COMPARATIVE STUDY BETWEEN EFFECTIVENESS OF PLACENTAL DRESSING OVER CONVENTIONAL DRESSING IN FIRST AND SECOND DEGREE BURNS PATIENT-PROSPECTIVE STUDY

Submitted by

Dr FIROS KHAN A

DISSERTATION SUBMITTED TO

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RESEARCH CENTRE, VIJAYAPURA, KARNATAKA

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MASTER OF SURGERY

In

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UNDER THE GUIDENCE OF

DR. GIRISH K. KULLOLLI

ASSOCIATE PROFESSOR, DEPARTMENT OF GENERAL SURGERY

B. L. D. E(Deemed to be university)'s SHRI B.M. PATIL MEDICAL COLLEGE HOSPITAL & RESEARCH CENTRE, VIJAYAPURA, KARNATAKA
2020

B. L. D. E. (Deemed to be university)

SHRI B. M. PATIL MEDICAL COLLEGE HOSPITAL &

RESEARCH CENTRE, VIJAYAPURA.

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I hereby declare that this dissertation "**Comparative study between effectiveness of placental dressings over conventional dressings in patients with first and second degree burns patient- prospective study"** is a bonafide and genuine research work carried out by me under the guidance of **Dr. GIRISH K. KULLOLLI** Associate Professor, Department of General Surgery at BLDE (Deemed to be university), Shri B. M. Patil Medical College Hospital and Research Centre, Vijayapura.

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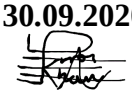

Dr. FIROS KHAN. A

B. L. D. E. (Deemed to be university)

SHRI B. M. PATIL MEDICAL COLLEGE HOSPITAL & RESEARCH CENTRE, VIJAYAPURA.

CERTIFICATE BY THE GUIDE

This is to certify that the dissertation entitled "**Comparative study between effectiveness of placental dressings over conventional dressings in patients with first and second degree burns patient- prospective study"** is a bonafide research work done by **Dr. FIROS KHAN. A** in partial fulfilment of the requirement for the degree of M.S in General Surgery.

Date: 30.09.2020
Place: Vijayapura

DR. GIRISH KULLOLLI
ASSOCIATE PROFESSOR
Department of General Surgery
B. L. D. E. (Deemed to be university)
Shri. B. M. Patil Medical College Hospital
& Research Centre, Vijayapura.

B. L. D. E. (Deemed to be university)

SHRI B. M. PATIL MEDICAL COLLEGE HOSPITAL & RESEARCH CENTRE, VIJAYAPURA.

ENDORSEMENT BY THE HOD AND PRINCIPAL

This is to certify that the dissertation entitled "**Comparative study between effectiveness of placental dressings over conventional dressings in patients with first and second degree burns patient- prospective study"** is a bonafide research work done by **Dr. FIROS KHAN. A** under the guidance of **Dr. GIRISH KULLOLLI**, ASSOCIATE PROFESSOR, Department of GENERAL SURGERY at BLDE (Deemed to be university) Shri. B. M. Patil Medical College Hospital and Research Centre, Vijayapura.

Dr.M B PATIL
Professor & Head,
Department of General Surgery
B. L. D. E. (Deemed to be university)
Shri. B. M. Patil Medical College
Hospital & Research centre
VIJAYAPURA.

Date: 30.09.2020
Place: Vijayapura

Dr. ARAVIND V PATIL
Principal,
B. L. D. E. (Deemed to be university)
Shri B.M. Patil Medical College
Hospital & Research Centre,
VIJAYAPURA.

Date: 30.09.2020
Place: Vijayapura

B. L. D. E. (Deemed to be university)

SHRI B. M. PATIL MEDICAL COLLEGE HOSPITAL & RESEARCH CENTRE, VIJAYAPURA.

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Date: 30.09.2020 **Dr. FIROS KHAN A**

Place: Vijayapura

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LIST OF ABBREVIATIONS

PDGF-AA-23	PLATELET DERIVED GROWTH FACTOR-AA 23
PDGF-B	PLATELET DERIVED GROWTH FACTOR BETA
EGF	EPITHELIAL GROWTH FACTOR
PLGF	PLACENTAL GROWTH FACTOR
TGF	TRANSFORMING GROWTH FACTOR
bFGF	BASIC FIBROBLAST GROWTH FACTOR
GCSF	GRANULOCYTE COLONY STIMULATING GROWTH FACTOR
IL	INTERLEUKINS
TMP	TISSUE METALLO PROTEINASES
HLA	HUMAN LEUCOCYTE ANTIGEN
TBSA	TOTAL BODY SURFACE AREA
ABA	AMERICAN BURN ASSOCIATION
GFR	GLOMERULAR FILTRATION RATE
AM	AMNIOTIC MEMBRANE
CD	CONVENTIONAL DRESSING

ABSTRACT

AIM

To compare between effectiveness of placental dressings over conventional dressings in patients with first and second degree burns.

METHODS

Prospective, comparative study.

In our study 70 cases were studied with 10-30%TBSA first and second degree burns allocated to 2 groups, 36 patients received amniotic membrane dressing prepared from human placenta (AM group) and 34 patients received conventional dressing with silversulphadiazine and cuticell (CD group) and assessed for compliance of patient on view of pain, number of dressing changes and time required for epithelialization and hospital stay.

RESULTS

In our study mean age in the Amniotic membrane dressing (AM) group is 18.9 years whereas in the Conventional dressing (CD) group is 30.9 years. Among the 36 patients in AM Group had 21 male (58.3%) and 15 female (47.1%) whereas among 34 patients in CD group had 16 males (47.1%) and 18 (52.9%) females and a mean percentage of TBSA first and second degree burns of 18.8% in AM and 21.1%

respectively. With a mean Pain score on day 1 post admission of 8.8 in AM group and 8.7 in CD, Pain score on Day 3 in the AM group was 3.5 and CD group is 7.6 with a significant p value. In AM group and CD group, Average total number of dressings used was 1.4 and 15.1, Mean time for epithelialisation is 14.5 days and 21.6 days, Mean hospital stay of 13.2 days and 19.7 days respectively with p value <0.001 which is highly significant.

CONCLUSION

With this it can be concluded that Amniotic membrane dressings in first and second degree burns are superior to conventional silversulphadiazine dressing in terms of less pain , practically a single application dressing , faster epithelialisation and thereby faster wound healing and a reduced hospital stay.

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1. INTRODUCTION

Burns are a prevalent and burdensome critical care problem. The priorities focus on stabilizing the patient, preventing infection, and optimizing functional recovery. Burn wounds are complex and can present unique difficulties that require late intervention or life-long rehabilitation. Burn injuries, especially thermal burns, are frequently observed in the hospital setting and requires much attention to prevent complications. Placental dressings as an alternative can be used for burn wound dressings. Amnion the innermost semi-transparent layer of the placenta contains innumerable cytokines, growth factors, and stem cells. Amniotic membrane is used nowadays in, burns, nerve regeneration, soft tissue reconstructive surgeries, ocular surgeries, and diabetic foot ulcers.

Placenta can be preserved in different ways like, cryopreservative liquid nitrogen, silver nitrate, in antibiotic solution for infection prevention. Amniotic membrane has several unique properties that contribute to the tissue's ability to promote healing and reepithelialisation. Amnion and amniotic membrane products contain growth factors such as platelet derived growth factor AA (PDGF-AA), PDGF-B, epidermal growth factor (EGF), placental growth factor (PLGF), transforming growth factor **α** (TGF-**α**), TGFB1, basic fibroblast growth factor (b-FGF), and granulocyte colony

stimulating factor (GCSF), all of which are implicated in healing and regeneration. Amnion also promotes angiogenesis. Amnion recruit stem cells to sites of healing and increase stem cell proliferation. Also contains anti-inflammatory cytokines such as IL-4, IL-6, IL-8, IL-10 and tissue inhibitor of metalloproteinase (TMP) 1, 2 and 4.Amniotic epithelial cells have been found to lack HLA-A,B, C, or DR antigens and beta-2 microglobulin and have also been shown to decrease cytokine synthesis and the inflammatory response in vitro and are generally non immunogenic.

2. AIM OF THE STUDY

To compare between effectiveness of placental dressings over conventional dressings in patients with first and second degree burns.

OBJECTIVES OF THE STUDY

- Time required for healing.
- Compliance of patient receiving both dressings.
- Number of dressing changes.

3. RESEARCH HYPOTHESIS:

Placental dressings for second degree burns increases patients comfort by decreasing pain sensation and improving the process of wound healing and can be a better alternative to conventional dressings.

4. REVIEW OF LITERATURE:

The recognition of burn wounds and subsequent quest in finding a cure for the same dates back to early civilization where man used anything and everything he could get his hands on to soothe the pain. The Egyptians in 1500BC documented the use of a concoction made of resin and honey for the treatment of burns. In 600BC, the Chinese, known for their profound admiration of herbs, made use of tinctures and extracts of tea leaves, for their medicinal values, to treat burns[1].

In the same year, a sea and a nation across, a scholar, a person with profound medical knowledge and a genius level intellect had already classified the burn wounds according to their causes and degree of skin and tissue involvement. He was treating the wounds with herbal oils and tangentially excising the wound area when and where needed and raising flaps and fixing skin grafts to treat the burn wound area without a shred of doubt about the good prognosis. He is known today, throughout the world, as the Father of Plastic Surgery. His name is Sushrutha! This surgeon from India is known for his immense contribution to the world of surgery through his Sushrutha Samhitha[2].

In 15th century AD, the French Surgeon, Ambroise Paré effectively treated burn wounds with onions and he was probably one of the first to describe a procedure for

early burn wound excision. In 1607, a German Surgeon, Guilhelmus Fabricius Hildanus, published a book, De Combustionibus, in which he described the pathophysiology of burn wounds and made unique contributions to the treatment of burn contractures [3].

The treatment of burns was started with topical application of a variety of substances and this was second only to the number of physicians and surgeons treating the same. From the use of honey, herbal oils, vinegar, wine and cold water to the usage of a concoction made of pig fat and resin, oak barks, hot soot, lime water and paraffin, anything that eased the suffering was used to treat burns[1]. The Scholars and Philosophers, Physicians and Surgeons alike contributed to the same.

From the likes of Hippocrates & Rhases, an Arabian physician, to the men of modern era, namely, Galen, Edward Kentish & Guillaume Dupuytren, all these men have contributed immensely in understanding the pathophysiology, treatment and management aspect of Burn trauma[4.]

Truman G.Blocker Jr may have been the first to demonstrate the value of a multidisciplinary team approach to a burn disaster during the 'Texas City Disaster' which killed nearly 560 people and injured more than 3000 people in the year 1947 [5].As early as 1947, researchers had recognized that prompt eschar removal and immediate wound closure could improve outcome in burn injuries. Application of

this approach to large burns had not been practical before the 1970's because of an associated high rate of infection, bleeding complications and requirement of large quantity of blood. Many burn units adopted the excision technique in which a single tangential slice was intended to remove the superficial layer of 2nd degree injuries [6, 7].

In the near future new standards of care potentially available for burn treatment would be liposomal gene transfer, the use of artificial skin substrates, such as dermal matrices with epidermal components, amniotic wound coverage devices and dermal component matrices [8-11].

Burn wound is a wound in which there is coagulative necrosis of proteins in dermal and epidermal parts of tissues or tissue injury from thermal heat or cold application or from the absorption of physical energy of chemical contact[1].

Burns and Burn trauma can be best understood under the following headings:

I. Definition

II. Classification

- According to the Causative Agent
- According to the Type of Burn trauma

III. Depth of Burn Trauma

- First Degree
- Second Degree
- Third Degree
- Fourth Degree

IV. Estimation of Burn trauma in TBSA

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iii. Cleansing the Burn area

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DEFINITION:

A burn may be defined as dissolution in tissue continuity consequent on thermal damage. It is a wound in which there is coagulative necrosis of proteins in tissues or injury to tissues from thermal heat application or exposure to extreme cold or due to the absorption of physical energy by conduction via contact with chemicals or radiation.

