

**UNIVERSITY OF ZAMBIA**  
**SCHOOL OF MEDICINE**

THE SIG  
KST  
1996

THE USE OF AMNIOTIC MEMBRANE IN THE TREATMENT OF BURNS IN  
CHILDREN

A CLINICAL TRIAL AT THE UNIVERSITY TEACHING HOSPITAL, LUSAKA.

BY

DR. KINGSTONE R.C. KATEBE, B.Sc.(Hb).MB.ChB.(UNZA)

A DISSERTATION IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE  
DEGREE OF MASTER OF MEDICINE (GENERAL SURGERY).

SUPERVISOR: Prof. Lupando Munkonge F.R.C.S.  
School of Medicine.  
University of Zambia.  
LUSAKA

## CONTENTS

I.	Acknowledgements	1
II.	Declaration	2
III.	Dedication	3
IV.	Abstract	4
V.	Introduction:	5
	1. Background information	5
	2. Pathophysiology of burns	5
	3. Basic principles of burns treatment	6
	4. Treatment of burns at the University Teaching Hospital	7
	5. Biological dressings	7
	6. Disinfection and Sterilization of biological dressings	9
	7. Gamma-Irradiation sterilization	10
	8. Project proposal	11
VI.	Aims and Objectives	12
VII.	Methodology	14
VIII.	Definition of terms	15
IX.	Materials and Methods	17
	1. Collection and storage technique for placenta	17
	2. Technique for cleaning, sterilizing and preparing amniotic membrane	18
	3. Technique for freeze drying of amniotic membrane (Lyophilization)	21
	4. Microbiological screening of amniotic membrane before sterilization by Gamma Irradiation	22

	5. Gamma Irradiation of Amniotic Membrane	24
	6. Sterility tests following Gamma Irradiation of Amniotic Membrane	24
X.	Clinical trial	25
XI.	Results:	28
	1. Annual distribution of burns	28
	2. Age and sex distribution of burns	28
	3. Mode of burns	29
	4. Degree of burns	29
	5. Regions of amniotic membrane application	29
	6. Treatment of burns by surgical firms	29
	7. Evaluation of treatment of burns with amniotic membrane	30
XII.	Discussion	34
XIII.	Conclusions	38
XIV.	References	39
XV.	Appendix:	
	1. Flow Chart showing patient selection for the clinical trial	
	2. Graphs	
	3. Estimation of Burns	
	4. Burn Chart	
	5. Questionnaire	

## ACKNOWLEDGEMENT

I must first thank my project supervisor; Professor Munkonge, for his guidance during the course of this work. I also thank the following staff on the Amniotic Membrane Tissue Bank project; Mr Kasobe, Mr Chikonda, Mr Chishimba and Mr Katebe who were involved in the production of the Amniotic Membrane and assisted me in carrying out the clinical trial. Thanks are also due to the International Atomic Energy Agency (IAEA) for sponsoring this project and to Dr S. Pellet the IAEA expert who helped in the setting up of the Tissue Bank Laboratory and procedures for preparing amniotic membrane homograft at the University Teaching hospital. I express my gratitude to the following members of the faculty; Professor Erzingatsian for his comments on the project; Professor Sims for helping with the statistics and Professor Karashani for editing the whole report.

I am greatly indebted to Mr Chabala for allowing me the use of his valuable Personal Computer and Mr R. Ngwisha for giving me help on its use. Lastly, but not the least I wish to thank my wife Joyce for her love and moral support.

DECLARATION

I hereby declare that the work presented in this study for the Degree of Master of Medicine (General Surgery) has not been presented either wholly or in part for any other degree and is not being currently submitted for any other degree.

Signed:.....*KR Raleby*.....

## DEDICATION

I dedicate this work to my sons; Chungu, Saili and Kapenda.

## ABSTRACT

This is a clinical trial which was carried out at the University Teaching Hospital, Lusaka from the 1st of July to the 31st of December, 1994. It involved treatment of burns in forty children using gamma irradiated amniotic membrane produced at the hospital.

The results showed that it is feasible to produce Gamma Irradiated biological dressings from amniotic membrane at this hospital. The amniotic membrane was easy to apply on burns and the treatment was acceptable to the majority of parents with burnt children. The use of amniotic membrane was non inflammatory to the wounds in all forty patients (100%), reduced wound infection in thirty three patients (82.5%), increased the rate of wound healing in thirty nine patients (97.5%) and resulted in good quality wound healing in thirty one patients (77.5%). Therefore, the treatment offers a good alternative in the treatment of burns in children at this hospital.

## **I. INTRODUCTION**

### **BACKGROUND INFORMATION.**

About six hundred burns' patients are admitted to the University Teaching Hospital every year, the highest number being admitted during the cold and dry months. Most of the burns are caused by hot water and fire from cooking places. Studies done at the University Teaching Hospital in the past have shown that there is a high mortality among children admitted with burns covering a Body Surface Area of over 30% (1).

### **PATHOPHYSIOLOGY OF BURNS.**

Morbidity and mortality are directly proportional to the extent and the depth of the thermal injury. Large burns are life threatening because they not only result in abnormal acute and chronic fluid loss but also destroy the protective skin barrier between man and the environment. This leaves him susceptible to infection from bacteria and opportunistic invaders such as viruses and fungi which normally are not pathogenic (2,3).

Wound closure is desirable in caring for burnt patients.

Ultimately, this is achieved when the partial thickness burn re-epithelializes or when split thickness skin grafts are applied to



full thickness burns. Until these goals are achieved, a temporary covering must be found to protect the integrity of granulating tissue and preserve a clean, viable wound surface that can accept skin grafts. Various materials, both natural and synthetic, have been used as coverings (2,4,5,6).

#### **BASIC PRINCIPLES OF BURNS TREATMENT.**

The properties of a wound cover, both practical and scientific, that are necessary are as follows:

1. Inexpensive.
2. Readily available.
3. Non inflammatory to the wound.
4. Non Antigenic.
5. Prevent bacterial access to the wound.
6. Able to decrease evaporative water loss (normal equals about 8.5 grams per square metre per hour).
7. Able to adhere well and so discourage fluid accumulation.

There is no single biological dressing or synthetic skin that satisfies all the above criteria. Obviously, the best substitute for human skin is an allograft; however this is very expensive and is not readily available in large quantities (2,3).

#### **TREATMENT OF BURNS AT THE UNIVERSITY TEACHING HOSPITAL.**

The common method of burns treatment at the University Teaching Hospital is the exposure method, with or without topical application of Silver Sulfadiazine cream (1). This method is widely used in other hospitals around the world and has shown good results and a reduction in mortality rate (7). However, at this Hospital the mortality rate among patients with severe burns is still very high. A review of surgical audits shows a mortality of 100% in burns over fifty percent and thirty percent in adults and children respectively. Therefore, it is useful to study other methods of treating burns in the hope of reducing the mortality rate.

#### **BIOLOGICAL DRESSINGS.**

Studies in centres which use biological dressings in treating burns have shown good results in severe burns. Some of the Biological dressings used in other burns units include: amniotic membrane, porcine xenograft, Composite Skin Equivalents and Cultured Epithelium (2,4,5,8). The author did not find any published

literature in the region on the use of biological dressings, however recently the author visited a Burns Unit at Baraguanath Hospital in Johannesburg, South Africa where a study on the use of porcine xenograft in the treatment of burns is in progress. At this Hospital a study on the "use of Amniotic Membrane as a dressing" by Professor Erzingatsian and Dr Ibrahim was approved by the Research and Ethics Committee in 1985, but results of the study have not been published (Personal Communication).

