"EVALUATION OF CHITOSAN BASED DRESSING IN COMPARISON TO CONVENTIONAL CHLORHEXIDINE IMPREGNATED DRESSING IN SUPERFICIAL FACIAL WOUNDS: A SINGLE BLINDED RANDOMIZED CONTROLLED TRIAL"

By

REG NO:IF0221002

Dissertation

Submitted to the
KLE Academy of Higher Education & Research Belagavi, Karnataka
In partial fulfillment of the requirements for the degree of

MASTER OF DENTAL SURGERY

In

ORAL AND MAXILLOFACIAL SURGERY

(BRANCH III)

DEPARTMENT OF ORAL AND MAXILLOFACIAL SURGERY

KAHER's V K INSTITUTE OF DENTAL SCIENCES

BELAGAVI, KARNATAKA

2021 – 2024

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH, BELAGAVI, KARNATAKA

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LIST OF ABBREVIATIONS

CHX	:	Chlorhexidine
NPR	:	Numeric pain rating scale
MSS	:	Manchester Scar Scale
VSS	:	Vancouver Scar Scale
DDA	:	Degrees of deacetylation

ABSTRACT

Introduction: The maxillofacial surgeon deals with the assessment of soft tissue wounds regularly and sufficing management of soft tissue injuries in the head and neck region are essential. Despite advancements in medical sciences with introduction of several new dressing materials the best available management strategy for superficial facial wounds still remains a subject of ongoing research. Chitosan which is a derivative of chitin, is a natural polysaccharide. When used as a wound dressing, chitosan film dressing has gained popularity because it is found out to be uniformly adherent, non-toxic, long-lasting, stress-resistant, and biocompatible with several healing properties and in this present study we intend to evaluate the efficacy of chitosan based dressing as compared to conventional CHX based dressing in patients with superficial facial wounds.

Materials and Method: Current study was performed on patients with the age group between 18-60 years of either sex reporting to Casualty and Oral & Maxillofacial Surgery OPD of KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Belagavi having superficial facial wounds. After primary wound management the patients were randomly allocated to one of the two groups: the study or the control group. The patients in the study group were treated with Chitosan dressing and control group with Chlorhexidine impregnated dressing. Wound healing, cosmetic outcome and pain on dressing removal were assessed.

Results: The study group of Chitosan dressing had better wound healing (P = 0.001) when compared to conventional chlorhexidine dressing material. In relation to pain on dressing removal, the study group as well as control group both experienced mild pain only however the majority of study group patients showed no pain with better results in cosmetic outcome at the 1st month follow-up.

Conclusion: In conclusion, chitosan dressing can be used as an alternative dressing material. It is a natural antimicrobial and aids in maintaining a physiologically moist wound environment, which speeds up the wound healing process. We recommend the use of chitosan dressing in facial wounds as it is better than the conventional Chlorhexidine impregnated dressing in all the assessed parameters.

Keywords: Chitosan, Superficial Facial Wounds, Chlorhexidine dressing, Abrasions.

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INTRODUCTION

The face is the most prominent characteristic that sets an individual apart and it serves as the primary interface for social interaction and identity expression. Soft tissue injuries of the craniofacial region accounts for nearly 10% of all the cases reporting to Accident and emergency department.[1]

Soft tissue wounds can be classified as based on the location, size, etc and these include contusion, abrasion, lacerations, avulsion and puncture wounds.[2] Abrasions result from partial loss of epidermis from trauma. [3]

Abrasions require primary management and dressing to promote faster healing process.[4] [5] Abrasions present unique challenges in both their management and subsequent aesthetic outcome owing to their fragile nature, making the effective treatment of superficial facial wounds crucial not just for physical healing as well as for psychological well-being and quality of life.[6] [7]

The maxillofacial surgeon deals with the assessment of soft tissue wounds regularly and sufficing management of soft tissue injuries in the head & neck region are essential because they enhance patient comfort and have a positive influence on the speed and quality of wound recovery. [8]

Despite advancements in medical sciences with introduction of several new dressing materials the best available management strategy for superficial facial wounds still remains a subject of ongoing research.

As a result of facial fractures these soft tissue injuries should be treated during the hospital stay. Abrasions require thorough irrigation and cleansing. [3]

Treatment for facial abrasions involves a variety of dressing materials like natural or synthetic bandages, foam dressing, alginate, tapes, collagen, mesh paraffin gauze impregnated with chlorehexidine.[8] Although all of the dressings aim for a fast, spontaneous re-epithelialization there exist a limitation of their application such as wound damage during dressing removal, can trigger inflammatory reaction resulting in lack of efficacy. [9]

Chlorehexidine (CHX) impregnated gauze for instance has a tendency for adherence to wounds, which can cause trauma to epithelial cells when removed.[10] Another disadvantage is that Chlorhexidine is an antibacterial agent considering the global challenge posed by antimicrobial resistance.

An up-to-date strategy for tackling antimicrobial resistance involves the exploration of alternative antimicrobial solutions. Due to its intrinsic antibacterial properties and ability to effectively transmit extrinsic antimicrobial chemicals into the affected region, chitosan, a natural polymer with cationic properties, has been thoroughly researched as an antimicrobial emissary for both prevention and treatment of infections.[11]

Henri Braconno first discovered chitosan in 1811.[11] Chitosan which is derived from chitin, is a natural polysaccharide.[12] Numerous natural origins of chitin exist, including aquatic animals like crabs, lobsters and shrimps, fungal and algal cell walls, exoskeletons of insects, and mollusks which are available for commercial application after processing at varied degrees of deacetylation (DDA) [13]

It has been shown that chitosan accelerates all phases of wound healing. By causing thrombosis, it prevents bleeding, improves the activity of inflammatory cells

like and macrophages and polymorph nuclear leukocytes which stimulates fibroblasts to produce a fresh matrix of collagen where tissue abnormalities exist. Furthermore, chitosan has reported to preserve a physiologically damp and moist environment that encourages healing as well as the development of new granulation tissue.

When used as a wound dressing, chitosan film dressing has gained popularity because it is found out to be uniformly adherent, non-toxic, long-lasting, stress-resistant, and biocompatible with several healing properties. [(12)]

Considering all the properties of chitosan in regard as a material for dressing, t shows great promise in the treatment of maxillofacial abrasions.

Hence, in the present study we intend to assess the efficacy of chitosan based dressing as compared to conventional CHX based dressing in patients with superficial facial wounds.

AIM AND OBJECTIVES

AIM: To judge the efficiency of Chitosan based dressing versus conventional Chlorhexidine impregnated dressing in facial wounds.

OBJECTIVES:

- To evaluate and compare the wound healing seen in both the dressing material.
- To evaluate and compare the cosmetic outcome of both the dressing material.
- To evaluate and compare the pain on dressing removal.

NULL HYPOTHESIS:

- There is no difference in the dressing properties of Chitosan dressing compared to conventional CHX-impregnated dressing in patients with superficial wounds on face with respect to wound healing, cosmetic outcome, pain during dressing removal.

ALTERNATE HYPOTHESIS:

- Chitosan dressing is suitable and an effective dressing material in patients with superficial wounds on the face as compared to conventional CHX-impregnated dressing with respect to wound healing, cosmetic outcome, pain during dressing removal.

REVIEW OF LITERATURE

Prasad, K., Lalitha, R. M., Haque, A. E., Ranganath, K., Munoyath, K., & Lalitha, R. M. (2020). Effectiveness of Chitosan versus Collagen Membrane for Wound Healing in Maxillofacial Soft Tissue Defects: A Comparative Clinical Study. In Trends Biomater. Artif. Organs (Vol. 34, Issue 2). www.sbaoi.org/tibao [(12)]

This study was done between July 2016 and July 2017, every patient with face soft tissue abrasions was split into two groups at random, with half receiving collagen treatment and the other half receiving chitosan membrane treatment. Comparisons were done based on scarring, the amount of discomfort, and the time it took for granulation tissue to develop.

The research involved sixty patients. Over the course of a week, it was shown that the Collagen group saw much more pain reduction than the Chitosan group. Regarding the mean time required for granulation tissue development and the colour of the precipitating scars, significant findings were seen in favour of chitosan. In comparison to collagen, results showed that chitosan promotes soft tissue healing, enhances colour matching, and reduces scarring.

Stone, C. A., Wright, H., Devaraj, V. S., Clarke, T., & Powell, R. (2000). Healing at skin graft donor sites dressed with chitosan. British Journal of Plastic Surgery, 53(7), 606. https://doi.org.2000.34782 [(13)]

This study assessed the rate of healing at donor sites for split skin grafts that were half-bandaged with chitosan and half-dressed with traditional dressing in twenty patients from July nineteen nighty eight to january nineteen ninty nine.

To establish a consistent donor site depth, the same surgeon collected all split thickness skin grafts with Zimmer dermatome utilization. After a month, the wound sites treated with chitosan and those treated with a standard mepitel dressing showed the same histological characteristics of skin maturation.

Chitosan was shown to promote quick injury re epithelialization and regeneration of nerve inside a vascular dermis in study participants. Additionally, chitosan-treated regions showed a quicker restoration to standard skin colour, according to digital colour separation examination of donor site scars.

