"EVALUATION OF MANUKA HONEY (LEPTOSPERMUM SCOPARIUM) IN COMPARISION TO CONVENTIONAL SOFRAMYCIN DRESSING IN FACIAL ABRASIONS: SINGLE BLINDED RANDOMIZED CONTROLLED TRIAL."

By

REG.NO. – IF0220001

Dissertation

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KLE ACADEMY OF HIGHER EDUCATION & RESEARCH

BELAGAVI, KARNATAKA

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Head of Department

Dr. SHRIDHAR D. BALIGA M.D.S
Professor & Head,
Department of Oral & Maxillofacial Surgery,
KAHER's V K Institute of Dental Sciences,
Belagavi - 590010
Date: 27-12-2022
Place: Belagavi

Principal

Dr. ALKA KALE M.D.S.
Principal,
KAHER's V K Institute of Dental Sciences, Nehru Nagar,
Belagavi-590010.
Date: 27/12/22
Place: Belagavi

PRINCIPAL
KLE V.K. Institute of Dental Sciences
Nehru Nagar, BELAGAVI-590010.

ii

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(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Nehru Nagar, Belagavi - 590 010, Karnataka State

Accredited 'A' Grade by NAAC (2nd Cycle) | Placed in Category 'A' by MHRD (GoI)

☎: 0831-2470362
FAX: 0831-2470640
Web: http://www.kledental-bgm.edu.in
E-mail:principal@kledental-bgm.edu.in

Date : 26/12/2022 Serial No. : 145

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UG / PG / Ph.D / Staff : Post graduate student
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LIST OF ABBREVIATIONS

NRS	:	Numeric rating pain scale
MRSA	:	Methicillin resistant staphylococcus aureus
VAS	:	Visual analog scale
CABG	:	Coronary artery bypass graft
kGy	:	kilograys

ABSTRACT

Introduction

Facial trauma includes hard and soft tissue injuries. Soft tissue injuries are most commonly seen in maxillofacial trauma and can range from a simple contusion or abrasion to more serious wounds involving the deeper anatomical structures. Abrasions are injuries to skin that are no deeper than the epidermis. These minor injuries are routinely neglected or treated with first aid dressings. This type of care usually results in a dry wound environment.

To overcome the dry wound environment dressings based on honey have been used all over the world. There are many varieties of honey available. However, medical grade manuka honey has shown broader antimicrobial activity and thus recommended for wound management.

Aim

The aim of the study was to evaluate the efficacy of manuka honey dressing in patients with abrasions over facial region with respect to wound healing, pain during dressing change, comfort to patient and frequency of dressing change in comparison with soframycin gauze dressing.

Materials and Methods

Present study was performed on patients with abrasions over facial region reported to KLE Prabhakar Kore Hospital, Belagavi. 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 manuka honey and control group with soframycin dressing.

Dressings were changed for 7 days. Pain on dressing change, wound healing, comfort of the patient and frequency of dressing change were assessed.

Results

A total of 62 patients were selected in the study and divided into two groups. The patients in the study group reported minimal pain and effective wound healing ($p < 0.05$). The difference in frequency of dressing change and comfort of the patient was not significant statistically.

Conclusion

In conclusion, manuka honey dressing can be used as an alternative dressing material. It is painless and aids in maintaining the moist wound environment, which speeds up the wound healing process. As a result, we highly suggest use of manuka honey dressing to the facial wounds.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF GRAPHS

LIST OF FIGURES

INTRODUCTION

Soft tissue injuries are most commonly seen in maxillofacial trauma either with or without bone involvement.[1] Soft tissue injuries are classified into: contusions, abrasions, and lacerations.

Contusions or bruises are the most common type of soft tissue injury. Facial lacerations are the most varied soft tissue injuries. They can be brought on by either blunt or sharp trauma.

Acute, superficial wounds caused by abrasions, cuts, or minor burns occur commonly. These minor injuries are routinely neglected or treated with first aid dressings. The first aid dressing protects against bacteria, and other factors such as pressure and friction. This type of at-home care usually results in a dry wound environment.

Abrasions are injuries to skin that are no deeper than the epidermis and result in minimal bleeding. [2] Abrasions can occur at any age or gender having no particular predilection. Abrasions are the most common among children, accounting for 70.7% of all injuries. The head, face and torso are the most commonly abraded areas, accounting for 50% of all abrasions. The upper limbs account for 15.4% of all abrasions, while the lower limbs account for 34.6%.[3][4]

Intentional sexual abrasive injuries associated with sexual offences are found to be more common in females. In comparison to the extremes of age, abrasions caused by intentional injuries are more common in the middle age groups.

Unintentional abrasions are commonly related to falls, sports-related injuries and road traffic accidents in children, adults as well as falls in older patients.

Minor abrasions rarely scar, but deep abrasions frequently bleed and may scar.[2] It is critical to understand that even superficial abrasions can become infected. They are highly susceptible to tetanus and methicillin-resistant Staphylococcus aureus, especially if they come into contact with dirt in case of sports injuries or road traffic accidents.

The standard treatment for abrasions is debridement of debris or other contaminants.[5] Particularly for larger abrasions, a cover dressing can be used. Gauze, adhesive bandages, or bio-occlusive dressings can be used. Large or deep abrasions are more likely to develop scar. Infection prevention is critical, especially in cases of deep abrasion. Scar formation can be significantly reduced by daily debridement with hydrogen peroxide and application of antibiotic ointment.

Managing wound is a significant challenge in clinical practice.[6] Breach in skin barrier, reduces protection against pathogen also affects regulation of temperature which start a series of timed events that lead to wound healing. Wounds are divided according to the duration of the healing process into acute and chronic wounds. (Simes et al, 2018).[6]

Dressings have been regarded as an essential component of managing the wound. They create a favorable environment for healing of the wound and to protect the underlying tissues from bacterial penetration. While choosing a dressing factors such as comfort of the patient, presence of infection, avoidance of pain and ease on application/removal should be considered.

The healing process in superficial wound is often distinctly evident, but in order to avoid any further complications and to achieve aesthetic result, optimal moist environment is required to promote wound healing.

Furthermore, wounds infected with infection specially those contaminated with MRSA are resistant to most of the conventional antibiotic treatment and are becoming an increasingly serious issue.

To overcome the dry wound environment and antibiotic resistant bacteria, Emergence of new dressing material is being taken into account. As a result, despite the ineffectiveness of antibiotics and other dressings, medical personnel have turned to antibacterial dressings for the treatment of wounds where infection may still persist. This has allowed other dressing materials such as honey into account for modern practice. (White, 2005).[7][8]

Nowadays, wound dressings based on honey have been used all over the world. The US Food and Drug Administration approved honey as a dressing material for wound care in 2007.[9]

Medical-grade honey dressings have shown to be beneficial in terms of promoting autolytic debridement of devitalized tissue, thereby reducing pain. It is seen that till now no significant cases of resistance to honey have been reported. (Cooper and Gray, 2012).[6]

There are many varieties of honey available. However, medical grade manuka honey (Leptospermum scoparium) has shown a broader antimicrobial activity and thus is recommended for wound management.[9]

Honey has been shown to promote wound healing as it keeps the wound moist by drawing lymph into the wound via osmosis and thus prevents the dressing from adhering to the wound surface. Honey's low ph creates promotes fibroblastic activity. Honey 1. promotes angiogenesis, which increases oxygen supply to the wound while also promotes formation of healthy granulation tissue; 2. accelerates epithelialization; and 3. promotes collagen production. [9]

So this revolutionary concept of moist wound healing by natural product that is honey will gain attention nowadays where one dressing material serves both moist healing and promotes antibacterial action. Hence, this study aim to compare the efficacy of Manuka honey with conventional soframycin dressing in facial abrasions.

AIM AND OBJECTIVES

AIM

To evaluate the efficacy of manuka honey dressing in patients with abrasions over facial region with respect to wound healing, pain during dressing change, comfort to patient and frequency of dressing change in comparison with soframycin gauze dressing.

OBJECTIVES

- Wound healing
- Pain on dressing removal
- Comfort to the patient, when dressing is placed over the wound
- Frequency of dressing change for 7 days

NULL HYPOTHESIS

- There is no difference in the dressing properties of honey dressing compared to conventional soframycin dressing in patients with abrasion on face with respect to wound healing, pain during dressing removal, comfort to the patients and frequency of dressing change

ALTERNATIVE HYPOTHESIS

- Honey dressing is a suitable and effective dressing material in patients with abrasions on face as compared to conventional soframycin dressing with respect to wound healing, pain during dressing removal, comfort to patients and frequency of dressing change.

REVIEW OF LITERATURE

In 2008, Van Robson et al conducted a randomized controlled trial of 105 participants. For patients in honey group; wound was covered with manuka honey upto 3mm depth followed by dressing over it. They evaluate the healing time and the time taken for 50% reduction of wound area at different time frames with the follow up of 24 weeks. It has been seen that reduction in wound area at 12 and 24 weeks is much higher in manuka honey group as compared to conventional dressing. Their study concluded that healing time of wound after treatment with honey is reduced as compared to conventional treatment.

In 2011, Von Robson et al conducted a randomised control trial on 49 participants to access the impact of manuka honey in wound healing. Wound dressing was applied after free tissue transfer to donor site and to the suture line daily.

Culture swabs were taken for all wounds and suture lines for 7 days after operation. Swabs were taken from, "free flaps, split skin sites, or full thickness grafts" after 7^{th} day removal of dressing and again at the time of discharge.

In experimental group, improved wound healing was seen which considerably took less time as compared to control group; though patient's comfort, pain score and frequency of dressing change is less in experimental group but was not considerable statistically. Due to considerably less follow up irradiation with pathogens at infected site is not conclusive.

In 2005, David Johnson et al lead a prospective randomized, controlled trial, on 101 patients required haemodialysis through newly inserted central tunnelled catheter.

Patients were randomly assigned in topical gamma irradiated manuka honey or 2% calcium mupirocin group.

