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A Comparative Study between Collagen Dressing and Conventional Dressing for Diabetic Foot Ulcer

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Chapter 1
Introduction

The diabetic foot syndrome is a triad of neuropathy, vasculopathy, and immunopathy that can lead to tissue breakdown which results in morbidity and possible amputation. The metabolic intricacy particularly raised blood sugar, can be easily controlled. While the foot, kidney, eye and heart are easy targets of deep-rooted complications. Among all the longstanding complexities, foot involvement is the supreme complication. The other organs impaired are brain, heart, kidneys and the eyes. Diabetic patients with foot ulcers aggregate the majority of hospital admissions. Diabetes is conjoined with various complications related to macrovascular, microvascular and metabolic etiologies. Diabetes extends to be the most prevalent underlying source of nontraumatic lower extremity amputations. The world is presently experiencing an wide spread of diabetes mellitus, particularly adult onset or type II. There is solid affirmation that this can be avoided by screening and community based health education programmes processed by a multidisciplinary team.

Skin is the natural outer covering of the human body and is the largest organ by virtue of its broad surface area. It plays a vital role in diverse of functions ranging from providing shelter of the underlying tissue to the maintenance. Ulcer can be characterised as a break in the continuity of covering epithelium either in the skin or probably on mucous membrane. Chronic non-healing ulcers does not just impose a medical challenge but have occupational, social and economic ramifications. An ideal dressing that is used in the wound management should be easy to apply, economical, readily available method of dressing or coverage that serves as a good pain relief, providing protection of wound from infection, keep moisture, promote healing, non – antigenic, be elastic, and heed well to the wound and waiting for healthy granulation tissue and spontaneous epithelialisation.

The management of diabetic foot ulcers that comprises in relieving of wounds using relevant therapeutic footwear. Other propositions incorporate similar dressings or usage of daily saline. It allows a moist wound environment, debridement, antibiotic therapy if bony involvement or cellulitis is present, optimal

control of blood sugar level, and assessment and correction of peripheral vascular insufficiency. Discrete topical medications and gels have been endorsed for ulcer curing and maintenance.

In addition to holding the infection, an ideal wound care product should be able to protect the normal tissues and should not intrude with the normal wound healing. Currently, diabetic foot ulcers are being handled by local dressing with usage of agents such as eusol, povidone- iodine, and hydrogen peroxide, but still they have their own restrictions. Application of collagen granules may be a productive alternative to the lately used conventional methods of dressings for diabetic wounds.

Collagen dressing helps in the formation of biofilm which prevents the entry of bacteria into the wound. Collagen, the ample protein in the body, plays a vital role in the successful completion of adult wound healing. It is also necessary to note that the deposition, maturation, and subsequent remodeling of collagen are essential to the functional integrity of the wound of haemostasis. The ultimate and extreme desire of patients and physicians alike is minimal time period of treatment, hospital stay, early return to the occupation and must be costs. There is a great need for the patients to have a cost-effective treatment option for such deep seated illness. Ulcers cause significant and prolonged distress for the patients. Often ulcers become secondarily infected along the production of a foul-smelling slough and copious exudates that promote general sadness, stress and increasing social isolation, conclusively reducing the quality of life.

Chapter 2

Aim of the Study

Primary

To study and compare the efficacy of collagen dressing with conventional dressing in patients with diabetic foot ulcers.

Secondary

1. To identify the etiological risk factor for diabetic foot ulcer

Chapter 3

Materials and Methods

Source of Data

This study is a prospective type which will include all patients who will be admitted in CHENGALPATTU MEDICAL COLLEGE with diabetic foot ulcers. The study will be conducted during the period of March 2018 to December 2019.

Methods of Collection of Data

Study type: Prospective study

Sample and Sampling Technique

The study is estimated to include 130 patients with diabetic foot ulcers in Chengalpattu medical college with simple random sampling technique, with each grouped into 65, one group treated with collagen dressing and other group treated with conventional dressing (saline dressing).

Primary source data will be collected from a specially designed case recording proforma (CRF) pertaining to the selected patients, after explaining the options of treatment to each of the patient in their respective language understood by them and getting their consent for study.

Inclusion Criteria

- Patients with diabetic foot ulcers.
- Patients who are willing to give informed consent.
- Patients greater than 18 years of age.

Exclusion Criteria

- Critically ill patients.
- Patients with any evidence of underlying bone osteomyelitis and Malignancy.

They will then be subjected for detailed clinical examinations with baseline investigations, posted for Surgical procedures if required & Follow up of patients during hospital stay will be done.

All the procedures and investigations will be conducted under direct guidance and supervision of my guide. Patients will undergo dressing everyday or more frequently until wound healing or for maximum period of 8 weeks. Improvement of the ulcer will be recorded periodically.

Healing time, Duration of Antibiotic Therapy and follow up period will be noted. All patients will be followed up for adverse events. It will then be subjected to statistical analysis using Descriptive Statistics (Bar Chart, Pie diagram, t-test & Chi Square Test). Demographic data will be presented innumbers & percentage. Before the start of our study a written/informed consent will be obtained from each patient in the language understood by them.

Study Requirements

- Hemoglobin, BT,CT
- Random Blood Sugar.
- Doppler – Lower limb.
- Monofilament.
- Blood Urea
- Serum Creatinine
- Urine- Albumin, Sugar, Microscopy
- X-ray of the involved part
- If pus exuding from the area-- then pus for Culture & Sensitivity
- ECG 12 leads

Chapter 4

Observation and Results

The number of patients analysed in this study is 130 and they are grouped into two groups,65 in each group. One receiving collagen dressing and another group receiving saline dressing .

Both groups were matched in terms of

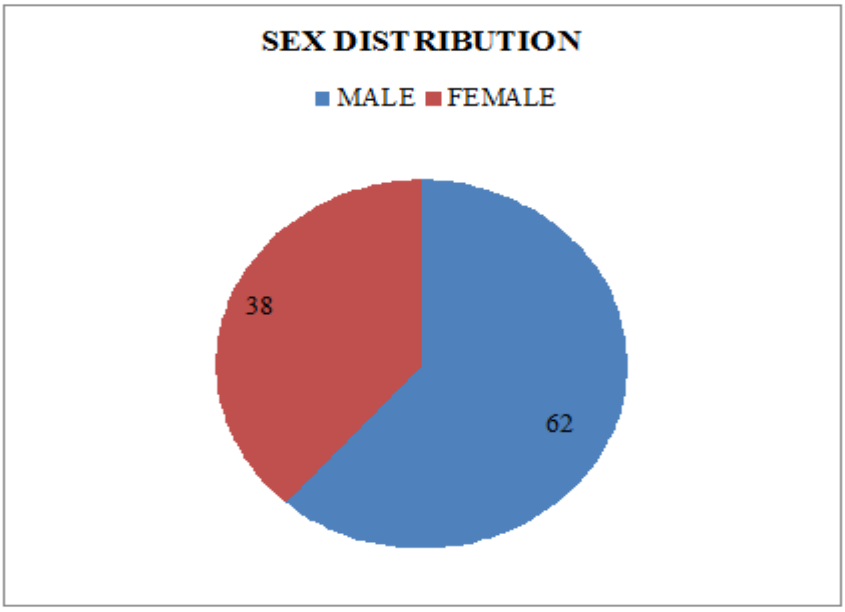
1. Sex distribution
2. Age wise distribution
3. Site of ulcer
4. Risk factor
5. Duration of hospital stay
6. Wound size reduction
7. No of dressings required

Results are shown as mean and standard deviation for continuous data. Here the frequency is expressed in numbers and percentages. Mean level between two groups is compared by unpaired t test. The final variable calculated is the P value. Here the P value is nothing but the probability of an event to occur. P value of 0.05 or less is considered as statistical significance.

Table 1: Sex Distribution

SEX	COUNT	%
MALE	80	61
FEMALE	50	39

In this study it seen that out of 130 patients male patients is 61% and female patients is 39%

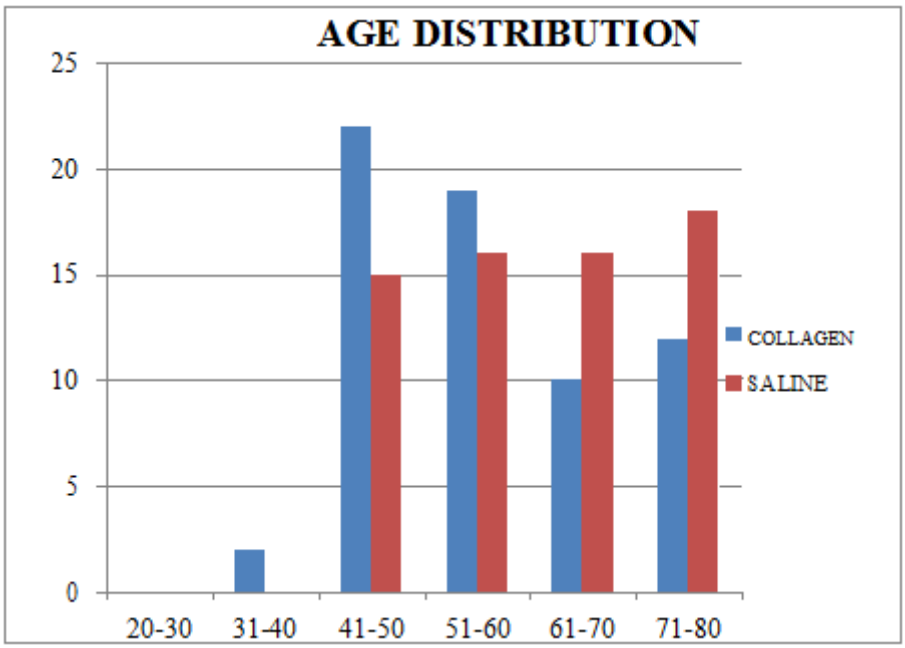


Graph 1: Sex Distribution

Table 2: Age Wise Distribution

AGE IN YEARS	COLLAGEN No	%	SALINE No	%
20-30	0	0	0	0
31-40	2	3	0	0
41-50	22	34	15	23
51-60	19	29	16	25
61-70	10	15	16	25
71-80	12	19	18	27
TOTAL	65	100	65	100

Mean age of collagen dressing group is 55
Mean age of saline dressing group is 60



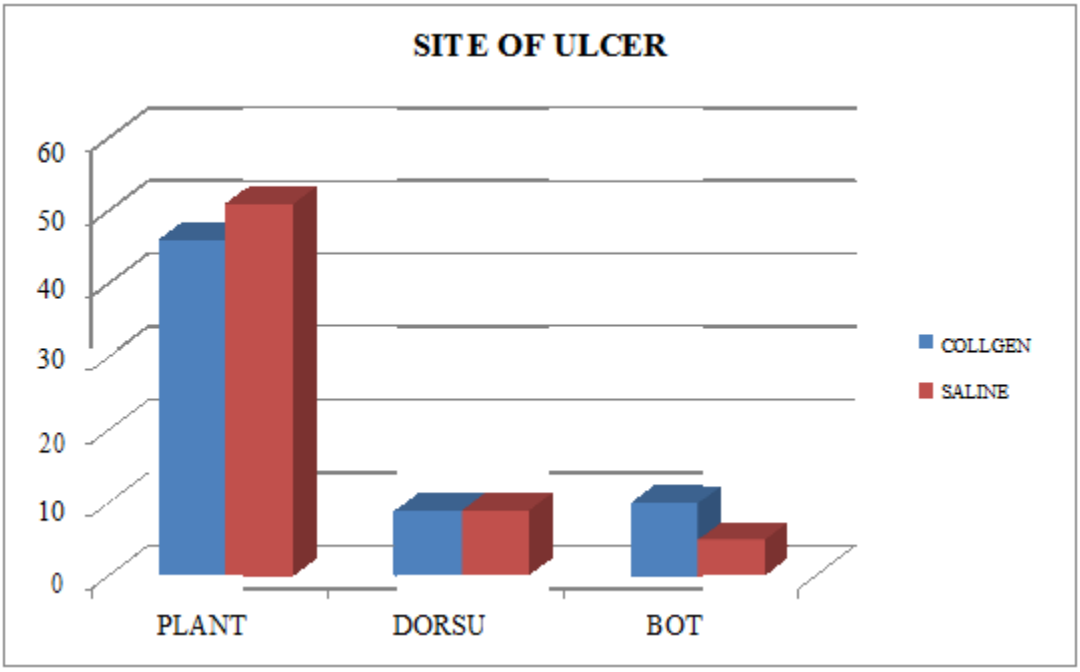
Graph 2: Age Distribution

Table 3: Site of Ulcer

SITE	COLLAGEN	SALINE
PLANTAR	46	51
DORSUM	9	9
BOTH	10	5

Total number patients having ulcer in the plantar aspect of foot is 75% Total number patients having ulcer in the dorsum aspect of foot is 14% Total number patients having ulcer in both plantar and dorsum is 11%

Due to increased foot pressure, diabetic foot ulcers are more common in plantar aspect.

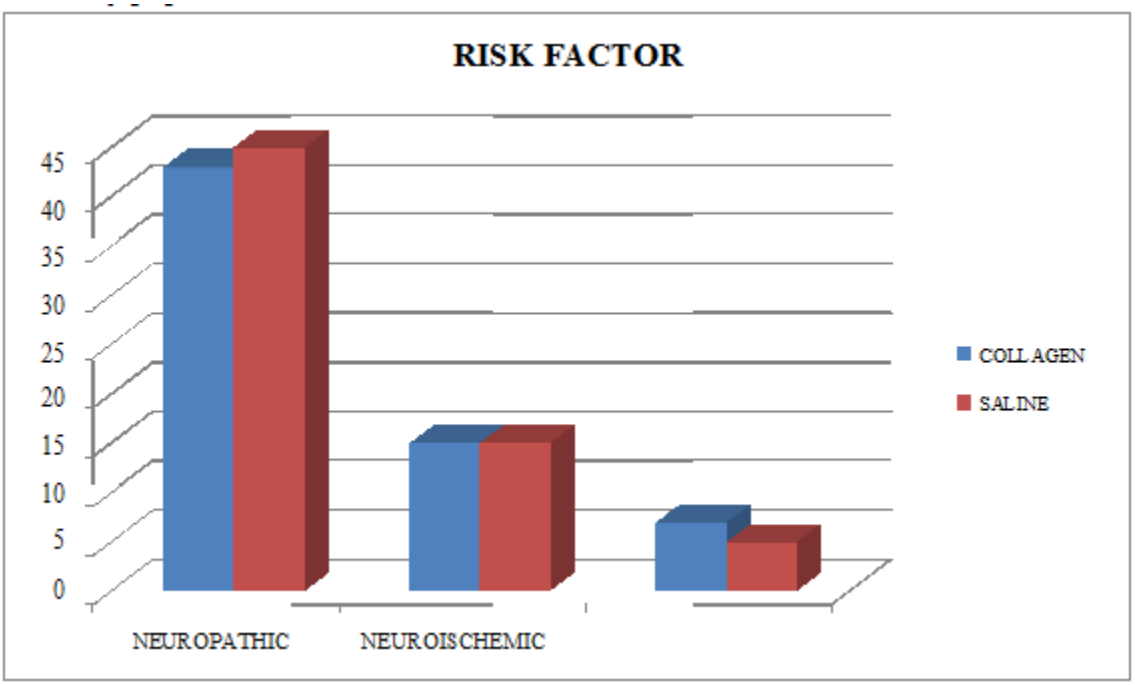


Graph 3: Site of Ulcer

Table 4: Risk Factor

RISK FACTORS	COLLAGEN	SALINE
NEUROPATHIC	43	45
NEURO ISCHEMIC	15	15
ISCHEMIA	7	5

68% of the study population is Neuropathic 30% of the study population is Neuroischemic 9% of the study population is Ischemia

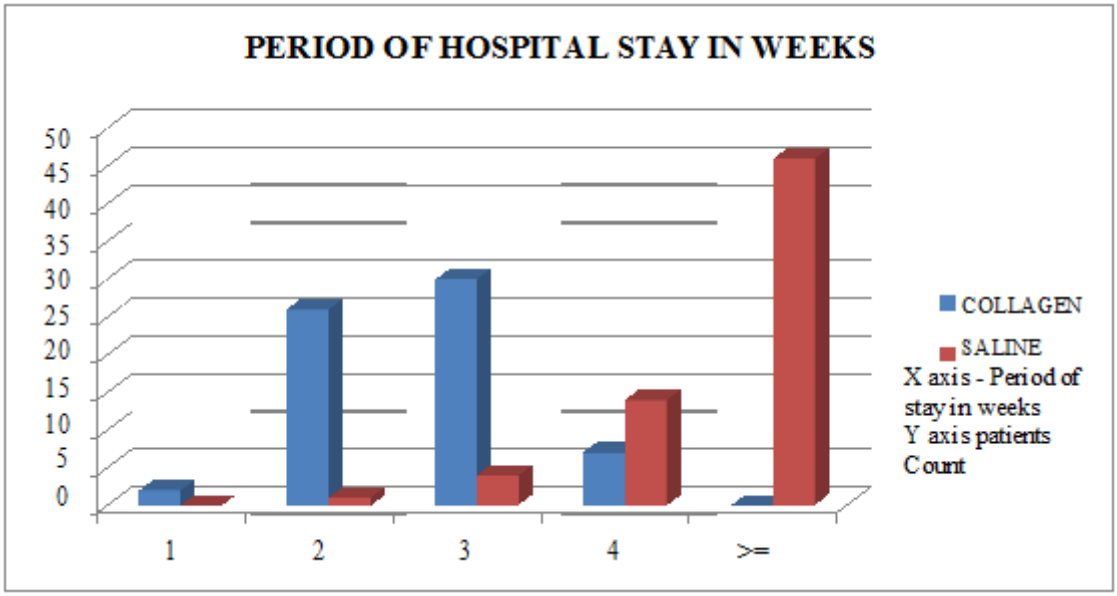


Graph 4: Risk Factor

Table 5: Period Of Hospital Stay In Weeks

PERIOD OF STAY IN WEEKS	COLLAGEN No. %		SALINE No. %	
1	2	3	0	0
2	26	40	1	2
3	30	46	4	6
4	7	11	14	22
>=5	0	0	46	70
TOTAL	65	100	65	100
MEAN±SD	2.64±0.58		4.53±0.64	

Mean Period of Stay for collagen is 2.64±0.58 (in weeks) Mean Period OF Stay for saline is 4.53±0.64(in weeks) P value is less than 0.0001. It is highly significant



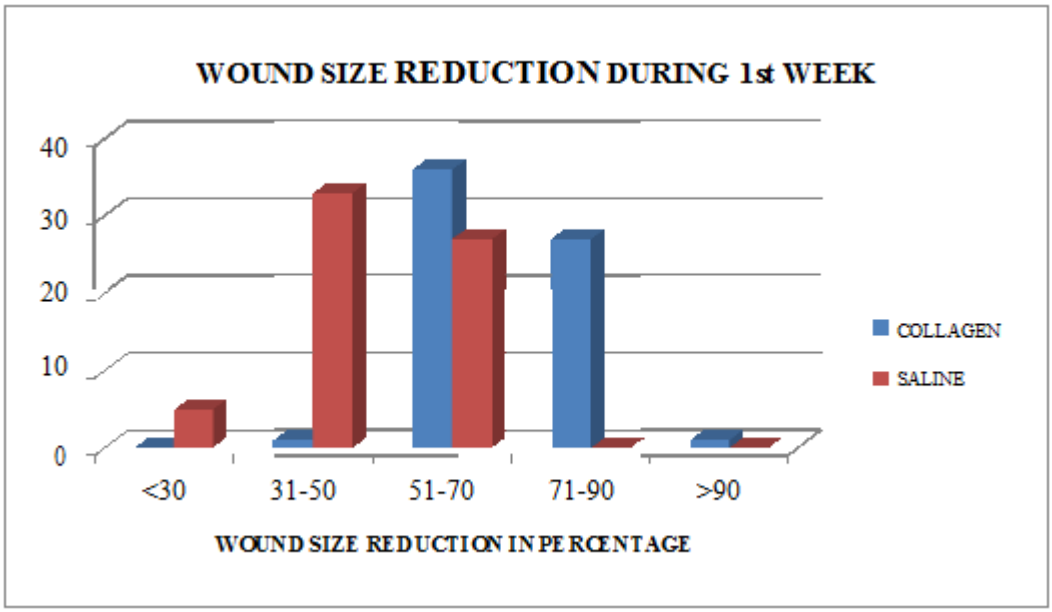
Graph 5: Period of Hospital Stay in Weeks

Table 6: Wound Size Reduction In Weeks Table 6.1: Wound Size Reduction in 1st Week

REDUCTION IN ULCER SIZE %	COLLAGEN No. %		SALINE No. %	
<30	0	0	5	8
31-50	1	2	33	51
51-70	36	55	27	41
71-90	27	41	0	0
>90	1	2	0	0
MEAN±SD	68±1.96		47.53±1.28	

68% of wound size reduction is in collagen dressing in 1st week 48% of wound size reduction is in saline dressing in 1st week

P value <0.0002.It is highly significant



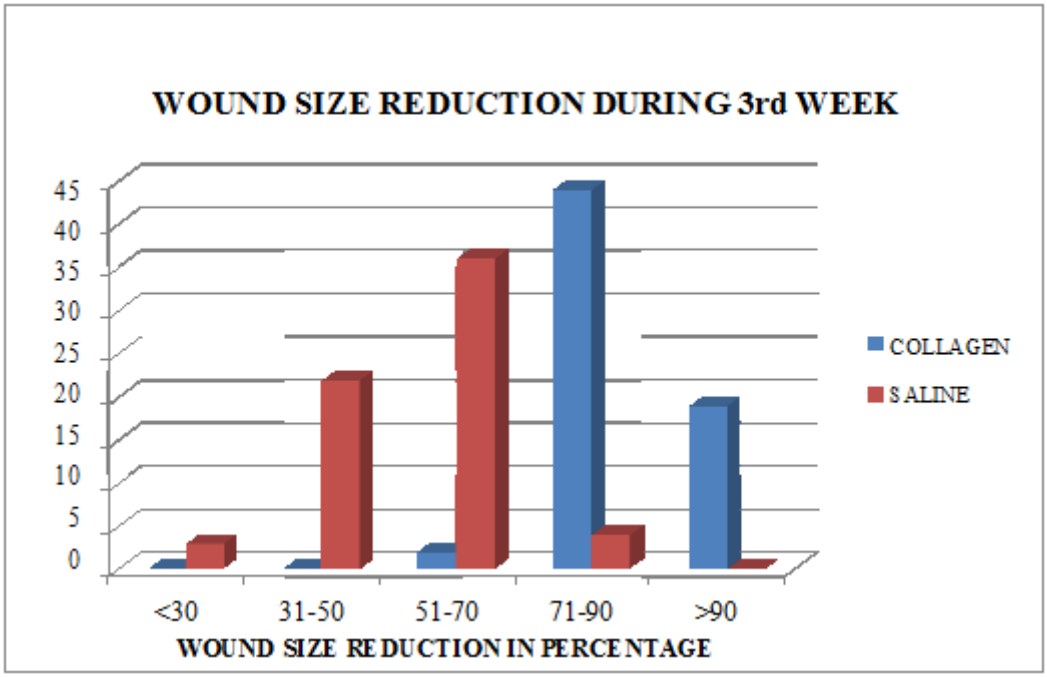
Graph 6(1) : Wound Size Reduction during 1st Week

Table 6.2: Wound Size Reduction in 3rd Week

REDUCTION IN ULCER SIZE %	COLLAGEN No.	%	SALINE No.	%
<30	0	0	3	5
31-50	0	0	22	34
51-70	2	3	36	55
71-90	44	67	4	6
>90	19	30	0	0
MEAN±SD	82.30±2.44		53.076±1.45	

82% of wound size reduction is in collagen dressing in 3rd week 53% of wound size reduction is in saline dressing in 3rd week

P value <0.0001.It is highly significant



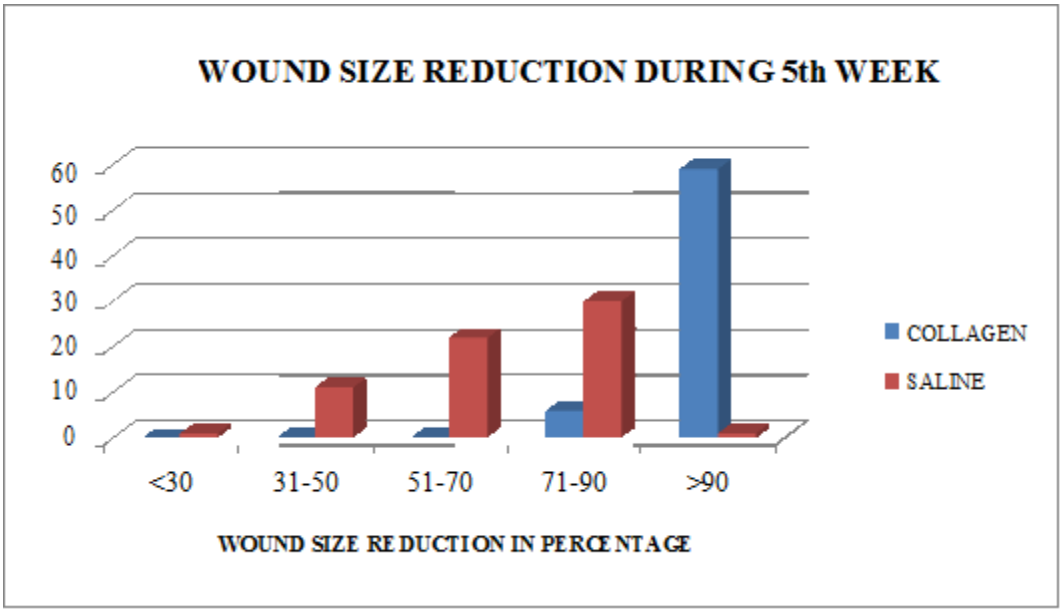
Graph 6(2) : Wound Size Reduction during 3rd Week

Table 6.3: Wound Size Reduction In 5th Week

REDUCTION IN ULCER SIZE %	COLLAGEN No.	%	SALINE No.	%
<30	0	0	1	2
31-50	0	0	11	17
51-70	0	0	22	34
71-90	6	9	30	46
>90	59	91	1	1
MEAN±SD	89.07±2.73		65.84±1.86	

89% of wound size reduction is in collagen dressing in 5th week 66% of wound size reduction is in saline dressing in 5th week

P value <0.0001.It is highly significant



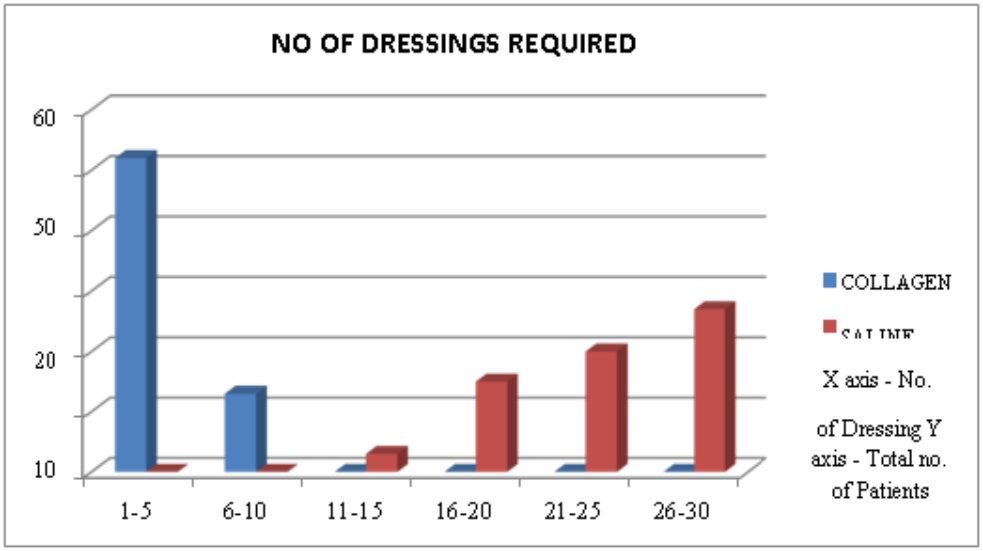
Graph 6(3) : Wound Size Reduction During 5th Week

MEAN±SD for collagen is 4±0.77 dressings MEAN±SD for saline is 23.46±0.605 dressings P value is less than 0.0001.It is highly significant

Table 7: No of Dressings Required

NO OF DRESSINGS REQUIRED	COLLAGEN No.	%	SALINE No.	%
1-5	52	80	0	0
6-10	13	20	0	0
11-15	0	0	3	5
16-20	0	0	15	23
21-25	0	0	20	31
26-30	0	0	27	41
TOTAL	65	100	65	100
MEAN±SD	4±0.77		23.46±0.605	

Graph 7: No of Dressings Required



Collagen Granule

Case 1: Collagen Dressing Day 0

Normal Saline for Conventional Dressing

Case 1 : Reduction of Wound Size by 1st Week

Case 1: Reduction of Wound Size by 3rd Week

Case 2: Collagen Dressing

Day 0: Saline Dressing 1st Week

3rd Week

Chapter 5
Data Analysis

Total number of population – 130.
Saline dressing – 65
Collagen dressing –65

Sex Distribution

- In our study total number of males patients is 80(61%)
- Total number of females patients is 50(39%)
- Males show increasing trend of diabetic foot ulcer (61 %).

Age Distribution

- In our study the mean age of collagen dressing is 55 years and saline dressing is 61 years
- In 5^{th} and 6^{th} decade diabetic foot ulcers are more common.
- Prevalence of diabetic foot ulcer progressively raises with increasing age.

Site of Ulcer

- Total number patients having ulcer in the plantar aspect of foot is 75%
- Total number patients having ulcer in the dorsum aspect of foot is 14%
- Total number patients having ulcer in both plantar and dorsum is 11%
- Due to increased foot pressure, diabetic foot ulcers are more common in plantar aspect.

Risk Factor

In our study 68 % are neuropathic,9% ischemic and 23% is neuroischemic. Neuropathy is the most common risk factor in diabetic foot ulcer formation.

Duration of Hospital Stay

Duration of hospital stay for collagen dressing is 2.6 weeks and for saline dressing is 5 weeks. There is significant reduction in the duration of hospital stay for collagen dressing.

Wound Size Reduction

- Wound size reduction is calculated using gauze piece and blotting paper.
- In first week there is 68% of wound size reduction in collagen whereas 48% for saline dressing.
- In third week there is 82% of wound size reduction in collagen whereas 53% for saline dressing.
- In fifth week there is 89% of wound size reduction in collagen whereas 66% for saline dressing.
- Comparing the above values, collagen shows maximum percentage of wound size reduction which is significant.

No of Dressings

No of dressings per patient in collagen is 4 whereas saline is 23.So clearly Collagen reduces pain and frequent change of dressings than saline which requires lots of effort and time.

Chapter 6
Summary

The number of patients under study is 130 and randomly divided in to two test groups 65 each. Both groups were analysed. One group receives collagen dressing and other group receives saline dressing which is conventional. A comparative analysis was done for both the groups regarding number of dressing, duration of hospital stay and wound size reduction

1. Male (80) are affected more than female (50).
2. In Age distribution 37 patients are between 41-50 years of age and 35 are between 51-60 years of age
3. Plantar aspect is most common site of ulcer in diabetes (75%)
4. Neuropathy is the most common risk factor for diabetic foot ulcer and it is 68%

5. Average period of hospital stay for collagen is 2 to 3 weeks whereas saline dressing it is 4-5 weeks. P value is less than 0.0001 and is highly significant
6. Percentage reduction of ulcer is 90 % in collagen whereas in saline is 6%. Maximum percentage of wound size reduction is achieved in collagen dressing. P value is less than 0.0001 and is highly significant.
7. Total dressings done per patient in collagen is 4 whereas in saline is 23.P value less than 0.0001 and is significant.

Collagen has no adverse effects or reactions when applied over the wound and also prevents the infection by forming biofilm over the wound. It promotes granulation tissue and aids in faster healing when compared to saline dressing.

Chapter 7

Conclusion

Collagen dressings are safe and effective with the beneficial edge over the conventional dressing with saline in terms of wound healing. In view of patients, collagen shows

1. Faster healing
2. Maximum percentage of ulcer size reduction
3. Decreased duration of hospital stay
4. Less number of dressings are required.

The above results suggest that collagen dressing can be used as an efficient alternative to conventional dressing in the management of diabetic foot ulcer.