Fetal membranes were first reported to help wound healing in 1910 and the amniotic membrane alone in 1913, but it was not until the 1970s that real interest was rekindled (8).

The amniotic membrane is the nearest thing to the epidermis. Formed by the ectoderm of the fetus, it is like an extension of the baby's skin. It is extremely elastic and more easily manipulated than a thin skin graft itself. Its application to denuded dermis stops pain and fluid loss immediately (9,10).

The fear of transmitting infection by its application to burns has no doubt prevented its general acceptance (11,12), but over the years more effective methods of disinfection and sterilization have been studied and should eliminate this fear (8,12,13).

## DISINFECTION AND STERILIZATION OF BIOLOGICAL DRESSINGS.

As mentioned before, biological tissue grafts have to be rendered free of harmful micro-organisms before they can be used on patients.

Isolated living tissue is deprived of many of the defence mechanisms which normally protect an intact living organism. Dead tissue represents a good culture medium for microbes. Infection is therefore the major enemy of tissue allograft. Therefore, good manufacturing practice must be strictly observed.

Even when all the hygienic measures have been observed during tissue withdrawal, grafts may still be contaminated. There is a need therefore for grafts to be sterilized before they can be safely used. However, the sterilization procedure can also damage the tissue.

Heat, ethylene oxide gas, aqueous chemicals (including antibiotics) and ionizing radiation have been employed for effecting sterilization. When used under the most advantageous conditions, ionizing radiations have proved their value and allowed the processing sequence to develop along routine and more recently, into commercial manufacturing production (13).

## **GAMMA-IRRADIATION STERILIZATION.**

Gamma-radiation is now being used extensively to safely and economically sterilize human and animal tissue for use in implant surgery and the treatment of burns, particularly bone, cartilage, skin, dura mater, fascia lata and amnion (13).

The practice of establishing human Multi-tissue Banks is growing rapidly and the International Atomic Energy Agency has initiated a co-ordinated programme to transfer this relatively low technology to developing countries.

In 1989 the International Atomic Energy Agency sponsored a project at the University Teaching Hospital whose objective was to establish a Tissue Bank of Gamma sterilized Amniotic Membrane and Pig skin for use in the treatment of burns. The project was to run over a five year period and involved supply of equipment, technical expert support and training of local personnel.

The University Teaching Hospital was going to be among the first centres in the region to establish a Tissue Bank and it was hoped that it would eventually act as a training centre to transfer the technology to other hospitals.

## AIMS AND OBJECTIVES.

The main objectives of the pilot project were:

1. To study the local effects of applying Amniotic Membrane on burns.
2. To compare the rates of wound healing between burns treated with Amniotic Membrane and those treated by conventional methods.
3. To compare the quality of wound healing between burns treated with Amniotic Membrane and those treated by conventional methods.

The aims of the pilot project were to establish whether:

1. Use of Amniotic Membrane in the treatment of burns at the University Teaching Hospital was feasible.
2. Use of Amniotic Membrane would be accepted by the parents with children admitted with burns to the University Teaching Hospital.
3. Nursing staff could adjust and adapt to the idea of using Amniotic Membrane in the treatment of burns.

4. There were special problems related to the use of Amniotic Membrane in treating burns at the University Teaching Hospital.

## METHODOLOGY.

The clinical trial was an Experimental Case-Control study involving children up to the age of 10 years admitted with burns covering less than 20% of total body surface area.

The reason for selecting children with burns less than 20% of total body surface area was to exclude patients with a higher risk of mortality (14) as the pilot project was only aimed at studying the local effects of applying Amniotic Membrane on burns.

The study on the effect of treating burns with Amniotic Membrane on mortality was going to be carried out after establishing whether Amniotic Membrane is a good dressing with few complications and also whether its use is feasible and acceptable to patients.

Patient selection was done at random. When children were transferred to the wards from the Casualty wards, a day after admission, permission was sought from the accompanying parent, after explanation of the nature and purpose of the study. Only children of consenting parents were included in the clinical trial.

During the six months, forty five children were identified for inclusion in the Clinical Trial but five parents refused to give consent and only forty children had their burns treated with Amniotic Membrane.



## DEFINITION OF TERMS.

- Burn : A wound resulting from thermal injury to skin.
- Amniotic Membrane : Membrane attached to the placenta which contains the fetus.
- Gamma Radiation : Atomic Energy emitted by a Radioactive source
- Biological dressing : A dressing material made from human or animal cells or tissue.
- Allograft : A graft taken from the same species as the recipient.
- Porcine xenograft : A graft produced from pig skin for application on humans.
- Sterilization : Refers to the killing of vegetative organisms, viruses and spores.
- Infection : Presence of pus on the wound.

## DEFINITION OF TERMS.

- Burn : A wound resulting from thermal injury to skin.
- Amniotic Membrane : Membrane attached to the placenta which contains the fetus.
- Gamma Radiation : Atomic Energy emitted by a Radioactive source
- Biological dressing : A dressing material made from human or animal cells or tissue.
- Allograft : A graft taken from the same species as the recipient.
- Porcine xenograft : A graft produced from pig skin for application on humans.
- Sterilization : Refers to the killing of vegetative organisms, viruses and spores.
- Infection : Presence of pus on the wound.

Healing rate : Number in days taken for wound healing to take place.

Healing quality : Healing by re-epithelialization;  
granulation tissue or scar formation

## MATERIALS AND METHODS.

### PREPARATION OF AMNIOTIC MEMBRANE HOMOGRAFT.

- I. Collection and storage technique for the Placenta.
  - a. Materials needed: Iodophor solution diluted 1:4 with sterile saline for irrigation; sterile bags to contain Placenta; standard Refrigerator for temporary storage.
  - b. Procedure: Placenta from serologically negative mother to HIV, Hepatitis B and Syphilis with no premature membrane rupture, was removed from sterile basin after delivery. The amniotic membrane was stripped from the Placenta and placed in a sterile bag with 200 ml of Betadine:Saline 1:4 and immediately refrigerated (not frozen). It was labelled with the date, time and code number of the donor.

II. Technique for cleaning, sterilizing and preparing amniotic membranes.

a. Materials needed:

1. Iodophor solution.
2. Sterile saline for irrigation.
3. Aqueous Penicillin (Multi-use vials) 5 million units.
4. Sterile tubes for storage of tissues.
5. Sterile surgical gloves.
6. Sterile drape sheet for work table.
7. Sterile "Prep Kit" containing: 500 cc Stainless Basins (6), forceps and heavy Scissors (MAYO), 50cc Syringe with 20 gauge needle, 8 x 8 cm Gauze Pads (20).
8. Clean Gown, Cap, Mask for person preparing amnion.

5. The amniotic membrane was placed in the first test tube.
6. Each amniotic membrane was placed on sterile sheet and scrubbed gently to remove all blood and loose mucus and debris using several moist 8 x 8 cm. gauze pads. When clean, they were cut into pieces approximately 8 to 12 square cm, using scissor and transferred to the second test tube. Sequentially the specimens were drained, transferred and agitated (approximately one minute per test tube) to the last test tube. Some additional scrubbing was sometimes necessary for residual blood prior to final transfer of each piece to a separate container for capping and storage in a refrigerator.

III. Technique for freeze drying of amniotic membrane  
(Lyophilization).

a. Materials needed: Freeze drier, Plastic bags,  
Sealing machine.

b. Procedure.

1. Amniotic Membrane was collected from last test tube.
2. Amniotic Membrane was put on top of the swab and mounted on freeze drier rack (more than one layer was put on each plate but not more than three, each separated by gauze barrier).
3. After mounting amniotic membrane on to the rack, it was put in the plastic bag and placed in the deep freezer until ready for freeze drying (40°C)
4. Frozen amniotic membrane was placed in freeze drier and condenser turned on for 24 hours.
5. Amniotic Membrane "harvest" was removed from freeze drier and stored in refrigerator.

6. Each piece of amniotic membrane was double packed in two plastic packs and sealed using a heat Sealing machine.
7. The Amniotic Membrane in packs were stored at room temperature
8. The Amniotic Membrane in packs were transported to National Council for Scientific Research for sterilization by Gamma Irradiation.

IV. Microbiological screening of amniotic membrane before sterilization by Gamma Irradiation.

Upon the receipt of the amniotic membranes for sterilization, one pack from ten was picked at random for initial screening for contamination. The amniotic membranes were tested for the following microbes;

- a. Total Bacteria count
- b. Staphylococcus aureus
- c. Streptococcus
- d. Pseudomonas aeruginosa



e. Enterobacteriaceae

f. Molds/Yeasts

The biological media used to detect the above microbes were;

a. Tryptone Glucose Yeast Agar

b. Baird-Parker

c. Tryptose Blood Agar Base

d. Constituted King A and King B

e. Brilliant Green-Bile broth

f. Sabouraud Dextrose

The incubation period for bacteria is 24 hours at 37°C and for Molds/Yeasts, it is one week at ambient temperature.

V. Gamma Irradiation of Amniotic Membrane.

- a. Materials needed: Irradiation Equipment, Dosimetry Instruments.
- b. The sterilizing dose for the Amniotic Membranes ranges from 25 to 35Kg (Kilo Gray).

VI. Sterility tests following Gamma Irradiation of Amniotic Membrane.

The Biological media employed were;

- a. Thioglycollate
- b. Hitchen
- c. BY-Ferde agar
- d. Sabouraud Dextrose
- e. Blood agar.

The incubation period for bacteria was 24 hours at 37°C and that for Molds/Yeast was one week at ambient temperature.

### III CLINICAL TRIALS

Before beginning the clinical Trial, permission was sought from all Heads of Surgical Units through the head of department. The author explained the nature of the study to all doctors concerned in person, in order to get their full co-operation. Similar explanation was made to the Sisters-in-Charge of wards and the attending Nurses.

After obtaining consent from the parent, a full clinical evaluation was carried out on the patient to assess the type of burns. History of the burns and information on vital statistics was obtained from the parent and entered on a Questionnaire.

Using the Lund and Browder Charts (see Appendix), each region of the body was given a number. A total of nineteen regions were identified. After calculating the total body surface area of burns, a number of each burnt region was written on a piece of paper and drawn randomly to select the region of the body to be dressed with Amniotic Membrane. The remaining burnt areas on the same patient served as the control and their treatment was left to the choice of the attending Surgical Firm.

Therefore, apart from the difference in the type of dressing applied on the burns, all the other confounding factors, that is, age, sex, weight, nutritional status, etc. were the same in both the Case and Control groups.

Application of Amniotic Membrane Dressing was done in the Treatment Room of the Surgical Ward, which was kept warm with an Electric Heater.

The dressing trolley included the following items: Pre-packed Amniotic Membrane, sterile kidney dish, sterile forceps, sterile scissors, sterile gloves, sterile gauze and cotton wool, sterile normal saline solution.

With gloved fingers, the burn area selected for dressing with Amniotic Membrane was cleaned with sterile Saline and Cotton Wool.

Amniotic Membrane on gauze was removed from the sterile pack by cutting the plastic seal with a sterile scissors and immersed in sterile saline contained in a sterile kidney dish for about three to five minutes to make it wet and pliable.

The Amniotic Membrane dressing was applied on the burns with the Chorionic side facing the wound. No other dressing was applied on top of the amniotic membrane as the membrane adhered to the wound well.

The patient was identified by a number which was put on the questionnaire. A note was attached to the patient's file indicating that the patient was included in the Clinical Trial and that the Author should be informed before discharge of the patient.

by the attending Surgical Firm. The attending Firm was also requested not to disturb the Amniotic Membrane dressing on the burns.

When the Amniotic Membrane dressing was dry, usually by the next day, it was easy to peel off the gauze leaving the Amniotic Membrane adherent to the burns.

While on the ward, the care and general treatment of the patient was carried out by the attending surgical unit.

Every day, the patient was visited and the amniotic membrane inspected. If the burns showed collection of pus, the amniotic membrane was also removed, the wound cleaned and new membrane re-applied.

Observations on the local effects of Amniotic Membrane Dressing on the burns and the rate and quality of wound healing were compared with the control and results recorded on 2 x 2 Tables and calculations done by Computer using EPI-INFO program.

#### IV. RESULTS

##### ANNUAL DISTRIBUTION.

During the year 1994, five hundred and forty two patients were admitted with burns to the Surgical Department of the University Teaching Hospital. The average number of admissions for each of the five Surgical Firms was one hundred and eight patients per annum (Graphs 1 and 2).

The highest number of patient admissions were during the months of June, July, August, September and October. Thirty six patients died during the year, representing an annual mortality of 6.6%

##### AGE AND SEX DISTRIBUTION.

Out of two hundred and seven children below the age of ten years admitted with burns covering up to 20% of the total body surface area, 57.5% were boys and 42.5% girls.(Graphs 3 and 4).

Out of the two hundred and seven, forty five children with burns below 20% total body surface area were selected for the clinical trial. Parents to five of the children refused to give consent leaving forty children for the clinical trials (19.3%). Twenty five of the children were boys (62.5%) and fifteen were girls (37.5%).

Reasons for refusal included: unwillingness by attending parent (mother) to give consent without consulting the father to the

child; fear of subjecting the child to an experimental treatment which has not been tried before; and fear that discharge of the child was likely to be delayed as a result of the clinical trials. Others feared that the amniotic membrane dressing would introduce infection to the patient.

#### MODE OF BURNS.

The commonest cause of burns was hot water followed by fire. (Graph 5)

#### DEGREE OF BURNS.

All the forty children included in the clinical trials had superficial burns on initial assessment.

#### REGION OF AMNIOTIC MEMBRANE APPLICATION.

Most of the Amniotic Membrane dressings were applied on the upper and lower limbs as these constituted the most commonly burnt regions of the body in children below ten years. (Graph 6).

#### TREATMENT OF BURNS BY SURGICAL FIRMS.

Most of the burns in children were treated by application of silver sulfadiazine (69.2%), others by exposure method only (25.6%) and a few by vaseline gauze dressings (5.1%). ( Graph 7).

# EVALUATION OF TREATMENT WITH AMNIOTIC MEMBRANE.

Results on effect of Amniotic Membrane Dressing on burns in relation to the Control treatment were entered on 2 x 2 Tables as shown below:

TABLE 1.

## RESULTS OF 2 X 2 TABLES ON REJECTION

	REJECTION	NO REJECTION	
	-----		
CASES	0	40	40
CONTROL	0	40	40
	-----		
	0	80	80



TABLE 2.

RESULTS OF 2 x 2 TABLES ON  
INFECTION

	INFECTED	NOT INFECTED	
CASES	7	33	40
CONTROL	16	24	40
	23	57	80

Chi-Square - 4.88

P-Value - 0.027

TABLE 3.

RESULTS OF 2 x 2 TABLES ON  
HEALING RATE

	HEALED	NOT HEALED	
	-----		
CASES	39	1	40
CONTROL	10	30	40
	-----		
	49	31	80

Chi-Square - 43.74

P-Value - 0.000

TABLE 4.

RESULTS OF 2 X 2 TABLES ON  
HEALING QUALITY

	POOR	GOOD	
CASES	9	31	40
CONTROL	39	1	40
	48	32	80

Chi-Square - 46.29

P-Value - 0.000

## V. DISCUSSION

During the year 1994 five hundred and forty two patients were admitted to the Surgical wards of the University Teaching Hospital. Four hundred and six of these patients were children (74.9%). Thirty six patients (6.6%) died from complications of burns. There were more patients admitted with burns during the cold and dry months of June, July and August than other months of the year. During this period, temperatures range from 20°-25° Celsius during the day but dropping to approximately 10°Celsius at night. In the Summer, temperatures can rise up to 30°-38° Celsius (1). Of the four hundred and six children, three hundred and fourteen were below the age of five years (77.3%). The boy to girl ratio in this study was 1.4:1. These observations are similar to those found in the study by Christa Jansen in 1992 (1) and confirms that burns continue to be a significant cause of children admissions to this Hospital and require special attention in order to reduce the morbidity and mortality associated with it.

All the patients included in this study had superficial burns. However, the estimation of burns may have been misleading at the initial assessment. It is best to assess burns after five days of admission when it is easier to tell superficial from deep burns. In a Nigerian study, burns were categorized as major in 71% of cases (7). In a Nigerian study, The male:female ratio of patients

admitted with burns was 1.6:1 and about 70% of the cases were between one and ten years of age. Scalds were responsible for 50.6% of the cases while naked flames were responsible for 43.5% (7). These results are similar to the results in this study. In contrast, a study by Banco L. et al at the Connecticut Childhood Injury Prevention Center, Hartford showed that for children under eleven years, contact burns caused over half of all burns. The next most frequent causative agents were beverages. (7,15).

The number of parents refusing to give consent was quite significant; therefore if use of Amniotic Membrane dressings are to be introduced in the University Teaching Hospital, there is need to conduct an educational campaign to allay fears in parents bringing children with burns to the Hospital. This will reduce the number of parents refusing to give consent.

Most of the burns involved the upper and lower limbs and these were the regions which were commonly treated with the Amniotic Membrane dressings during the Clinical Trial. Burns to the upper and lower limbs are very special in that if they heal poorly, they can result in scarring and contracture formation and can cause great disability to the patient. Fortunately, the limbs are ideal for application of Amniotic Membrane dressings; dressings can easily be applied and are not removed easily by the mechanical effects of clothing and bedding. This is more likely to happen with burns on the trunk.

The commonest method of treating the control group by the various Surgical Firms was by application of silver sulfadiazine cream (69.2%) followed by exposure method alone (10%) and application of Vaseline Gauze (2%).

There was no evidence of hypersensitivity reaction in any of the forty children who had application of Amniotic Membrane. This compares favourably with the treatment in current use at the University Teaching Hospital. Waikakul et al, 1990 reported that application of Amniotic Membrane on burns resulted in pain reduction, but they also observed some hyperaemia and hypertrophic scar responses in some cases (10). Such a response could not be determined in this study because of the short follow up. Application of Amniotic Membrane resulted in reduced wound infection compared to the control group. Thirty-three burns dressed with Amniotic Membrane remained clean throughout the period of treatment. However, these results were not statistically different from results of the control group.

Amniotic Membrane has antibacterial properties that reduce bacterial counts and promote wound healing (16). Human Amniotic Interferon has been identified. This has antiviral action and has anti-cellular and natural killer cell stimulating activity (17). In their study, Talmi et al, 1991 showed that antimicrobial effects of Amniotic Membrane in vitro are due to their close adherence to the wound surface (17).

There was increased rate of wound healing in burns treated with Amniotic Membrane as compared to the control group. Studies have shown that Amniotic Membrane facilitates wound healing (17,18). This means that burns can heal quicker and patients' hospital stay would be reduced. This would reduce a lot of costs associated with prolonged Hospitalization which is associated with burns.

The quality of wound healing was good in burns treated with Amniotic Membrane as compared to the control group. Studies have shown that Amniotic Membrane not only facilitates wound healing, but also induces epithelialisation (18). This would mean that with the use of Amniotic Membrane, the rate of scarring and contracture formation would be reduced. However in this study amniotic membrane was not applied to joint surfaces and there was no long term follow up to confirm this view.

This study shows that amniotic membrane dressings result in improved healing of burns. There may have been some bias in the results as the investigator made the selection of patients and evaluated all the results but results from other centres seem to support this finding.

## VI. CONCLUSIONS

1. This study has shown that a Tissue Bank of good quality Gamma sterilized Amniotic Membrane can be established at the University Teaching Hospital.
2. Results of the use of Amniotic Membrane in the treatment of burns in children has shown superior results to the treatment methods currently in use at the University Teaching Hospital.
3. Application of Gamma irradiated Amniotic membrane to burns did not produce hypersensitivity reactions. Instead, it reduced wound infection, increased the rate of wound healing and resulted in good quality of wound healing over the short term.
4. The treatment method is easy to use and acceptable to both the Nursing Staff and the majority of parents with burnt children. However there is need to conduct an educational campaign in order to reduce fears in the few parents who may be reluctant to give consent.
5. There is need to carry out another study to investigate the effect of treating burns with Amniotic Membrane on mortality.



## VII. REFERENCES

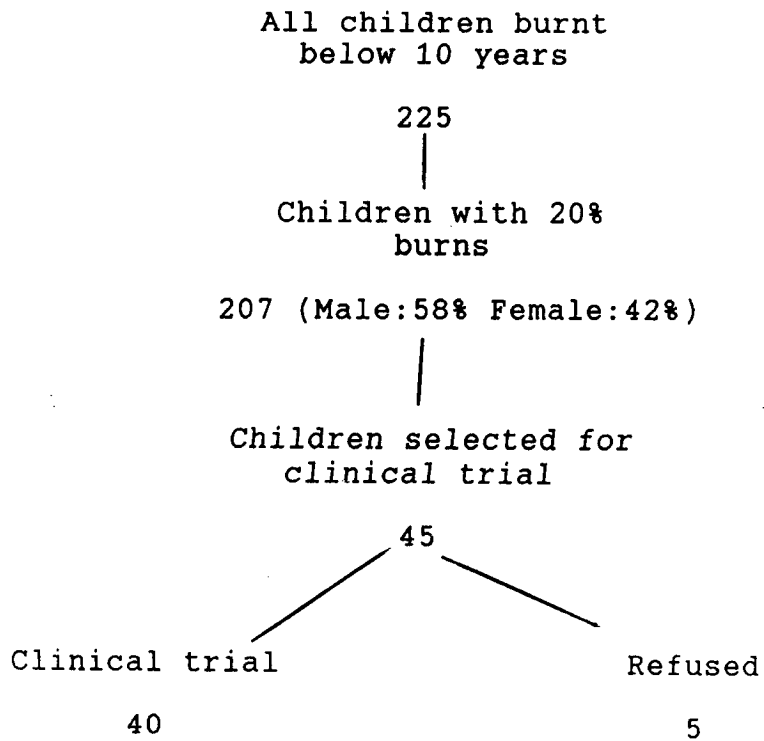
1. Christa Jansen.  
(A study on burn injuries in Lusaka in the University Teaching Hospital).  
Rijksuniversiteit Groningen, Holland.  
A Thesis Report.  
1992.
2. Krijci NC., McGuire J.  
Treatment of burns with skin substitutes, (Review).  
Journal of Dermatological Science.  
4(3):149-55, 1992 Nov.
3. Roger E Salisbury.  
Synthetic Skin and Skin substitutes.  
Biomaterials in Reconstructive Surgery.  
1983.
4. Gao Z. R. et al.  
Porcine dermal collagen as a wound dressing for skin donor sites and deep partial skin thickness burns.  
Burns.  
18(6):492-6, 1992 Dec.

5. Housinger T. A. et al.  
The use of Biobrane for coverage of the donor site.  
Journal of Burn Care and Rehabilitation.  
14(1):26-8,1993 Jan-Feb.
6. Seah C. S.  
Skin graft and skin equivalent in burns (Review).  
Annals of the Academy of Medicine, Singapore.  
21(5):685-8,1992 Sep.
7. Adesunkanmi K., Ooyelani O. A.  
The pattern and outcome of burn injuries at Wesley Guild  
Hospital, Ilesha, Nigeria: a review of 156 cases.  
Journal of Tropical Medicine and Hygiene.  
97(2):108-12, 1994 Apr.
8. Redmond A. D.  
Amnion dressing.  
The Lancet.  
1:902 1984.
9. Wallbank M. Alfred.  
Disinfectant inactivation of AIDS virus in blood or  
serum.  
The Lancet.  
1:642,1985 Mar.

10. Waikakul S. et al.  
Application of freeze-dried amniotic membrane: a control trial at the donor site of split skin grafting.  
Bulletin of the Hospital for Joint Diseases Orthopaedic Institute.  
50(1):27-34,1990 Spring.
11. Mathews R. N.  
Transmission of HIV infection by amniotic membrane dressing (Letter;comment).  
Burns.  
16(4):313,1990 Aug.
- 12 William W. Tomford.  
Disease Transmission.  
Musculoskeletal Tissue Banking  
Pages 209-226, 1993.
- 13 Go-Phillips.  
(Biological Tissue for surgical implants).  
North East Wales Institute of Higher Education,  
Kelsterton College, U.K. 1978 181

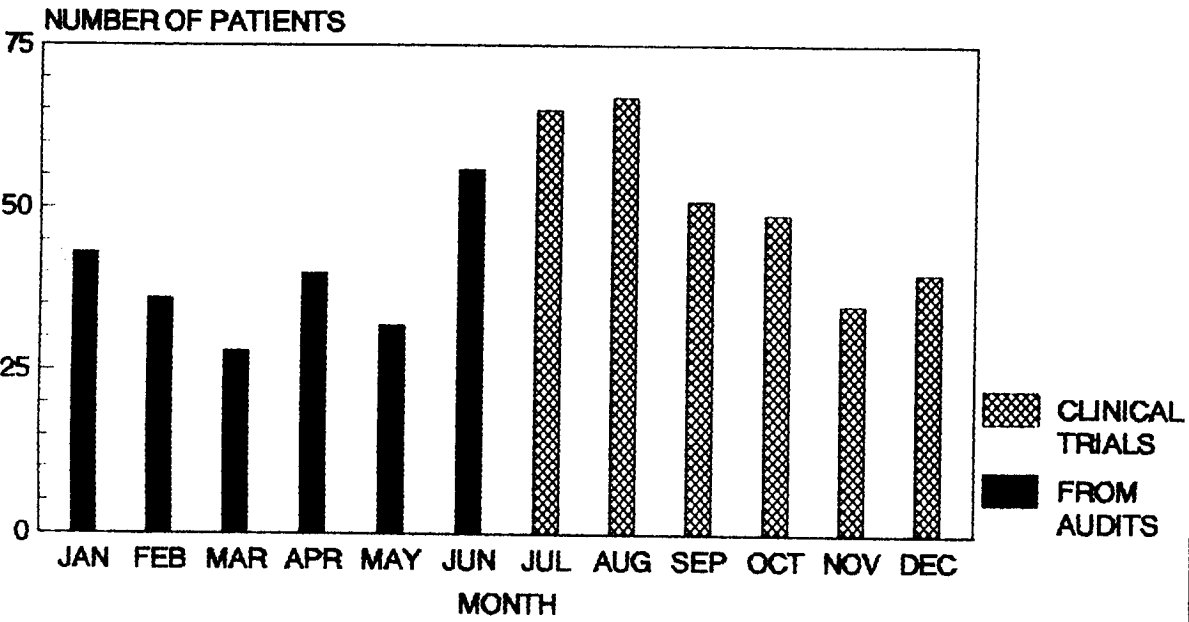
14. Schlager T. et al.  
Hospital acquired infection in pediatric burn patients.  
Southern Medical Journal.  
87 (4) : 481-4,1994 Apr.
- 15 Banco L. et al.  
Burn injuries among children in an urban emergency  
department.  
Paediatric Emergency Care.  
10(2):98-101,1994 Apr.
- 16 Ferreira P. C. et al.  
Some biological properties of the human amniotic  
membrane interferon.  
Memorias do Instituto Oswaldo Cruz.  
87(1):149-54,1992 Jan-Mar.
17. Talmi Y. P. et al.  
Antimicrobial properties of human amniotic membranes.  
Placenta.  
12(3):285-8,1991 May-Jun.
18. Onerci M.  
The effects of Lyophilized homograft amniotic membrane  
on wound healing on Rabbits.  
Acta Otorhinolaryngologica Italica.  
1(5):491-6,1991 Sep-Oct.

FLOW CHART SHOWING PATIENT SELECTION FOR THE  
CLINICAL TRIAL.



Graph 1

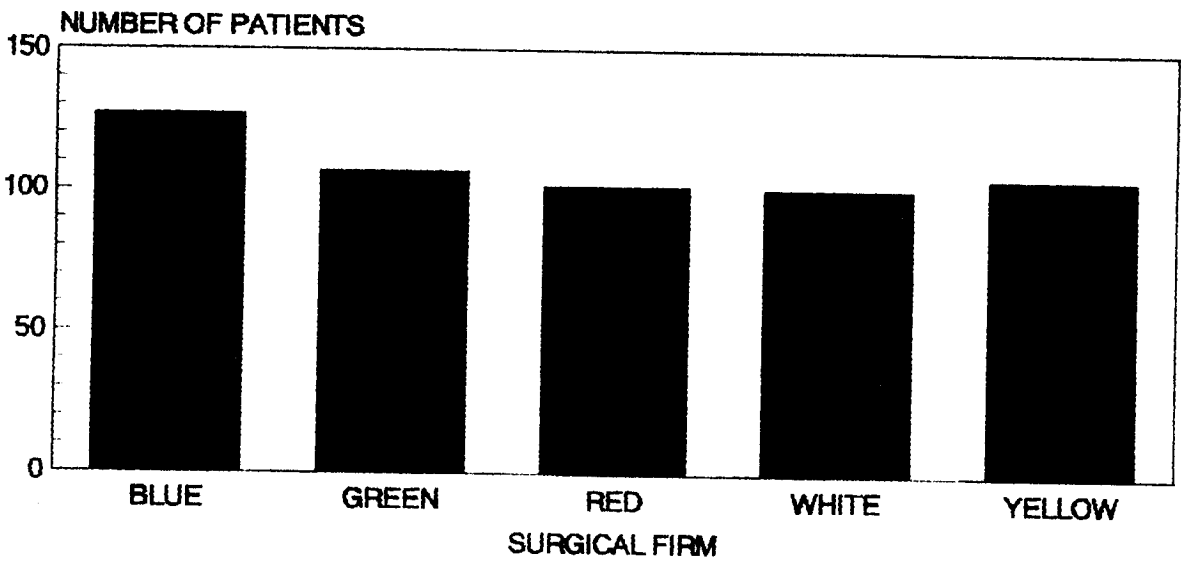
**ANNUAL DISTRIBUTION OF BURNS.**  
**ADMITTED FROM 1/01/94-31/12/94.**



Graph 2

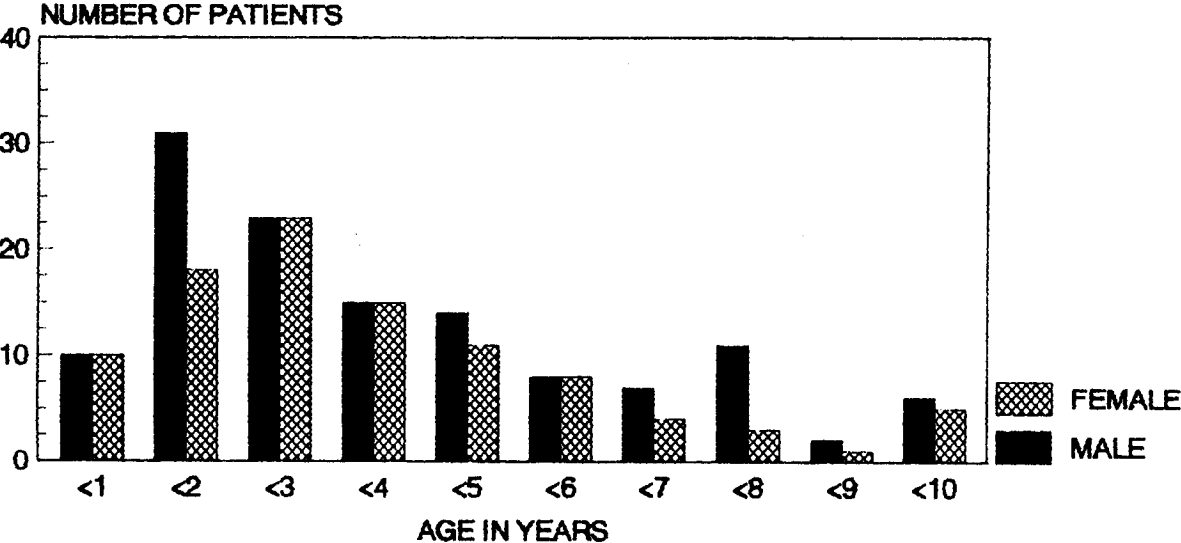
## ANNUAL BURNS DISTRIBUTION BY SURGICAL FIRMS

ADMISSIONS FROM 1/01/94-31/12/94



Graph 3

**AGE/SEX DISTRIBUTION OF BURNT  
CHILDREN BELOW 10 YEARS  
ADMITTED FROM 1/07/94-31/12/94**



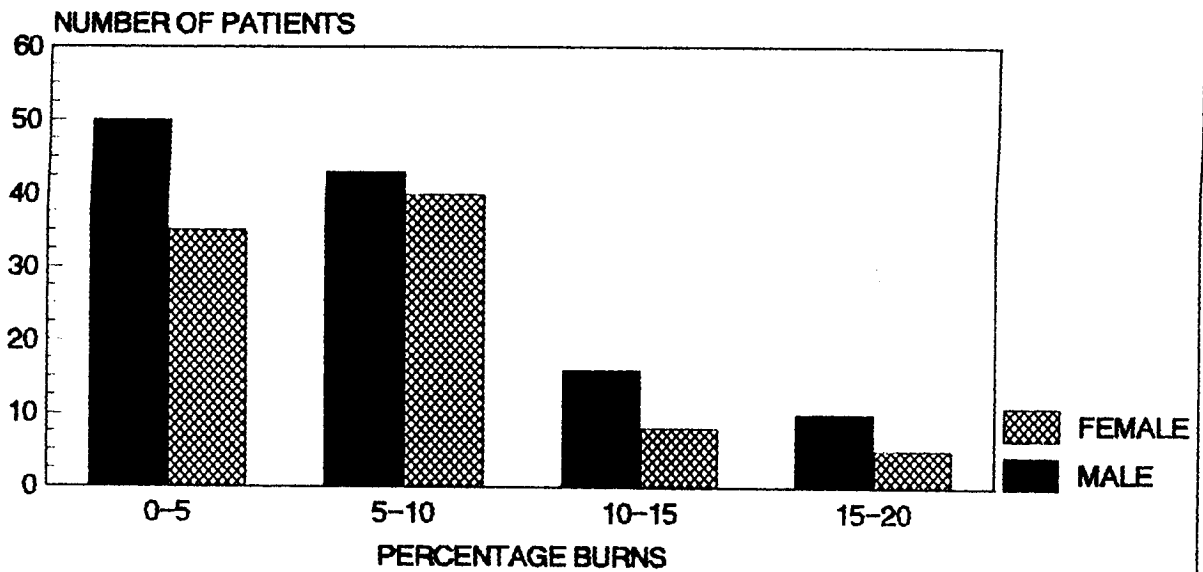


Graph 4

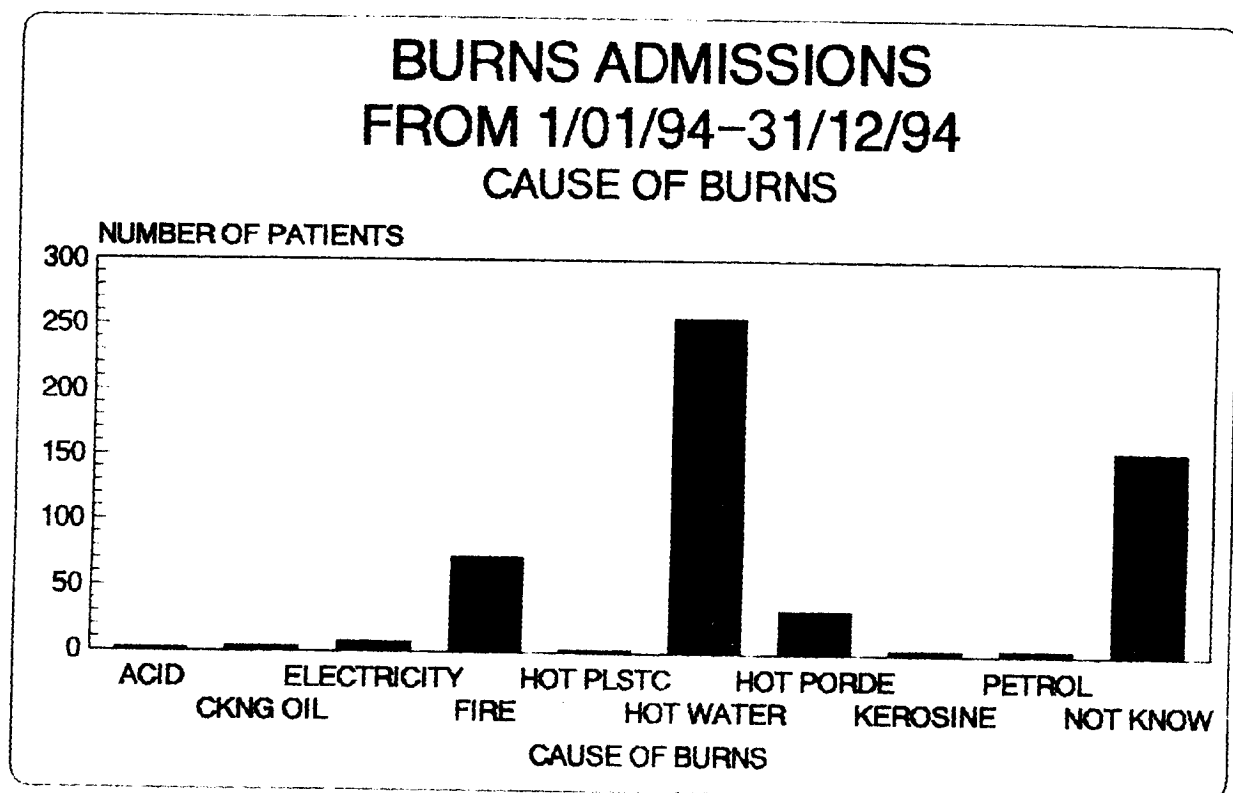
## BURNS IN CHILDREN BELOW 10 YEARS.

CHILDREN WITH BURNS LESS THAN 20%

ADMITTED FROM 1/07/94-31/12/94



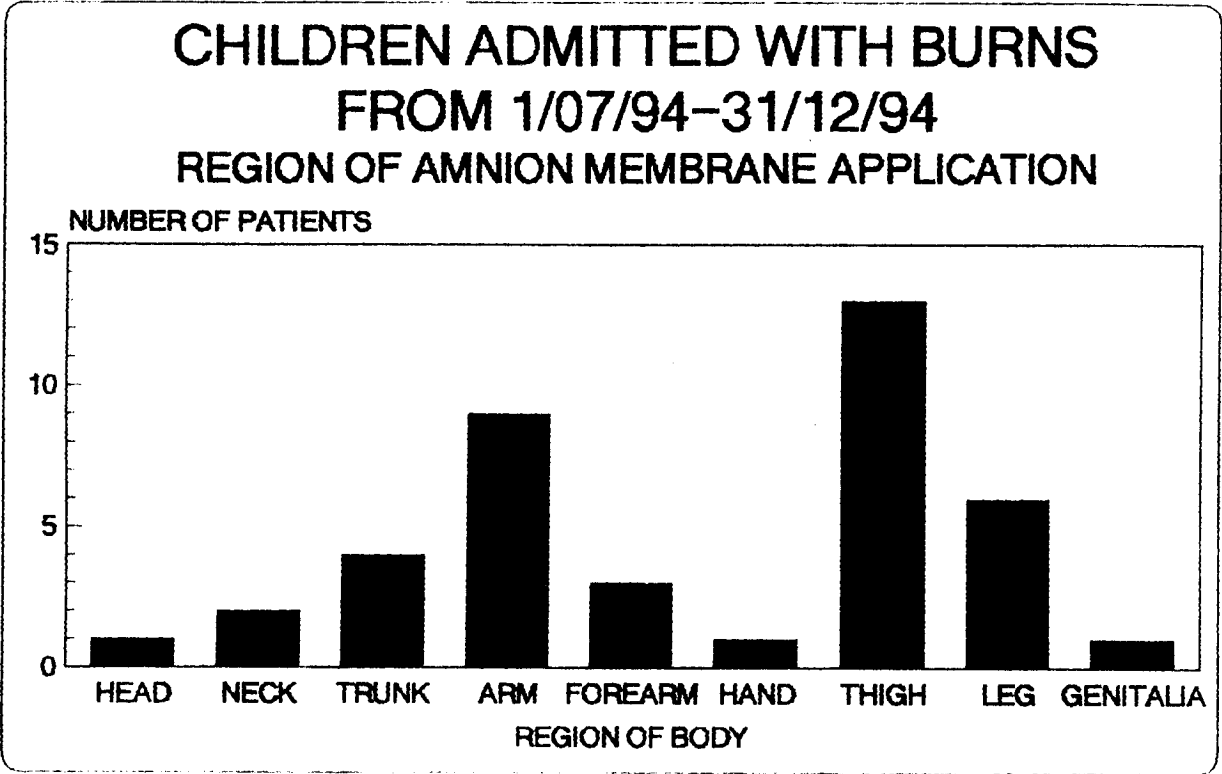
Graph 5



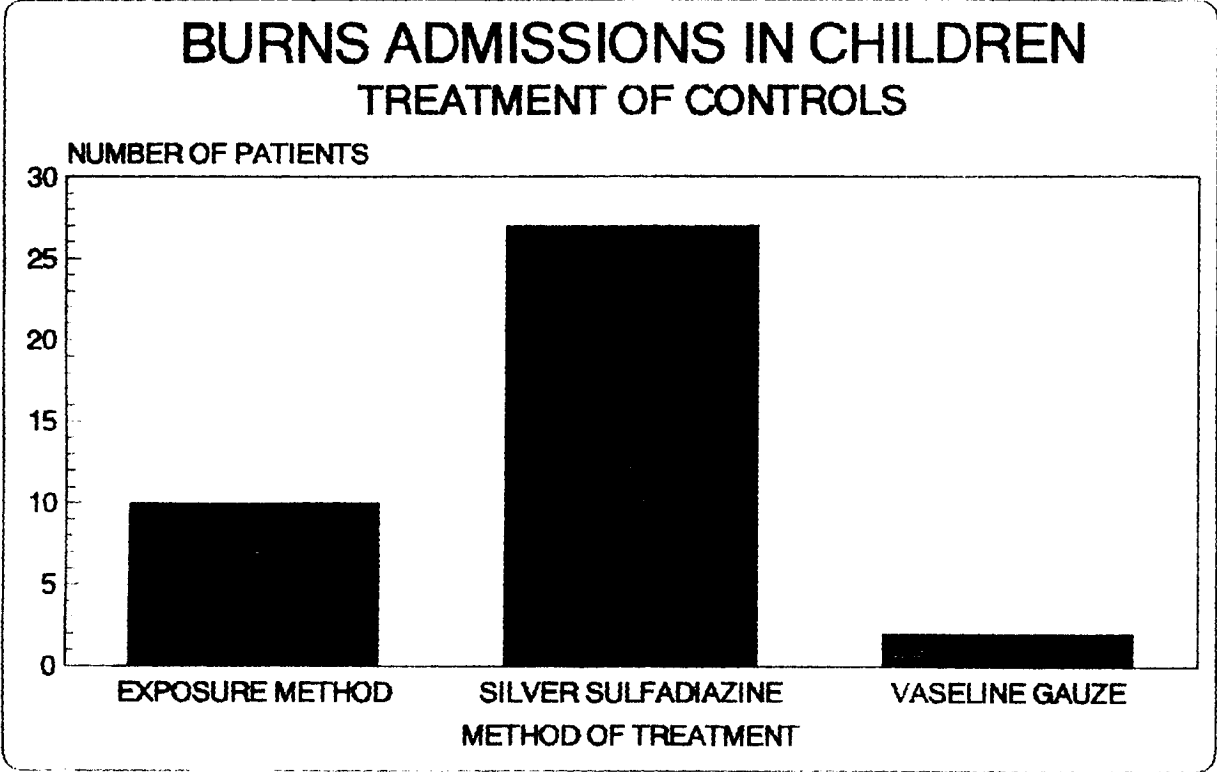
KEY TO ABBREVIATIONS

CKNG OIL	=	COOKING OIL
HOT PLSTC	=	HOT PLASTIC
HOT PORDE	=	HOT PORRIDGE

Graph 6



Graph 7



**ESTIMATION OF BURNS (SEE LUNO AND BROWDER CHARTS)**

<b>NO.</b>	<b>REGION</b>	<b>%</b>	<b>TYPE</b>
1.	HEAD		
2.	NECK		
3.	ANT TRUNK		
4.	POST TRUNK		
5.	RIGHT ARM		
6.	LEFT ARM		
7.	RIGHT FOREARM		
8.	LEFT FOREARM		
9.	RIGHT HAND		
10.	LEFT HAND		
11.	RIGHT BUTTOCK		
12.	LEFT BUTTOCK		
13.	GENITALIA		
14.	RIGHT THIGH		
15.	LEFT THIGH		
16.	RIGHT LEG		
17.	LEFT LEG		
18.	RIGHT FOOT		
19.	LEFT FOOT		
	T O T A L		

**KEY: S - SUPERFICIAL BURN**

**D - DEEP BURN**

## AMNIOTIC MEMBRANE IN THE TREATMENT OF BURNS

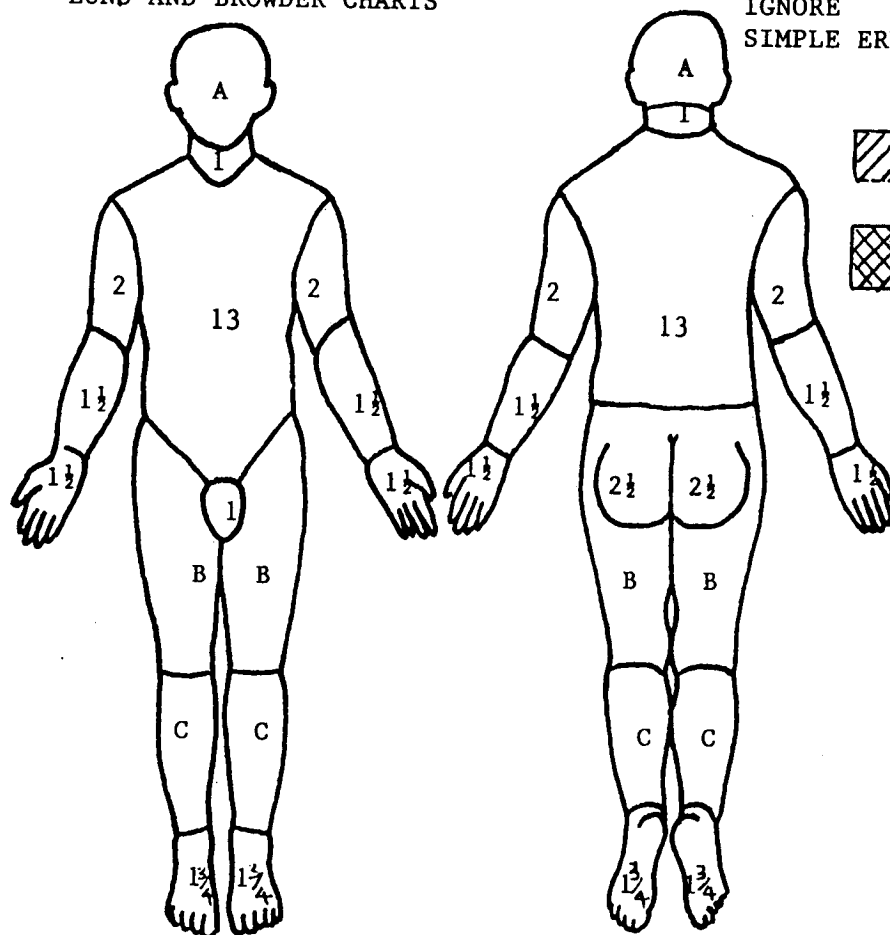
## B U R N   C H A R T

NAME: ..... M/F AGE.....(ADULT)

DATE OF BIRTH: .....(CHILD)

WARD:..... NUMBER:..... DATE:.....

## LUNG AND BROWDER CHARTS

IGNORE  
SIMPLE ERYTHEMA

Superficial

Deep Mark in  
5 - 7 days  
when this isRELATIVE PERCENTAGE OF BODY SURFACE AREA  
AFFECTED BY GROWTH

AREA	AGE 0	1	5	10	15	ADULT
A= $\frac{1}{2}$ OF HEAD	$9\frac{1}{2}$	$8\frac{1}{2}$	$6\frac{1}{2}$	$5\frac{1}{2}$	$4\frac{1}{2}$	$3\frac{1}{2}$
B= $\frac{1}{2}$ OF ONE THIGH	$2\frac{3}{4}$	$3\frac{1}{4}$	4	$4\frac{1}{2}$	$4\frac{1}{2}$	$4\frac{3}{4}$
C= $\frac{1}{2}$ OF ONE LEG	$2\frac{1}{2}$	$2\frac{1}{2}$	$2\frac{3}{4}$	3	$3\frac{1}{4}$	$3\frac{1}{2}$

The area of the palm of the hand of the patient is equivalent to 1% of body surface

## QUESTIONNAIRE

### CLINICAL TRIALS ON TREATMENT OF BURNS WITH GAMMA IRRADIATED AMNIOTIC MEMBRANE AT U.T.H.

(July - December 1995)

#### SECTION 1: PERSONAL DATA

CASE NO.....

SSURGICAL FIRM.....

DATE.....

001 DATE OF BIRTH.....

002 SEX.....

003 RESIDENTIAL ADDRESS.....

004 OCCUPATION OF PARENTS.....

#### SECTION II MEDICAL HISTORY

005 INTERVAL OF BURNS.....

006 CAUSE OF BURNS.....

#### SECTION III MEDICAL EXAMINATION

007 SURFACE AREA OF BURNS.....

008 TYPE OF BURNS.....

009 REGION OF BODY CHOSEN FOR APPLICATION OF  
AMNIOTIC MEMBRANE.....

010 METHOD OF TREATMENT OF OTHER AREAS USED BY  
ATTENDING FIRM.....

SECTION IV: EVALUATION OF TREATMENT

	TRIAL (GRAFT)	CONTROL (NO GRAFT)
REJECTION		
INFECTION		
HEALING RATE		
HEALING QUALITY		