Primary Outcome - in this study was catheter-related bacteraemia

Secondary Outcome in this study was catheter exit-site infection and adverse reactions

Dressings were changed three times a week during each haemodialysis treatment. This study concluded that application of manuka honey to the hemodialysis catheters was safe, effective and associated with low catheter-related bacteremia rates compared with topical 2% calcium mupirocin dressing.

In 2008 Gethin et al performed a prospective multicentre randomised control trial. 108 participants with venous leg ulcer were compared for wound healing and antimicrobial properties of manuka honey and hydrogel.

Culture swabs were taken before and after cleansing of wound in all patients to check for bacterial colonization. Weekly each wound size and also pain was assessed using VAS scale. Patients were treated for 4 weeks and followed up at 12 week to determine the wound healing and bacterial colonization. The mean surface area was evaluated for bacterial colonization which is reduced to 60% from 83% but not statistically significant.

In conclusion, though there is no statistically significant difference seen in reduction of bacterial colonization in both group but effective pain reduction seen in patients with honey dressing.

In 2011, Biglari et al conducted a prospective, observational, open label study in 9 centres over 20 patients. In this study patients with pressure ulcers were treated with manuka honey and each patient had undergone unsuccessful treatment for pressure ulcers previously. Their study concluded improved wound healing and less bacterial colonization after one week of treatment. Follow up after 3 weeks shows less scarring and complete wound healing compared to other conventional treatment.

In 2008, Georgina Gethin et al, conducted a study with sample of 20 patients to assess the efficacy of manuka honey in wound size reduction and as desloughing agent by lowering the ph levels. They have included superficial non healing wounds in which the wound size is not decreased over period of three weeks.

They directly apply manuka honey over the wound surface along with calcium alginate fibres. Dressing was changed once or twice weekly and the ph was recorded to analyse the data.

This study concluded that patients treated with manuka honey demonstrated lower ph levels and reduction in wound size in non-healing venous ulcers that is statistically significant.

In 2011 Betina nielson et al, lead a prospective, open-labelled randomized controlled trial on seventy-five patients with malignant wounds to access the effect of honey and silver-coated bandages on the basis of wound size, cleanliness, malodour, exudation, and wound pain. They divided participants into two groups- Honey coated bandages and Silver coated bandages.

The effect of wound cleanliness is much higher in honey group but the difference in reduction of malodour, exudation and wound pain was not statistically significant as patients taken in this study were of advanced stage. The difference in wound size reduction though clinically visible was not statistically significant.

A multicentre, prospective, descriptive, non-randomised study was led by **Dunford et al** in **2015** to study the effectiveness of manuka honey in non-healing venous ulcers in 40 subjects. The primary aim of this study is to evaluate healing of wound, frequency of dressing change, patient comfort, management of exudate, reduction in pain and odour.

Though there was no comparative trial done with conventional dressing material yet effective wound healing, patient comfort, reduction in pain and frequency of dressing change seen in patients with manuka honey dressing.

In 2008, Andrew Jull et al, lead a multicentre randomized controlled trial on 368 patients with venous leg ulceration. The study divided in two parts:

They have divided the participants in two groups-

First group received honey coated dressing .

Second group received alginate, hydrogel or silver dressing.

The second part is to evaluate the primary outcome which is wound healing and secondary outcome that is time to heal, change in ulcer area from base line and any complications. Though clinically effective wound healing seen in honey group but statistically not significant.

In 2014, Alexandros et al evaluated the efficacy of manuka honey-impregnated dressings in healing of diabetic neuropathic foot ulcers. In this study they evaluated 63 patients.

In first group Medihoney Tulle dressing was applied.

In second group saline-soaked gauze dressing was applied.

There was decrease in bacterial load in case of group I and effective wound healing as compared to conventional group. Though there is no significant evidence of reduce MRSA bacterial strain.

In 2016, Peiman et al conducted a randomized clinical trial on 52 participants to evaluate the efficacy of honey dressing as compared to conventional dressing where patient and observer surgeon were both blinded. Aesthetic results and wound healing were evaluated in this study. Pain evaluation is not mentioned in this study. However, the study group demonstrate enhanced aesthetic result and wound healing process. [5]

G Blaser et al in **2007** reported a case series of seven patients having bacterial colonization with MRSA had been found in wound swab over five years and were treated with manuka honey dressing. Wounds with clinical sign of infection treated with hydrogen peroxide and then application of honey was done. T evaluate the microbial colonization wound swabs were investigated.

It was seen that wounds treated with manuka honey had effective wound healing with no bacterial colonization. It was seen that MRSA had been eradicated from all wounds without use of antiseptics topically or any systemic antibiotics.

A retrospective case series by **Cecilia Gray et al** in **2015** evaluated action of manuka honey on necrotic wounds that were difficult to heal. This study shows effective wound healing and autolytic debridement action of manuka honey that is not usually seen with conventional dressings.

Case series of eight patients led by **Georgina Gethin et al** in **2005** evaluated effectiveness of manuka honey in wound size reduction. There was signification reduction seen in wound size and malodour within four weeks after application of manuka honey.

The limitation of this study is that they included heterogenous sample and patients with different aetiologies.

An article by **Bhavin Visavadia et al** in **2006** shows significant wound healing in chronic wounds. Wound site harvested with split thickness graft already treated with routine dressing but was not effective, application of manuka honey was done and significant wound healing seen within two weeks. It also maintains moist wound environment and autolytic debridement action.

Janice Leigh Sare et al in **2017** led a study to illustrate the efficacy of manuka honey in leg ulcers. The objective of this study is to improve patient's quality of life during healing process by reducing pain, protection against infection and patient's comfort.

With manuka honey, improvement was seen after first application and the adjacent tissue improved significantly within a time period of two weeks. There is also pain reduction and infection seen with honey dressing in this study.

Tanisha Smith et al in **2009** studied the efficacy of topical manuka honey in Venous Leg ulcerations. Patients with recalcitrant lower extremity chronic venous leg ulcerations were participated. The honey wound dressing was applied to recalcitrant venous ulcerations that had previously failed to respond to treatment modalities such as 4-layer compression, topical silver, nonadherent dressings, and antibiotic therapy for bacterially burdened ulcerations.

They concluded that the osmotic action of manuka honey accounts for drawing moisture out of local wound area creating a gradient which leads to autolytic and mechanical debridement of nonvital tissues and debris leading to wound healing.

Sharon Bateman et al in **2007** evaluate the use of manuka honey on surgical wounds post-CABG. In this study in all the patients the saphenous vein was harvested from the leg for use as a graft. They use manuka honey as a primary dressing material for all the wounds at graft site. Almost in all patients, wound healing occurred within 4 weeks. Pain at the wound site was initially assessed to be mild but was reported to be absent on completion of the evaluation. Patient comfort also recorded as high. Both exudate levels and malodour decreased with time.

In 1993, J. K. Yadav et al led a study to evaluate the effiacy of topical phenytoin in treatment of split-thickness skin autograft donor sites. 60 patients were assigned to three different treatment groups:

Group I – Thirty sites were given phenytoin dressing

Group II- Fifteen sites were given opsite dressing

Group III- Fifteen sites were given soframycin dressing

This study concluded early complete healing in phenytoin group, soframycin treated sites were related with significantly higher levels of pain than either phenytoin or OpSite, also both phenytoin and OpSite have reduced microbial colonization and infection than a conventional soframycin dressing.

In 2008, Rajeev Ahuja et al performed a prospective, double blinded study on forty participants to evaluate the topical containment of bacterial colonization after soframycin and silver sulphadiazine dressing. Patients with six hours of flame burns or scalds were selected for this study.

Silver sulphadiazine shows better wound healing but there was statistically no significant difference seen in reduction of bacterial colonization between soframycin and silver sulphadiazine dressing.

In 2007, Shweta Sethi et al led a study of thirty patients with vitiligo having minimum of three patches. Dermabrasion treatment was given to all the patients and three different dressing materials seven days after the procedure.

Group I - Soframycin tulle dressing

Group II - Topical 5% 5-fluorouracil dressing

Group III - Topical placentrex gel dressing

Patients followed up for six months and it was concluded that dermabrasion with soframycin dressing and dermabrasion along with placentrex gel showed similar results in localized stable vitiligo and dermabrasion along with 5-fluorouracil is the most effective of the three treatment modalities.

In 1971, D. S. C. Procter et al led a study with five hundred and two burn patients to evaluate the effectiveness of three different dressing material in reducing the bacterial load.

GROUP I – Gentamycin dressing

GROUP II – Neomycin dressing

GROUP III – Soframycin dressing

All the dressing were placed for about two weeks and regular swab cultures were taken to evaluate reduction in bacterial colonization. Wound healing is seen most effective in case of gentamycin but not statistically significant. The incidence of bacterial organism when dressed with soframycin as compared to gentamycin and neomycin is higher.

MATERIALS AND METHODS

SOURCEOF DATA:

- Present study was performed on patients with the age group between 18-45 years of either sex with abrasions over facial region reported to KLE Prabhakar Kore Hospital, Belagavi
- A standard Performa was used to collect information regarding each case.

INSTRUMENTS AND MATERIALS:

- Saline
- Cotton swabs
- Adson forceps
- Gauze
- Soframycin
- Wooden spatula
- Manuka honey.
- Manuka honey imported from Comvita Ltd, New Zealand having unique manuka factor 15+, manufactured under stringent quality control is used.
- Manuka honey sterilized with 25 kGy Cobalt-60 gamma irradiation.[10]
- The abrasions were irrigated with saline and explored for any foreign body present or not.
- The area was dabbed with sterile cotton swab.
- Study group received thin layer of sterile honey applied by wooden spatula along with some amount of honey has been placed on gauze and dressing was done.[11]

- Control group received soframycin and gauze was put over it to hold the dressing in place.
- All wounds were cleaned once daily with normal saline for 7 days.[11]
- Daily dressing was changed for 7 days and patient recalled on 14th day for follow-up and evaluation of wound healing.[12]
- If any sign of infection was seen during the procedure, stoppage of application of honey was done and the wound was managed as per the standard hospital protocol.