Azad, A. K., Sermsintham, N., Chandrkrachang, S., & Stevens, W. F. (2004). Chitosan Membrane as a Wound-Healing Dressing: Characterization and Clinical Application. Journal of Biomedical Materials Research - Part B Applied Biomaterials, 69(2), 216–222. https://doi.org/10.1002/jbm.b.30000 [(14)]

The purpose of the study was to treat patients who need split skin transplants. Azad et al applied chitosan at the donor area in half of the patients and the other half received dressing of bactigrass. In total 20 patients were nursed by the chitosan membrane.

The final data showed that successful adhesion, hemostasis, wound healing, and re-epithelialization by mesh chitosan membrane. The histology slide revealed better stimulation of cells by chitosan helping to initiate a sound tissue architecture

with collagen fibers consolidating in a more mature fashion. In control group of Bactigrass , the fibers stayed in a less noticeable shape and regular shape.

Liu, Shen [15] and colleagues did a retrospective study in eighty patients with chronic refractory wounds from October two thousand eighteen to October two thousand twenty to check the benefit of chitosan based hydrocolloid dressing.

Cases of pressure ulcers, vascular ulcers, diabetic foot ulcers etc. were included. Patients were arbitrarily grouped into control and study batches, with each group of 140 cases. The control batch patient received inherent saline soaked gauze dressing and study batch received hydrocolloid dressing based on chitosan. After 3 weeks of wound dressing, blinded observers compared the wound healing and degree of pain and noteworthy distinction was seen between the study and control group in the favor of chitosan.

Hu J, Lin Y and colleagues did a study aimed to assess the effectiveness and harmlessness of combining wet dressing with chitosan wound dressing for treating second 2nd degree burned wound. Over the period from October two thousand ninteen to October two thousand twenty one, eighty patients with such burns were selected. They were randomly grouped into two batches: the control batch (40 patients) managed with wet compress alone, and the study batch (40 patients) treated with wet compress combined with chitosan wound dressing. The study found that time taken for wound healing in the study batch was significantly lesser compared to the control batch with a higher % of wound healing at 14 days post treatment. Three months post-wound healing, scar scores were lower in the study group. Furthermore, the pragmatic rate of secretion culture on the seventh and fourteenth day was significantly lower in the study group compared to the control group.

Halim AS et al [17] did a randomised control trial in a total of two hundred forty four patients. The effectiveness of chitosan derived film v/s hydrocolloid for the treatment of superficial wounds/abrasions was compared. Of the total 244 patients, 84 patients were treated with hydrocolloid and 86 with a film derived from chitosan and the remaining patients were lost to follow up. The mean percentage of epithelisation did not significantly differ across the groups. When the dressing was removed, patients who used chitosan derivative film felt more pain in as opposed to patients in the hydrocolloid group. In contrary to the control lot, the chitosan derivative film group exhibited reduced exudate and odour. In addition, no appreciable variations were seen between the groups with respect to adhesion, ease in removal, drainage of wound, redness , itching, discomfort, or soreness.

Kumar NH and Samuel S with their colleagues (PMCID: PMC10883204) did a study to evaluate and contrast the effectiveness and strength of nano chitosan membrane & collagen-chitosan membrane as surgical dressings for soft-tissue injuries in the maxillofacial area. Thirty patients enduring soft-tissue injury on the face were segregated into three groups. Participants in Group A received treatment using a nano chitosan membrane infused with chlorhexidine, while those in Group B were treated with a collagen mixed in chitosan membrane also containing chlorhexidine. Group C participants underwent conventional wound care management using chlorhexidine powder. The effectiveness of wound healing was similar between participants in Groups A and B, with Group A showing superior wound healing compared to conventional chlorhexidine dressing. Regarding pain levels, Group A experienced lower intensity, and at the three-month follow-up, they exhibited better outcomes in scar evaluation.

Theerawattanawit C, Phaiyarin P et al [18] did a study of 24 individuals with clinical seborrhoea on their faces, ages 18 to 40, participated in a randomized, double-blinded, placebo-controlled trial. For four weeks, participants were randomized to receive either a placebo (gum without any additives) or chitosan gum dressing twice a day. Patients with facial skin sebum saw a considerable reduction in sebum levels with Chitosan nanoparticle gel application and that too with acceptable safety profile.

Nathan Bachtell MD, Teresa Goodell RN and other authors [19] in this study compared the time it took to achieve haemostasis in puncture wounds for dialysis access b/w traditional gauze dressings with that of an innovative and new chitosan-based bandage.

On two consecutive visits, 50 patients were promiscuously allocated to receive one of the standard gauze dressing or the chitosan-based dressing. Duration of haemostasis and the use of compression straps were contrasted amongst the visits. At two and four minutes, the binary response variable was used to examine the time to haemostasis. In the event that dressing application failed after four minutes, a compression strap was utilized. In thirty eight % of the traditional dressings and thirty % of the chitosan-based, haemostasis was reached in 2 minutes; haemostasis was reached in four minutes in eighty six percent of the chitosan based seventy two percent and of the conventional dressings.

Mason S, Clarke and their colleagues.[20] from eleven community care centres in Staffordshire conducted a multicentre cohort evaluation of chitosan gelling fibre dressing (Kytocel®). Examining whether the novel fibre dressing enhanced healing results for patients with persistent chronic wounds lasting six week or more than that

was the goal of this evaluation. Type of tissue, handling of fluid , haemostasis in bleeding friable wounds, and escalated granulation were noted. There were eighteen patients in total—seven women and five men. The wounds of eleven patients (61%) healed in 4 weeks. A number of concerns, such as fluid handling and malodour reduction, were effectively handled. Sixteen of the total eighteen participants in the study thought that the dressing performed rather well overall.

Mo X, Gibson E et al. [21] in three Chinese medical facilities hosted this open multi centre comparative prospective randomized clinical research. A gross of ninety patients with persistent chronic wounds like ulcers because of prolonged pressure, vascular ulcers and foot ulcers because of diabetes, were treated with one of the traditional vaseline gauze as a control or the new age chitosan dressing as the test lot. There were 45 patients in test lot and 45 patients in control lot. Reduced wound area was the main goal of the baseline evaluations that were conducted. The length of the treatment, wound depth, wound exudate levels, and pain reduction during dressing changes were the secondary end goals. Following a 4-week course of treatment, the decrease in test group's wound area was noticeably larger in contrary to the control lot. In the test batch, the average pain level was 1.12 ± 0.23, while in the control group it was 2.30. Additionally, the test batch's depth of wound was 0.30 cm less than that of the control batch's (054 ± 0.86 cm).

MATERIALS AND METHODS

SOURCE OF DATA:

- Present study was carried out on patients with the age group between 18-60 years of either sex reporting to Casualty and Oral & Maxillofacial Surgery OPD of KLE' S Dr. Prabhakar Kore Hospital ,Belagavi having superficial facial wounds.
- A standard Performa was used to collect information regarding each case.

INCLUSION CRITERIA:

- Patients with superficial facial wounds/abrasions between the age of 18-60 years, males and females.
- Patients who agreed to give informed consent.

EXCLUSION CRITERIA:

- Patients with extensively deep wounds / full-thickness wounds/ wounds with tissue loss.
- Medically compromised patients, i.e., patients with bleeding disorders, immune compromised patients (diabetes mellitus)
- Physically or intellectually impaired patients and patients unable to respond to questions.
- Patients who were not eager to take part in the study

INSTRUMENTS AND MATERIALS:

- Saline
- Cotton swabs
- Gauze
- Adson's tissue forceps
- Chitosan wound dressing in sizes of 5 * 10 cm and 10 * 10 cm were used. The dressing was cut into desired size for application onto the wound and a gauze with tissue plaster was used to hold the dressing in position.
- CHX- impregnated dressing of size 10 * 10 cm cut into desired size secured with gauze and tissue plaster.

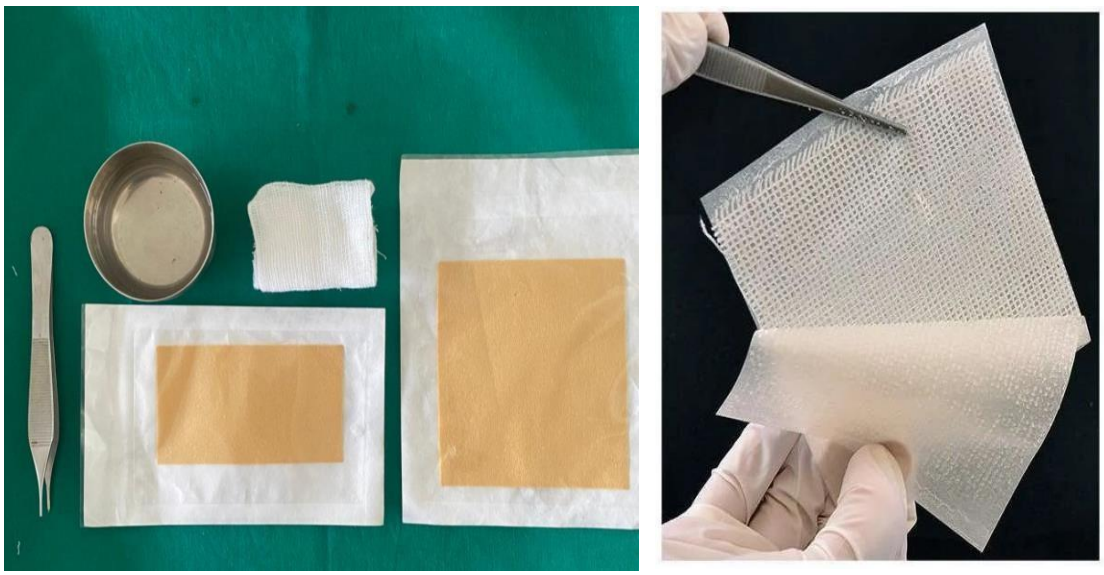


Figure 1 - Armamentarium

ESTIMATION OF SAMPLE SIZE: Formula used-

$$N = \frac{(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2 (p_1 q_1 + p_2 q_2)}{(p_1 - p_2)^2}$$

- At 95 percent confidence interval $Z_{1-\alpha/2} = 1.96$
- At 80 percent power $Z_{1-\beta} = 0.85$
- P 1=16.7% P2= 46.7 %
- Q1= 83.3% Q2= 53.3%
- N= 34.04≈34 (per group)

Therefore, the sample size is **34 * 2 = 68**.

METHODOLOGY

- A total of 68 study participants were categorized into two groups using **Random Allocation Lottery method**
- **Group I (Study group):** 34 patients with superficial facial wounds which received Chitosan dressing.
- **Group II (Control group):** 34 patients with superficial facial wounds which received conventional CHX-impregnated dressing.

Parameters assessed

1. Wound Healing

- Clinical assessment of wound healing was done by the 6-point re epithelialisation score at the end of 7th day.

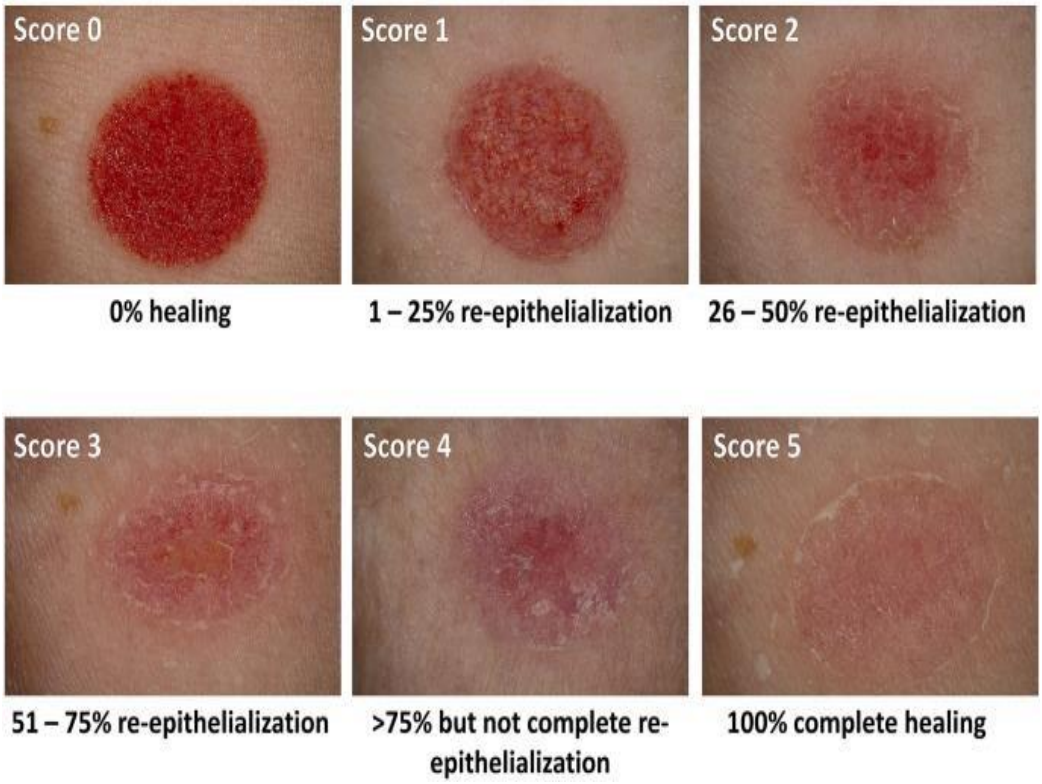


Figure 2 6-point re-epithelialisation score

2. Cosmetic outcome

- Cosmetic outcome was evaluated using Manchester scar scale on Day 31.

- Manchester scar scale included five components – Colour, Finish, Contour, Distortion and texture. Total points were added of all the components, with 5 being the worst score and 18 being the best.

COMPONENT	POINT
Color	
Perfect	1
Slight mismatch	2
Obvious mismatch	3
Gross mismatch	4
Finish	
Matte	1
Shiny	2
Contour	
Flush with surrounding skin	1
Slightly raised or indented	2
Hypertrophic	3
Keloid	4
Distortion	
None	1
Mild	2
Moderate	3
Severe	4
Texture	
Normal	1
Just palpable	2
Firm	3
Hard	4

Figure 3 Manchester Scar scale score

3. Pain on dressing removal

    - Numeric pain rating scale (NPR) scale was used to assess pain during dressing change
    - The patients were asked the following question during dressing change:

i. On a scale of 0 to 10, how much would you rate your pain during dressing removal?

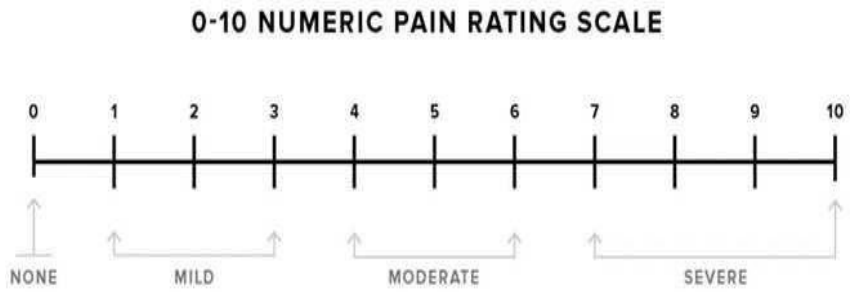


Figure 4 Numeric pain rating scale

STATISTICAL ANALYSIS: The statistical analysis used were

- Descriptive statistical analysis was done for demographic details.
- Chi-square test was done to form the association and compare both the groups.

METHODOLOGY WITH FLOWCHART

Sixty Eight patients in all with abrasions over face were arranged in 2 equal groups by random lottery allocation method.

Group A (Study group) Application of Chitosan dressing

Group B (Control group) Application of CHX-impregnated dressing

↓

The abrasions were irrigated with saline and wound was explored for any foreign body present.

↓

The wound area was dabbed with sterile cotton swab.

↓

Chitosan dressing or the CHX-impregnated dressing was secured by placing a gauze piece over it.

↓

Dressing was changed after every 48-60 hours and pain on dressing removal was evaluated after first dressing change.

↓

Wound healing was evaluated on Day 7

↓

Cosmetic outcome was evaluated on Day 31

PATIENTS IN STUDY GROUP- CHITOSAN DRESSING

Figure 5a -CASE I- SUPERFICIAL FACIAL WOUND ON DAY 1

Figure 5b-FOLLOW UP DAY 7

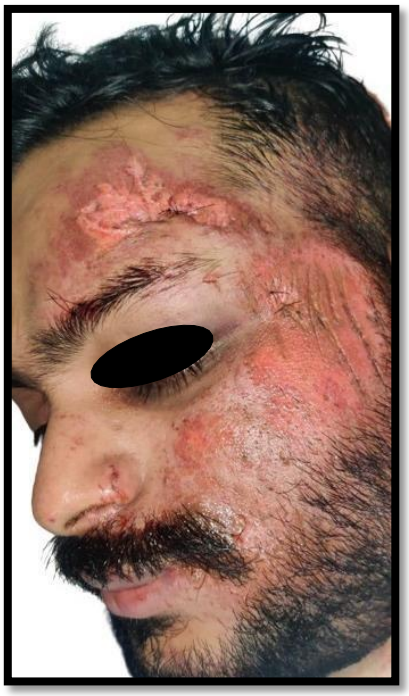


Figure 5c- FOLLOW UP DAY 31

Figure 6a -CASE II- SUPERFICIAL FACIAL WOUND ON DAY 1

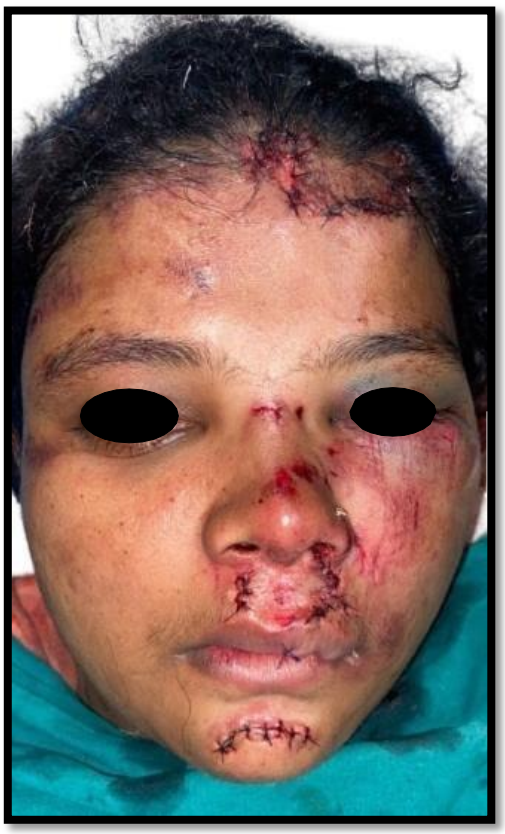


Figure 6b-FOLLOW UP DAY 7

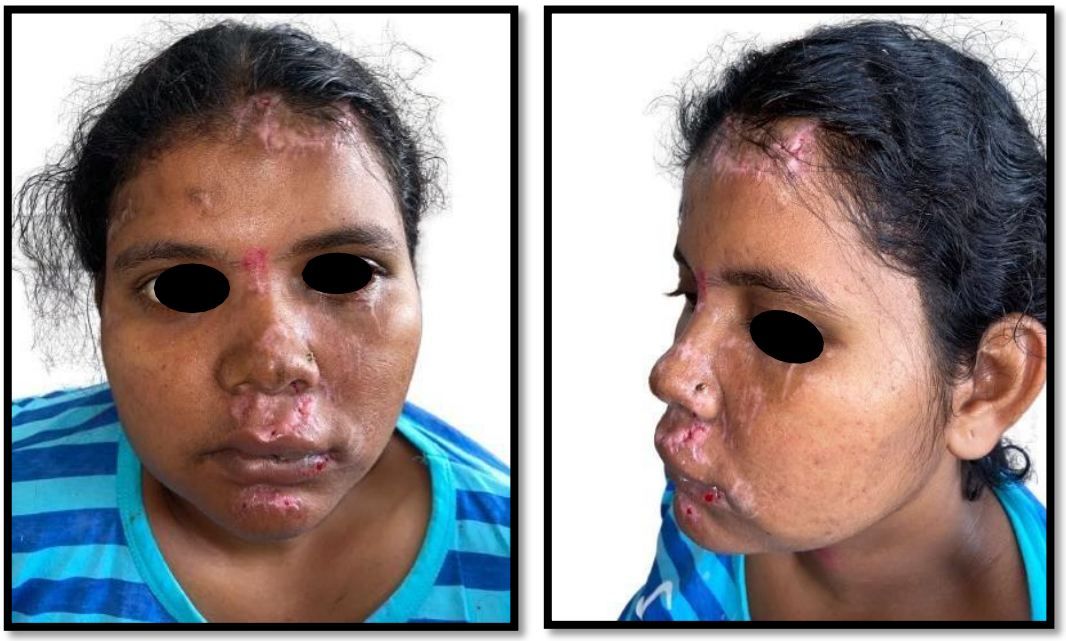


Figure 6c-FOLLOW UP DAY 31

PATIENTS IN CONTROL GROUP- CHX-IMPREGNATED DRESSING

Figure 7a -CASE III- SUPERFICIAL FACIAL WOUND ON DAY 1

Figure 7b-FOLLOW UP DAY 7

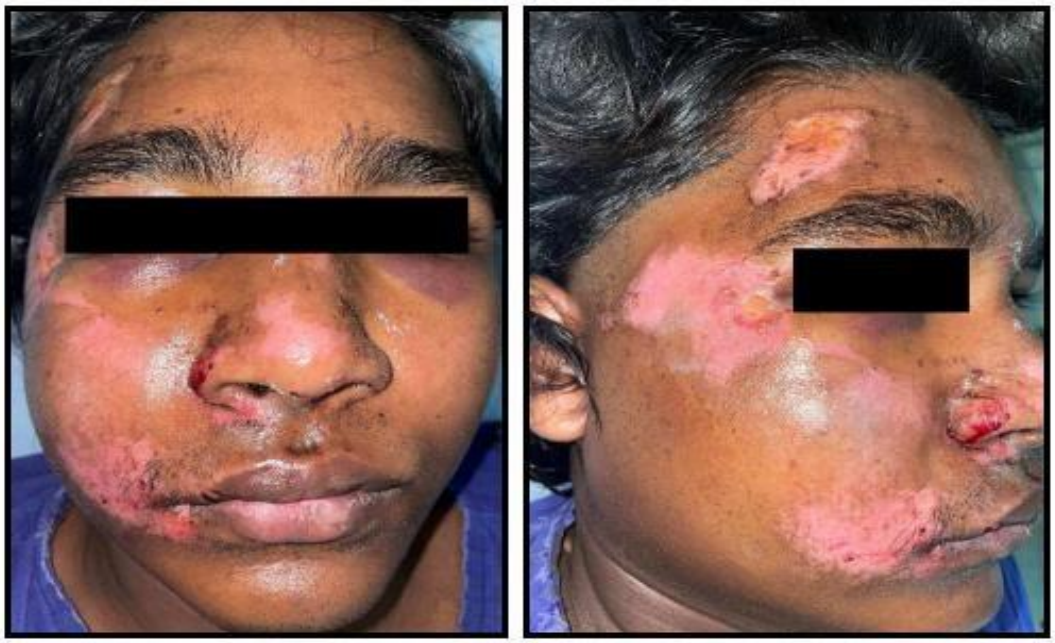


Figure 7c -FOLLOW UP DAY 31

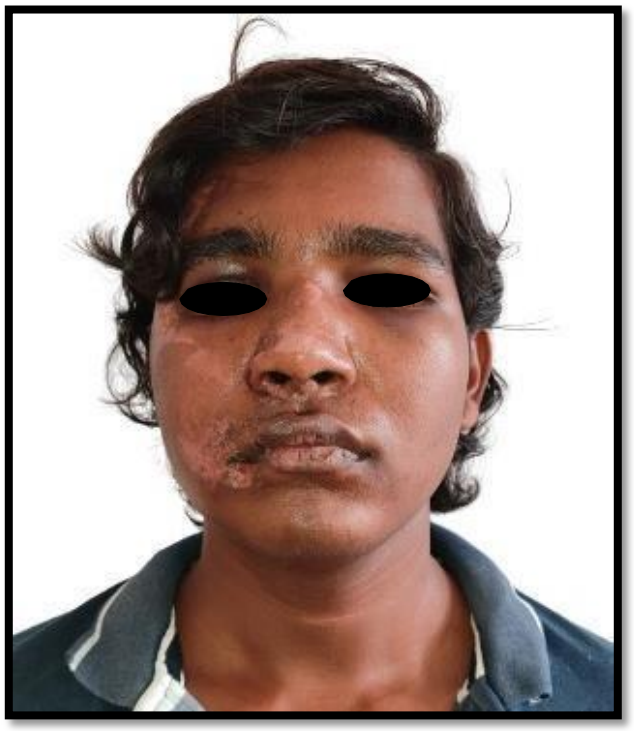


Figure 8a -CASE IV- SUPERFICIAL FACIAL WOUND ON DAY 1

Figure 8b-FOLLOW UP DAY 7

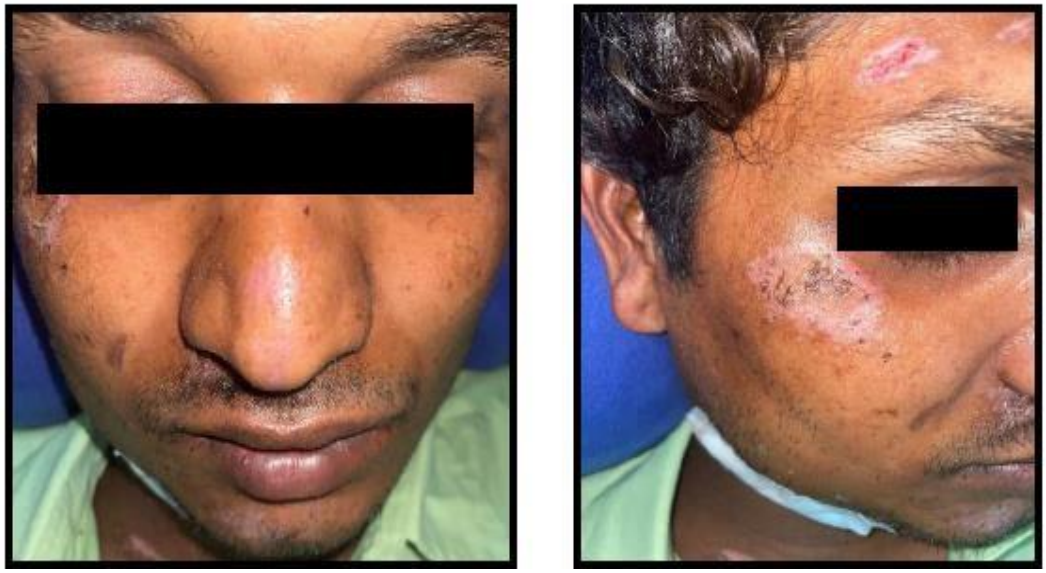
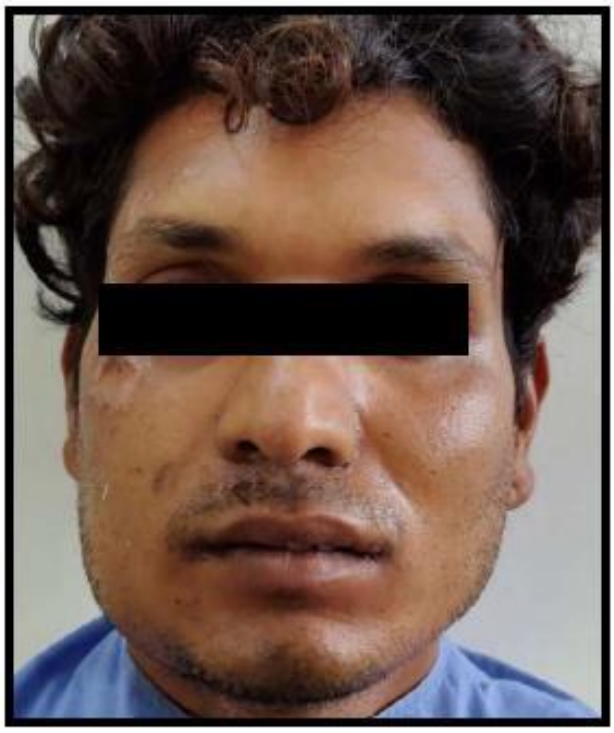


Figure 8b- FOLLOW UP DAY 31



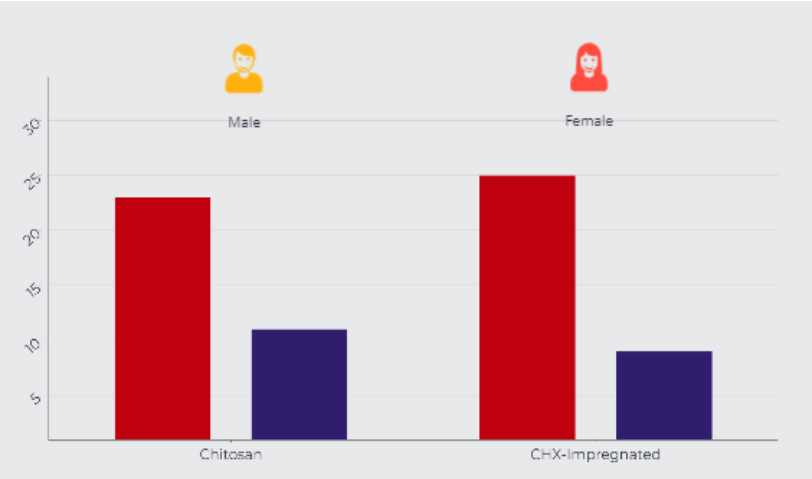
RESULTS

DEMOGRAPHIC DATA

Table 1: Distribution of Chitosan and CHX-impregnated group according to gender

Sex	CHITOSAN	%	CHX-IMPREGNATED	%	Total
Male	23	67.64	25	48.6	48
Female	11	32.36	9	51.4	20
Total	34	100	34	100	68

Graph 1: Distribution of Chitosan and CHX-impregnated group according to gender



In this single blinded, randomized control trial of 68 participants (48 M and 20 F) were included. Table 1 provides the distribution of the males and female participants for the two groups, Chitosan dressing and CHX-impregnated dressing.

There were 23 males and 11 females in the chitosan group. CHX-impregnated dressing group included 25 males and 9 females. At baseline, there was no correlation which was statistically significant between them.

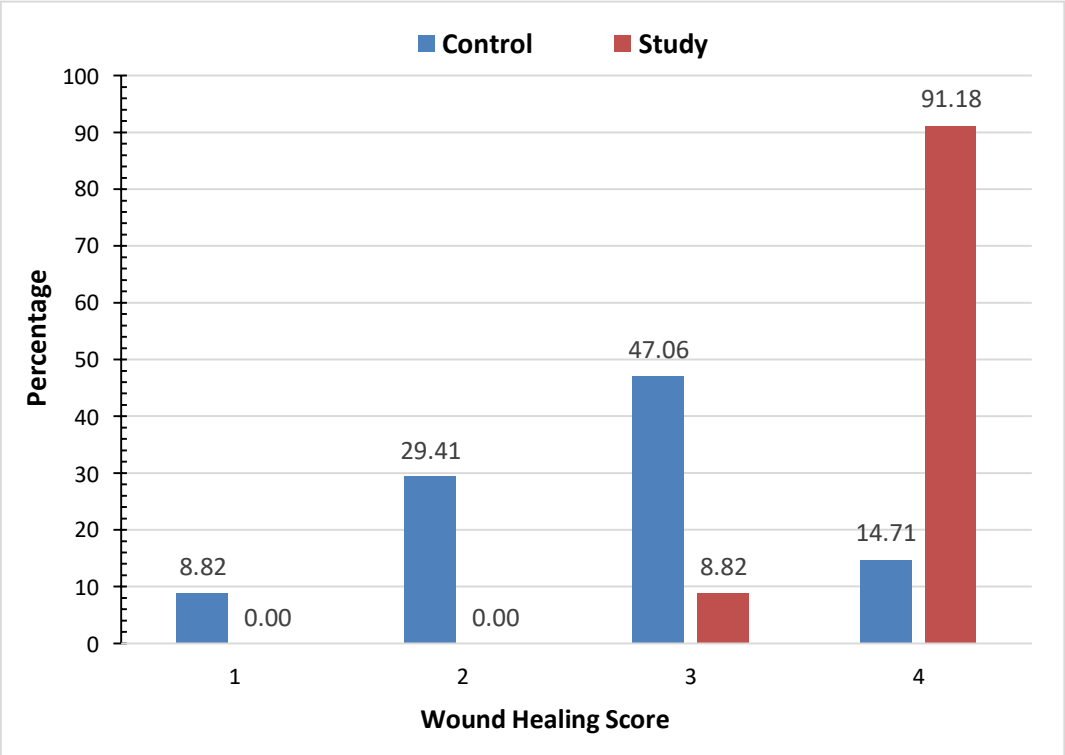
Wound healing:

Table 2: **Comparison of wound healing between Chitosan group and CHX-Impregnated dressing group with 6-point re-epithelialization score by chi square test**

Wound Healing	Control	Study	Grand Total
0	0	0	0
1	3	0	3
2	10	0	10
3	16	3	19
4	5	31	36
5	0	0	0
Grand Total	34	34	68
Chi-square=	40.67251462		
Chi-square (3df)	16.27		

$p<0.001$*= statistically significant

Graph 2: Comparison of wound healing between Chitosan group and CHX-Impregnated dressing group



The table 1 shows wound healing between both study and control group on day 7. Clinical assessment of wound healing was done by means of 6-point-re-epithelialization score and 91.18% of study group patients scored 4 i.e. >75% but not complete re- epithelialization

Cosmetic Outcome:

In order to evaluate the cosmetic outcome Manchester Scar scale was used on the 31st day

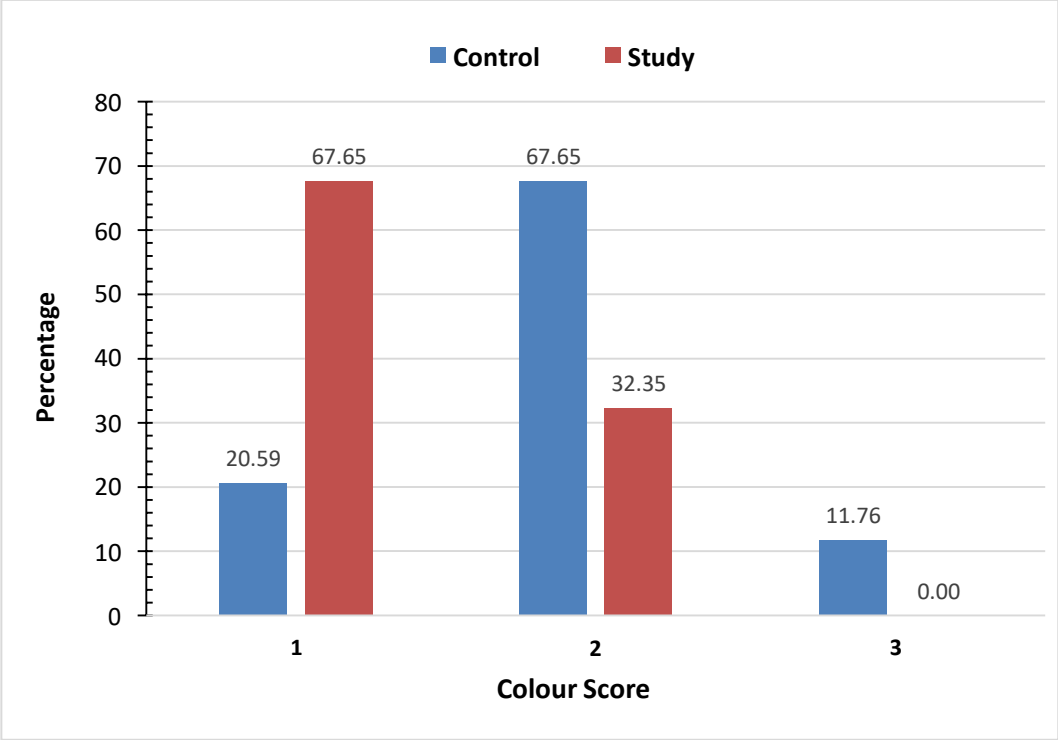
1) **Color**

Table 3: Comparison of color between Chitosan group and CHX- Impregnated dressing group by chi square test

Color score	Control group	Study group	Total
1	7	23	30
2	23	11	34
3	4	0	4
Grand Total	34	34	68
Chi square=	16.76862745		
Chi-square (2df)=	13.82		

$p<0.001$* = statistically significant

Graph 3: Comparison of color between Chitosan group and CHX- Impregnated dressing group



Majority of the patients in study group (67.65%) had perfect color match (cosmetic outcome) on 31st day of evaluation whereas 67.65% of control group patients had slight color mismatch.

2) Finish

Table 4: Comparison of Finish between Chitosan group and CHX- Impregnated dressing group by chi square test

Matte(1) v Shiny (2)	Control	Study	Grand Total
Matte - 1	23	34	57
Shiny - 2	11	0	11
Grand Total	34	34	68
Chi-square=	13		
Chi-square (1df)=	10.83		

*p<0.001= statistically significant

Graph 4: Comparison of Finish between Chitosan group and CHX- Impregnated dressing group

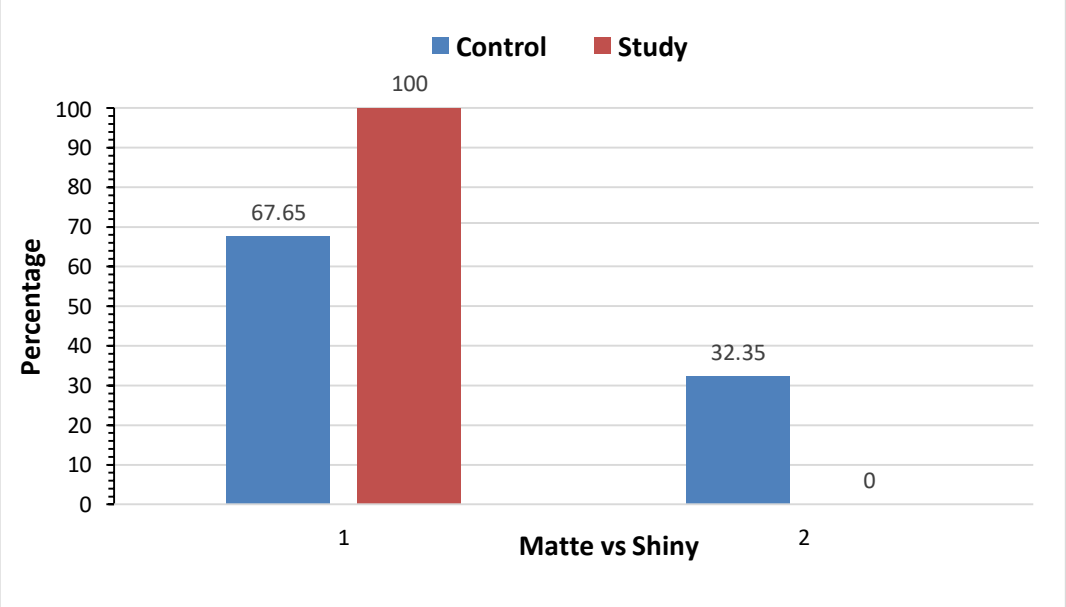


Table 4 shows that in all the study group patients the wound had matte finish which is considered superior than shine finish in terms of facial cosmetics.

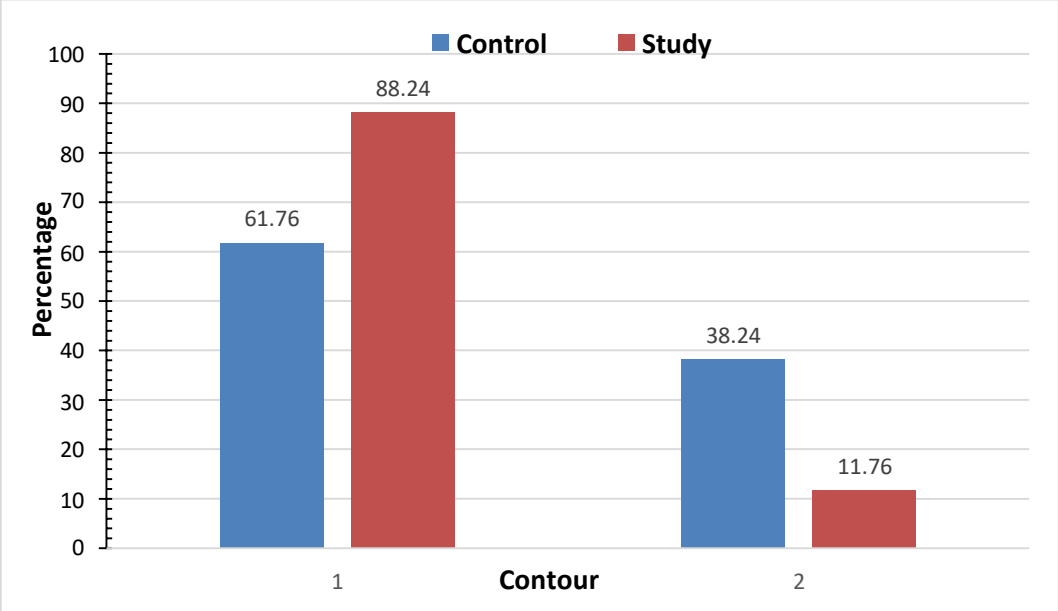
3) Contour

Table 5: Comparison of Contour between Chitosan group and CHX-Impregnated dressing group by chi square test

Contour	Control	Study	Grand Total
1	21	30	51
2	13	4	17
Grand Total	34	34	68
Chi-square=	6.352941176		
Chi-square (1df)=	10.83		

p<0.001* = statistically significant

Graph 5: Comparison of Contour between Chitosan group and CHX-Impregnated dressing group



The wound margins flushed with the surrounding skin in 88.24% cases in study group. In control group 38.24% of patients shows indented wound

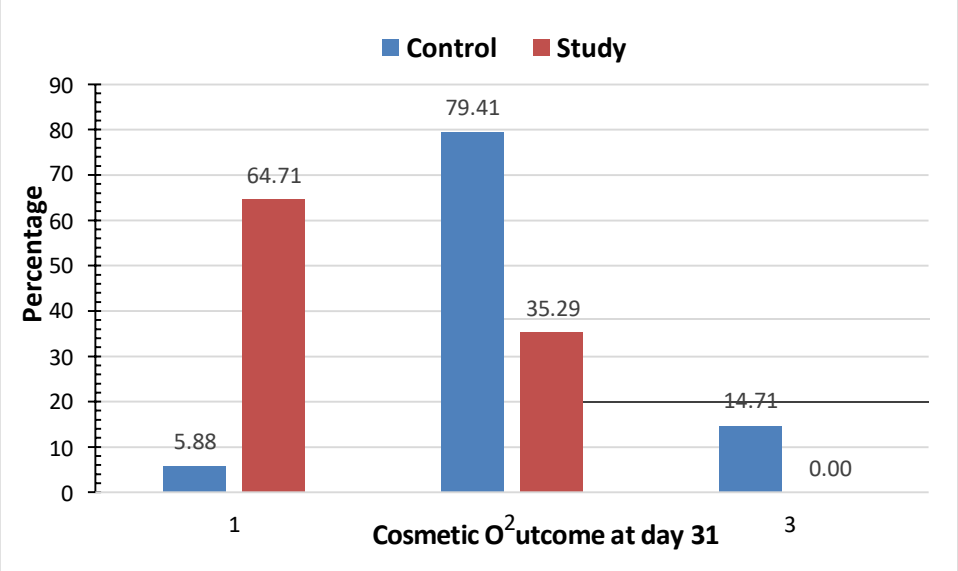
4) Distortion

Table 6: Comparison of Contour between Chitosan group and CHX-Impregnated dressing group by chi square test

Distortion	Control	Study	Grand Total
1	2	22	24
2	27	12	39
3	5		5
Grand Total	34	34	68
Chi-square=	27.43589744		
Chi-square (2df)	13.82		

p<0.001*= statistically significant

Graph 6: Comparison of Contour between Chitosan group and CHX-Impregnated dressing group



In 79.41% of control group patients the wound was mildly distorted. In more than 50 % of study group cases the wound healed normally with no distortion.

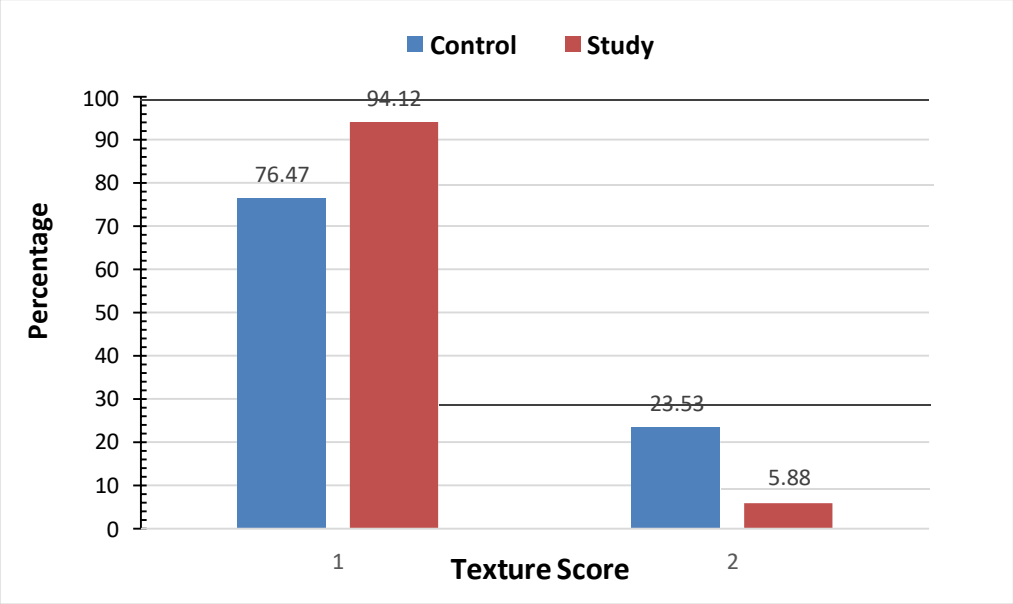
5) Texture

Table 7: Comparison of Texture between Chitosan group and CHX-Impregnated dressing group

Texture	Control	Study	Grand Total
1	26	32	58
2	8	2	10
Grand Total	34	34	68
Chi-square=	4.220689655		
Chi-square (1df)=	10.83		

*p<0.001= statistically significant

Graph 7: Comparison of Texture between Chitosan group and CHX-Impregnated dressing group



In 94.12% of study group patients the texture of the wound was normal and in 23.53 % of control group cases the wound was palpable.

Pain on dressing removal

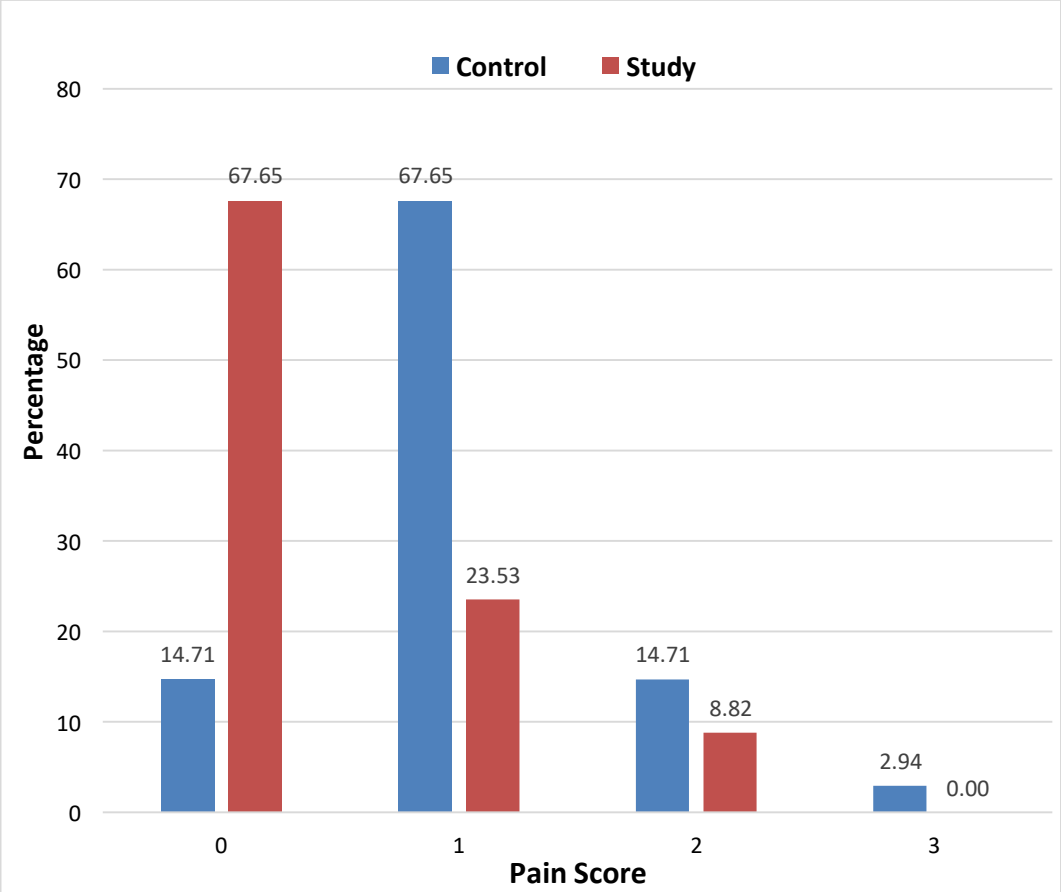
This parameter was evaluated at the time of first dressing change i.e. on the third day

Table 8: Comparison of pain at the time of dressing removal between Chitosan group and CHX- Impregnated dressing group using Chi-square test

Pain	Control	Study	Grand Total
0	5	23	28
1	23	8	31
2	5	3	8
3	1		1
Grand Total	34	34	68
Chi-square=	20.32949309		
Chi-square (3df)	16.27		

*$p<0.001$= statistically significant

Table 8: Comparison of pain at the time of dressing removal between Chitosan group and CHX- Impregnated dressing group



Numeric pain scale was used to assess pain during the first dressing change. Patients in both study and control group experienced mild pain (1-3). 61.65% of study group patients experienced no pain during the first dressing removal.

DISCUSSION

There is a dearth of research on the assessment of acute wounds and dressing methods to make a rational decision to treat superficial facial wounds. In our study chitosan dressing was compared with CHX-impregnated dressing and three primary parameters were assessed namely wound healing, cosmetic outcome and pain on dressing removal. In this study 91.18 % patients treated with maxillofacial abrasions with chitosan dressing recovered with > 75% re - epithelialisation at the end of 7^{th} day with better wound healing.

Halim et al in their multicentre study in 2018 with 244 patients compared chitosan dressing with hydrocolloid dressing. In the study the investigators compared percentage of epithelialisation, clinical signs and patient comfort on application as well as removal of dressing. The rate of re- epithelialization was similar in both the groups treated with chitosan and hydrocolloid dressing. [17]

The chitosan derivative film group displayed decreased exudate and odour compared to the control group of hydrocolloid dressing. The same finding of increased rate of re-epithelialization with chitosan based dressing was proved in our study as well.

Another literature where chitosan has been used as a dressing material in maxillofacial region include study by **Haque et al** which compared wound healing properties of chitosan with collagen material in facial soft tissue abrasions.

The study involved sixty patients. They were split into two groups at random, with half receiving collagen treatment and the other half receiving chitosan membrane

treatment. The time taken for average granulation tissue formation in chitosan group was less by avoiding dehydration and wound infection and preserving a sterile wound exudate resulting in better wound healing. The difference in healing rates favouring chitosan was found out to be significant (p=0.05).[14]

According to **Liu**, the wound healing using chitosan stemmed hydrocolloid dressing was statistically significant post three weeks of treatment in chronic refractory wounds which included burns, trauma, senile diseases and metabolic disorders like foot ulcers because of diabetes and pressure injuries from bed ridden status. Chitosan based hydrocolloid dressing also showed significantly lower pain score in such wounds. [15]

In another study by **Sutto et al** a double-blinded randomized control trial in diabetic foot ulcer treatment. Patients were arbitrary grouped into four lots. Group 1 was managed with chitosan gel; 2nd group with isosorbide dinitrate spray; third group with combination of isosorbide dinitrate spray & chitosan gel; last and the fourth group with placebo. On 45th day the wound healing was better in group 3 i.e. combination group compared to chitosan group and placebo group, but at the end of 60th and 75th day the combination therapy was only better than placebo group. The complete healing of ulcer was greater in patients treated with combination therapy (group 3). [22]

The Manchester scar scale (MSS), proposed by Beausang et al in 1998 was used to evaluate the cosmetic outcome on day 31. The score range was from 5 to 18 with 5 being the best score and 18 being the worst. The MSS can be applied to a larger variety of scars since it classifies pigmentation and vascularity combined under the heading of "colour mismatch" with respect to the surrounding tissue.

In the research conducted by **Haque et al**, major part of the patients with facial abrasions treated with chitosan attained normal pigmentation in comparison to patient with collagen dressing showing better cosmetic using Vancouver scar scale. (14)

Hu et al in their study mentioned that the wound healing time was significantly shorter in second degree burn wounds when treated with wet dressing with chitosan as compared to a normal wet compress dressing . Also the scar scores were lower in the study group at three months post wound healing. (16)

Kumar et al in their comparative study divided the patients in three groups, participant in Group A received treatment using a nano-chitosan membrane infused with CHX, while those in Group B were managed by a collagen-chitosan membrane also containing CHX. Group C participants underwent conventional wound care management using CHX powder. Patients managed by nano-chitosan membrane infused with CHX exhibited superior wound healing, lower pain intensity and at the end of three month follow up scar healing was better compared to other groups.(25)

In the present study the cosmetic outcome of chitosan dressing was statistically significant in all the parameters assessed as compared to CHX-impregnated dressing.

In our study majority of the f patients with Chitosan dressing showed perfect color match and had a matte finish at the end of 31st day which was statistically significant.

In terms of the contour, the wound margins flushed with the surrounding skin in 88.24% cases in study group. As regard to distortion, more than 50 % of study

group cases the wound healed normally with no distortion in our study. The texture of the wound was normal in 94.12% of study group patients and in 23.53 % of control group cases the wound was palpable with neither of the cases exhibiting firm or hard texture at the end of one month.

Usually the dressing change is thought to be the most painful time for the patients and pain during dressing removal was one of the objective which was evaluated in this study along with wound healing and cosmetic outcome.

In our study, we discovered that chitosan dressing caused less pain than control group during dressing change. The findings from our study shed insight on the use of chitosan membrane in wound care and its importance in Oral and Maxillofacial Surgery. Chitosan dressing which was used in the present study being a completely natural material also works as a suitable response to the problem of antibiotic misuse. It offers hope for more prudent and effective wound healing.

In neither group were there were any recorded adverse effects. Finally, by promoting faster wound re- epithelialisation, better cosmetic result and lowering patient discomfort on dressing removal this comparative prospective randomized clinical investigation has demonstrated with strong evidence that chitosan wound dressings can improve wound progression towards healing.

LIMITATION

- The widespread use of chitosan dressing may remain limited due to its high cost.
- Chitosan is contraindicated to use with products containing oxidizing agents such as Hydrogen Peroxide, as they might lead to disintegration of the dressing if left in contact for long.
- Chitosan is procured and attained from natural marine sources like crab shells, which may deter some patients from opting for treatments involving chitosan.

SUMMARY

The present study was a clinical randomized controlled trial. A total of 68 participants were categorized into two groups: Group I Study group– Chitosan dressing and Group II-control group (CHX-impregnated dressing). Follow up period was on 3rd day, 7thday and 31st day to evaluate pain on dressing removal, wound healing and cosmetic outcome respectively.

It was evident from our study that Chitosan dressing was more effective as compared to conventional CHX-impregnated dressing in all the parameters which were assessed. Chitosan has several properties that make it useful as a dressing material like biocompatibility, moisture retention, promotes tissue regeneration and a natural antimicrobial.

Chitosan also has shown no known reported allergic reactions in the study and has proven to be a reliable and functional dressing to treat maxillofacial superficial wounds. Therefore based on our research, we recommend using chitosan treatment for facial abrasions

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ANNEXURE I

ETHICAL CLEARANCE CERTIFICATE

Research and Ethics Committee
KLE VK INSTITUTE OF DENTAL SCIENCES
A Constituent Unit of KLE Academy of Higher Education & Research
Accredited 'A' Grade by NAAC Placed in Category 'A' by MHRD (GoI)
Nehru Nagar, Belagavi - 590 010, Karnataka State
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CERTIFICATE

Sl. No. : 1596

EC/NEW/INST/2021/2435
Research & Ethics Committee

This is to Certify that the synopsis titled

Evaluation of Chitosan Based Dressing in Comparison to conventional Chlorhexidine impregnated dressing in superficial facial wounds - A Single Blinded Randomized Controlled Trial *Submitted by*

Dr. **REG NO:IF0221002** *P. G. Student /*

Staff, Guided by _ *rom Department of*

Oral and maxillo facial Surgery *has been critically evaluated by committee members and granted ethical clearance to conduct the above mentioned study*

Date : 30/8/24

Member Secretary
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

Chairman
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

ANNEXURE II

BIOSTATISTICS CLEARANCE CERTIFICATE

K L E VISHWANATH KATTI
INSTITUTE OF DENTAL SCIENCES
(A Constituent unit of KLE Academy of Higher Education & Research
Formerly known as KLE University) Deemed-to-be-University u/s 3 of the UGC Act, 1956)
J.N.M.C. Campus, Nehru Nagar, Belagavi-590 010, Karnataka, India
Accredited 'A+' grade by NAAC (3rd Cycle) Placed in Category 'A' by MHRD (GoI)
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Biostatistics Clearance Certificate

This is to certify that Biostatics aspect of the Dissertation/Research work of

REG. NO. IF0221002 under the guidance of **Department of Oral & Maxillofacial Surgery,** entitled **"Evaluation of Chitosan Based dressing in comparison to conventional Chlorhexidine impregnated dressing in superficial facial wounds: A single blinded randomized controlled trial"** has been done under my guidance and considered satisfactory.

18/04/24.
Anushri P. Patil.

Place: Belagavi
Date: Name & Signature of Biostatistician

ANNEXURE III

PLAGERISM CHECK CERTIFICATE

Scientific Correspondence and Review Committee

KLE VK Institute of Dental Sciences

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Date :

Serial No. : 192

PLAGIARISM CHECK REPORT

Name of the Applicant : **REG NO:IF0221002**
UG / PG / Ph.D / Staff : Post Graduate Student
Batch & Year : 2021 - 2024
Department : Oral & Maxillofacial Surgery

The soft copy of Research Work / Manuscript by **REG NO:IF0221002** entitled

"Evaluation of chitosan based dressing in comparison to chlorhexidine impregnated dressing on superficial facial wounds: single blinded randomized controlled trial"

under the guidance of .....has been submitted for Anti-Plagiarism check to the Scientific Correspondence & Review Committee of KLE VK Institute of Dental Sciences using "Turn-it-in" software.

The scan has been carried out and the scanned output reveals a Similarity Index of .....2.....%, which is **within** / **not within** the acceptable limits of 10% as per the UGC guidelines.

22/04/2024

Member Secretary
entific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER-Belagavi

Chairman
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER - Belagavi

ANNEXURE-IV

KAHER's KLE VK Institute of Dental Sciences
Department of Oral and Maxillofacial Surgery
Belagavi

"EVALUATION OF CHITOSAN BASED DRESSING IN COMPARISON TO CONVENTIONAL CHLORHEXIDINE IMPREGNATED DRESSING IN SUPERFICIAL FACIAL WOUNDS: A SINGLE BLINDED RANDOMIZED CONTROLLED TRIAL**"**

K.L.E.'s V.K. Institute of Dental Sciences
Department of Oral and Maxillofacial Surgery, Belgaum
CONSENT TO SURGERY & ANAESTHETICS

Date: Time: a.m./ p.m.

1. I authorize the performance upon self or Mr./Miss./Mrs._____the following operation (Nature and extent) to be performed under the direction of Dr._____and by Dr._____in my own vernacular language.
2. I agree to give my personal details like name, age, sex, address, history of treatment taken and any other details required for the study to the best of my knowledge.
3. I will cooperate with the surgeon for examination and also for various investigations.
4. I consent to the administration of anesthetics as may be considered necessary or advisable by the doctor responsible for this service.
5. I consent to the administration of drugs as may be considered necessary or advisable by the doctor responsible for this service.
6. I permit the surgeon to utilize the information given by me and the results obtained from this study for presentation and publication.
7. I permit the surgeon to take my photographs to utilize it for the study and presentation purpose.
8. I am participating in this study with my own wish and will and the surgeon has explained the nature,effect and purpose of the operation and the materials being used, possible alternative methods of treatment, the risk involved and the possibility of complications in my vernacular tongue. No guarantee or assurance has been given by anyone as to the results that may be obtained.
9. I have read and understood the above information given by surgeon about the study and willingly agree to participate in the study and willingly agree to come for follow up on the 3rd ,7th and 31st day.

Name: Date:
Signature: Mob. No:

ANNEXURE V

KLE Vishwanath Katti Institute of Dental Sciences, Belagavi
Department of Oral and Maxillofacial Surgery

Patient Information Sheet

'EVALUATION OF CHITOSAN BASED DRESSING IN COMPARISON TO CONVENTIONAL CHLORHEXIDINE IMPREGNATED DRESSING IN SUPERFICIAL FACIAL WOUNDS: A SINGLE BLINDED RANDOMIZED CONTROLLED TRIAL'

Dear Patient,

You are invited to take part in a research study to examine and compare your wound healing, pain, with two different wound healing materials. This research is a part of a MDS, main dissertation at KLE Academy of Higher Education and Research. Before you decide whether to take part in the study it is important that you understand what the research is for and what you will be asked to do. Please take time to read the following information and discuss it with others if you wish. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep. You will be also asked to sign a consent form. You can change your mind at any time and withdraw from the study without giving any reason. The standard of care you receive will not change whether or not you decide to participate in this study. You are welcome to call me (@ if you would like any further information.

You have been chosen because you have facial abrasion which requires intervention with wound dressing material. The study will involve participants who will be examined and advised for topical application of Chitosan and Chlorehexidine dressing. Chitosan is a natural polymer and is derived from shell of crustaceans. Chitosan is known for its various properties and minimum side effects.

You will be asked to report for a review and follow-up visit after one month, seventh day and third day. The information gained from this research will be used to publish in scientific platforms/ journals without revealing your identity to make recommendations for the best practice and the results of the study may also lead onto further studies into the management of Facial Abrasions.

Place:
Date:
Signature of participant:
Contact no:
Address: