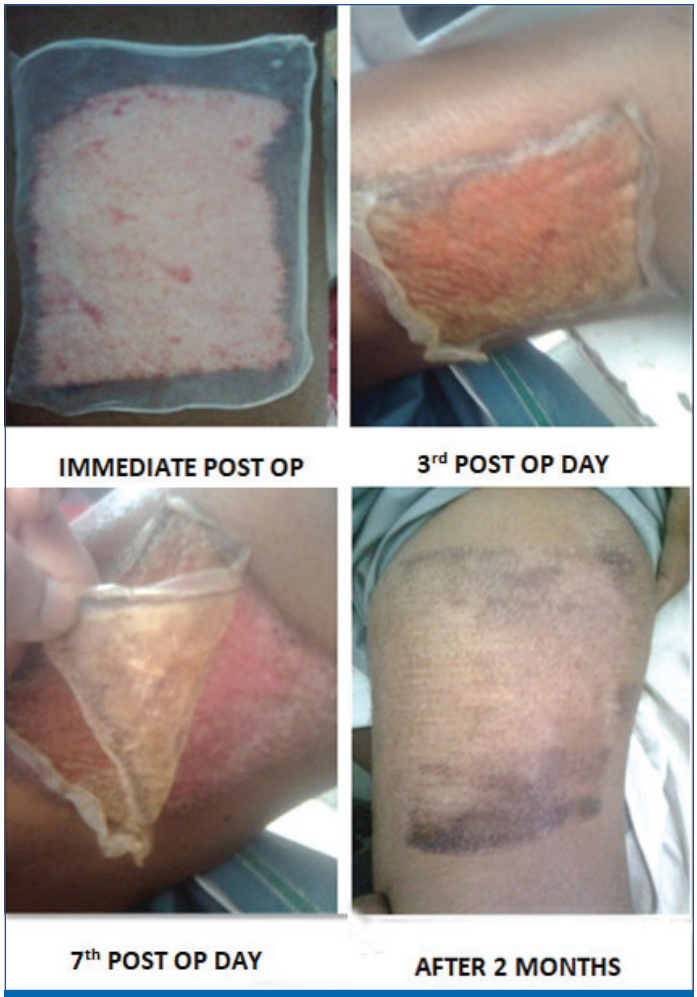
Groups	No. of patients		Total
	Infection	No Infection	
Group A	0	110	110
Group B	11	99	110
Total	11	209	220

[Table/Fig-6]: Frequency of postoperative infections.

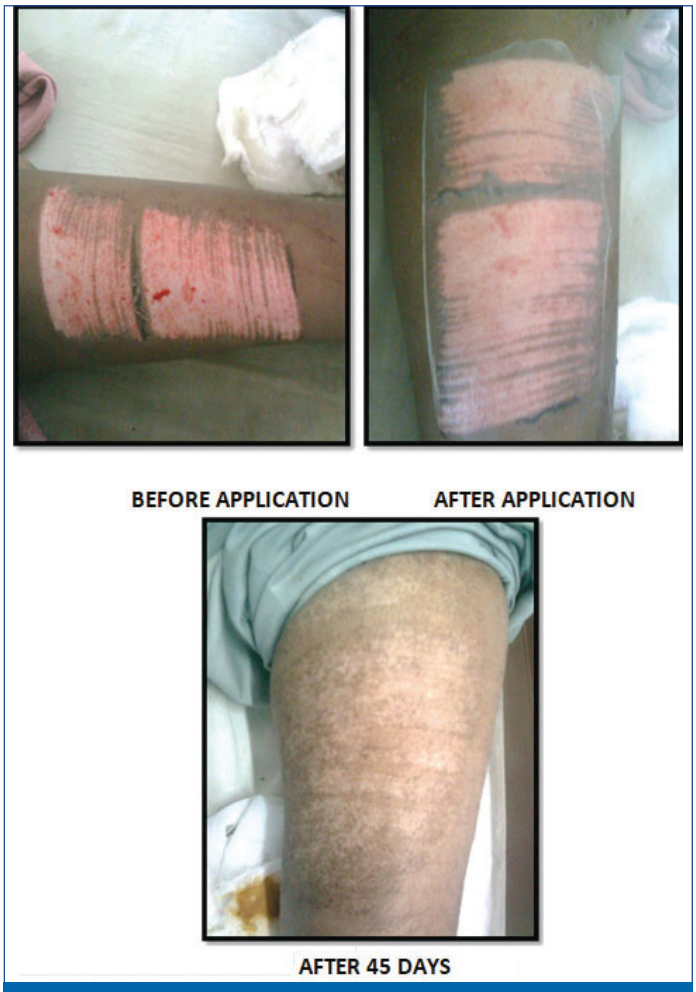
Groups	Mean	SD	p-value
Group A	11.72	1.88	<0.0001
Group B	14.89	2.08	

[Table/Fig-7]: Days required for complete healing.

In group A, patients were given transparent collagen sheet dressing at donor site. Out of 110 patients, no soakage was found in any one till 2nd postoperative day. After that the padded dressing over collagen sheet was removed and was left open and hence was not needed to be examined for soakage. The [Table/Fig-8,9] shows pictures taken after different time period after the surgery in patients with dressing using collagen sheets.



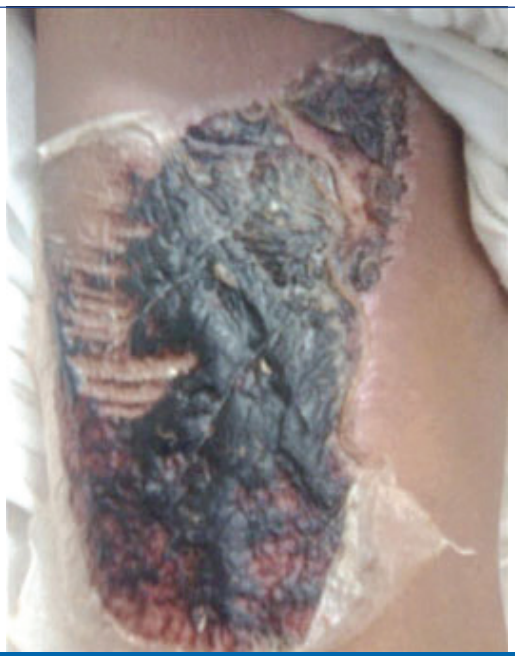
[Table/Fig-8]: Collagen sheet dressing.



[Table/Fig-9]: Collagen sheet dressing.

In group B, patients were given vaseline gauze dressing over donor site. Out of 110 patients, 23 (20.9%) patients had soakage at some point of time during study. Out of those 23 patients, 8 (34.7%) patients had foul smelling discharge with local tenderness at donor site. In those 8 (34.7%) patients, primary dressing was removed and swabs were taken for culture and sensitivity from the wound. Those 8 (34.7%) patients were given alternate day dressing with vaseline gauze and systemic antibiotics were given according to culture and sensitivity reports. Rest of the patients in group B with soakage (without foul smelling discharge or tenderness) were given secondary light padded dressing (soakage dressing) over primary dressing without removing it.

In group A, no patient was found to have any allergic reaction to collagen sheet. However, in group A, at 2nd postoperative day light dressing over collagen sheet was removed from the donor site. Out of 110 patients, two patients had developed haematoma underneath the collagen sheet. Out of these two patients one patient had small haematoma which was removed by making a slit opening in collagen sheet and then observed as per protocol [Table/Fig-10]. The other patient had developed large haematoma underneath the collagen sheet. In that patient, the collagen sheet was removed by making it wet with normal saline. The haematoma was removed and the donor site was again dressed with another collagen sheet in sterile condition. Then both these patients were observed as per our study protocol and no other morbidity found. In group B, the dressing was kept closed, so it was not possible to evaluate the donor site for haematoma formation.



[Table/Fig-10]: Haematoma formation in patient with collagen dressing.

DISCUSSION

In present study, collagen sheet dressing was compared with conventional vaseline gauze dressing for donor site in Split-Thickness Skin Graft (STSG). The comparison was done in terms of pain using VAS score, infection and healing at skin graft site.

The donor site wound usually less taken care of and is often associated with delayed wound healing with significant pain and discomfort. Hence, after split skin grafting patient complains of pain which is far more severe in donor site wound area compared to the recipient site. In a study by Halankar P et al., assessed 30 patients with collagen sheet and found 21 patients had minimal pain, seven patients had moderate pain and two patients had severe pain [9]. Another study Ramesh BA et al., used sterile collagen film as a dressing for 20 donor areas and pain in the postoperative period was assessed by Numerical Pain Rating (NPR) scale [6]. They had found pain relief was superior with collagen sheet dressing when compared with petroleum gauze dressing. Similarly in present study also, it was found that in group with collagen sheet used as a dressing, patients had experienced less pain than group in whom vaseline gauze was used.

It was noted in present study that, mean healing time was 11.72 days for collagen sheet and 14.89 days for vaseline gauze dressing. And the difference was statistically significant. Collagen sheet is retained in the tissue and gradually absorbed by inflammatory cellular activity; the fibrous tissue is replaced by fibroblasts. Granulation tissue developed at a normal rate and the cellular events were precisely the same as those occurring in normal wounds. Study by Sreekumar NC et al., used bovine collagen preparation consisting of type-I collagen was prospectively compared with polyurethane film dressing in a study of 20 split thickness skin graft donor sites [7]. They found average epithelisation was higher in the test area compared to the control area among non infected cases ($p<0.001$). Also, study by Malpass KG et al., noted 10.6±2.8 healing time for jelonet as a dressing material for donor site at thigh [10]. The study by Thakur PB et al., found the average time for appearance of granulation tissue was 6.59±1.75 days in collagen sheets dressing as compare to conventional dressing (9.52±3.72) [11].

The infection rate was noted in group using collagen sheet as a donor site dressing was 0% and rate in group using vaseline gauze as a donor site dressing was 10% in present study. In an another study by Halankar P et al., found donor site infections amongst 2 out of 30 patients with use of collagen sheet [9]. A study by Bunyan AR and Mathur BS shows 19% infection rate among 52 donor areas with use of paraffin gauze dressing [12]. In present study, soakage was found in 23 (28.75%) patients out of 80 patients with vaseline gauze dressing. Also, study by Singh O et al., shows collagen treated wounds were rendered significantly more sterile as compared to those treated with conventional dressings [13]. In group with vaseline gauze close dressing was used and suspected wound discharge was found in 23 patients having soakage of dressing. The nature of discharge was judged by smell and local tenderness. Discharge with foul smell or local tenderness was considered as infection. In group with collagen sheet dressing found no discharge from the wounds.

In the present study, we had found haematoma formation in two patients in group with collagen sheet dressing. In one patient, haematoma was small and removed by making slit opening in collagen sheet. In another patient, large haematoma was dealt by removing collagen sheet and removal of haematoma. In this patient another collagen sheet was applied and no other morbidity found thereafter. The haematoma formation might be due to improper haemostasis. So, proper haemostasis before collagen sheet application is important. Collagen sheet dressing has added advantage of examination of donor site with naked eye for any complications like haematoma formation due to its transparency. And the patients can be dealt early for the same and made them experience less morbidity which is not possible with conventional vaseline gauze dressing.

Limitation(s)

Follow-up till complete healing could not be done. So, complete healing time and other complications that occurred could not be included in the study.

CONCLUSION(S)

Collagen sheet dressing is clinically more efficient and appear to have a great advantage as a donor site dressing material especially in terms of its ease of application, a pain free donor site, decreased additional analgesic requirement with lower infection rate, early mobilization of the patient, decreased morbidity, less healing time with no need for redressing and thus saving the time of hospital personnel and total cost of treatment, it attempts to fulfill the criteria of an ideal donor site dressing.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]

- Plagiarism X-checker: Jul 21, 2021
- Manual Googling: Jan 06, 2022
- iThenticate Software: Mar 10, 2022 (20%)

ETYMOLOGY: Author Origin

AUTHOR DECLARATION:

- Financial or Other Competing Interests: None
- Was Ethics Committee Approval Obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. Yes

Date of Submission: **Jul 08, 2021**
Date of Peer Review: **Oct 14, 2021**
Date of Acceptance: **Jan 06, 2022**
Date of Publishing: **Apr 01, 2022**