INCLUSION CRITERIA

- All patients between the age of 18-45 years, males and females.
- Abrasions measuring up to 8cm x 8cm and 2mm depth on face.
- Patients willing to give informed consent.

EXCLUSION CRITERIA

- Medically compromised patients
- Malnutrition
- Infection
- Any Underlying Disease such as Diabetes Mellitus etc
- Maceration that is excess wound exudates or contact with bodily fluids
- Alcoholics and cigarette smokers
- Known allergy to bee/honey products

METHODOLOGY:

- A total of 62 patients with abrasions on face was divided into 2 equal groups-
- **STUDY GROUP-** Thirty-one patients with facial abrasions received manuka honey dressing.

- **CONTROL GROUP-** Thirty-one patients with facial abrasions received conventional soframycin dressing.

- **Random Allocation Lottery method** was used for the sample selection. On the basis of their similar characteristics controls and samples were selected.

PARAMETERS ASSESSED:-

1. **NRS pain scale** is used to assess pain during dressing change [13]

The patients were asked the following questions during dressing change:

1. What number would you assign to your current pain?

2. On a scale of 0 to 10, how would you rate your pain when it is at its worst and when it is at its best.

3. At what point does the pain become tolerable for you?

2. <u>WOUND HEALING</u>

- Clinical assessment of wound healing is done by the following 6-point-re-epithelialization score at the end of 7^{th} and 14^{th} day.[12]

- Individual wound is assessed daily for 7 days and on 14^{th} day.

3. COMFORT CHARACTERISTICS [14]

- Comfort characteristics were assessed through comfort score.
- Patients were asked to score their level of comfort while dressing was placed over the wound

4. EVALUATION OF DRESSING: EXUDATE INTERACTION [14]

STATUS	INDICATOR
Dry	• Wound bed is dry • There is no visible moisture and the primary dressing is unmarked • Dressing may be adherent to wound
Moist	• Small amounts of fluid are visible when the dressing is removed • The primary dressing may be lightly marked
Wet	• Small amounts of fluid are visible when the dressing is removed • The primary dressing is extensively marked but strikethrough is not occurring
Saturated	• Primary dressing is wet & strikethrough is occurring • Dressing change is required more frequently than usual • Peri-wound skin may be macerated
Leaking	• Dressings are saturated and exudate is escaping from the primary &Secondary dressings onto clothes or beyond • Dressing change is required much more frequently than usual.

- (World Union Wound Healing Societies, 2007)

DRESSING STATUS	FREQUENCY OF DRESSING CHANGE
1. Dry	Once a day
2. Moist	Once a day
3. Wet	Twice a day
4. Saturated	Thrice a day
5. Leaking	Thrice a day

GROUP A – MANUKA HONEY DRESSING

DAY	PAIN DURING DRESSING CHANGE	COMFORT CHARACTERISTICS	FREQUENCY OF DRESSING CHANGE	WOUND HEALING
1				
2				
3				
4				
5				
6				
7				
14				

GROUP B – SOFRAMYCIN DRESSING

DAY	PAIN DURING DRESSING CHANGE	COMFORT CHARACTERISTICS	FREQUENCY OF DRESSING CHANGE	WOUND HEALING
1				
2				
3				
4				
5				
6				
7				
14				

Pre operative assessment:

Name :

Age :

Sex:

Date of admission:

Medical history:

Dental history:

Local examination:

- Inspection and palpation of the wound followed by a detailed examination of the underlying soft tissue
- Presence of any infection, foreign body in wound
- Size of the wound

Diagnosis:

Dressing method:

Follow up details – after 14 days

- Date :
- Presence of any Infections :
- Presence of any Discharge through wound:

DATA ANALYSIS METHOD

STATISTICAL TEST:

- Mann-Whitney U test
- Wilcoxon matched pairs test
- Fishers exact test

Figure 1: ARMAMENTARIUM

Figure 2: MANUKA HONEY

Figure 3: SOFRAMYCIN

Figure 4: APPLICATION OF MANUKA HONEY ON ABRASIONS OVER NOSE RIGHT MALAR AND FOREHEAD REGION

Figure 5: DRESSING IN SITU

MANUKA HONEY GROUP

CASE 1

Figure 6: ABRASION OVER RIGHT CHEECK AND FOREHEAD REGION DAY 1

Figure 7: FOLLOW UP DAY 7

Figure 8: FOLLOW UP DAY 14

CASE -2

Figure 9 : ABRASION OVER BILATERAL CHEECK REGION DAY 1

Figure 10 : FOLLOW UP DAY 7

Figure 11 : FOLLOW UP DAY 14

SOFRAMYCIN GROUP

CASE 1

Figure 12 : ABRASION OVER RIGHT SIDE OF FACE AND NOSE DAY 1

Figure 13 : FOLLOW UP DAY 7

Figure 14 : FOLLOW UP DAY 14

CASE 2

Figure 15 : ABRASION OVER RIGHT MALAR REGION DAY 1

Figure 16 : FOLLOW UP DAY 7

Figure 17 : FOLLOW UP DAY 14

RESULTS

DEMOGRAPHIC DATA

Table 1: Comparison of Honey group and Soframycin group according to age

Age group	Honey group	%	Soframycin group	%	Total	%
20-29yrs	3	9.68	3	9.68	6	9.68
30-39yrs	12	38.71	10	32.26	22	35.48
40-49yrs	12	38.71	13	41.94	25	40.32
50+yrs	4	12.90	5	16.13	9	14.52
Total	31	100.00	31	100.00	62	100.00
Mean age	39.61		40.71		40.16	
SD age	8.04		8.49		8.22	
Chi-square=0.3330, p=0.9540						

Graph 1: Comparison of Honey group and Soframycin group according to age

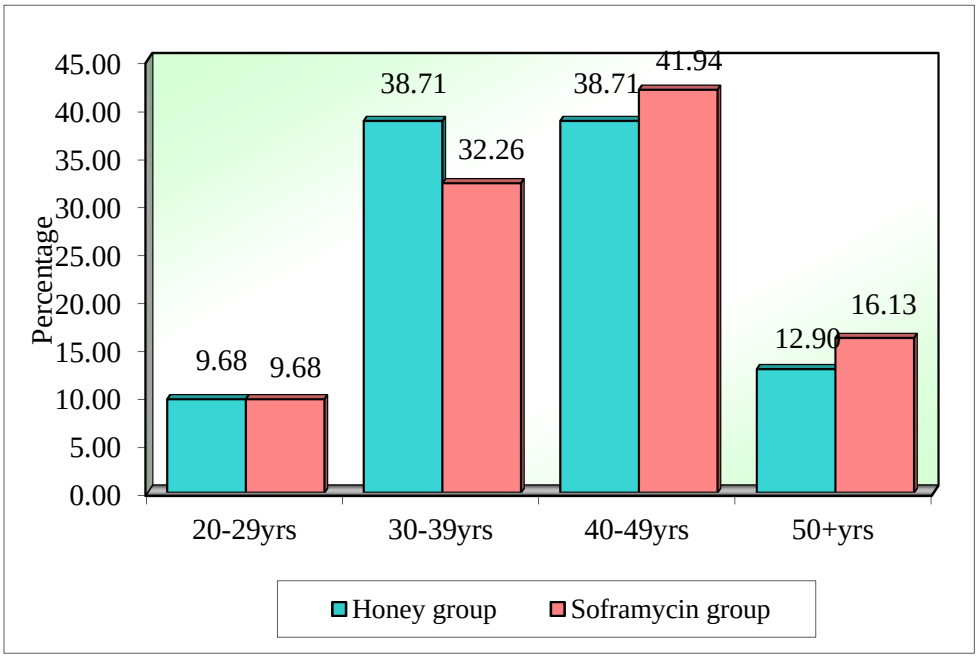


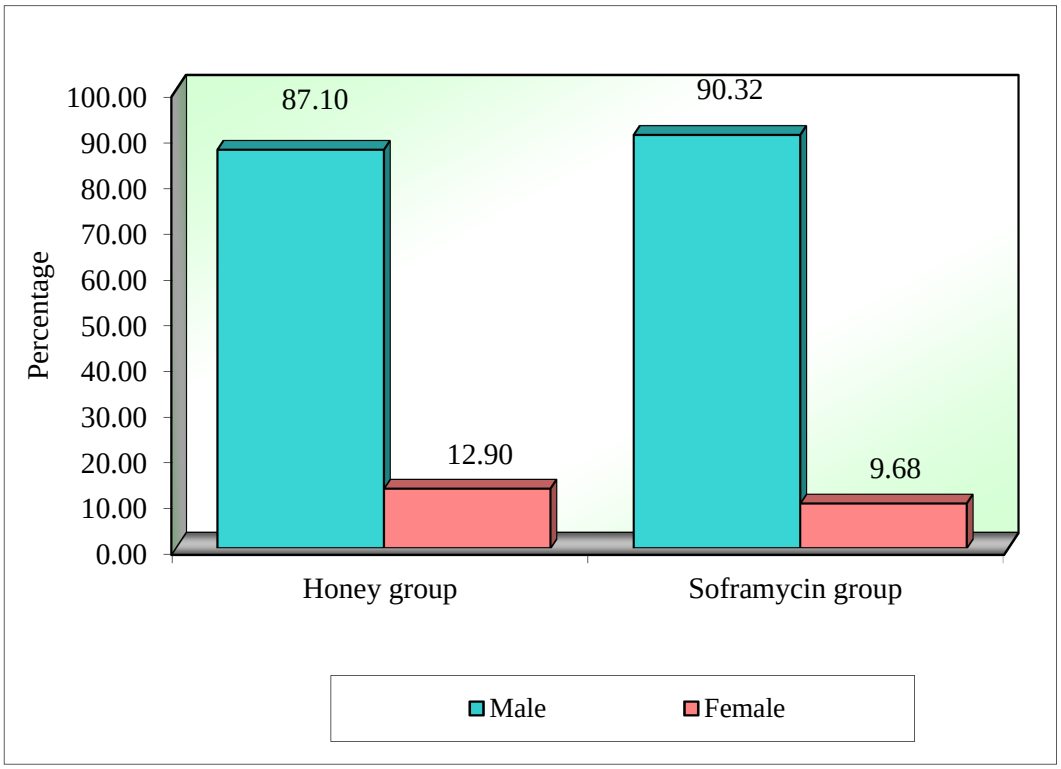
Table 2: Comparison of Honey group and Soframycin group according to gender

Gender	Honey group	%	Soframycin group	%	Total	%
Male	27	87.10	28	90.32	55	88.71
Female	4	12.90	3	9.68	7	11.29
Total	31	100.00	31	100.00	62	100.00
Chi-square=0.1610, p=0.6880						

In this single blinded, randomized control trial a total of 62 subjects (56 males and 6 females) were included. Twenty-seven males and four females were present in the study group. Twenty-eight males and three females constituted the control group. Majority of the patients that is 24 patients in the experiment group were between 30 to 49 years old. The remaining seven were either between 20 to 29 years old or above 50. Control group has 23 patients between 30 to 49 years, three from 20 to 29 years and four above 50.