CLASSIFICATION:

Burn trauma is classified according to

Table 1: Causative Agent

TYPE	CAUSE
Flame	Damage due to superheated or oxidised air
Scald	Damage due to contact with hot liquids
Conduction via Contact	Damage due to contact with hot/cold surfaces
Chemical	Damage due to contact with acids/alkalis
Electrical	Damage due to contact with electric current

Table 2: Type of Burn Trauma

TYPES OF BURNS	LEVEL OF INVOLVEMENT IN TISSUES
Scald	Superficial to Partial thickness skin loss
Flame	Patches of Full thickness skin loss

Fat burns	Full thickness skin loss
Electrical Burns	Full thickness skin loss with deeper extension
Frostbite	Local Vasospasm, Crust formation
Ionizing Radiation	Tissue necrosis due to exposure to excessive cGy
Chemical Burns	Tissue Necrosis with Systemic effects

❖ DEPTH OF BURN TRAUMA: [1,12,13]

Thermal injury or burn trauma can involve various layers of epidermis, dermis, subcutaneous tissue, fat and even viscera. They are classified according to the degree of involvement of tissues:

i. First Degree Burns
ii. Second Degree Burns
iii. Third Degree Burns
iv. Fourth Degree Burns

- **First Degree Burns** are superficial burns involving only the epidermis and are erythematous and present with minimal oedema. They typically

heal within five to seven days and topical antimicrobial therapy is not really indicated. (Ex: Sunburn, Flame Burns)

- **Second Degree Burns** are injuries that involve epidermis & a part of dermis and hence can be sub-classified as superficial second degree and deep second degree. **Superficial second degree** burns are pinkish-red, moist, and erythematous and blanch on touching. They heal within twelve to fourteen days and usually do not leave a scar. These are best treated with topical antimicrobial agents and paraffin or greasy gauze application. **Deep second degree** burns include involvement of epidermis in toto along with extension into the reticular dermis, present typically as a dry wound with mottled pinkish-white appearance with loss of sensation to touch but remain tender to pressure or needle pricks. These typically need about 18-21 days to heal with adequate protection from infection. If healing is delayed beyond 3 weeks (upto 8 weeks), then application of various skin substitutes or split thickness skin grafting is a more viable option. Both Superficial and Deep Second degree burns involve the hair follicles and sweat glands, the difference being that the former heals with regeneration of the lost tissues and the latter heals with minimal scarring post re-granulation.

- **Third Degree Burns** involve the entirety of epidermis and dermis and are hence referred to as full thickness burns. These present as leathery (usually brown-black), completely mottled, insensitive to touch and pressure. They heal by scarring as no epidermal and dermal layers remain for regeneration, hence wound edges act as sample tissues from which regeneration starts. Excision of burn area and split thickness or complete thickness skin grafting yields productive results in these patients. Healing period is variable.
- **Fourth Degree Burns** involve the viscera beneath all protective layers of subcutaneous tissue. Commonly muscles and long bones are involved. Management of these depend upon the area and the extent of involvement. (eg: Electric Burns)

Table 3: Degree of burns

Old Nomenclature	Revised Nomenclature	Depth of Involvement	Presenting Features
First Degree	Superficial	Only Epidermis	Pink, Erythematous, mild pain, no blisters

Second Degree	Superficial Partial thickness	Epidermis and Papillary Dermis	Pinkish-Red, painful, Oedematous with blisters
Second Degree	Deep Partial Thickness	Involvement of Reticular Dermis	Appear white and pale, painless
Third & Fourth Degree	Full thickness	Dermis and underlying deeper tissues	Brown-black leathery eschar, insensitive

- Estimation of Burn Trauma: [14]

Estimating a burn size with regards to total body surface area (TBSA) is essential in calculating the amount of fluid required to resuscitate a patient. The following have been used as a standard in most centres to calculate the TBSA involved:

- Lund & Browder Chart
- The Wallace "Rule of Nine"
- The "Rule of Palms"

Lund and Browder Chart: This was first described to calculate the TBSA of burn trauma in children as their head is of a greater proportion of body mass in comparison to their body, which differentiates them from adult TBSA. [12-14]

Table 4 : Lund and Browder chart.

	Age in years					
	1	**1 to 4**	**5 to 9**	**10 to**	**15**	**Adult**
Area Burned	**Percentage of Total Body Surface**					
Head	19	17	13	11	9	7
Neck	2	2	2	2	2	3
Anterior Trunk	13	13	13	13	13	13
Posterior Trunk	13	13	13	13	13	13
Left Buttock	2.5	2.5	2.5	2.5	2.5	2.5
Right Buttock	2.5	2.5	2.5	2.5	2.5	2.5
Right Upper Arm	4	4	4	4	4	4
Left Upper Arm	4	4	4	4	4	4
Right Lower Arm	3	3	3	3	3	3
Left Lower Arm	3	3	3	3	3	3
Right Hand	2.5	2.5	2.5	2.5	2.5	2.5
Left Hand	2.5	2.5	2.5	2.5	2.5	2.5
Right Thigh	5.5	6.5	8	8.5	9	9.5
Left Thigh	5.5	6.5	8	8.5	9	9.5
Right Lower Leg	5	5	5.5	6	6.5	7
Left Lower Leg	5	5	5.5	6	6.5	7
Right Foot	3.5	3.5	3.5	3.5	3.5	3.5
Left Foot	3.5	3.5	3.5	3.5	3.5	3.5

- **The Wallace "Rule of Nines" Chart**: This chart is used world over as a routine to calculate the TBSA of burn trauma in adults. This chart is also useful in calculating the amount of fluid that should be used in resuscitation.

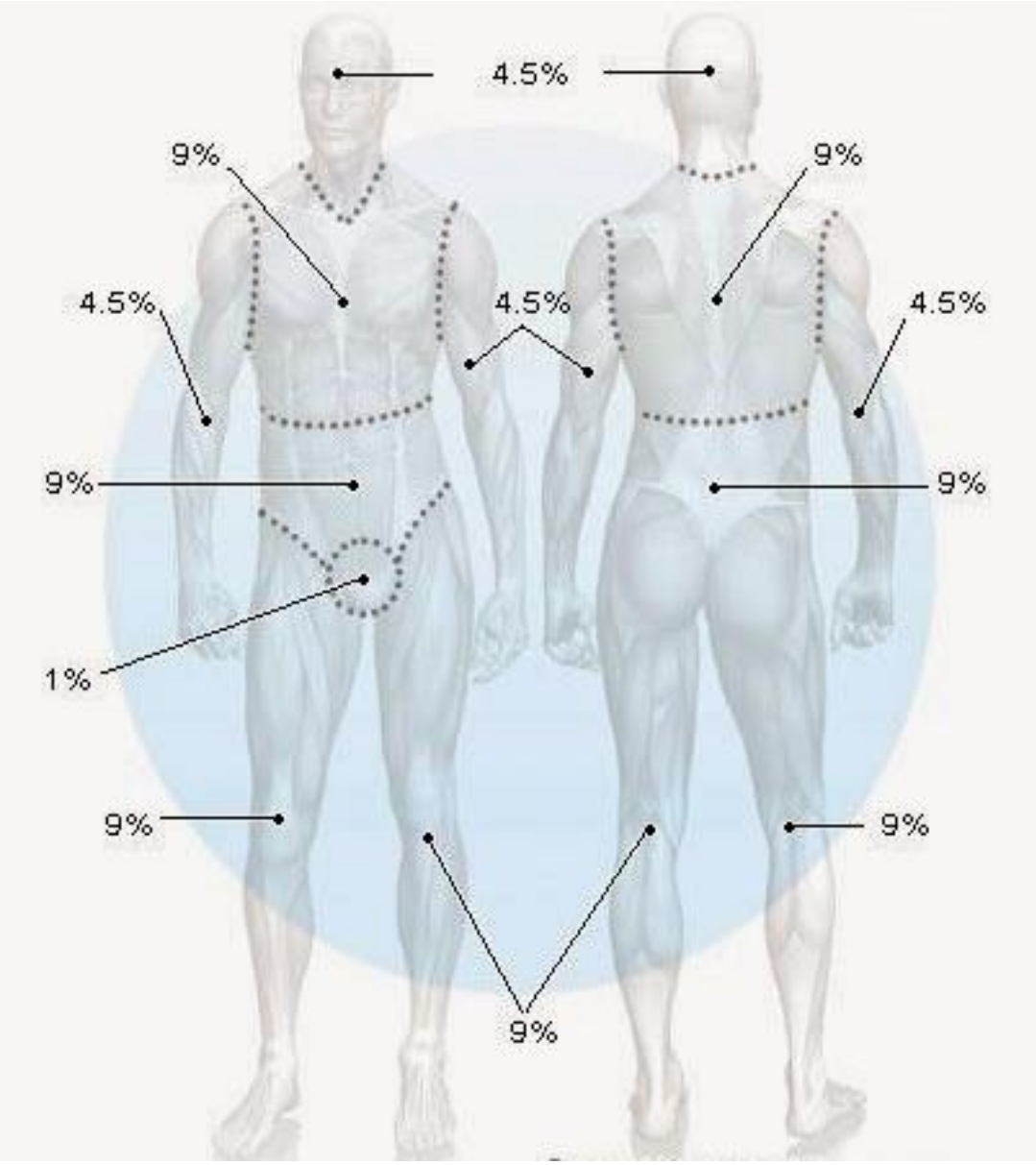


Figure 1: Wallace's Rule of Nine

The "Rule of Palms": This technique is useful in calculating percentage of burn trauma in small and minimal burns and in burns involving patches with intact healthy skin in between

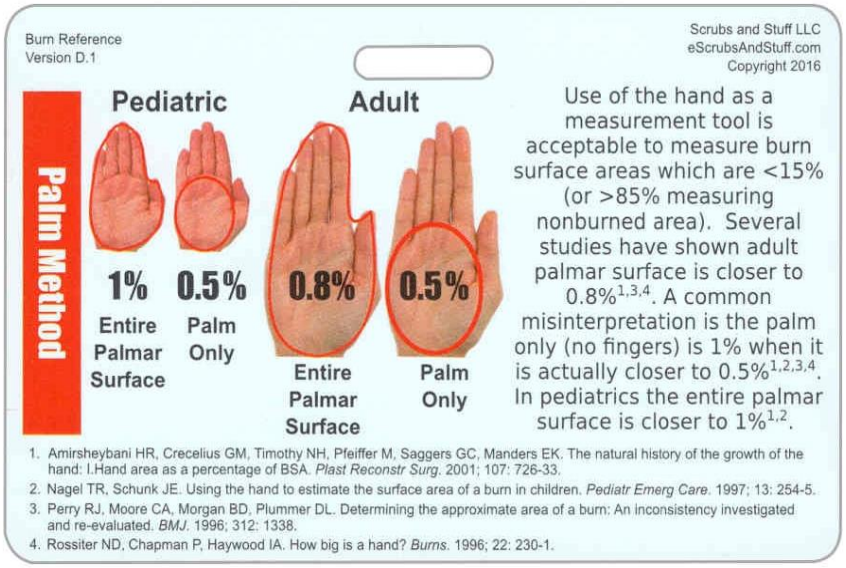


Figure 2: Rule of Palms

❖ Categorization of Burn Severity: [14]

The categorization of the severity of burn trauma includes the following factors:

i. The Site, Extent and Depth of Burn Injury

ii. Age of the Patient

iii. Aetiology of the Burn Trauma

iv. Presence or Absence of Inhalational Injury

v. Associated Co-morbid conditions/ Pre-existing Illness

The above parameters were used to establish and set guidelines to categorize and classify the severity of burn trauma by The American Burn Association. They have defined the categories into 3 classes:

I. Minor Burn Injury:

II. Moderate Burn Injury

III. Major Burn Injury

- **Minor Burn Injury:** These include the following

  a. Burn trauma involving less than 15% TBSA in adults or less than 10% in extremes of age (i.e. children and elderly)

  b. Less than 2% TBSA full thickness burns which is not a serious threat to functional or cosmetic risk to the eyes, ears, face, hands, feet and perineum.

     These are burn injuries that are managed on outpatient basis and effectively treated conservatively.

- **Moderate Burn Injury:** These include the following

  a. 15-25% TBSA partial thickness burns in adults or 10-20% TBSA in children as well as adults.

  b. 2-10% of TBSA full thickness burns without serious threat, functional or cosmetic risk to the eyes, ears, face, hands, feet and perineum. High-voltage electrical injury is excluded from this category.

c. All inhalational injury, other trauma related to burn and burn trauma sustained by high risk patients.

   Patients with moderate burn injury should be hospitalised for initial management and treatment but need not be in a burn centre.

- **Major Burn Injury:** These include the following

a. More than 25% TBSA partial thickness burns in adults and greater than 20% TBSA in less than 10 years of age.
b. In burns involving eyes, ears, face, hands, feet or perineum which results in functional/cosmetic impairment in more than 10% TBSA full thickness burns in adults aged more than 50 years.
c. Caustic chemical agents induced burns.
d. Inhalational injury or major trauma as a complication of high-voltage Electrical burns.
e. Burns in high risk patients.

   Dedicated burn centre with professional's expertise to treat burn patients in acute care, resuscitation and rehabilitation is required to manage these patients.

- **Burn Centre Referral Criteria:** [16]

The following injuries are identified by American Burn Association (ABA) as requiring burn centre referral once assessment and stabilization of patient is done in primary hospital.

i. Partial thickness burns and full thickness burns amounting to more than 10% TBSA in patients under 10 years or over 50 years of age.

ii. Partial thickness burns and full thickness burns amounting to more than 20% Total body surface area in other age groups.

iii. Burns over face, hands, feet, genitalia, perineum and major joints if any with partial thickness or full thickness burns.

iv. Greater than 5% TBSA full thickness burns in any age group.

v. Electrical burns including lightning injury.

vi. Chemical Burns.

vii. Inhalational burns with burn injury.

viii. Circumferential burns with burn injury.

ix. Burn injury which has a greater risk of morbidity and mortality in a patient with concomitant trauma. Incase if trauma has a greater immediate risk than burn injury then, patient should be initially stabilized and then transfer to a burn centre.

x. Patient having previous medical diseases which may lengthen recovery time, affect mortality or may complicate management of burn trauma.

xi. If children are admitted with burn injury in hospitals where qualified staff or paediatric care equipment's are not available.

xii. If patients requires social, emotional and or long term support in terms of rehabilitation including cases of alleged child abuse.

