



A Hospital based prospective study to evaluate the effect of collagen dressing in diabetic foot ulcer patients

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ABSTRACT

Background: Diabetic foot ulcer (DFU) is a severe and common consequence of diabetes mellitus. The present study was conducted to assess the effect of collagen dressing in diabetic foot ulcer patients.

Materials & Methods: 70 diabetic foot ulcer (DFU) patients of both genders were divided into 2 groups of 35 each. In group I, patients were treated with a 100% porcine type I collagen sheet covered by a polyurethane foam dressing and patients in the group II were treated with only polyurethane foam dressing. DFU size was measured using a digital planimetry wound measurement system.

Results: In group I, males were 20 and females were 15 and in group II, males were 17 and females were 18. Duration was 18.5 weeks in group I and 13.2 weeks in group II. Side was right in 16 and 18 and left in 19 and 17 in group I and II respectively. Location was interphalangeal area in 1 and 12, sole in 14 and 10, heel in 11 and 8, Toe in 8 and 3 and Malleolus in 1 and 2. Wagner grade was grade I in 31 and 33 and grade II in 5 and 2 in group I and II respectively. Adverse events reported were infective events in 1 and 1, pain in 2 and 2 and maceration in 1 and 2 in group I and II respectively. The mean size of ulcer initially in group I was 4.82 cm² and in group II was 4.35 cm² and at 3 months follow up was 0.56 cm² in group I and 1.64 cm² in group II.

Conclusion: Wound management using collagen materials in DFUs showed faster and complete healing rate.

Key words: Diabetic foot ulcer, Collagen, polyurethane foam

Introduction

Diabetic foot ulcer (DFU) is a severe and common consequence of diabetes mellitus that considerably increases treatment expenditures. Diabetes mellitus affects around 8.3% of the population in the United States, with more than 79 million people being pre-diabetic.¹

Patients with diabetes have a 12% to 25% lifetime risk of having a foot ulcer. Diabetic foot ulcers are the major cause of lower leg amputation in patients with diabetes, and surgery is used to treat diabetic foot ulcer progression in 85% of amputation cases.²

DFU is the leading cause of lower leg amputation in diabetic patients, and in 85% of the amputation cases, surgery is performed to address DFU progression.³ After an amputation, ~30% of patients lose their contralateral limb within 3 years. However, it is difficult in clinical practice due to several limitations including neuropathy, angiopathy, concomitant infection, and impaired process of wound healing in diabetic patients. Various dressing materials have been developed to overcome these factors.⁴

Collagen-based biological dressings provide a proper physiological contact between the ulcer and the environment, as well as prevent bacterial infection of the ulcer.⁵ Collagen, as a key component of the extracellular matrix, is a vital component of the human body.⁶ It influences connective tissue tensile strength and gives muscle strength and flexibility. Collagen is a fibrous protein that is found in the skin, bones, tendons, cartilages, blood vessels, and teeth. Because of its simple form and manageability, it is commonly utilised as a medical device.⁷ The present study was conducted to assess the effect of collagen dressing in diabetic foot ulcer patients.

Materials & Methods

The present consisted of 70 diabetic foot ulcer (DFU) patients of both genders. All gave their written consent to participate in the study.

Data such as name, age, gender etc. was recorded. A thorough clinical examination was carried out. Patients were divided into 2 groups of 35 each. In group I, patients were treated with a 100% porcine type I collagen sheet covered by a polyurethane foam dressing and patients in the group II were treated with only polyurethane foam dressing. Complete blood count, serum chemistry and urinary analysis was done. The ulcer size measurement, microbial culture, DFU description, and clinical photography was done. DFU size was measured using a digital planimetry wound measurement system. Data thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

Results

Table I Distribution of patients

Groups	Group I	Group II
M:F	20:15	17:18

Table I shows that in group I, males were 20 and females were 15 and in group II, males were 17 and females were 18.

Table II Assessment of parameters

Parameters	Variables	Group I	Group II	P value
Duration (weeks)		18.5	13.2	
Side	Right	16	18	0.94
	left	19	17	
Location	Interphalangeal area	1	12	0.15

	Sole	14	10	
	Heel	11	8	
	Toe	8	3	
	Malleolus	1	2	
Wagner grade	Grade I	31	33	0.05
	Grade II	5	2	
Adverse events	Infective events	1	1	0.91
	Pain	2	2	
	Maceration	1	2	

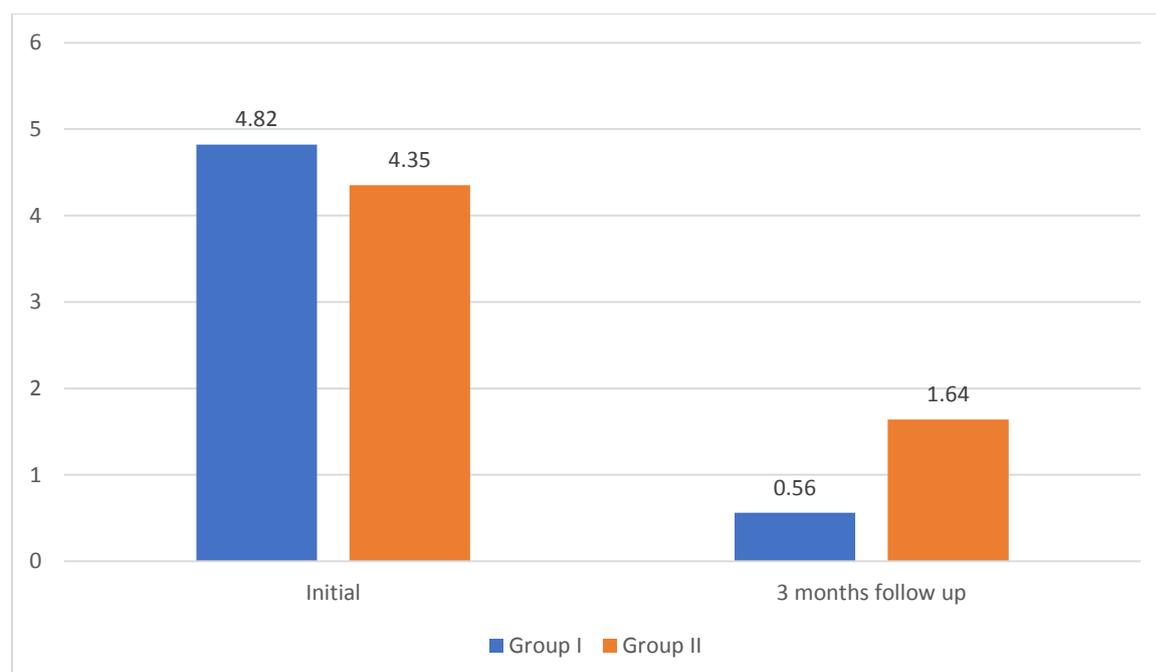
Table II shows that duration was 18.5 weeks in group I and 13.2 weeks in group II. Side was right in 16 and 18 and left in 19 and 17 in group I and II respectively. Location was interphalangeal area in 1 and 12, sole in 14 and 10, heel in 11 and 8, Toe in 8 and 3 and Malleolus in 1 and 2. Wagner grade was grade I in 31 and 33 and grade II in 5 and 2 in group I and II respectively. Adverse events reported were infective events in 1 and 1, pain in 2 and 2 and maceration in 1 and 2 in group I and II respectively. The difference was significant ($P < 0.05$).

Table III Comparison of size of ulcer

Period	Group I	Group II	P value
Initial	4.82	4.35	0.91
3 months follow up	0.56	1.64	0.02

Table III, graph I shows that mean size of ulcer initially in group I was 4.82 cm² and in group II was 4.35 cm² and at 3 months follow up was 0.56 cm² in group I and 1.64 cm² in group II. The difference was significant ($P < 0.05$).

Graph I Comparison of size of ulcer



Discussion

Diabetic foot ulcer is a severe and common consequence of diabetes mellitus that considerably increases treatment expenditures.^{8,9} Diabetes mellitus affects around 8.3% of the population in the United States, with more than 79 million people being pre-diabetic.¹⁰ Patients with diabetes have a 12% to 25% lifetime risk of having a foot ulcer. Diabetic foot ulcers are the major cause of lower leg amputation in patients with diabetes, and surgery is used to treat diabetic foot ulcer progression in 85% of amputation case.¹¹ The present study was conducted to assess the effect of collagen dressing in diabetic foot ulcer patients.

We found that in group I, males were 20 and females were 15 and in group II, males were 17 and females were 18. Saravanan et al¹² included 50 diabetic foot ulcer patients. Out of the 50 patients, 25 patients were subjected to collagen treatment and 25 patients to conventional treatment with normal saline. 80% granulation was observed in collagen treated group while there was no granulation was observed in the normal saline-treated group on day 7. The 62% epithelial tissue was present in the collagen treated group whereas 10% epithelial tissue was present in the normal saline-treated group on day 7.

We found that duration was 18.5 weeks in group I and 13.2 weeks in group II. Side was right in 16 and 18 and left in 19 and 17 in group I and II respectively. Location was interphalangeal area in 1 and 12, sole in 14 and 10, heel in 11 and 8, Toe in 8 and 3 and Malleolus in 1 and 2. Wagner grade was grade I in 31 and 33 and grade II in 5 and 2 in group I and II respectively. Adverse events reported were infective events in 1 and 1, pain in 2 and 2 and maceration in 1 and 2 in group I and II respectively. Park et al¹³ examined the effectiveness and safety of collagen dressing material in DFU treatment. Thirty patients were included (collagen group: 17, control group: 13). There were no significant differences in demographic factors or baseline DFU characteristics. Compared to the control group, the collagen group presented a higher rate of complete healing [82.4% vs. 38.5%, $P = .022$], faster healing velocity ($P < .05$), and shorter median time to 50% size reduction (21 versus 42 days; hazard ratio = 1.94, $P < .05$).

We found that mean size of ulcer initially in group I was 4.82 cm² and in group II was 4.35 cm² and at 3 months follow up was 0.56 cm² in group I and 1.64 cm² in group II. Rao et al¹⁴ compared collagen to traditional dressings in 100 patients with persistent foot ulcers caused by diabetes or burn injuries. The 75 of the 100 patients were treated with collagen dressing, while the others received standard dressing. The study found that collagen dressing had a significantly greater rate of wound healing than moistened gauze. The healing time for patients who received collagen dressing was 4.63±1.18 weeks, which was significantly less than the healing period for patients who received conventional dressing (7.79±1.61 weeks). The study indicated that collagen dressing is dependable and effective for the treatment of chronic foot ulcers, considerably reducing healing time, SSG demand, and follow-up time

The limitation the study is small sample size.

Conclusion

Authors found that wound management using collagen materials in DFUs showed faster and complete healing rate.

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