The above table compares the demographic profile of patients included in both the groups.

Graph 2: Comparison of Honey group and Soframycin group according to gender



PAIN

Table 3: Comparison of Honey group and Soframycin group with NRS pain scores at different treatment time points by Mann-Whitney U test

Times	Honey group				Soframycin group				U-value	Z-value	P-value
	Mean	SD	Median	IQR	Mean	SD	Median	IQR			
Day 1	1.1	0.8	1.0	1.0	2.5	1.0	2.0	0.5	137.50	-4.8219	0.0001*
Day 2	0.8	0.8	1.0	0.5	2.0	0.9	2.0	1.0	150.00	-4.6459	0.0001*
Day 3	0.6	0.7	1.0	0.5	2.0	0.9	2.0	1.0	134.00	-4.8712	0.0001*
Day 4	0.5	0.6	0.0	0.5	1.7	0.9	2.0	0.5	131.50	-4.9064	0.0001*
Day 5	0.3	0.6	0.0	0.5	1.6	0.9	2.0	0.5	126.50	-4.9768	0.0001*
Day 6	0.2	0.4	0.0	0.0	1.5	1.0	1.0	0.5	133.50	-4.8782	0.0001*
Day 7	0.2	0.4	0.0	0.0	1.3	1.0	1.0	0.5	163.00	-4.4629	0.0001*

*p<0.05

Graph 3: Comparison of Honey group and Soframycin group with NRS pain scores at different treatment time points

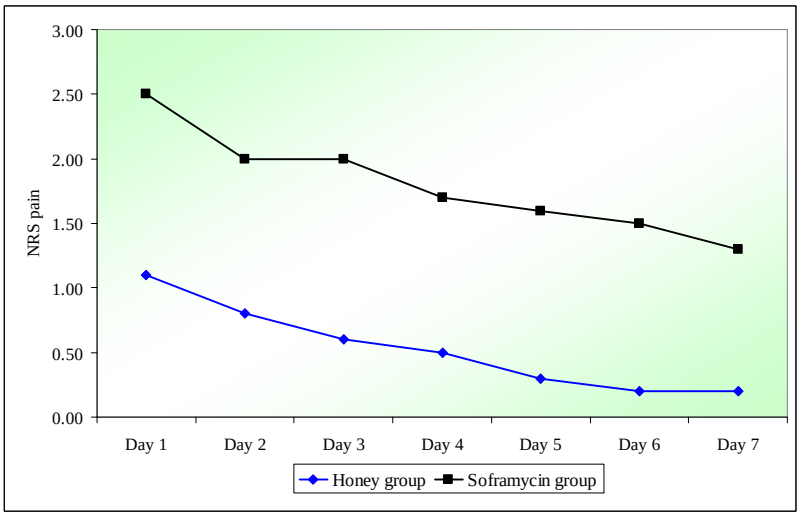


Table 4: Comparison of different treatment time points with NRS pain scores in Honey group and Soframycin group by Wilcoxon matched pairs test

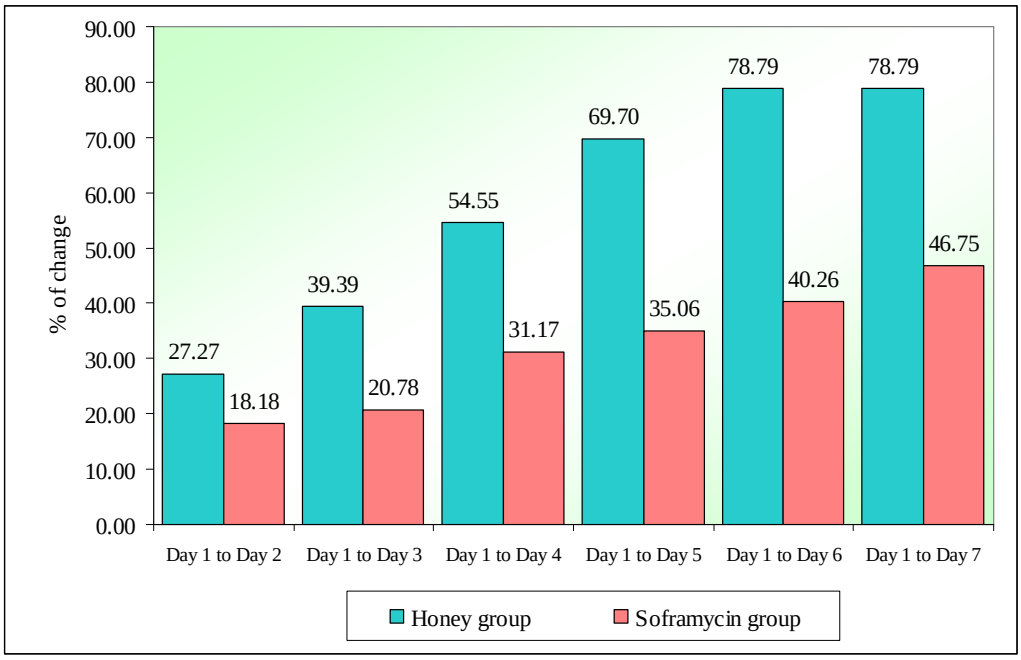
Groups	Changes from	Mean Diff.	% of change	Z-value	P-value	Friedman test	p-value
Honey group	Day 1 to Day 2	0.29	27.27	2.6656	0.0077*	75.0523	0.0001*
	Day 1 to Day 3	0.42	39.39	2.8563	0.0043*		
	Day 1 to Day 4	0.58	54.55	3.3534	0.0008*		
	Day 1 to Day 5	0.74	69.70	3.5212	0.0004*		
	Day 1 to Day 6	0.84	78.79	3.9199	0.0001*		
	Day 1 to Day 7	0.84	78.79	3.9199	0.0001*		
Soframycin group	Day 1 to Day 2	0.45	18.18	3.0594	0.0022*	89.1929	0.0001*
	Day 1 to Day 3	0.52	20.78	3.0386	0.0024*		
	Day 1 to Day 4	0.77	31.17	3.8230	0.0001*		
	Day 1 to Day 5	0.87	35.06	4.0145	0.0001*		
	Day 1 to Day 6	1.00	40.26	4.1069	0.0001*		
	Day 1 to Day 7	1.16	46.75	4.3724	0.0001*		

*$p<0.05$

Pain score between both the groups were compared using NRS pain score at various time frames: from day one to day seven using Mann-Whitney U test. A statistical difference in pain was found between study and control group.

It was observed that mild to no pain was seen in study group as compared to controls in which patients experience mild to moderate pain. So, we can conclude that minimal pain during dressing change in manuka honey group.

Graph 4: Comparison of % changes from day 1 to other treatment time points with NRS pain scores in Honey group and Soframycin group

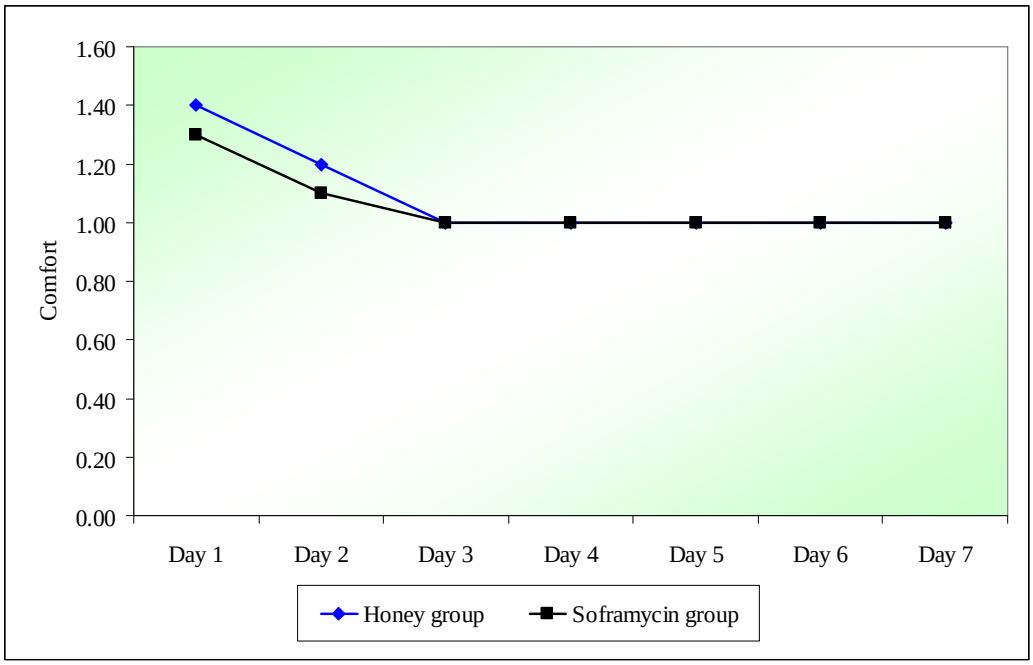


COMFORT

Table 5: Comparison of Honey group and Soframycin group with COMFORT scores at different treatment time points by Mann-Whitney U test

Times	Honey group				Soframycin group				U-value	Z-value	P-value
	Mean	SD	Median	IQR	Mean	SD	Median	IQR			
Day 1	1.4	0.5	1.0	0.5	1.3	0.5	1.0	0.5	434.00	0.6476	0.5172
Day 2	1.2	0.4	1.0	0.0	1.1	0.3	1.0	0.0	434.00	0.6476	0.5172
Day 3	1.0	0.2	1.0	0.0	1.0	0.2	1.0	0.0	480.50	-0.0070	0.9944
Day 4	1.0	0.0	1.0	0.0	1.0	0.0	1.0	0.0	480.50	-0.0070	0.9944
Day 5	1.0	0.0	1.0	0.0	1.0	0.0	1.0	0.0	480.50	-0.0070	0.9944
Day 6	1.0	0.0	1.0	0.0	1.0	0.0	1.0	0.0	480.50	-0.0070	0.9944
Day 7	1.0	0.0	1.0	0.0	1.0	0.0	1.0	0.0	480.50	-0.0070	0.9944

Graph 5: Comparison of Honey group and Soframycin group with COMFORT scores at different treatment time points



The comfort scores were measured from day 1 to day 7 during the application of different dressing material that is manuka honey and soframycin.