❖ Pathophysiologic Response:

These are categorised into two types:

➢ Local Response:

The skin provides an effective barrier to the transfer of energy to the deeper tissues, but however even after the initiating focus is removed; the response of local tissues can cause an injury to the deeper tissue layers.

The three zones [13] of a burn wound are three dimensional and were described by Jackson in 1947 as follows:

i. **Zone of Coagulation** – This occurs at the point of maximum damage. There is irreversible tissue loss due to coagulation of the constituent proteins in this zone.

ii. **Zone of Stasis** – The surrounding zone of stasis is characterised by decreased tissue perfusion. This zone is an area in which the tissue

injury can be reversed if adequate resuscitation is given at the right time. The main aim of burn trauma resuscitation is to increase tissue perfusion here and prevent any damage becoming irreversible. Additional insults such as prolonged hypotension, infection or oedema can convert this zone into an area of complete tissue loss.

iii. **Zone of Hyperaemia** - In this outermost zone, tissue perfusion is increased. The tissue in this zone usually recovers unless there is severe sepsis or prolonged period of hypo perfusion.

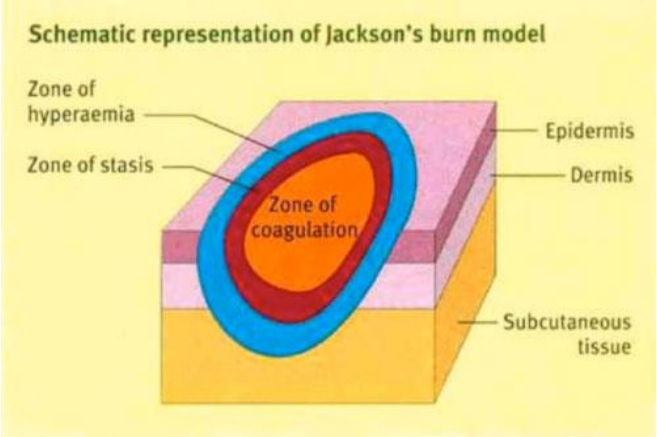


Figure 3: Jackson Burn Model

Burns are followed by the development of an area of hyperalgesia (and/or Allodynia) around the lesion, which is known as the area of Primary hyperalgesia. Surrounding this area, a zone of Secondary hyperalgesia appears in the intact skin and gradually increases in diameter with time. Hyperalgesia indicates a greater sensitivity to pain caused by the reduction in the pain threshold and an increase in the intensity of

responses to the supraliminal noxious stimuli. In comparison, Allodynia is a painful sensation induced by normally non painful, supraliminal noxious stimuli.

In the area of Secondary hyperalgesia, there are symptoms only for mechanical stimuli and not for heat. In the normal skin, heat resulting in painful sensation by nociceptors, carries a risk of tissue damage; but the hyperthermia used in post-heat shock tolerance is too mild to induce any specific tissue injury. This mild painful stimulus can result in the induction of descending anti-nociceptive mechanisms, especially in the adjacent burnt area. Some of these inhibitory mechanisms can modify peripheral tissue inflammation as mentioned above[17].

- Systemic Response:

  A wide variety of inflammatory mediators involved in burn trauma are responsible for most of the systemic effects. Burn trauma initiates systemic inflammatory reactions producing toxins and oxygen radicals which finally lead to per oxidation. The relationship between the amount of oxidative metabolism and natural scavengers of the free radicals determines the outcome of local and distant tissue damage and further organ failure in burn injuries [18, 19].

  The various systemic effects of burn injury can be discussed under following headings:

  i. Effects on cardiovascular system

ii. Effects on respiratory system

iii. Metabolic response to burn trauma

The effects on cardiovascular system: The changes in the heart and blood vessels begin almost immediately after burn trauma. The extent of these changes depends primarily on the size of the burn trauma and to a lesser extent on the depth of the burn. Fall in cardiac output and an increase in peripheral vascular resistance are immediate cardiovascular response to thermal injury. In there is no cardiac pathology, ventricular ejection fraction and velocity of the myocardial fibre shortening are actually increased during thermal injury. Severe burn trauma results in significant hypovolemic shock and substantial tissue trauma, both of which cause the formation and release of many local and systemic mediators which further continue the pathological cascade [18].

The effects on respiratory system: The changes in pulmonary functions after the burn trauma are similar to those seen in other forms of traumatic injuries. Respiratory minute ventilation usually increases as soon as the burn trauma occurs. After resuscitation, the respiratory rate and tidal volume progressively increase which in turn increase the minute ventilation. After burn trauma pulmonary vascular resistance increases, and may result in vasoactive amine release and so many mediators. They

acts as a protective effect during the fluid resuscitation by reducing the pulmonary capillary hydrostatic pressure thus lowering susceptibility to pulmonary edema[17].

Metabolic response to burn trauma:

a) Hyper metabolic and Neuroendocrine response
b) Effects on Gastrointestinal system
c) Effects on Renal system
d) Effects on Immune system

Hyper metabolic and Neuroendocrine response: The primary mediators of hyper metabolic response following burn trauma greater than 40% are Catecholamines and Corticosteroids. They raise up to fifty fold and last up to nine months post burn trauma in the body. Burn patients have increased resting energy expenditure, increased cardiac workload, increased myocardial oxygen consumption, marked tachycardia, severe lipolysis, liver dysfunction, severe muscle catabolism, increased protein degradation, insulin resistance and growth retardation [20].

Effects on Gastrointestinal System: Burn trauma induces the degradation of muscle protein and huge amounts of amino acids are released from muscle. Increase in cortisol level along with reduction in growth hormone and insulin,

which results in increased proteolysis of muscle and release of amino acids. The basal energy expenditure is thus increased three fold than normal and the calorie requirement rises three and a half times normal requirement per day. Supplementation of nutritional support through enteral route prevents bacterial translocation from gut and thereby systemic sepsis[22].

Effects on Renal system: In acute phase of burn injury, renal blood flow and glomerular filtration rate (GFR) as measured by increase in creatinine clearance, shows impairment in tubular function. As the phase of burn trauma progresses, decrease in the blood volume and cardiac output cause a decrease in renal blood flow and glomerular filtration rate, which if not corrected with adequate fluid resuscitation results in oliguria which progresses to acute renal failure (ARF)[23]. This is associated with high mortality rates.

Effects on Immune system: It has been implied that the elevated production of PGE_2 & Nitrous oxide by macrophages can suppress T-cell activity and impaired T-cell function may be the end point in the development of burn trauma induced immunosuppression[25].

❖ Treatment of Burns:

Pre Hospital

Before undergoing any specific treatment burned patients must be removed from the source of injury and the burning process stopped. While removing the patient from the source of injury, care must be taken to ensure that the rescuer does not become another victim .Some amount of inhalation injury is always present and 100% oxygen should be given by facemask. Burnt clothing is extinguished and removed as soon as possible to prevent further injury. Room-temperature water can be poured on the wound within 15 minutes of injury to decrease the depth of the wound, but any subsequent measures to cool the wound are avoided to prevent hypothermia during resuscitation.

Initial Assessment

As with any trauma patient, the initial assessment of a patient with burn trauma is divided into a primary and a secondary survey[12]. In the primary survey, immediate life threatening conditions are quickly identified and treated. In the secondary survey, a more thorough head-to-toe evaluation of the patient is undertaken.

Primary Survey: Management of a patient who had burn trauma is same as that of any other trauma patient. A primary survey is done with the following in mind:

Airway with Cervical Spine control

Breathing and Ventilation-

Circulation

Disability

Exposure

Fluid Resuscitation

Airway with Cervical Spine Control:

Assessment includes to determine compromised airway or is about to be compromised. Cervical spine on other hand has to be safeguarded first till definite injury to spine is ruled out. Hot gas inhalation leads to burns above the vocal cords and with time leads to oedema of the same, will be more evident after fluid resuscitation is started. That is an airway which is patent on arrival at hospital may occlude even some time after admission mostly in small children. Acute upper airway obstruction occurs in approximately one-fifth to one-third of hospitalized burn victims with inhalation injury and is a major problem because of the possibility of rapid progression from

mild pharyngeal oedema to complete upper airway obstruction with asphyxia[15, 18]

Breathing and Ventilation:

As a sequelae to burn trauma airway can get compromised affecting respiration. Mechanically restriction of breathing can occur in deep dermal burns or full thickness circumferential burns of the chest. These can limit chest movements during inspiration and prevent adequate ventilation: usually requires escharotomy and/or debridement. A blast injury or an explosion can cause lung trauma and contusion over lung surface, cause alveolar trauma and progress to ARDS. These can complicate ventilation and can cause tension pneumothorax if penetrating injury is present. It is advisable to initiate 100% oxygen to all patients who present with burn trauma, through a non-rebreathing mask.

Circulation:

Two or three large bore cannula for intravenous access must be secured at presentation only, ideally placed through tissue which is not burnt in patients with more than 20% burns. Any circumferential extremity deep or full thickness burn may act as a tourniquet, especially after fluid resuscitation due to development of oedema. Escharotomy that is release

of the circumferentially burnt tissue if there is any suspicion of decreased perfusion needs to be done.

Disability:

All patients should be assessed for level of consciousness using Glasgow coma scale as they may be have clouding of their consciousness due to either hypoxia or hypovolaemia.

Exposure:

All clothing should be removed to assess accurate estimate of total burn area and to assess any other concomitant injuries. Patients who sustained burns are susceptible to hypothermia. Hence, after estimating the burn area, the clothing (preferably hospital sterilised gown) should be used to cover the patient and provide adequate warmth as soon as possible.

Fluid resuscitation:

Based on the estimation of the burn area, fluid resuscitation regimen should be determined and begun immediately. Urine output to be monitored with a urinary catheter, which is mandatory in all adults with burns more than 20% of total body surface area and in patients with abdominal burns, abdominal compartment pressures to be checked. Urine

output in children can be assessed by weight of nappies, if total body area injured is < 20%. Interosseous route may be used for administration of fluids in case intravenous access is not able to be secured, and replaced by intravenous lines at the earliest[27]. The ultimate goal of resuscitation is to maintain adequate tissue perfusion and to therefore preserve organ function. Delays in resuscitation must be minimized as delays result in poorer outcomes. The adequate resuscitation of a burned patient depends on establishment and maintenance of reliable intravenous access. The traditional method of assessing the adequacy of resuscitation has been based on the observations of blood pressure, heart rate and urine output, and fluids are titrated as to maintain a urine output of 0.5-1ml/min or 30-50ml/hr. (refer table 5)

Table 5: Fluid resuscitation Formulas:

Formula	Fluid in First 24 Hours	Crystalloids in	Titration
Parkland	RL at 4 mL/kg per percentage burn	20-60% estimated plasma volume	Titrated to urinary output of 30 mL/h
Evans	NS at 1 mL/kg per percentage burn, 2000 mL D5W*, and colloid at 1 mL/kg per	50% of first 24-hour volume plus 2000 mL D5W	50% of first 24-hour volume

Slater	RL at 2 L/24 h plus fresh frozen plasma at 75 mL/kg/24 h		
Brooke	RL at 1.5 mL/kg per percentage burn, colloid at 0.5 mL/kg per percentage burn,	50% of first 24-hour volume plus 2000 mL D5W	50% of first 24-hour volume
Modified Brooke	RL at 2 mL/kg per percentage burn		
Metro Health (Cleveland)	RL solution with 50 mEq sodium bicarbonate per liter at 4 mL/kg per percentage burn	Half NS titrated to urine Output	1 U fresh frozen plasma for each liter of half NS used + D5W as needed for Hypoglycemia
Monafo hypertonic Demling	250 mEq/L saline titrated to urine output at 30 mL/h, dextran 40 in NS at 2 mL/kg/h for 8 hours, RL titrated to urine output at 30 mL/h, and fresh frozen plasma 0.5 mL/h for 18 hours beginning 8 hours post burn	One-third NS titrated to urine output	
Ideal formula	2-4ml RL/kg/% burns	Maintain urine output 0.5-1 ml/kg	50% of the dose given in 24 hrs.

Augmented electrolyte solution	5%dextrose saline + 20 mEq of Sodium Bicarbonate 3ml/kg/%burns	Maintain urine output 0.5-1 ml/kg	50% of the dose given in 24 hrs.

Gastrointestinal dysmotility, ranging from a moderate delay in gastric emptying to marked gastro paresis, has been described in critically ill patients with conditions such as burns. To combat any regurgitation and to decompress the stomach in patients with intestinal ileus, a nasogastric tube is inserted in all patients with major burns. Decompression of the stomach is necessary because the apprehensive patient will swallow considerable amounts of air and distend the stomach [28].

Secondary Survey:

A secondary survey is mandatory after the primary survey for starting emergency management:

- Elicit a thorough Medical history
- Thorough Head-to-toe examination
- Estimate Burn Size and Depth with diagrammatic representation
- Tetanus Prophylaxis
- Antibiotics, analgesics and sedatives
- Psychiatric counselling

- **Burn Wound Management:**

DRESSINGS:

Earlier, twice daily dressings were used by surgeons till completely healed or any intervention like wound closure is required. Daily dressing changes, thereby a significant reduction in costs, nursing time, and pain are the current practise.

Tannic acid spray was used by Davidson in 1925. To reduced pain and produce a cleaner wound bed. Gentamycin sulphate was briefly utilized as 0.1% topical cream burn dressing, intended for anti-pseudomonas coverage of invasive burn wounds but now discontinued due to its ototoxicity and nephrotoxicity.

Silver sulfadiazine a sulpha derivative topical antibacterial used as a topical b u r n cream on second- and third-degree burns whose broad-spectrum antibacterial activity is made use of and has little complications than others. The efficacy of silver sulfadiazine is thought to result from its slow and steady reactions with serum and other sodium chloride containing body fluids, which permits the slow and sustained delivery of silver ions into the wound environment.

Escharotomy:

Severely burned extremities should be elevated, reverse trendelenberg position and range of motion exercises for the limbs performed every 15-30 minutes as tolerated

by the patient to minimize tissue oedema and tissue pressures. Indications for emergency escharotomy are the presence of a circumferential eschar with any one of the following features:

- Impending or established vascular compromise of the extremities or digits
- Impending or established respiratory compromise [28]

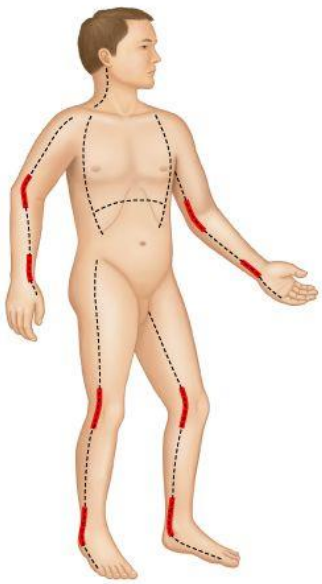


Figure 4: Escharotomy Incisions

Skin Grafting in Burns: [29-31]

Skin grafting in burns is not a new concept. Reverdin applied small grafts to an old burn ulcer as early as 1869. In 1886, a German surgeon named Carl Thiersch described the technique of skin grafting using a straight razor to excise long thin strips of skin containing some dermis and applying them to a freshly debrided

granulation tissue bed. Since then various types of grafts like the pinch graft, sandwich graft etc have been used. Both allografts and xenografts have been used in burn treatment. Initial grafts were obtained free hand with long, thin bladed knives. Finochietto developed an improved knife for controlling the depth of skin harvest in 1920 followed by multiple improvements in surgical burn knives. Braithwaite, Watson, Goullian and Humby are names still associated with knives used to harvest skin and remove burned tissues today. As the art and science of skin grafting developed it became clear early on that allograft skin, while a good temporary burn covering, was not a long-term solution to treating burns. As grafting of larger burned areas was undertaken, methods to provide broader coverage of the excised bed were needed, when the concept of "meshing" the skin graft to allow it to stretch for greater coverage was introduced. Lanz, a German surgeon made a hand held device for meshing and this was further improved by the hand cranked double roller graft mesher developed by Tanner and Vandeput. Current graft meshers function in a similar fashion. Today electrical dermatomes like that of Brown, Padgets, etc can take graft from any site in the body and mesh it.

The timing of surgical intervention and grafting in burns had previously been an area of spirited debate. Tangential excision refers to the shaving of multiple thin parallel layers of the burn until healthy tissue. The efficacy of this technique was confirmed in a study by Heimbach. The technique of tissue cultures has been further refined

and it is now possible to grow large sheets of the patient's epidermal cells in tissue cultures which can then be transferred to the prepared burn wound to provide autologous epidermal coverage. Effective techniques using artificial skin substitutes have also been tried in burn treatment.

The ideal skin replacement product is one that is readily available off the shelf, is dependable, easy to use, and infection resistant, has a low profile of side effects, demonstrates an acceptable appearance, is reasonably priced and restores both the dermal and epidermal layers of the skin to its original state. Skin substitutes are often categorised as either temporary or permanent and are also thought of as products that provide temporary wound coverage of wound closure.

Temporary skin substitutes, as a group, include a collection of varied, topically applied agents that are thought to offer more than a simple protective covering to a healing burn. Such skin substitutes include products that have inherent healing properties of their own or have added biologically active substances, presumably able to advance wound healing. The term "skin substitute" entered the burn literature in the 1980s when Burke *et al* developed a skin substitute "Integra".

Integra was approved by the United States FDA for use in the treatment of burns in 1996. It is a bilayered skin substitute composed of an outer layer of silicone, covering a bioengineered collagen matrix. The product is marketed as a "dermal regeneration

template" that allows the in growth of fibroblasts, vascular tissues and cells in a more organized fashion. While the bovine collagen in the dermal template is ultimately replaced by the patient's collagen and cell in growth, the reformed "neodermis" has architecture that more closely resembles normal dermis than that of simple scar tissue. The outer semi permeable silicone membrane functions as a protective barrier while revascularization and remodelling occur, much like normal epidermis. After maturation of the framework, this neodermis is covered by thin sheets of the patient's auto graft skin.

Dermal replacement products offer many advantages. When healing is complete, the amount of scar tissue formation in the wound is markedly decreased. This results in a measured improvement in elasticity and flexibility of the healed burn. Scar contracture is lessened and leads to a reduction in the number of scar contracture procedures and plastic surgical reconstructions required long term. Dermal replacement has therefore been a major advancement in the treatment of burns.

Amniotic membrane[32]

The amnion membrane or amnion is the internal layer of the placenta and is in contact with the amnion liquid. Macroscopically the amnion membrane is thin, transparent, resistant, adherent to the chorion from which it can be easily parted with

simple traction. The normal amnion membrane is 0.02–0.05 mm thin, which is equivalent to 6–8 rows of cells, and has a surface of 1600 cm2.

Histologically, the amnion membrane consists of a thin cubical epithelium, a thick basal membrane and an avascular stromal matrix. The basal side of the amnion membrane is an ideal kind of substrate which helps the growth of the epithelial cells by prolonging their life and maintaining the clonogenecity. Also, few factors of growth are identified in the amnion membrane. The stromal side of the amnion membrane contains a rare matrixiel component which suppress fibroblast proliferation. This action explains why transplantation of the amnion membrane helps the reduction of the cicatrix during epithelialization[33].

Actually, the amnion membrane is similar to a "chemical sandwich" which contains anti-inflammatory and cytostimulatory components. The mitogen factor was separated from the human amnio-chorion which can explain the profuse neovascularisation and the accelerated process of re-epithelialization during the treatment of burns with amnion membrane as a biological skin substitute.

The anti-angiogenesis and anti-inflammatory proteins – interleukin-1, receptoral antagonists, all four TIMPs, collagen IV, laminin, and interleukin-10 – were isolated.

Different growth factors have been isolated: the basal fibroblast factor of growth, the transforming β growth factor, the hepatocyte growth factor. The presence of certain protein growth factors can be of benefit to epithelialization after the transplantation of amnion membrane. The high level of EGF, KGF, HGH and b-FGF in the amnion membrane with an epithelium, compared with amnion membrane without an epithelium, suggests the epithelial origin of these growth factors[34-40].

The amnion membrane does not produce the usual histo-compatabile antigens HLA-A or DR. As a result of this the amnion membrane does not induce an immunological reaction after the transplantation, thus taking the primacy as "the ideal" temporary skin substitute.

The amnion membrane as a biological skin dressing, when treating burns, is closest to the "ideal" temporary skin substitute.

The amnion membrane has these qualities: transparency; semi-permeability; elasticity, and adherence. Its importance as a biological skin substitute when treating burns comes down to: control of water loss, a barrier to bacterial colonization, and acceleration of epithelialization[41].

The basic qualities which prove the usefulness of the amnion membrane as a biological skin substitute when treating burns are: amnion membrane is not an immunogenic tissue; its bacteriostatic characteristic; its anti-phlogistic characteristic; it reduces angiogenesis; it inhibits the fibroblastal function by reducing the cicatricial tissue; it prevents the degradation of collagen; and it facilitates epithelialization[41].

5. MATERIALS AND METHODS

SOURCE OF DATA:

All burns patient admitted with upto 10-30% first and second degree burns in Department of Surgery, Shri B M Patil Medical College and Research Centre, Vijayapura during the period from November 2018 to July 2020.

METHOD OF COLLECTION OF DATA:

The burns patient with upto 10-30% first and second degree burns admitted in Department of Surgery, Shri B M Patil Medical College and Research Centre, Vijayapura are selected. Placenta is collected from healthy mother without TORCH infection, hepatitis B, hepatitis C, AIDS, and syphilis who underwent either vaginal delivery or caesarean section from Obstetrics and Gynecology department. Under all aseptic precautions, placenta is harvested on the day of admission of the patient. Two trays are taken. In the first tray, semitransparent amniotic membrane is separated and removed in total and washed in normal saline solution, such that all the clots and the debris are washed away. In the second tray, gentamicin solution is prepared, by adding five ampules of gentamycin each containing 80mg to 1000ml of normal saline. The amniotic membrane is carefully transferred to the same, and preserved in the solution for 6 hours. After 6 hours, the burnt area is cleaned with normal saline and the amniotic membrane is carefully placed over the area, and dressing with plain pads is done. The dressing will be removed after 48hrs

and while removing the dressing the pain score is calculated. In case of control group (conventional dressing) the dressing will be done with silver sulphadiazine and cuticell and shall change on daily or alternate day based on daily assessment. Day 1 and Day 3 pain scores are calculated. Patients are discharged once fit and followed up in the OPD.

Figure 5: Preserving amniotic membrane in gentamycin

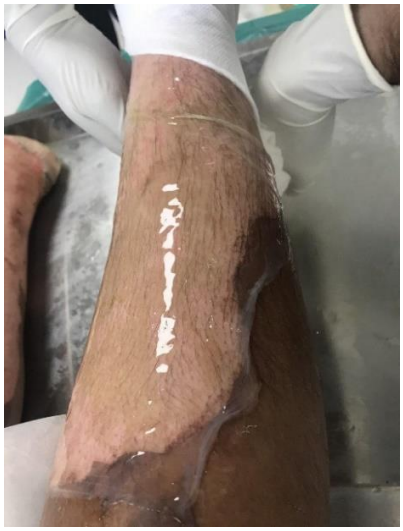


Figure 6a: Application of Amniotic membrane after preservation.

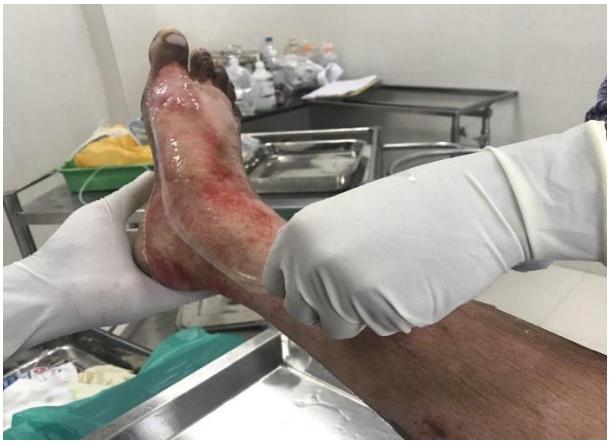


Figure 6b: Application of Amniotic membrane after preservation.

Figure 7A: Serial Photograph of patient where Amniotic membrane is applied as dressing

CLINICAL PICTURES AMNIOTIC MEMBRANE DRESSINGS

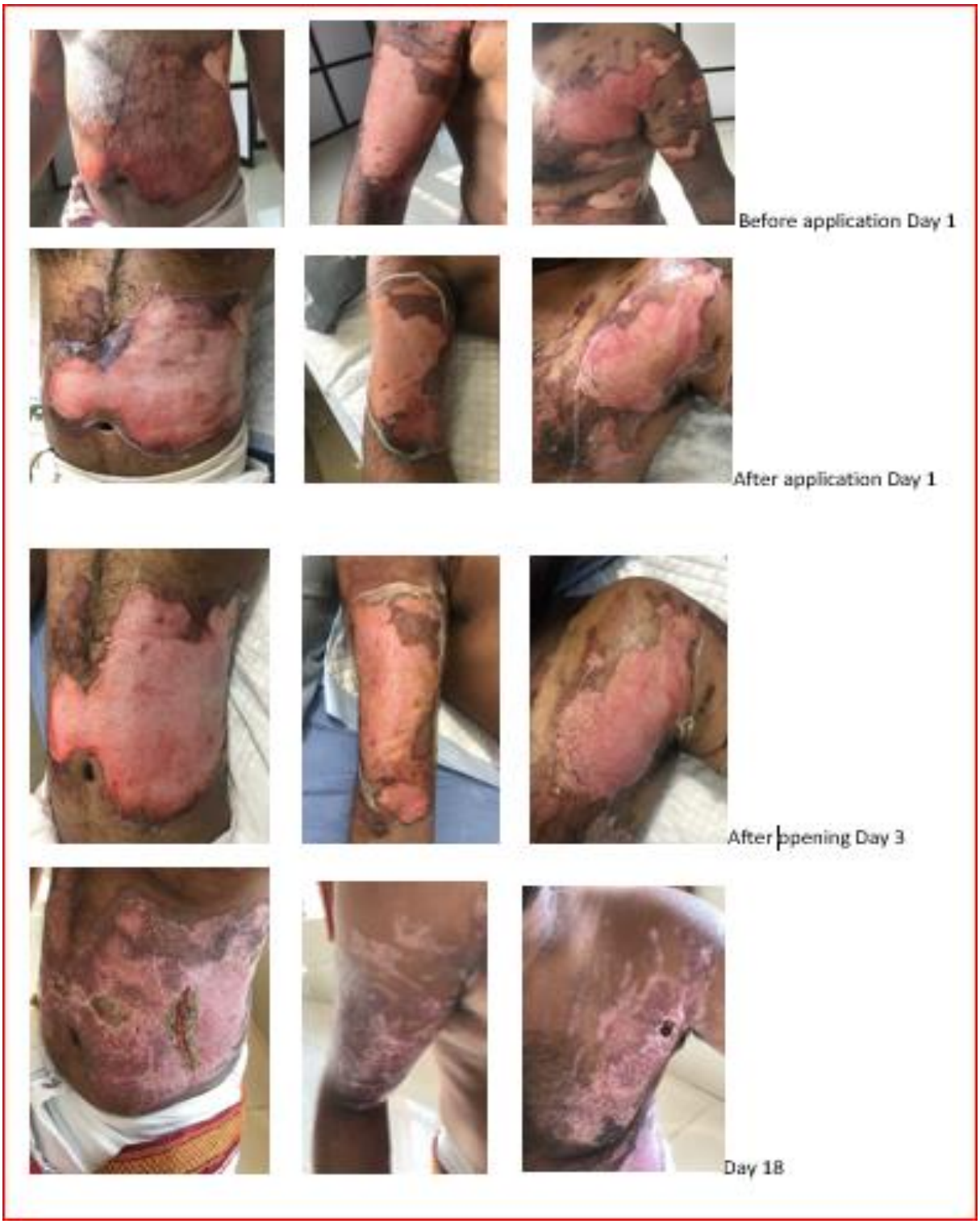


Figure 7B: Serial Photograph of patient where Amniotic membrane is applied as dressing

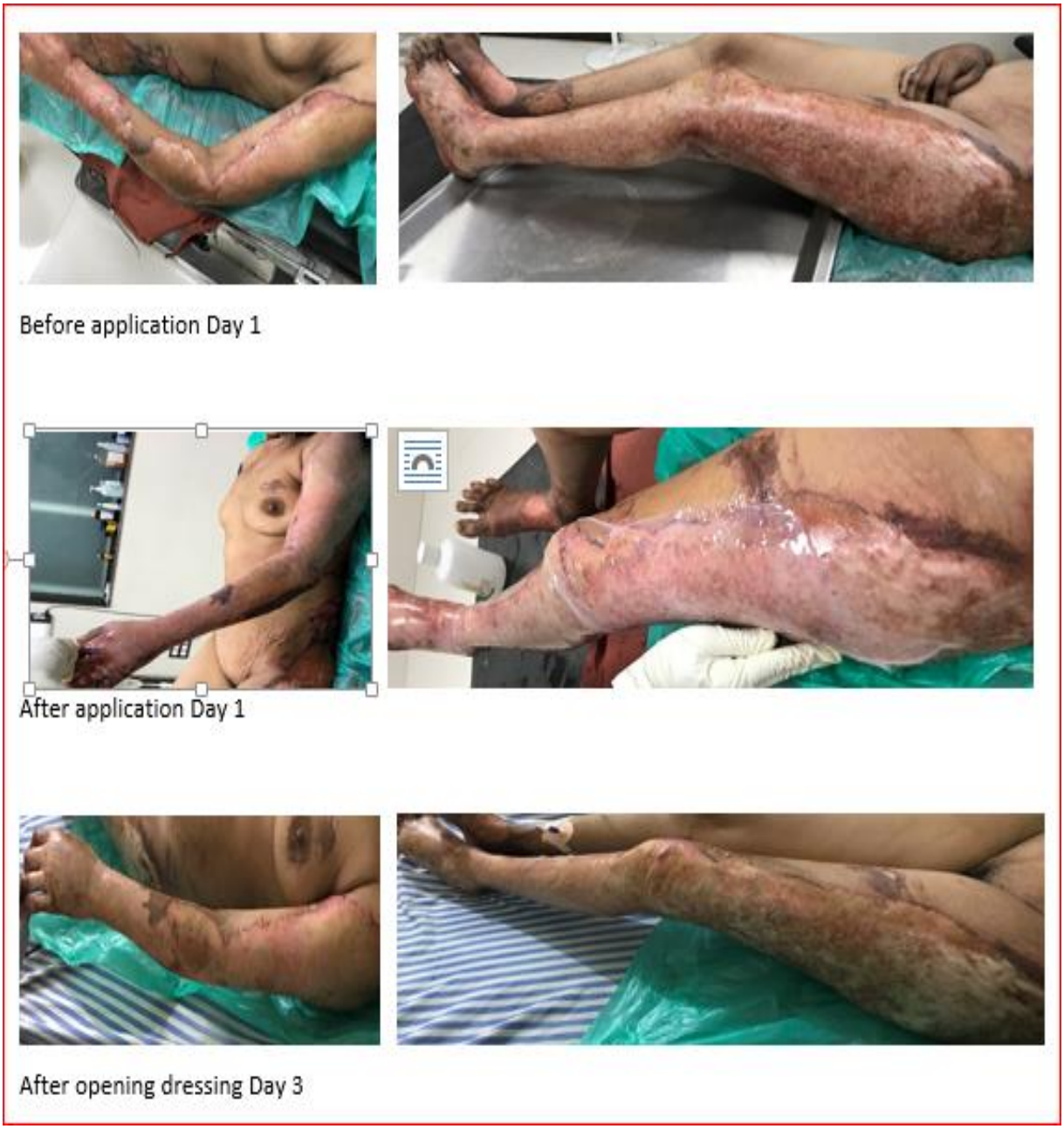


Figure 7C: Serial Photograph of patient where Amniotic membrane is applied as dressing

Figure 7D: Serial Photograph of patient where Amniotic membrane is applied as dressing

Figure 7E: Serial Photograph of patient where Amniotic membrane is applied as dressing

Figure 7F: Serial Photograph of patient where Amniotic membrane is applied as dressing

Figure 7G: Serial Photograph of patient where Amniotic membrane is applied as dressing

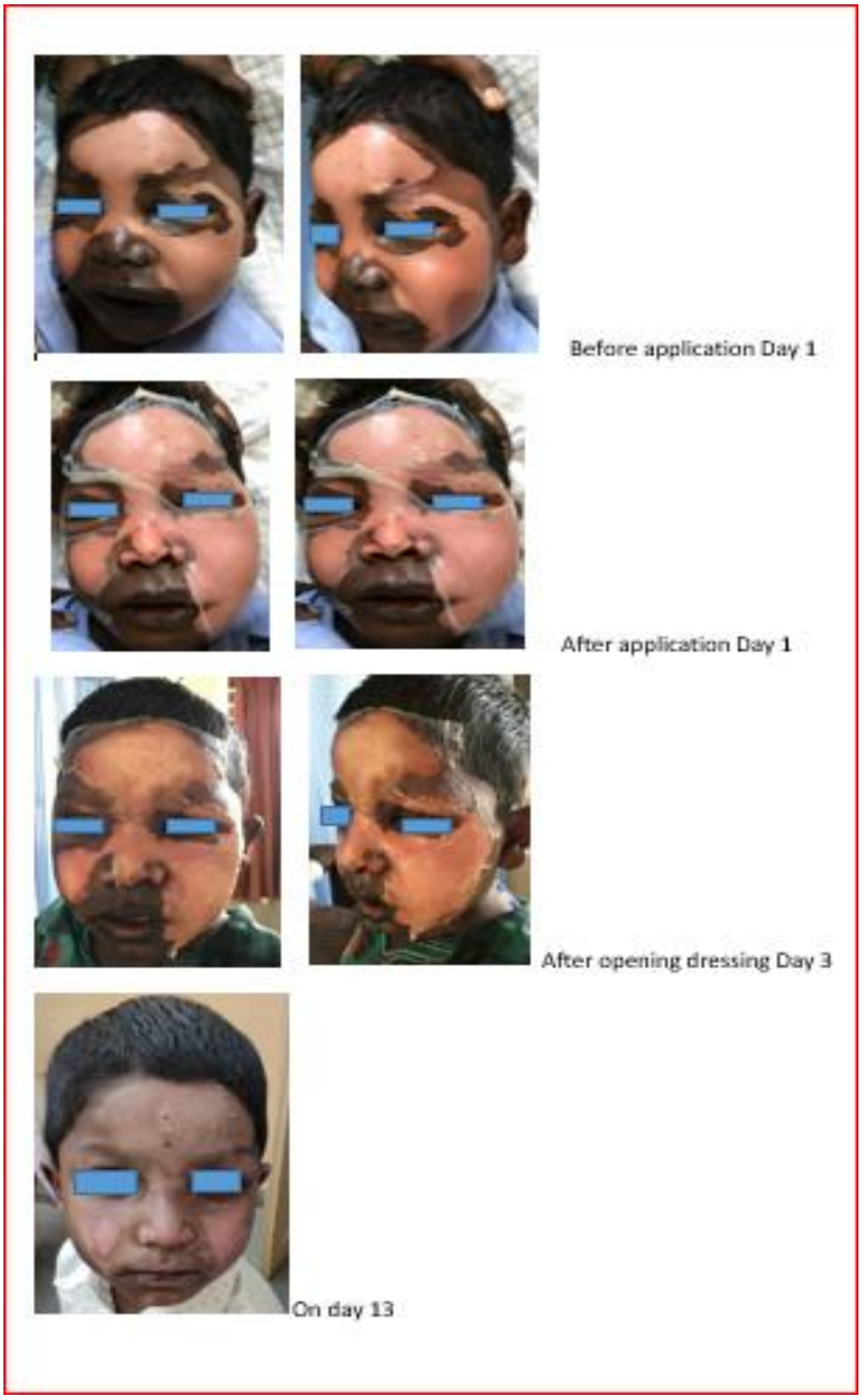


Figure 7H: Serial Photograph of patient where Amniotic membrane is applied as dressing

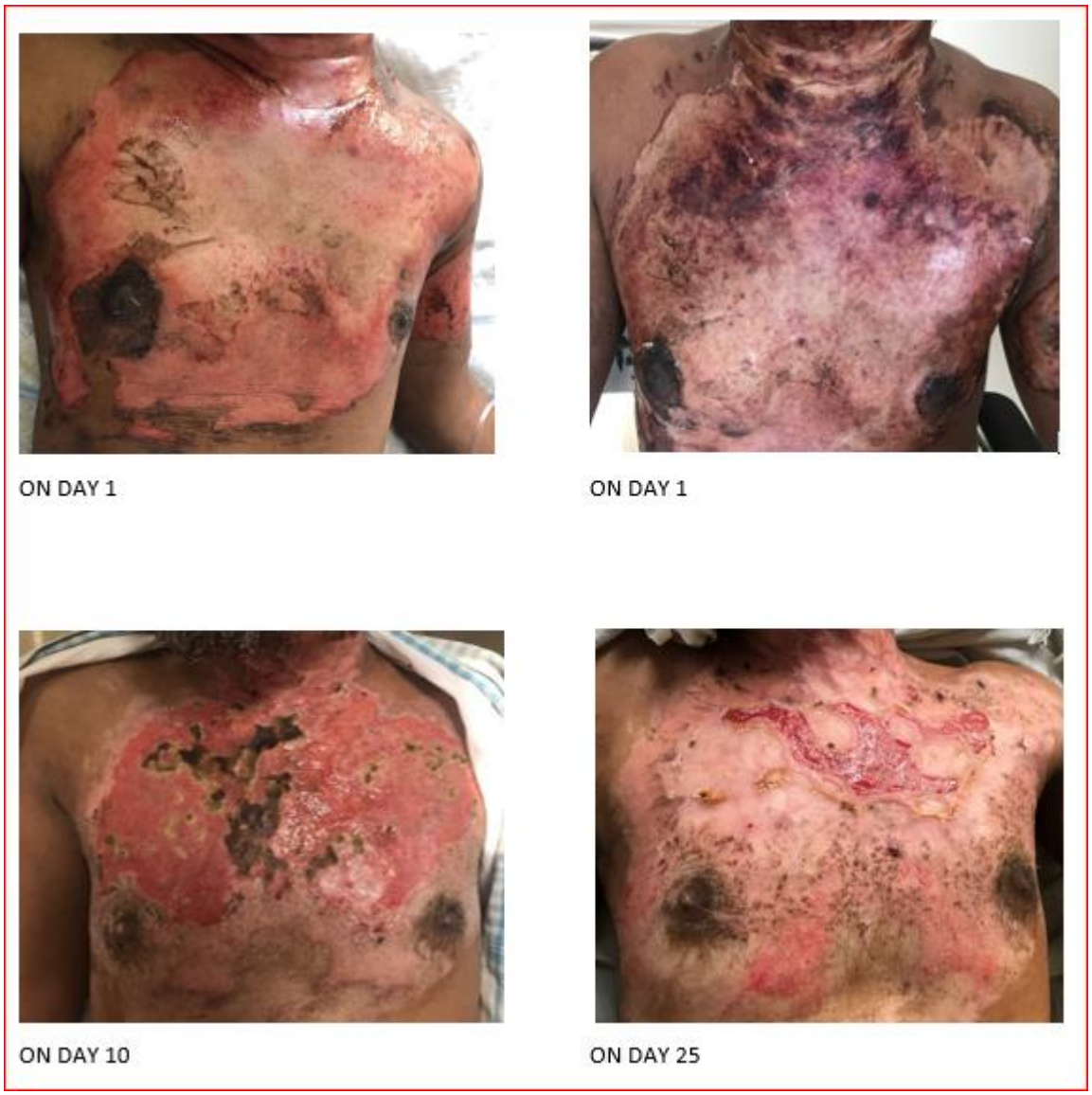


Figure 7I: Serial Photograph of patient where conventional (Silver sulphadiazine and cuticell) dressing

INCLUSION CRITERIA

- 10-30% first and second degree burn patients.

EXCLUSION CRITERIA

- More than 30% burns.
- All deep thermal burns.
- Chemical and Electric burns.

SAMPLING

- Prospective, comparative study.

STATISTICAL ANALYSIS:

All characteristics were summarized descriptively. For continuous variables, the summary statistics of mean± standard deviation (SD) were used. For categorical data, the number and percentage were used in the data summaries and diagrammatic presentation. Chi-square (χ^2) test was used for association between two categorical variables.

The formula for the chi-square statistic used in the chi square test is:

$$\chi_c^2 = \sum \frac{(O_i - E_i)^2}{E_i}$$

The subscript "c" are the degrees of freedom. "O" is observed value and E is expected value. C= (number of rows-1)* (number of columns-1)

The difference of the means of analysis variables between two independent groups was tested by unpaired t test.

The t statistic to test whether the means are different can be calculated as follows:

$$t = \frac{(\overline{x_1} - \overline{x_2}) - (\mu_1 - \mu_2)}{\sqrt{\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}}}$$

where $\bar{x}_1$ = mean of sample 1

$\bar{x}_2$ = mean of sample 2

n_1 = number of subjects in sample 1

n_2 = number of subjects in sample 2

s_1^2 = variance of sample 1 = $\frac{\Sigma(x_1 - \bar{x}_1)^2}{n_1}$

s_2^2 = variance of sample 2 = $\frac{\Sigma(x_2 - \bar{x}_2)^2}{n_2}$

If the p-value was < 0.05, then the results were considered to be statistically significant otherwise it was considered as not statistically significant. Data were analysed using SPSS software v.23 (IBM Statistics, Chicago, USA) and Microsoft office 2007.

6. RESULTS

A total of 70 patients were included in the study and were randomly divided into two groups, 36 patients in Amniotic membrane dressing (AM) Group and 34 patients in Conventional Dressing (CD) Group.

Table 6: Distribution of Age between Study Groups

AGE(yrs.)	GROUP AM		GROUP CD		p value
	N	%	N	%	
≤10	17	47.2%	4	11.8%	0.015*
11-20	2	5.6%	5	14.7%	
21-30	9	25.0%	8	23.5%	
31-40	2	5.6%	8	23.5%	
41-50	5	13.9%	6	17.6%	
>50	1	2.8%	3	8.8%	
Total	36	100.0%	34	100.0%	

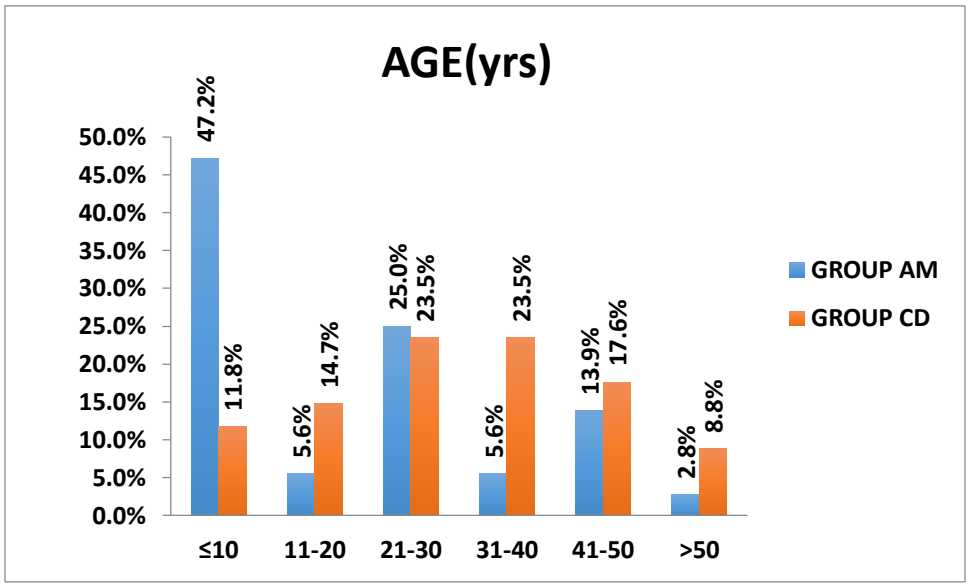
Note: * significant at 5% level of significance (p<0.05)

Parameters	GROUP AM		GROUP CD		p value
	Mean	SD	Mean	SD	
AGE(yrs.)	18.9	16.4	30.9	18.6	0.006*

Note: * significant at 5% level of significance (p<0.05)

Mean age in the AM group in this study is 18.9 years whereas in the CD group is 30.9 years.

Figure 8: Distribution of Age between Study Groups

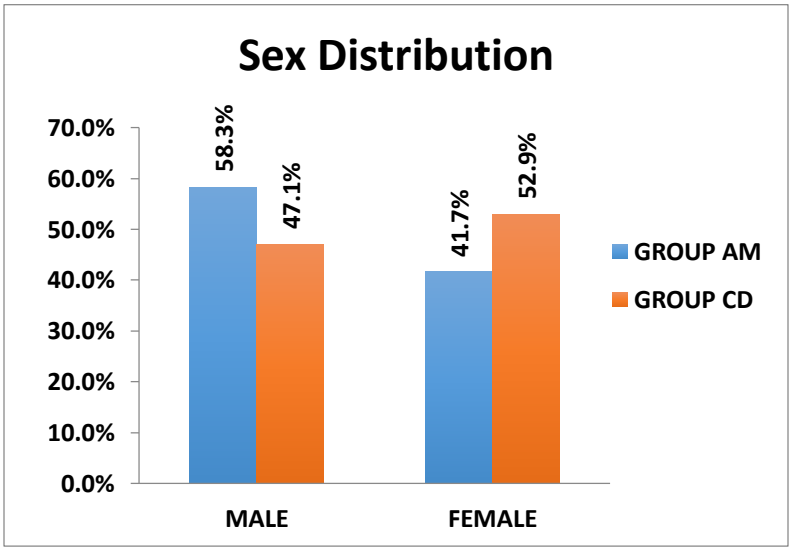


In this study most patients who received Amniotic membrane dressing belonged to less than 10 years of age where as in control group its between 20-40 years of age.

Table 7: Distribution of Sex between Study Groups

SEX	GROUP AM		GROUP CD		p value
	N	%	N	%	
MALE	21	58.3%	16	47.1%	0.345
FEMALE	15	41.7%	18	52.9%	
Total	36	100.0%	34	100.0%	

Figure 9: Distribution of Sex between Study Groups

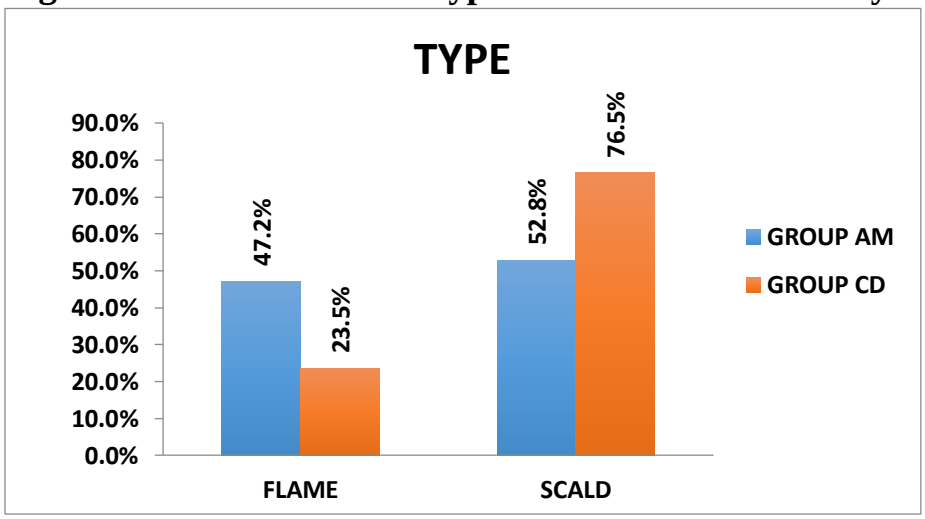


The Amniotic membrane Group had 21 male (58.3%) and 15 female (47.1%) patients as compared to the control group which had 16 male (47.1%) and 18 (52.9%) female patients.

Table 8: Distribution of Type Of Burns between Study Groups

TYPE	GROUP AM		GROUP CD		p value
	N	%	N	%	
FLAME	17	47.2%	8	23.5%	0.039*
SCALD	19	52.8%	26	76.5%	
Total	36	100.0%	34	100.0%	

Figure 10: Distribution of Type of burns between Study Groups



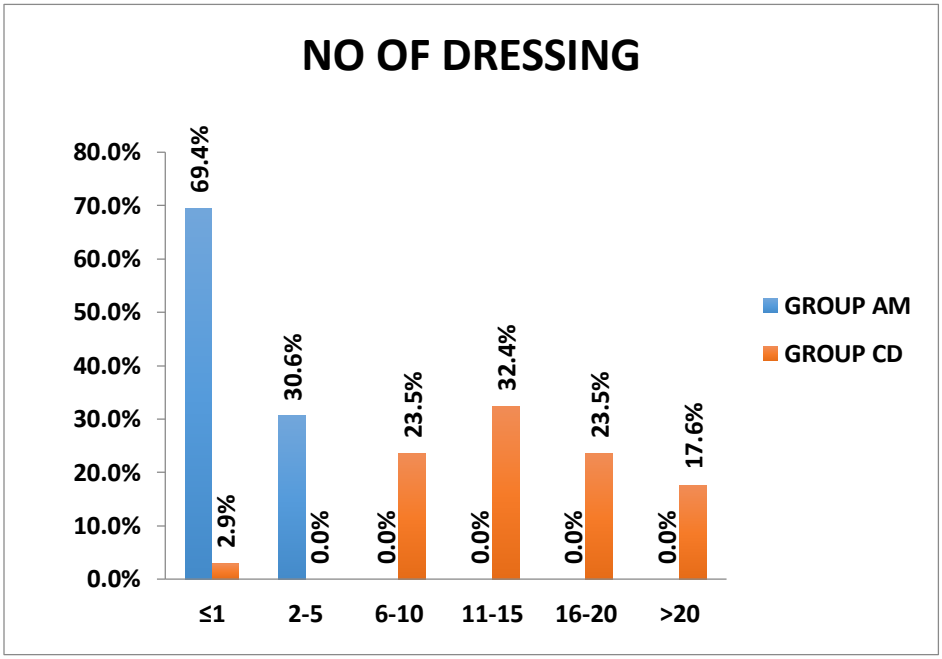
In Amniotic membrane dressing group 19(52.8%) sustained scald burns and 17(47.2%) flame burns whereas in conventional dressing group 26(76.5%) and 8(23.5%) had scald and flame burns respectively.

Table 9: Distribution of No of Dressing between Study Groups

Parameters	GROUP AM		GROUP CD		p value
	Mean	SD	Mean	SD	
NO OF DRESSING	1.4	0.6	15.1	7.6	<0.001*

Note: * significant at 5% level of significance (p<0.05)

Figure 11: Distribution of No of Dressing between Study Groups



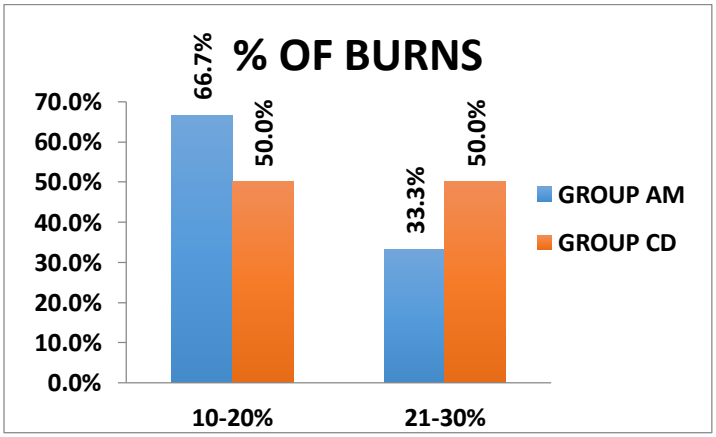
Mean number of dressings used in Amniotic membrane group is 1.4 and that of conventional group is 15.1. In a study by Branski et al the amount of re-applications of facial dressings in the amnion group was significantly lower than in the control group (0.5 - 2 versus 6 - 3 re-applications)[8].

Table 10: Distribution of % of Burns between Study Groups

% OF BURNS	GROUP AM		GROUP CD		p value
	N	%	N	%	
10-20%	24	66.7%	17	50.0%	0.351
21-30%	12	33.3%	17	50.0%	
Total	36	100.0%	34	100.0%	

Parameters	GROUP AM		GROUP CD		p value
	Mean	SD	Mean	SD	
% OF BURNS	18.8	7.3	21.1	7.1	0.171

Figure 12: Distribution of % of Burns between Study Groups



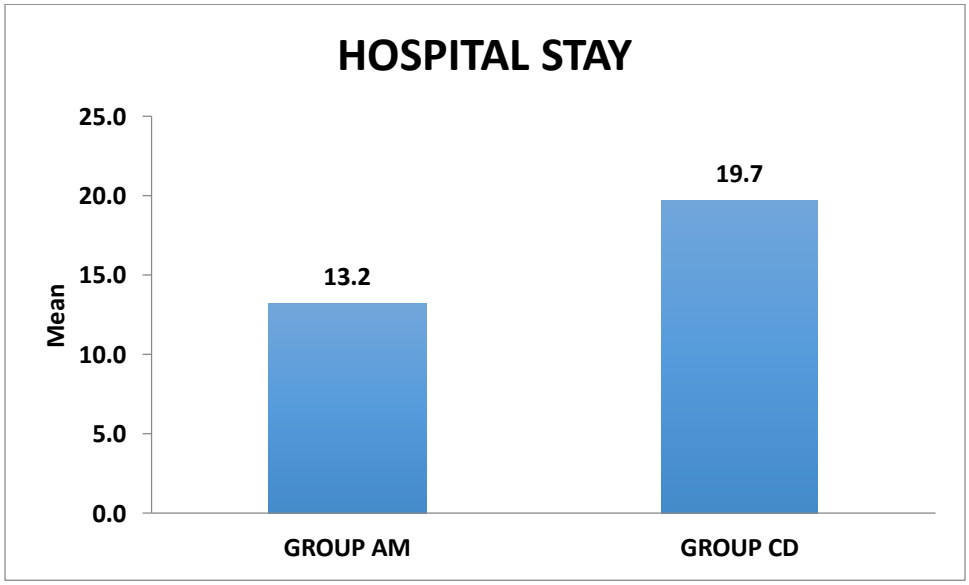
66.7% and 50% patients in Amniotic membrane group and conventional dressing group sustained 10-20% TBSA burns respectively while 33.3% and 50% in AM group and CD group sustained 21-30% TBSA burns.

Table 11: Distribution of Mean Hospital Stay between Study Groups

Parameters	GROUP AM		GROUP CD		p value
	Mean	SD	Mean	SD	
HOSPITAL STAY	13.2	6.1	19.7	9.2	0.001*

Note: * significant at 5% level of significance (p<0.05)

Figure 13: Distribution of Mean Hospital Stay between Study Groups



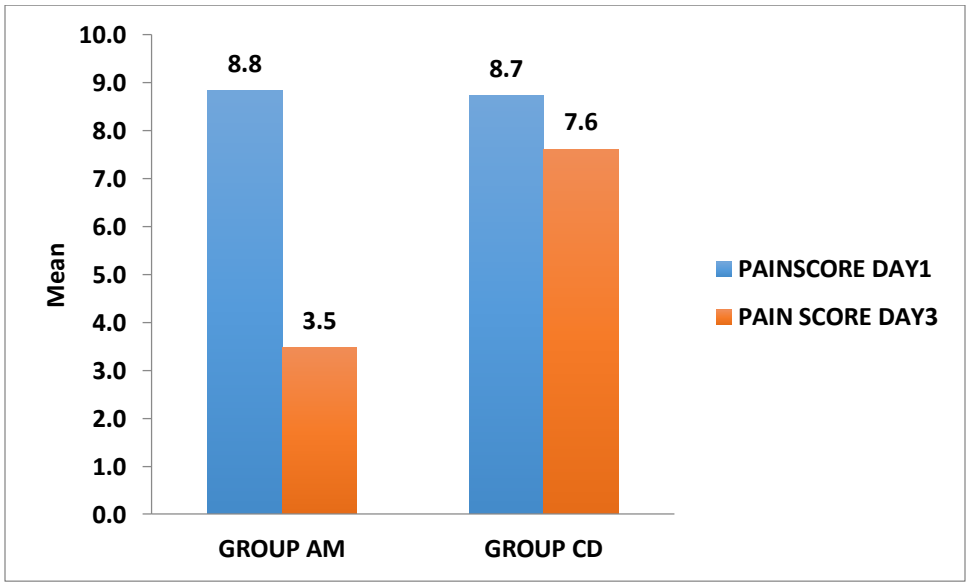
Mean hospital stay in those in Amniotic membrane group was 13.2 days wherein the conventional dressing group it is 19.7 days.

Table 12: Distribution of Pain Score between Study Groups

Parameters	GROUP AM		GROUP CD		p value
	Mean	SD	Mean	SD	
PAIN SCORE DAY1	8.8	0.7	8.7	0.9	0.610
PAIN SCORE DAY3	3.5	1.1	7.6	0.9	<0.001*

Note: * significant at 5% level of significance (p<0.05)

Figure 14: Distribution of Pain Score between Study Groups



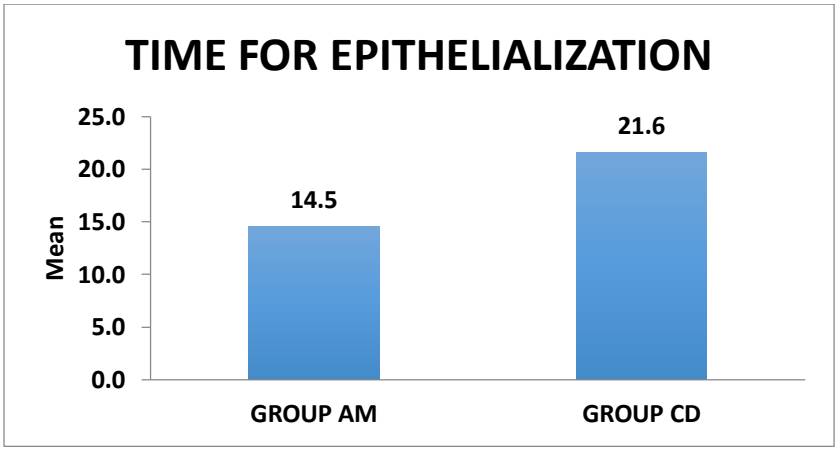
Mean pain score on Day 1 in this study 8.8, 8.7 whereas Mean Pain score on Day 3 was 3.1, 7.6 in Amniotic membrane group and conventional dressing group respectively.

Table 13: Distribution of Time for Epithelialization between Study Groups

Parameters	GROUP AM		GROUP CD		p value
	Mean	SD	Mean	SD	
TIME FOR EPITHELIALIZATION	14.5	3.5	21.6	4.4	<0.001*

Note: * significant at 5% level of significance (p<0.05)

Figure 15: Distribution of Time for Epithelialization between Study Groups



Time for Epithelialization in those in Amniotic membrane group was 14.5 days (Range of 8-24 days) wherein the conventional dressing group it is 21.6 days (Range of 14-30 days). Quinby et al conducted a study and inferred average wound healing of 12 days (with a range of 8 to 19 days) with amniotic membrane dressings and an average of 15.2 days in silver sulphadiazine dressing (range of 10-23 days)[41].

7. DISCUSSION

Burn wound management is always a clinical challenge to the practitioners. With the aim of tackling this, the study is conducted on a total of 70 patients who had 10 to 30% total body surface area first to second degree burns. 36 patients in this study had amniotic membrane dressings over the burnt site (AM group) whereas 34 patients had conventional dressing with silver sulphadiazine and cuticell (CD group).

AGE GROUP

In our study mean age in the AM group is 18.9 years whereas in the CD group is 30.9 years with most patients who received Amniotic membrane dressing belonged to less than 10 years of age 47.2% where as in control group its between 21-30yrs and 31-40 years of age with a percentage of 23.5% each constituting a total percentage of 47% in between the age group of 21-40years.

GENDER

In the present study the Amniotic membrane Group had 21 male (58.3%) and 15 female (47.1%) patients as compared to the control group which had 16 male (47.1%) and 18 (52.9%) female patients respectively.

PERCENTAGE OF BURNS

Our study is done in patients sustained 10 to 30% first to second degree burns , in which 66.7% (24 patients) in the AM group and 50% (17 patients) in CD group had 10-20% first to second degree burns whereas 33.3% (12 patients) in the AM group and 50% (17 patients) in CD group had 21-30% first to second degree burns. Mean percentage of burns in AM group is 18.8% and that of CD group is 21.1%,

PAIN SCORE

Pain score of the patient is assessed on the day 1 and day 3 in both the groups and the mean pain score of Day 1 when the amniotic membrane is applied and dressing was done is 8.8 in AM group and 8.7 in CD group which is almost same whereas pain assessment on Day 3 in the AM group was 3.5 and CD group is 7.6 with a p-value of <0.001 which is highly significant.

NUMBER OF DRESSINGS

Total number of dressings done is assessed in AM group and CD group and yielded an average of 1.4 in AM group and 15.1 in conventional dressing with a p value of <0.001 and is highly significant.

TIME FOR EPITHELIALISATION

Mean time for epithelialisation is 14.5 days in amniotic membrane group with a mean epithelialisation time of 21.6 days in conventional group with a p value <0.001 which is highly significant suggesting amniotic membrane helps epithelialisation of wound early compared to the conventional dressing group.

MEAN HOSPITAL STAY

Mean hospital stay in those in Amniotic membrane group was 13.2 days wherein the conventional dressing group it is 19.7 days with p value 0.001 which is significant in the sense the patients who received amniotic membrane dressing had relatively less number of hospital stay compared to the conventional dressing group.

8. CONCLUSION

This study has concluded the following:

- Number of dressings are significantly less, almost one dressing, in patients who received amniotic membrane dressing compared to the conventional silversulphadiazine and cuticell dressing group.
- Pain is significantly less for those who receive amniotic membrane dressing for first and second degree burns.
- Mean hospital stay is less in those who received the amniotic membrane dressing.
- Wound healing is faster in those who received amniotic membrane dressing.
- Reduced hospital stay, faster wound healing and less number of dressing indirectly reduces the financial burden of the patient.

9. SUMMARY

In our study we compared how effective amniotic membrane dressings are for 10-30% of first and second degree burns with that of conventional silver sulphadiazine dressings in a total number of 70 patients with 36 patients in amniotic membrane group and 34 patients in conventional dressing group and came to the conclusion that with the use of amniotic membrane as dressing there is hardly any need for repeated dressing rather than the application dressing. In addition there is drastic reduction in Pain score on Day 3 of opening the amniotic membrane dressing following which the membrane itself acts as the biological dressing. Both these parameters, pain and total number of dressings needed, had a highly significant p-value. In addition, time for epithelialisation of the burnt area and mean hospital stay is found to be significantly less in the amniotic membrane group than the conventional dressing group.

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11. ANNEXURE I CERTIFICATE OF ETHICAL CLEARANCE

B.L.D.E (Deemed to be University)
SHRI.B.M.PATIL MEDICAL COLLEGE HOSPITAL & RESEARCH CENTRE
VIJAYAPUR – 586103

IEC/NO:286/2018
17-11-2018

INSTITUTIONAL ETHICAL COMMITTEE

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this college met on 13-11-2018 at 03-15 PM scrutinize the Synopsis of Postgraduate Students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected and revised version synopsis of the Thesis has accorded Ethical Clearance.

Title : Comparative study between effectiveness of placental dressing over conventional dressing in first and second degree burns patient-prospective study.

Name of P.G. Student : Dr Firos Khan A.
Department of General Surgery

Name of Guide/Co-investigator: Dr Girish Kullolli, Associate Professor of Surgery

DR RAGHAVENDRA KULKARNI
CHAIRMAN
Institutional Ethical Committee
BLDEU's Shri B.M. Patil
Medical College,BIJAPUR-586103.

Following documents were placed before E.C. for Scrutinization:

1) Copy of Synopsis/Research Project
2) Copy of informed consent form.
3) Any other relevant documents.

12. ANNEXURE II-STUDY SUBJECT CONSENT STATEMENT

I confirm that Dr Firos Khan A has explained to me the purpose of this research, the study procedure that I will undergo and the possible discomforts and benefits that I may experience, in my own language.

I have been explained all the above in detail in my own language and I understand the same. Therefore I agree to give my consent to participate as a subject in this research project.

_____ _____

(Participant) Date

_____ _____

(Witness to above signature) Date

RISKS AND DISCOMFORTS:

I understand that I/my ward may experience some pain while cleaning the wound before application of placenta and chance of rejection of the same and the need for reapplication if not taken up.

ALTERNATIVES:

Even if you decline in participation, you will get the routine line of management.

CONFIDENTIALITY:

I understand that medical information produced by this study will become a part of this hospital records and will be subjected to the confidentiality and privacy regulation of this hospital. Information of a sensitive, personal nature will not be a part of the medical records, but will be stored in the investigator's research file and identified only by a code number. The code key connecting name to numbers will be kept in a separate secure location.

If the data are used for publication in the medical literature or for teaching purpose, no names will be used and other identifiers such as photographs and audio or video tapes will be used only with my special written permission. I understand that I may see the photograph and videotapes and hear audiotapes before giving this permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time. Dr.Firos Khan A is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of this study, which might influence my continued participation.

If during this study, or later, I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me.

And that a copy of this consent form will be given to me to keep it and for careful reading.

REFUSAL OR WITHDRAWL OF PARTICIPATION:

I understand that my participation is voluntary and I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital.

I also understand that Dr.Firos Khan A will terminate my participation in this study at any time after he has explained the reasons for doing so and has helped arrange for my continued care by my own physician or therapist, if this is appropriate.

INJURY STATEMENT:

I understand that in the unlikely event of injury to me/my ward, resulting directly to my participation in this study, if such injury were reported promptly, then medical treatment would be available to me, but no further compensation will be provided.

I understand that by my agreement to participate in this study, I am not waiving any of my legal rights.

I have explained to _____ the purpose of this research, the procedures required and the possible risks and benefits, to the best of my ability in patient's own language.

Date: Dr Girish K.Kullolli (Guide) Dr Firos Khan A (Investigator)

13. ANNEXURE III- PROFORMA

SL NO:

NAME: CASE NUMBER:

AGE: IP NO:

SEX:

OCCUPATION: DATE OF ADMISSION:

DATE OF OCCURRENCE: DATE OF DISCHARGE:

ADDRESS:

Chief Complaints:

History of presenting illness:

Past history**:**

Personal history:

GENERAL PHYSICAL EXAMINATION

BUILT: WELL/MODERATE/POOR

NOURISHMENT: WELL/MODERATE/POOR [BMI= kg/m^2]

PALLOR , ICTERUS , CYANOSIS , CLUBBING, PEDAL EDEMA , GENERALISED LYMPHADENOPATHY

VITALS DATA:

TEMPERATURE: ^{0}F PULSE: bpm

RESPIRATORY RATE: cpm BLOOD PRESSURE: mm/Hg

SYSTEMIC EXAMINATION

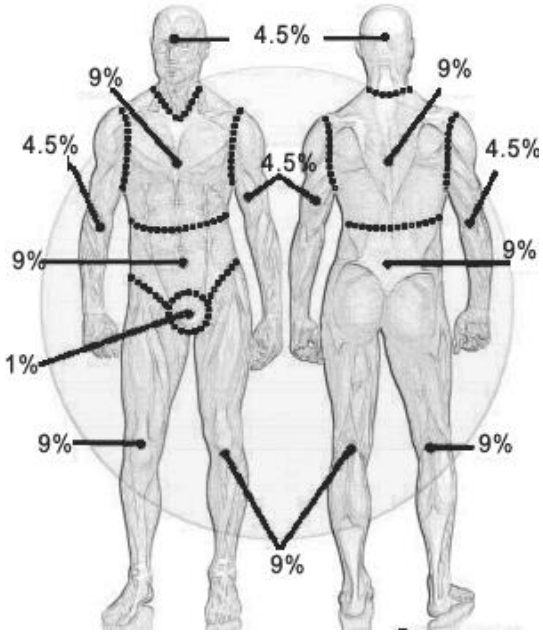
PER ABDOMEN:

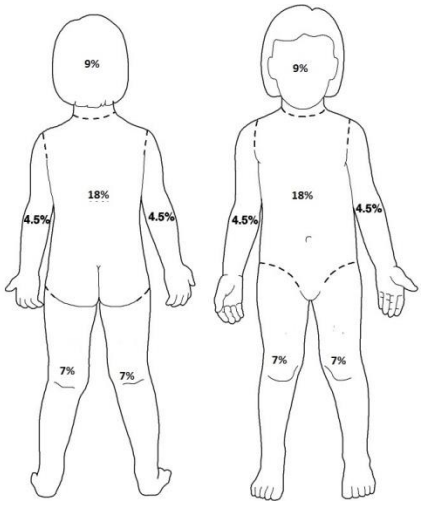
RESPIRATORY SYSTEM:

CARDIOVASCULAR SYSTEM:

CENTRAL NERVOUS SYSTEM:

LOCAL EXAMINATION (Sites involved)





CLINICAL DIAGNOSIS: % first and second degree burns

LABORATORY TESTS

HEMOGLOBIN:

TC: (N L M E B)

CHEST X RAY:

WOUND CULTURE:

CAUSE OF BURNS: Scald / Flame

TYPE OF DRESSING USED: AMNIOTIC MEMBRANE / CONVENTIONAL

DATE OF PLACENTAL DRESSING APPLICATION:

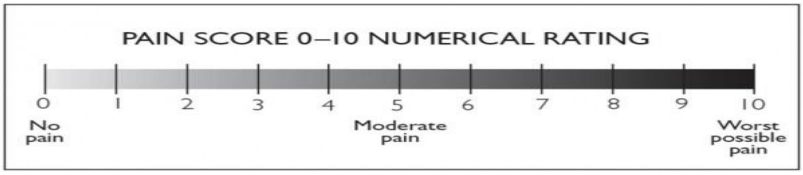
HOSPITAL STAY: days

Total number of dressing change:

Time needed for epithelial coverage:

Application: painful/painless.

PAIN ASSESSMENT



Patient's pain after application: mild/moderate/severe

FOLLOW UP-

FOLLOW UP AFTER 1 MONTH IN OPD

KEY TO MASTER CHART

SL. NO – Serial Number

AGE – Age in years

G – Gender

IP NO: - In Patient number

DOA – Date of admission

HS - Hospital stay in days

DRESSINGS – Number of dressings

PS D1 – Pain Score Day 1

PS D3 – Pain Score Day 3

TE – Time for Epithelialisation of wound in days

CASES (AMNIOTIC MEMBRANE DRESSING)

SL NO:	NAME	AGE	G	IP NO:	DOA	TYPE	% OF BURNS	HS	DRESSINGS	PS D1	PS D3	TE
1	BHUVANESHWARI	24	F	35685	12-11-18	SCALD	12	18	2	8	4	18
2	MALLAMMA	51	F	38681	12-11-18	SCALD	30	28	2	9	4	21
3	MALLAPPA	50	M	38626	12-11-18	FLAME	20	22	3	8	3	20
4	KAILASAYYA	32	M	41980	12-12-18	SCALD	25	18	2	8	2	15
5	SHRAVANI	1	F	864	08-01-19	SCALD	20	10	1	8	4	16
6	BHIMSHANKAR	4	M	1159	10-01-19	FLAME	20	10	1	10	5	14
7	BHUMIKA	9	F	1533	14-01-19	SCALD	10	5	1	8	4	11
8	SANDEEP	4	M	1539	15-01-19	SCALD	30	9	1	9	3	13
9	SOBHA	28	F	2931	27-01-19	FLAME	25	31	2	8	3	24
10	UMESH	2.5	M	2932	27-01-19	FLAME	10	8	1	9	3	15
11	KRUTIKA	10	F	4627	11-02-19	SCALD	10	8	1	8	2	14
12	SUDYANI	45	F	6965	25-02-19	SCALD	10	14	1	9	1	14
13	ANISH	4	M	11267	11-04-19	SCALD	30	13	2	9	4	17
14	PREETAM	1	M	7426	08-03-19	SCALD	30	18	2	9	3	18
15	SHARANAYYA	21	M	30470	12-09-19	FLAME	15	7	1	9	3	11
16	GAJANAND	21	M	30471	12-09-19	FLAME	10	7	1	8	3	10
17	UMERA	3	F	31597	21-09-19	SCALD	25	12	1	10	5	16
18	BHIMARAYA GOUD	6	M	41436	09-12-19	FLAME	10	7	1	9	2	11
19	ROHINI	4	F	42202	16-12-19	SCALD	18	7	1	8	2	9
20	ROHIT KUMAR	6	M	42203	16-12-19	SCALD	20	11	1	10	4	12
21	CHANDAN	2	M	43519	26-12-19	SCALD	24	14	1	9	5	16
22	AMIT	9	M	2822	23-01-20	SCALD	18	10	1	9	6	10
23	VITTAL MUTTAPPA	19	M	1484	13-01-20	FLAME	25	18	3	8	3	17
24	KORA	5	M	8107	03-02-20	FLAME	10	9	1	10	4	12
25	SEETAWWA	50	F	8964	19-03-20	FLAME	18	13	1	9	4	16
26	ASHA	22	F	13586	26-05-20	SCALD	20	14	1	10	4	14
27	VEERESH	43	M	1662	20-05-19	SCALD	10	11	1	8	5	14
28	LAKKAWWA	25	F	13159	18-05-20	FLAME	18	16	1	10	3	15
29	YALLALING	23	M	14015	01-06-20	FLAME	12	21	1	9	4	20
30	ABHISHEK	33	M	10939	06-04-20	FLAME	10	5	1	9	3	8
31	SANGAPPA	50	M	7277	02-03-20	SCALD	30	20	2	8	4	12
32	MAHANTESH	24	M	3100	04-02-20	FLAME	25	13	2	9	2	17
33	RESHMA	25	F	8401	07-03-20	SCALD	30	14	1	10	3	14
34	BHAGYASHREE	16	F	12659	01-05-20	FLAME	20	16	2	9	4	15
35	PREETAM	5	M	8286	27-02-20	FLAME	15	10	1	9	4	13
36	IQRA	2	F	8107	04-03-20	FLAME	10	8	1	8	3	11

CONTROLS (CONVENTIONAL DRESSING)

SL NO:	NAME	AGE	GENDER	IP NO:	DOA	TYPE	% OF BURNS	HS	DRESSINGS	PS D1
1	HANAMAVVA	85	F	38773	13-11-18	SCALD	20	40	35	8
2	ZABEEN	18	F	41638	08-11-18	SCALD	25	19	12	10
3	LAXMI	25	F	1792	16-01-19	SCALD	30	24	21	8
4	AMINABI	35	F	13496	06-05-19	SCALD	10	10	8	7
5	MADASAB	55	M	14183	06-05-19	SCALD	30	25	17	9
6	PARESHURAM	43	M	15904	20-05-19	SCALD	25	7	10	8
7	JAGADISHWARI	25	F	2895	26-01-19	SCALD	30	24	16	9
8	NAGARAJ	35	M	5588	19-02-19	SCALD	30	29	20	10
9	BOURAMMA	45	F	12812	24-04-19	SCALD	15	30	25	10
10	AKASH	16	M	19111	15-06-19	SCALD	15	27	20	9
11	LAXMI	13	F	18170	07-06-19	SCALD	10	9	7	8
12	RENUKA	32	F	21110	02-07-19	SCALD	25	14	12	8
13	MALLIKARJUN	5	M	22455	12-07-19	SCALD	10	4	12	8
14	BHARATI	31	F	24160	24-07-19	SCALD	30	36	30	9
15	SHANKARALING	25	M	26246	08-08-19	FLAME	30	8	18	8
16	SABIYA	13	F	26774	13-08-19	SCALD	25	33	30	8
17	PARAVEEN	35	M	26773	13-08-19	SCALD	20	33	26	8
18	KIRAN KUMAR	18	M	30946	16-09-19	SCALD	10	5	1	10
19	ANAND	22	M	42190	16-12-19	FLAME	12	10	6	9
20	BASAVARAJ	39	M	42997	21-12-20	SCALD	18	16	11	8
21	SUSHILA	1.5	F	3101	31-01-20	SCALD	12	16	11	9
22	SIDDAWWA	70	F	40758	12-04-20	SCALD	20	22	16	10
23	SALMA	1.5	F	6191	19-02-20	SCALD	25	17	12	10
24	SANGAPPA	50	M	7277	27-02-20	SCALD	12	10	6	9
25	SURESH	29	M	7563	29-02-20	SCALD	24	21	13	8
26	RAJAWWA	38	F	7562	01-03-20	FLAME	30	30	20	8
27	KAMALABAI	35	F	8548	08-03-20	FLAME	20	15	9	8
28	BHARATH	2	M	11782	20-04-20	SCALD	22	25	18	8
29	SEETAMMA	43	F	12877	13-05-20	SCALD	27	20	14	10
30	ASHA	22	F	13586	26-05-20	FLAME	15	16	10	9
31	SHARADHABAI	50	F	9843	19-03-20	FLAME	30	21	14	9
32	REVANASIDDA	22	M	5784	01-02-20	FLAME	17	20	10	8
33	BHIMU	45	M	7565	29-02-20	SCALD	18	16	11	10
34	MAIBOOB	25	M	17802	29-07-20	FLAME	27	18	12	9