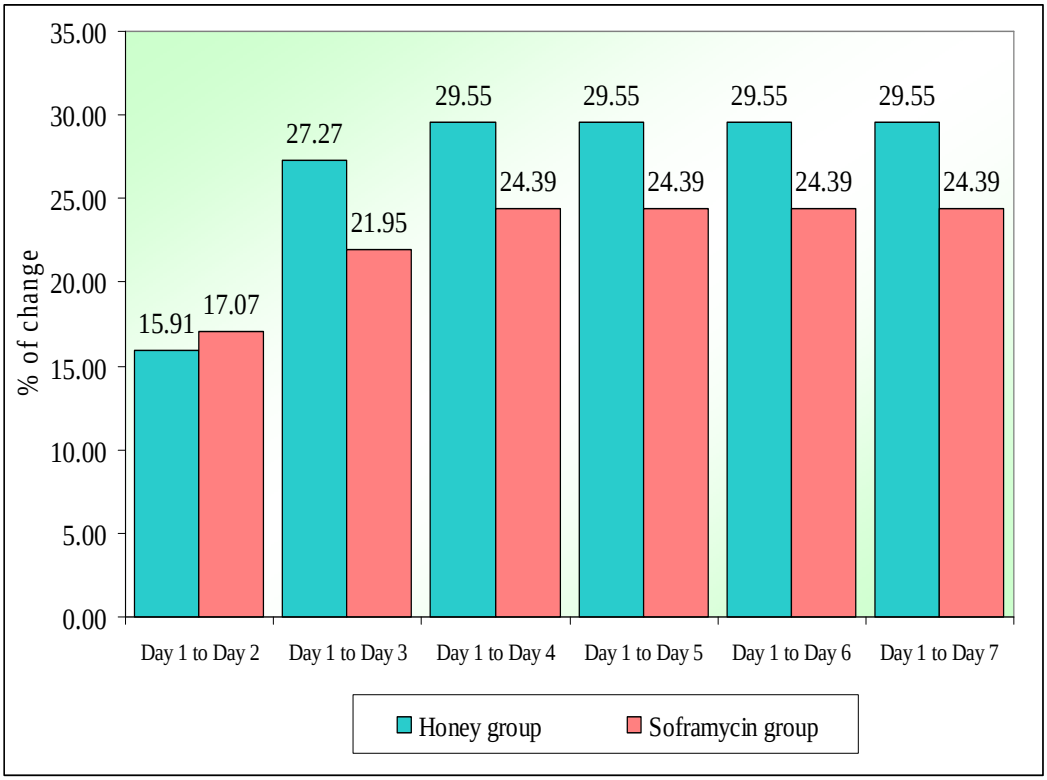
The above graph shows the mean value of both the groups from day 3 to day 7 are similar. The experiment group has slightly lesser values but no statistical significant difference was seen. It can be summarized that both dressings are comfortable to the patients.

Table 6: Comparison of different treatment time points with COMFORT scores in Honey group and Soframycin group by Wilcoxon matched pairs test

Groups	Changes from	Mean Diff.	% of change	Z-value	P-value	Friedman test	p-value
Honey group	Day 1 to Day 2	0.23	15.91	2.0732	0.0382*	58.9811	0.0001*
	Day 1 to Day 3	0.39	27.27	3.0594	0.0022*		
	Day 1 to Day 4	0.42	29.55	3.1798	0.0015*		
	Day 1 to Day 5	0.42	29.55	3.1798	0.0015*		
	Day 1 to Day 6	0.42	29.55	3.1798	0.0015*		
	Day 1 to Day 7	0.42	29.55	3.1798	0.0015*		
Soframycin group	Day 1 to Day 2	0.23	17.07	2.3664	0.0180*	46.5405	0.0001*
	Day 1 to Day 3	0.29	21.95	2.6656	0.0077*		
	Day 1 to Day 4	0.32	24.39	2.8031	0.0051*		
	Day 1 to Day 5	0.32	24.39	2.8031	0.0051*		
	Day 1 to Day 6	0.32	24.39	2.8031	0.0051*		
	Day 1 to Day 7	0.32	24.39	2.8031	0.0051*		

*$p<0.05$

Table 6: Comparison of % changes from day 1 to other treatment time points with COMFORT scores in Honey group and Soframycin group



WOUND HEALING

Table 7: Comparison of Honey group and Soframycin group with Wound Healing scores at different treatment time points by Mann-Whitney U test

Times	Honey group				Soframycin group				U-value	Z-value	P-value
	Mean	SD	Median	IQR	Mean	SD	Median	IQR			
Day 1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	480.50	0.0000	1.0000
Day 2	0.3	0.5	0.0	0.5	0.5	0.5	1.0	0.5	372.00	-1.5205	0.1284
Day 3	1.0	0.2	1.0	0.0	1.1	0.4	1.0	0.0	449.00	-0.4364	0.6625
Day 4	1.4	0.5	1.0	0.5	1.7	0.5	2.0	0.5	335.50	-2.0344	0.0419*
Day 5	2.1	0.4	2.0	0.0	2.2	0.6	2.0	0.5	418.50	-0.8658	0.3866
Day 6	2.3	0.5	2.0	0.0	2.7	0.7	3.0	0.5	305.50	-2.4567	0.0140*
Day 7	3.3	0.4	3.0	0.5	3.3	0.7	3.0	0.5	449.00	-0.4364	0.6625
Day 14	4.3	0.5	4.0	0.5	4.6	0.6	5.0	0.5	351.50	-1.8091	0.0704

*$p<0.05$

Graph 7: Comparison of Honey group and Soframycin group with WOUND HEALING scores at different treatment time points

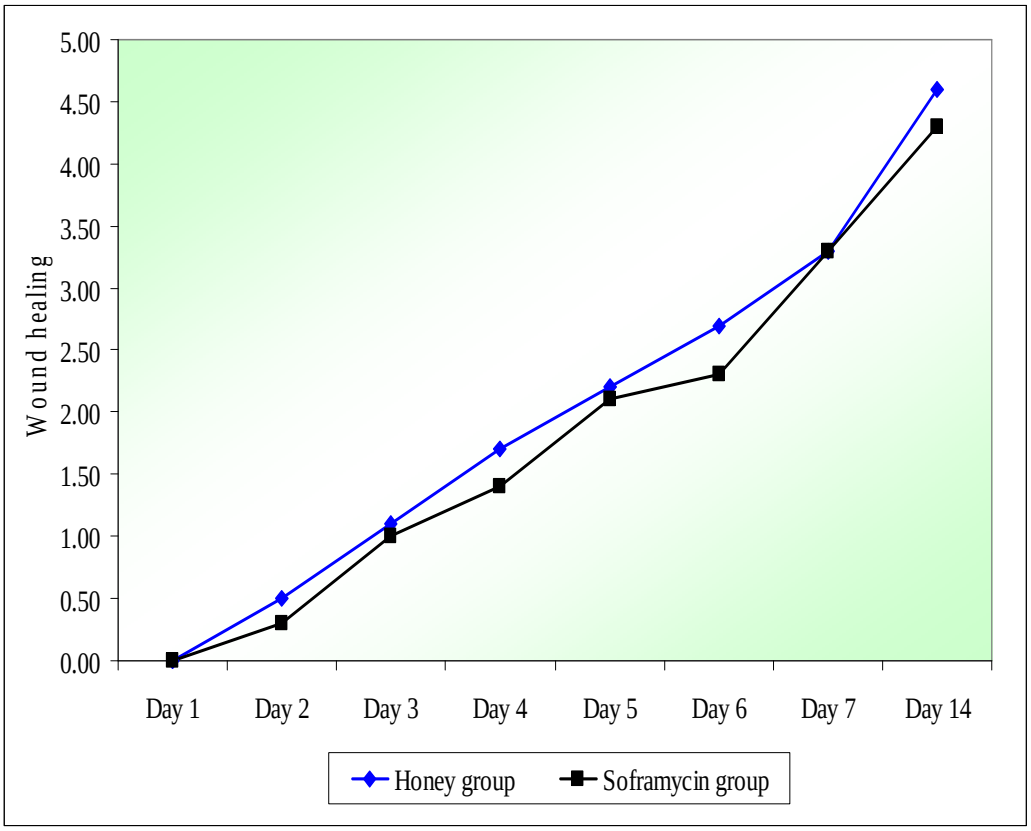


Table 8: Comparison of different treatment time points with WOUND HEALING scores in Honey group and Soframycin group by Wilcoxon matched pairs test

Groups	Changes from	Mean Diff.	% of change	Z-value	P-value	Friedman test	p-value
Honey group	Day 2 to Day 3	0.71	220.00	4.1069	0.0001*	210.585	0.0001*
	Day 2 to Day 4	1.03	320.00	4.7821	0.0001*		
	Day 2 to Day 5	1.74	540.00	4.8599	0.0001*		
	Day 2 to Day 6	1.94	600.00	4.8599	0.0001*		
	Day 2 to Day 7	2.94	910.00	4.8599	0.0001*		
	Day 2 to Day 14	4.00	1240.00	4.8599	0.0001*		
Soframycin group	Day 2 to Day 3	0.55	100.00	3.6214	0.0003*	208.221	0.0001*
	Day 2 to Day 4	1.13	205.88	4.6226	0.0001*		
	Day 2 to Day 5	1.65	300.00	4.8599	0.0001*		
	Day 2 to Day 6	2.13	388.24	4.8599	0.0001*		
	Day 2 to Day 7	2.74	500.00	4.8599	0.0001*		
	Day 2 to Day 14	4.03	735.29	4.8599	0.0001*		

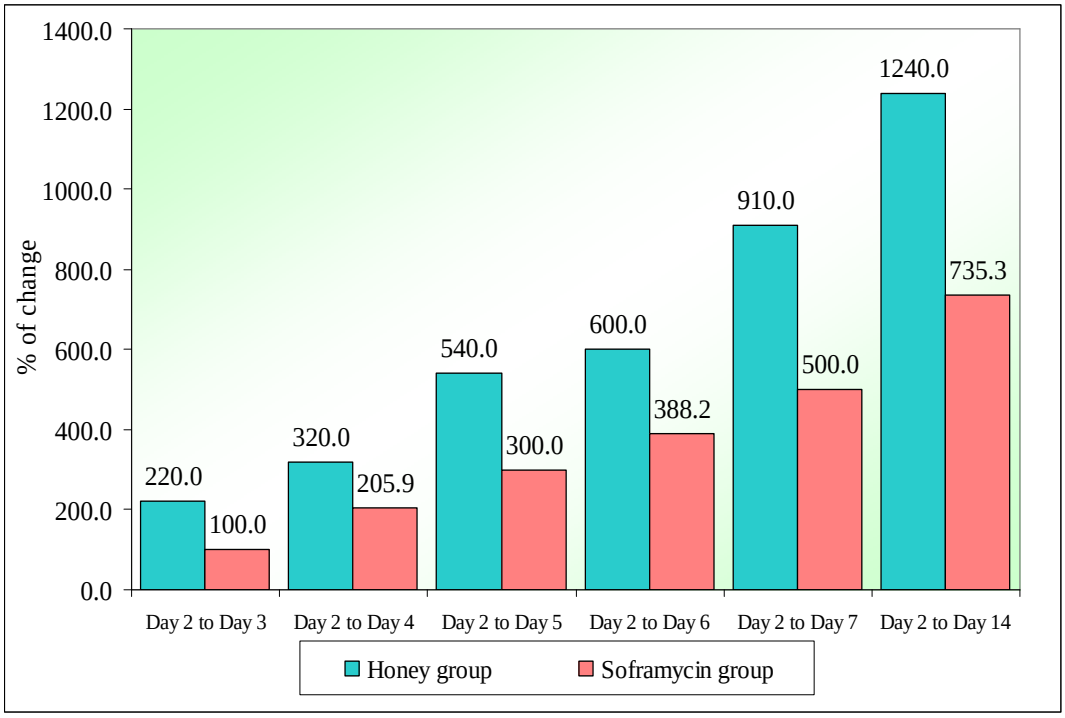
*$p<0.05$

The table shows wound healing between both study and control group at different time period that is from day 1 to day 7 and on day 14th.

Wound healing was significantly seen in both the groups from day 2 - day 7. At the end of day 7 more higher scores shows faster wound healing with respect to study group.

Statistical significant difference seen within subjects of study group on day 14 shows faster and effective wound healing than control group.

Graph 8: Comparison of changes in different treatment time points with WOUND HEALING scores in Honey group and Soframycin group



FREQUENCY OF DRESSING CHANGE

Table 9: Comparison of Honey group and Soframycin group with FREQUENCY OF DRESSING CHANGE at different treatment time points by Fishers exact test

Times	Honey group		Soframycin group		P-value
	Once	%	Once	%	
Day 1	1	3.23	0	0.00	1.0000
Day 2	1	3.23	0	0.00	1.0000
Day 3	0	0.00	0	0.00	1.0000
Day 4	0	0.00	0	0.00	1.0000
Day 5	0	0.00	0	0.00	1.0000
Day 6	0	0.00	0	0.00	1.0000
Day 7	0	0.00	0	0.00	1.0000

The table depicts the distribution of subjects based on wound bed status. For both the dressing wound bed is moist most of times, mostly in case of study group but that is not statistically significant.

We can summarize that frequency of dressing change is similar in both the groups.

DISCUSSION

We now speak of the wounds of the face, if but for this, that when they are carelessly handled, they leave deformed scars in the most special and beautiful part of the body.

Ambrose Pare (1587)

The skin covers the entire body. It is the first line of defence against various insults like physical, chemical, mechanical, bacterial etc. It is the barrier membrane which separates our internal environment from the outside.[15] When there is a deficit in the skin it is very important to repair it so that the skin can return to normal functions like defence, regulation of body temperature, providing sensation and aesthetics.

The face is the most distinctive feature of an individual, as well as most displayed part of the body, making it especially prone to traumatic injuries.

Trauma to the head and face also elicits a psychological response from the patients. Hence the management of facial trauma is challenging as patients demand or expect the function and aesthetics to be restored back to normal.

The primary cause of facial trauma is a motor vehicle accident. 70% of all car accidents result in head and face injuries. [6] The incidence of road traffic accidents and injuries to the maxillofacial skeleton increased in India as a result of high-speed vehicles and poor road conditions.

Facial trauma includes hard and soft tissue injuries. Soft tissue injuries can range from a simple contusion or abrasion to more serious wounds involving the deeper anatomical structures.[16]

According to type of insult, soft tissue injuries are categorized as contusion, laceration, abrasion, avulsion, punctured wound, or wounds associated with thermal or blast damage.[16]

Abrasion is a type of superficial facial injury that results in the removal of the epithelial layer and the papillary layer of the dermis, leaving the reticular layer of the dermis exposed and raw.[17]

The most frequent soft tissue injuries in the head and neck area are abrasions. Abrasions have long been thought of as minor wounds that heal on their own without the need for medical attention. There is little literature on acute wound examination and dressing methods to guide clinical decisions.[18][19] Even today, the majority of medical personnel do not cover abrasion.

As a result of facial fractures these soft tissue injuries should be treated during the hospital stay. Even abrasions require primary management and dressing to promote faster healing process and moist environment.

The primary management consists of thorough irrigation and wound debridement to remove any foreign body, dirt, or any tar, and placement of non-adherent dressing material. During the re-epithelialization process, the wound should not be dried out.[17] Healing is the mechanism by which the body maintains normal anatomical structure and restores functions.

Wound dressings reduce the risk of infection and create optimal conditions for healing.[20] Dressings are classified based on their mode of action and composition.[21] The various dressings used are : alginates, knitted gauze, hydrofibers, hydrating gels and solids, hydrocolloids, transparent adhesive dressing, non-adherent gauze.[22]

Gauze dressings which are most incorrectly used cause limited absorption and require frequent dressing change.[22] It can slow down the process of wound healing by drying out and adhering to the wound surface, resulting in traumatic removal when dressings are changed resulting in increased pain for patients.[21]

An ideal dressing material should decrease loss of electrolytes, proteins and fluids from the wound, in addition to accelerate wound healing and also help to reduce pain and infection. The main purpose is to promote moist wound healing process.[23]

As a result, an ideal dressing material is one that can aid in reduction of microbial loads, management of wound exudate, and the maintaining of a moist and protected wound surface.[22] It should be non-toxic, non-allergenic, and should be easily removed without causing trauma[21] and discomfort.

However, the dressing change is thought to be the most painful time for the patients. Traditional gauze dressings tends to dry out and adhere to the wound surface, causing trauma to the wound surface and eventually delaying the wound healing process.[21] Recently alternative dressing materials have been used to reduce the pain during dressing change which includes honey, hydrocolloids, collagen etc.[24][25]

The literature shows us studies where honey has been used as a dressing material. **In 2008 Gethin**[26] led a prospective randomised control trial.

108 patients with venous leg ulcer were compared for wound healing and antimicrobial properties of manuka honey and hydrogel. Culture swabs were taken before and after cleansing of wound in all patients. Patients were given treatment for four weeks and then followed up at 12 week to determine the wound healing and bacterial colonization. In conclusion, minimal pain during dressing change was seen in patients with honey dressing.

In our study, we discovered that manuka honey dressing caused less pain than soframycin group during dressing change. Since honey dressing is less adherent due to the release of hydrogen peroxide, pain was minimal. In contrast, the soframycin gauze dressing was completely adherent. Pain during change of dressing was less in manuka honey group than in soframycin and also had a significant value ($p<0.0001$). Both the materials were equally comfortable and easy to handle.

Review of literature revealed limited studies in which honey was used as an alternate dressing material. In addition, various researchers have experimented with a variety of materials in order to determine the most effective dressing for abrasion.

Dunford[27] led a multicentre study in **2015** to evaluate the efficacy of manuka honey in non-healing venous ulcers. This study was conducted to evaluate healing of wound, frequency of dressing change, patient comfort, management of exudate, reduction in pain and odour. Effective wound healing, patient comfort, reduction in pain and frequency of dressing change seen in patients with manuka honey dressing. Our conclusions were parallel to that of Dunford. The results of our study showed that honey dressings were less painful and was in accordance with that of above studies.

Taking into account the findings of **Sharon Bateman et al** [28] in **2007** to evaluate the use of manuka honey on surgical wounds post-CABG. In this study in all the patients the saphenous vein was harvested from leg for use as a graft. They use manuka honey as a primary dressing material for all the wounds at graft site. Almost in all patients, wound healing occurred within 4 weeks. Pain at the wound site was initially assessed to be mild but was reported to be absent on completion of the evaluation. Patient comfort also recorded as high. Both exudate levels and malodour decreased with time. In our study manuka honey and soframycin dressings were used for facial abrasions and have observed a correlation between our findings and those of Dr. Sharon.

A study also performed by **Val Robson** in **2009**[10] to compare the antibacterial property of manuka honey with standard therapy in wound care in 105 patients. They stated statistically significant reduction in wound healing time in manuka honey group than in conventional dressing. In our study also manuka honey dressing shows better wound healing as compared to conventional dressing. Our findings are similar to those of Val Robson.

In another study by **Alexandros** in **2014**[29] comparison of manuka honey tulle dressing with conventional dressings – saline soaked gauze was done to evaluate the bacterial load and effective healing of wound in diabetic neuropathic foot ulcers. Their results showed that there was decrease in bacterial load in case of manuka honey tulle dressing and effective wound healing as compared to conventional group.

According to **Molan** in **2001**, [30]the antibacterial property of manuka honey is due either the sugar molecules within honey hold the water molecules, providing less water to bacteria therefore reducing their growth or due to the release of hydrogen

peroxide even if the wound is diluted by exudate, the antimicrobial properties of the wound are sustained.

The hydrogen peroxide is released at a 1000-fold lower concentration than the traditional 3% hydrogen peroxide solution, which was previously used as a debriding agent, eliminating the possibility of any cellular damage.[7]

In 2008, Georgina Gethin[31] study shows that patients treated with manuka honey demonstrated significantly lower ph levels and reduction in wound size in non-healing venous ulcers.

Tanisha Smith et al, conducted research on Recalcitrant Venous Leg Wounds in **2009**[32] to compare manuka honey with three different treatment modalities. They concluded that osmotic action of manuka honey, which accounts for withdrawing moisture out of the local wound surface, creating a moisture gradient, and resulting in autolytic and mechanical debridement of nonviable tissues and debris, will hasten wound healing.

All of these above studies suggest that using a non-adherent dressing material for abrasions to keep the area moist helps to reduces time of healing of wound and pain during dressing change.

62 patients with facial soft tissue injuries who reported to the Emergency department of KLE's Dr Prabhakar Kore hospital Belgaum, Karnataka, were included in our study. Patients were divided into:

GROUP A (31 patients) - Manuka honey dressing

GROUP B (31 patients) - Conventional soframycin dressing.

Gamma irradiated manuka honey were used in Group A patients.

Daily dressings were changed for seven days and following parameters were observed:

1. Pain on dressing change.
2. Comfort characteristics.
3. Wound Healing.
4. Frequency of dressing change.

In patients with manuka honey dressing was used, pain score on dressing change ranged between score 0-2. In patients with soframycin dressing, pain score ranged between 0-4 which has statistically significant value ($p<0.001$).

Both manuka honey and soframycin dressing material were equally comfortable. Status of the wound bed was moist at every dressing change for both manuka honey and soframycin dressing material.

Based on our findings and the existing literature, we conclude that manuka dressing when applied to facial abrasions, is a good dressing material. It possesses all of the characteristics of an ideal dressing material and causes minimal pain during removal of dressing. Its properties are identical to nonadherent dressing materials in every way except for mild pain during dressing change in some cases.

In conclusion, manuka honey dressing can be used as an alternative dressing material. It is painless and aids in maintaining the moist wound environment, which speeds up the wound healing process. As a result, we highly suggest use of manuka honey dressing to the facial wounds.

SUMMARY AND CONCLUSION

Our study was conducted to compare the efficacy of manuka honey dressing as an alternative to soframycin dressing in facial abrasions. Because of its non-adherent property, manuka honey dressing is a good alternative to conventional dressing materials.

Manuka honey causes mild pain during dressing change. In our study patients with manuka honey experienced mild pain in initial days of dressing change due to its smooth and completely non-adhering nature. In case of soframycin dressing pain was there during dressing change as it adheres to the wound surface.

Manuka honey delivers moist wound environment which not only fasten the wound healing process but also decrease the bacterial load which lead to effective wound healing. Whereas, in case of soframycin dressing it adhere, to wound surface, affect the epithelization of wound bed and lead to slow down the wound healing process.

Therefore, both manuka honey and soframycin can be used as a dressing material for facial abrasion. We suggest the use of manuka honey dressing in facial abrasions.

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ANNEXURE - I - CONSENT FORM

VK INSTITUTE OF DENTAL SCIENCES,

DEPARTMENT OF ORAL &MAXILLOFACIAL SURGERY

" EVALUATION OF MANUKA HONEY (leptospermum scoparium) AS AN ALTERNATIVE WOUND DRESSING MATERIAL IN COMPARISION TO CONVENTIONAL SOFRAMYCIN WITH GAUZE DRESSING ON FACIAL ABRASIONS: A RANDOMIZED CLINICAL CONTROLLED TRIAL ''

Time : a.m / p.m

I, _____ aged_____ years have been informed about my involvement in the study.

- **I agree to give my personal details like Name Age, Sex, Address, Past dental and any other details required for the study to the best of my knowledge.**
- **I will cooperate with the surgeon for examination and also for various investigations.**
- **I permit the operator to utilize the information given by me and the results obtained from this study for presentation and publication.**
- **I permit the surgeon to take my photographs to utilize it for the study and presentation purpose.**
- **I am participating in this study with my own wish and will and the surgeon has explained the nature and the effect of the procedure in my vernacular language.**
- **I have read and understood the above information given by surgeon about the study.**

Name : **Doctor:**

Date :

ANNEXURE - II - PROFORMA

PREOPERATIVE RECORDS

Name : **Age :**

Sex: **Date of admission:**

Medical History :

Dental history :

GENERAL EXAMINATION :

- **GCS –**
- **Vitals :**
    1. **Pulse :**
    2. **BP :**
    3. **Temperature :**
    4. **Respiration :**
- **Gait –**
- **Height –**
- **Weight -**
- **Built -**

LOCAL EXAMINATION:

- **Site –**
- **Size –**
- **Wound bed –**
    1. **Granulating**
    2. **Sloughy**
    3. **Necrotic**
- **Exudate –**
    1. **Serous**
    2. **Hemoserous**
    3. **Sanguinous**
    4. **Purulent**

- **Infection –**
- **Pain –**
- **Surrounding skin -**

DIAGNOSIS :

DRESSING METHOD:

FOLLOW UP DETAILS –

S.NO	NAME	AGE/SEX	PAIN DURING DRESSING CHANGE	STATUS OF WOUND BED	COMFORT CHARACTERISTICS	WOUND HEEALING

AFTER 14 DAYS :

- **Date :**
- **Photographs :**
- **Presence of any Infections :**
- **Presence of any Discharge through wound:**

ANNEXURE - III

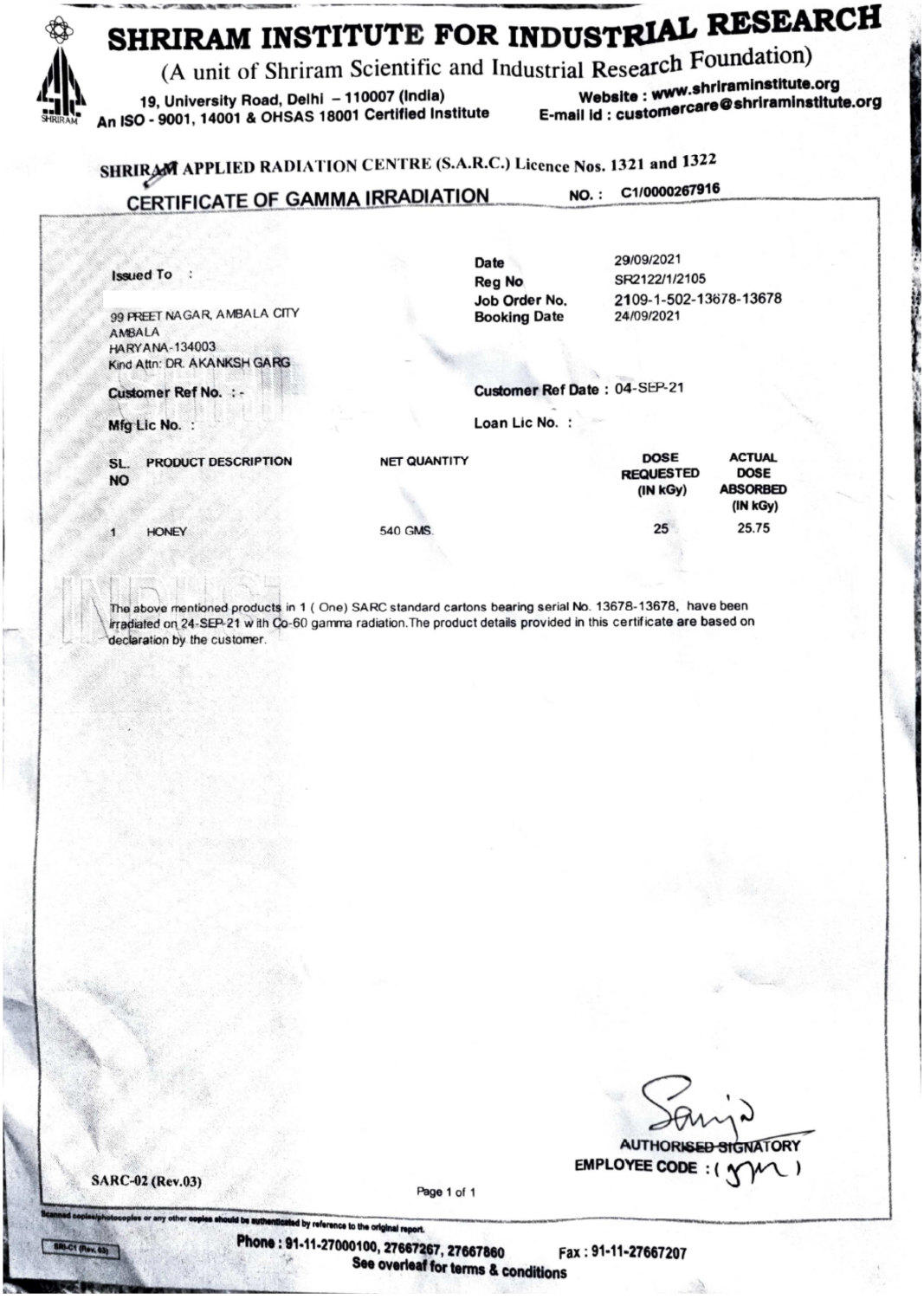
TABLE 1 – MANUKA HONEY DRESSING

S.NO	NAME	AGE/SEX	PAIN DURING DRESSING CHANGE	FREQUENCY OF DRESSING CHANGE	COMFORT CHARACTERISTICS	WOUND HEALING
1	Rahul	20 yrs/ Male	1	0	1	5
2	Ajit	32 yrs/ Male	0	0	1	4
3	Prithviraj	31 yrs/ Male	0	0	1	5
4	Ashwini	35 yrs/ Female	0	0	1	5
5	Laxman	30 yrs/ Male	0	0	1	4
6	Umesh	40 yrs/ Male	0	0	1	4
7	Basavraj	44 yrs/ Male	0	0	1	5
8	Abhishek	38 yrs/ Male	0	0	1	3
9	Sidappa	50 yrs/ Male	0	0	1	5
10	Pandurang	46 yrs/ Male	0	0	1	5
11	Bassava	39 yrs/ Male	1	0	1	4
12	Nikhil	29 yrs/ Male	1	0	1	5
13	Sateppa	44 yrs/ Male	0	0	1	5
14	Praveen	42 yrs/ Male	0	0	1	4
15	Nagraj	46 yrs/ Male	1	0	1	4
16	Nandini	33 yrs/ Female	0	0	1	5
17	Ankit	27 yrs/ Male	1	0	1	4
18	Sumati	38 yrs/ Female	0	0	1	5
19	Bassapa	48 yrs/ Male	0	0	1	5
20	Babu	44 yrs/ Male	1	0	1	4
21	Shantavva	39 yrs/ Female	0	0	1	5
22	Jahoor	35 yrs/ Male	0	0	1	4
23	Irappa	46 yrs/ Male	0	0	1	5
24	Santosh	37 yrs/ Male	0	0	1	5
25	Veeresh	31 yrs/Male	1	0	1	5
26	Hanumanth	55 yrs/Male	0	0	1	4
27	Ashish	42 yrs/Male	0	0	1	5
28	Sangappa	51 yrs/Male	0	0	1	5
29	Vithal	41 yrs/Male	0	0	1	5
30	Prashant	44 yrs/Male	0	0	1	4
31	Anappa	51 yrs/Male	0	0	1	5

TABLE 2 – SOFRAMYCIN DRESSING

S.NO	NAME	AGE/SEX	PAIN DURING DRESSING CHANGE	FREQUENCY OF DRESSING CHANGE	COMFORT CHARACTERISTICS	WOUND HEALING
1	Mahesh	22 yrs/Male	3	0	1	4
2	Sidhagouda	54 yrs/ Male	3	0	1	4
3	Channagouda	30 yrs/ Male	2	0	1	5
4	Gauri	34 yrs/Female	0	0	1	4
5	Yallapa	31 yrs/ Male	2	0	1	4
6	Rudrappa	44 yrs/ Male	2	0	1	4
7	Suhas	42 yrs/ Male	2	0	1	4
8	Aditya	50 yrs/ Male	1	0	1	5
9	Vinayak	51 yrs/ Male	1	0	1	4
10	Pawan	43 yrs/ Male	0	0	1	4
11	Ballapa	37 yrs/ Male	4	0	1	5
12	Basavraj	27 yrs/ Male	1	0	1	4
13	Manohar	41 yrs/ Male	0	0	1	5
14	Mahantesh	45 yrs/ Male	1	0	1	5
15	Nandish	44 yrs/ Male	2	0	1	4
16	Gangavva	39 yrs/Female	1	0	1	5
17	Bhimrao	29 yrs/ Male	2	0	1	4
18	Sanjana	36 yrs/ Female	2	0	1	4
19	Rammana	38 yrs/ Male	3	0	1	5
20	Rangnath	45 yrs/ Male	1	0	1	4
21	Sunita	33 yrs/Female	0	0	1	4
22	Baburam	35 yrs/ Male	1	0	1	4
23	Udesh	49 yrs/ Male	1	0	1	5
24	Darigouda	27 yrs/ Male	0	0	1	4
25	Himanshu	36 yrs/ Male	1	0	1	4
26	Anand	45 yrs/ Male	1	0	1	5
27	Kallapa	52 yrs/ Male	0	0	1	4
28	Chanbassappa	41 yrs/ Male	1	0	1	4
29	Harish	31 yrs/ Male	1	0	1	4
30	Soumit	47 yrs/ Male	1	0	1	5
31	Ashok	48 yrs/ Male	1	0	1	4

ANNEXURE IV.a



SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH

(A unit of Shriram Scientific and Industrial Research Foundation)

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Website : www.shriraminstitute.org
E-mail id : customercare@shriraminstitute.org

SHRIRAM APPLIED RADIATION CENTRE (S.A.R.C.) Licence Nos. 1321 and 1322

CERTIFICATE OF GAMMA IRRADIATION NO. : C1/0000267916

Issued To :

99 PREET NAGAR, AMBALA CITY
AMBALA
HARYANA-134003
Kind Attn: DR. AKANKSH GARG

Date 29/09/2021
Reg No SR2122/1/2105
Job Order No. 2109-1-502-13678-13678
Booking Date 24/09/2021

Customer Ref No. : -

Customer Ref Date : 04-SEP-21

Mfg Lic No. :

Loan Lic No. :

SL. NO	PRODUCT DESCRIPTION	NET QUANTITY	DOSE REQUESTED (IN kGy)	ACTUAL DOSE ABSORBED (IN kGy)
1	HONEY	540 GMS.	25	25.75

The above mentioned products in 1 (One) SARC standard cartons bearing serial No. 13678-13678, have been irradiated on 24-SEP-21 with Co-60 gamma radiation.The product details provided in this certificate are based on declaration by the customer.

AUTHORISED SIGNATORY
EMPLOYEE CODE : ( )

SARC-02 (Rev.03)

Page 1 of 1

Scanned copies/photocopies or any other copies should be authenticated by reference to the original report.

SRI-C1 (Rev. 03)

Phone : 91-11-27000100, 27667267, 27667860 Fax : 91-11-27667207
See overleaf for terms & conditions

ANNEXURE IV.b

SHRI B M KANKANAWADI AYURVED MAHAVIDYALAYA
A Constituent Unit of KLE ACADEMY OF HIGHER EDUCATION & RESEARCH (DEEMED-TO-BE-UNIVERSITY)
(Re-Accredited 'A' Grade by NAAC (2nd Cycle) || Placed under Category 'A' by MHRD GoI)
CENTRAL RESEARCH FACILITY
(AYUSH Approved ASU Drug Testing Laboratory Lic. No.TL-8/2011)

Outward No:BMK/CRF/96/2021-22

Reference No:CRF/RM/109/2021-22 Registration Dt:-03/04/2021
Submitted by: Requisition no:---
Sample :Manuka Honey Batch No.:NA Part/Form:Syrupy
Product : Plant Sample Qty:30ml Report Date:24/04/2021
(* N/A - Not Available)

TEST REPORT

Form-50 [See Rule 160-D (f)]
(The Drugs & Cosmetic Act 1940 and the rules there under)

Organoleptic Characters :

TESTS	**RESULTS**
Colour	: Brown
Odour	: Pleasant & flavour
Taste	: Sweet

Physico Chemical Standards :

Test for Adulterant (cotton wick test)	: Negative
Furfural Test	: Negative
Fiehe's Test	: Negative

ANALYST

Shri B. M. Kankanwadi Ayurved Mahavidyalaya K.L.E. University CRF SHAHAPUR, BELGAUM

AUTHORISED SIGNATORY

ANNEXURE IV.c – BIOSTATISTICS CLEARANCE CERTIFICATE

KLE V.K. Institute of Dental Sciences
(A Constituent unit of KLE Academy of Higher Education & Research
Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Nehru Nagar, Belagavi-590 010 INDIA
Re-Accredited 'A' grade by NAAC (2nd Cycle) & Placed in Category 'A' by MHRD (GoI)
0831-2470362
FAX: 0831-2470640
Web: http://www.kledental-bgm.edu.in
E-mail: principal@kledental-bgm.edu.in

Biostatistics Clearance Certificate

This is to certify that the Biostatistics aspect of the Dissertation / Research work of **REG.NO. – IF0220001** **Graduate Student**, under the guidance of **ofessor, Department of Oral And Maxillofacial Surgery**, entitled **"Evaluation of Manuka Honey(Leptospermum Scoparium) in comparison to conventional Soframycin dressing in facial abrasions: Single Blinded Randomized Controlled Trial"** has been done under my guidance and considered satisfactory.

Place: Belagavi
Date: 24·12·2022

Name & Signature of Biostatistician

Dr. S. B. Javali
Sr. Asso. prof. in statistics
Dept of com. medicine
USM KLE IMP, Belagavi.

ANNEXURE IV.d– ETHICAL CLEARANCE CERTIFICATE

Research and Ethics Committee
KLE V K INSTITUTE OF DENTAL SCIENCES
KLE University
Accredited 'A' Grade by NAAC Placed in Category 'A' by MHRD (GoI)
Nehru Nagar, Belagavi - 590 010, Karnataka State
☎: 0831-2470362 Web: http://www.kledental-bgm.edu.in
FAX: 0831-2470640 E-mail:principal@kledental-bgm.edu.in

Sl. No. : 1470

CERTIFICATE

This is to Certify that the synopsis titled

Evaluation of Manuka honey (Leptospermum Scoparium) in Comparision to Conventional Sofranyecin dressing in facial abrasions: Single Blinded Randomised controlled Trial. *Submitted by*

Dr. REG.NO. – IF0220001 *P. G. Student / Staff, Guided by* _____ *from Department of* Oral & Maxillofacial Surgery *has been critically evaluated by committee members and granted ethical clearance to conduct the above mentioned study*

Date : 5/5/21

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

Chairman
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi