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Research Paper

# A Study to Determine Role of Collagen Particles and Tens ( Transcutaneous Electrical Nerve Stimulation ) in the Healing of Diabetic Ulcer

Medical Science

KEYWORDS :

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## ABSTRACT

*Diabetic foot ulcers are a major source of morbidity, limb loss and mortality. A prolonged inflammatory response, extracellular matrix degradation irregularities, increased bacterial presence and tissue ischemia have all been hypothesized as major contributing factors in delayed healing of diabetic wounds.TENS (Transcutaneous Electrical Nerves Stimulation) increases blood flow in ischemic ulcers may induce healing in diabetic ulcers. Wound dressings that contains collagen products create a biological scaffold matrix that support the regulation of extracellular components and promote wound healing. Diabetic foot ulcers form a major case load of our hospital. The aim of the present study was to study the efficacy of TENS and Collagen particles in the healing of diabetic ulcers.*

**METHODS**

All cases reporting to JSS under the study period satisfying inclusion and exclusion criteria were studied.

The study comprises minimum of 30 patients as gauze dressing group, and minimum of 30 patients as TENS group and minimum of 30 patients as collagen particles + TENS group, with diabetic foot ulcers secondary to type 1 and type2 diabetes mellitus, admitted to JSS Hospital, Mysore during the study period i.e. from Nov 2012 to Nov 2014.

**RESULTS**

Among the patients who have undergone TENS dressing the mean score on the pain scale was 3.5 compared to 6 for gauze dressing group and 4 for TENS + collagen particles dressing.

The result showing statistical significance with P value being 0.0001. Of the TENS group 68% required 1 to 5 dressings whereas among the patients in gauze dressing group 58% required more than 12 dressings and collagen particles + TENS group 60% required 1 to 5 dressings showing statistically significant P value 0.0001. The mean duration for hospital stay for the patients who were in TENS group was 20.5 compared to 26.5 in gauze group and 19 in collagen particles + TENS group. The result shows statistically significant P value = 0.0001. For the patients who were in TENS group the mean duration of antibiotics administered were 21.6 days compared to 29.5 days for gauze dressing room and 21.67 days for collagen particles + TENS group with P = 0.008. The patients who had undergone TENS dressings 1 patient (5%) required further disarticulation / amputation to control the disease. Where as in gauze dressing group 4 patients (14%) required further disarticulation/ amputation and 1 patient (5%) for collagen particles + TENS group required further amputation with P=0.31. The mean hospital stay for TENS group 6141whereas it is 8332 for gauze dressing group and 6575 for collagen particles + TENS group with P=0.02.

**CONCLUSION**

The present study compares the efficacy of collagen particles dressings, TENS (Transcutaneous Electrical Nerve Stimulation) and gauze dressings in the healing of diabetic ulcers has shown that the patients who has undergone TENS dressings had

- Significant lesser pain
- Shorter duration of hospital stay
- Lesser no. of dressings
- Required lesser doses of antibiotics
- Lesser economic burden on the patients
- Greater limb salvage rate

When compared to gauze dressings

The study comparing TENS and TENS+ collagen particle groups has shown that there was no significant change in pain, duration of hospital stay, number of dressings required, number of patients requiring amputations / disarticulation and total cost of hospital stay. Hence this study has shown that collagen particles has no role in the healing of diabetic foot ulcers.

TENS is also easy to apply and can be used by patients at home following instructions from the doctors, which makes the patients have shorter hospital stay and lesser economic burden.

**INTRODUCTION**

**"Every other diabetic is a surgical diabetic" – Joslin.**

Diabetes is a worldwide problem. A majority of diabetic patients develop foot ulcers at one point of time or the other during the course of their illness. A significant number of such patients require long-term hospital treatment and may end up in amputations. The etiopathogenesis of diabetic foot lesions are multifactorial and includes diabetic neuropathy, vasculopathy, poor control of diabetes and bacterial infection.

Diabetes is one of the major problems of this generation with worldwide distribution. According to Modi et al., overall incidence of diabetics in India is 1.2%.[1] The mortality due to the complications of the diabetes mellitus in India is: 2.1% in urban, 1.5% in rural, which is usually common in age group of 40 – 60 years, affecting both sexes equally. The complications are more prevalent among the people of lower economic due to illiteracy, poverty and negligence.

**OBJECTIVES OF THE STUDY**

**Aims and objectives**

1. To study the efficacy of collagen particles in the healing of diabetic ulcer.
2. To study the efficacy of TENS (Transcutaneous electrical nerve stimulation) in the management of diabetic ulcers

**MATERIALS AND METHODS**

**SOURCE OF DATA**

The source of data is from pre tested proforma which takes into account clinical history, general physical examination relevant investigations and imaging modalities and follow-up of patients which is spread over the study period of NOV 2012 TO NOV 2014. All cases reporting to JSS hospital under the study period satisfying inclusion and exclusion criteria.

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The study comprises minimum of 30 patients in conventional dressing group, 30 patients in TENS group and 30 patients in TENS and collagen particle dressing group, with diabetic foot ulcer secondary to type I and type II diabetes mellitus admitted to JSS Hospital Mysore during the study period i.e. from NOV 2012 TO NOV 2014.

**METHODS OF COLLECTION OF DATA**
The data will be collected in a pretested proforma meeting the objectives of the study.

**MODE OF SELECTION OF CASES AND METHODS OF ANALYSIS**
Patient registered as in patients in department of surgery in JSS Hospital will be included in the study subjected to inclusion and exclusion criteria.

**STUDY DESIGN**
Comparative study – case control study.

**SAMPLING**
Simple random sampling technique.

**INCLUSION AND EXCLUSION CRITERIA**
**• Inclusion Criteria:-**
- Patients with diabetic foot ulcers with palpable peripheral pulses.
- Post debridement diabetic foot ulcer.

**• Exclusion Criteria:-**
- Diabetic patients with foot ulcers due to peripheral vascular disease.
- Diabetic patients with foot ulcer due to chronic venous insufficiency
- Patients with x-ray showing osteomyelitis.
- Patients receiving corticosteroids, immunosuppressive agents, radiation or chemotherapy are also excluded
- In situ cardiac pacemakers and other electronic implants

**PRETESTED PROFORMA**
**COMPARITIVE VARIABLES,**
**These variables will be compared between the two group:**
1. Pain scale- visual analogue scale.
2. Duration of hospital stay.
3. Total no. of dressings done during the hospital stay.
4. Total no. of days antibiotics given.
5. Total expenditure for the patient.
6. Morbidity

**Following investigations/interventions will be undertaken:**
• Routine investigations like Hb%, Tc, Dc, ESR, Urea. Creatinine.
• Investigations to know the diabetic status, like FBS, PPBS, HbA1c, urine routine.
• Pus for culture and sensitivity.
• 4. Foot X-ray
• 5. Debridement,
• 6. Collagen particle dressing
• 7. TENS application: Electrical stimulation is delivered through a TENS machine which has two conductive electrodes, the cathode and the anode, which are applied on either of the ulcer. The electrical stimulation is given daily for 20 mins until wound heals showing granulation issue.

**STUDY DESIGN - COMPARATIVE STUDY –case control study**
**• SAMPLING** - Simple Random Sampling Technique
**STATISTICAL METHODS APPLIED**
**Frequencies,Descriptive statistics,Crosstabs,Independent samples t test**

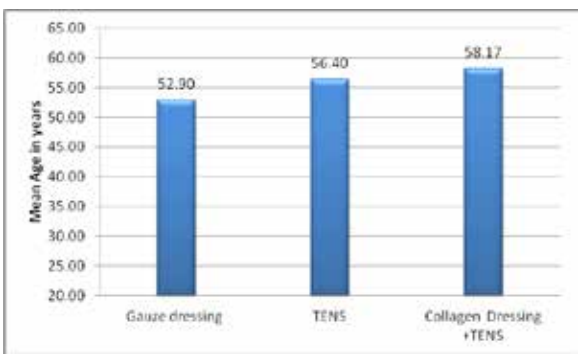
**RESULTS**
**1.AGE DISTRIBUTION:** The age of the patients were varied from 35-90 years. The maximum number of patients 60% belong to the age group 50-70 years. The average age of diabetic foot lesions in India is 60 years.

**TABLE 3. AGE DISTRIBUTION**

| | Gauze dressing (30) | | TENS (30) | | Collagen Dressing +TENS (30) | |
|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD |
| Age in years | 52.90 | 8.90 | 56.40 | 12.40 | 58.17 | 9.93 |

One way ANOVA, p=0.2

**GRAPH 1. AGE DISTRIBUTION**



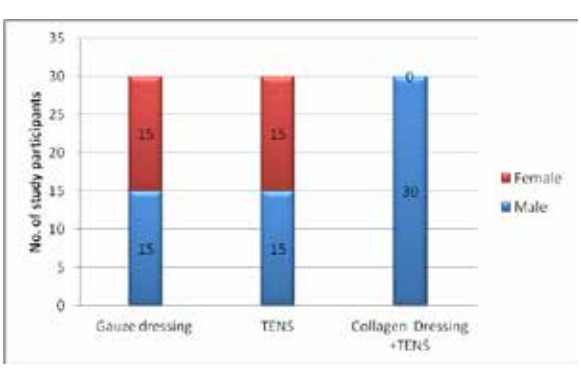

**2. SEX DISTRIBUTION:** Of 90 patients, 60 male, 30 female were chosen for study purpose. The groups were further divided comprising 15 male and 15 female patients in gauze dressing group, 15 male and 15 female patients in TENS group and 30 males in collagen particle dressing + TENS group.

**TABLE 4. SEX DISTRIBUTION**

| Gender | Gauze dressing (30) | | TENS (30) | | Collagen particle dressing +TENS (30) | |
|---|---|---|---|---|---|---|
| | No | % | No | % | No | % |
| Male | 15 | 50 | 15 | 50 | 30 | 100 |
| Female | 15 | 50 | 15 | 50 | 0 | 0 |
| Total | 30 | 100 | 30 | 100 | 30 | 100 |

P<0.0001, chi-square test

**GRAPH 2. SEX DISTRIBUTION**

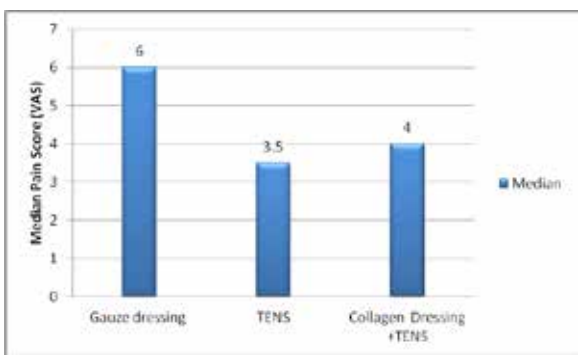


**3.COMPARISION OF PAIN SCALE:** Among the patients who have undergone TENS dressing group mean score on pain scale was 3.5, compared to 4 for patients undergone collagen particle dressing + TENS dressing and 6 for the patients undergone gauze dressings. The result showing statistical significance of P value is being 0.0001.

**TABLE 5.COMPARISION OF PAIN SCALE**

| | Gauze dressing (30) | | | TENS (30) | | | Collagen particle dressing +TENS (30) | | | p |
|---|---|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Median | Mean | SD | Median | Mean | SD | Median | |
| Pain (VAS) | 5.87 | 1.20 | 6 | 3.73 | 1.34 | 3.5 | 3.93 | 1.44 | 4 | <0.0001** |

**GRAPH 3.COMPARISION OF PAIN SCALE**

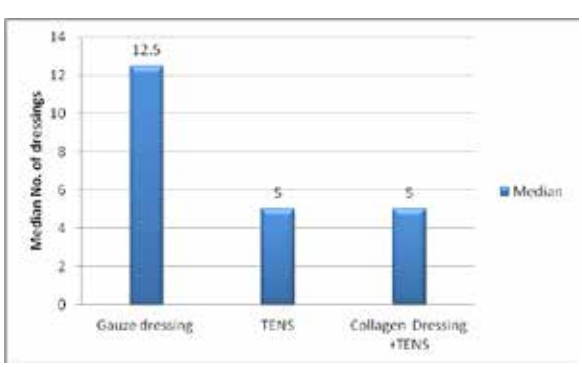



**4.COMPARISION OF TOTAL NUMBER OF DRESSING DONE-** Among patients studied gauze dressing group required mean of 13 dressings compared to TENS group and collagen particle dressing + TENS group requiring 5 number of dressings. The results showing statistical significance p=0.0001.

**TABLE 6. TOTAL NUMBER OF DRESSING DONE**

| | Gauze dressing (30) | | | TENS (30) | | | Collagen particle dressing +TENS (30) | | | p |
|---|---|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Median | Mean | SD | Median | Mean | SD | Median | |
| Number of dressings | 14.90 | 5.96 | 12.5 | 4.87 | 2.43 | 5 | 6.40 | 6.92 | 5 | <0.0001** |

**GRAPH 4. TOTAL NUMBER OF DRESSING DONE**

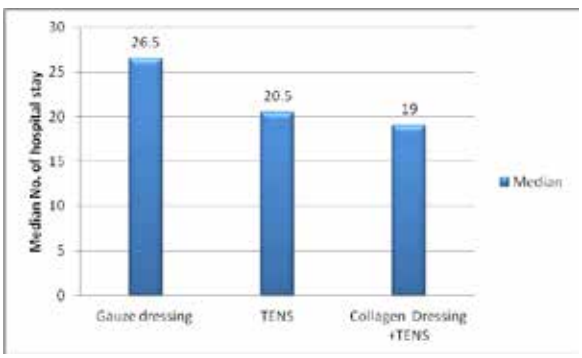



**5.COMPARISION OF DURATION OF HOSPITAL STAY** - Among the patients studied, the mean duration of the hospital stay for the patients who have undergone gauze dressing was 26.5, compared to TENS group, 20.5 and 19 for collagen particle dressing + TENS group. The result showing statistical significance with p value being 0.0001.

**TABLE 7. COMPARISION OF DURATION OF HOSPITAL STAY**

| | Gauze dressing (30) | | | TENS (30) | | | Collagen particle dressing +TENS (30) | | | p |
|---|---|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Median | Mean | SD | Median | Mean | SD | Median | |
| No. of days of hospital stay | 28.87 | 9.47 | 26.5 | 20.40 | 7.70 | 20.5 | 19.27 | 8.58 | 19.0 | <0.0001** |

**GRAPH 5. COMPARISION OF DURATION OF HOSPITAL STAY**

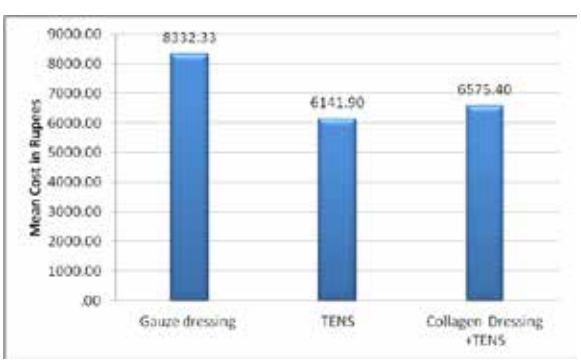



**6. COMPARISION OF COST EFFECTIVNESS** – Among the patients studied the mean cost of hospital stay for gauze dressing 8332.33, whereas it was 6141 for TENS group and 6575 for collagen particle dressing + TENS group. p=0.02

**TABLE 8. COMPARISION OF COST EFFECTIVNESS**

| | Gauze dressing (30) | | | TENS (30) | | | Collagen particle dressing +TENS (30) | | | p |
|---|---|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Median | Mean | SD | Median | Mean | SD | Median | |
| Cost (Rs) | 8332.33 | 3251.77 | 7313.5 | 6141.90 | 2891.3 | 5740.0 | 6575.40 | 3257.6 | 6395.0 | 0.02* |

**GRAPH 6. COMPARISION OF COST EFFECTIVNESS**




**7.COMPARISION OF TOTAL NUMBER OF DAYS ANTIBIOTICS WERE ADMINISTERED** – Among the patients studied, for the patients who had undergone gauze dressings, the mean duration of antibiotics administered was 29.53 days, compared to 21.3 days for TENS group and 21.67 days for collagen particles dressing + TENS group.

**TABLE 9. COMPARISION OF TOTAL NUMBER OF DAYS ANTIBIOTICS WERE ADMINISTERED**

| | **Gauze dressing (30)** | **TENS (30)** | **Collagen particle dressing +TENS (30)** | **P** |
|---|---|---|---|---|

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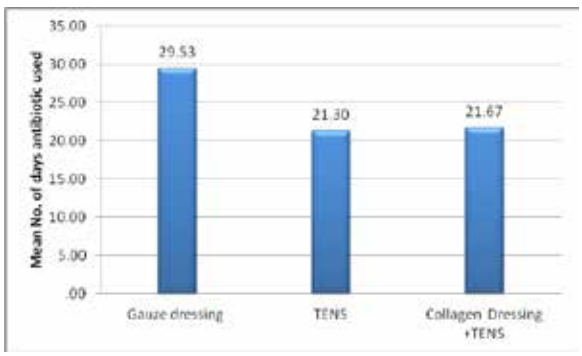
| | Mean | SD | Mean | SD | Mean | SD | |
|---|---|---|---|---|---|---|---|
| Mean number of days antibiotics used | 29.53 | 9.78 | 21.30 | 9.48 | 21.67 | 14.11 | 0.008 |

**GRAPH 7. COMPARISION OF TOTAL NUMBER OF DAYS ANTIBIOTICS WERE ADMINISTERED**

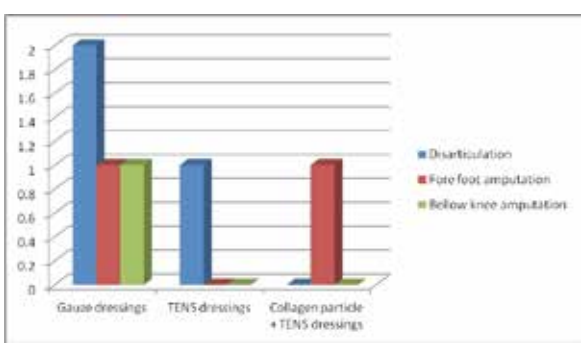



**8.COMPARISION OF MORBIDITY**— Among the patients who had undergone TENS dressing, 1 patient (5%) required further disarticulation/amputation to control the disease. Whereas in gauze dressing group, 4 patients (14%) require for the disarticulation/amputation and 1 patients (5%) for collagen particle + TENS group required further amputation.

**TABLE 10: MORBIDITY RATES**

| MORBIDITY | Gauze dressings | TENS dressings | Collagen particle + TENS dressings |
|---|---|---|---|
| Disarticulation | 2 | 1 | 0 |
| Fore foot amputation | 1 | 0 | 1 |
| Bellow knee amputation | 1 | 0 | 0 |

**GRAPH 8. MORBIDITY RATES**




**DISCUSSION**

Wound dressings have evolved from the status of providing physical protection to the raw surface, absorbing exudates and controlling local infections by local medications to the level of providing adequate environment promoting wound healing. This has been achieved by modern wound dressing which promotes granulation tissue formation.

The concept of moist wound dressings which came into vogue in 1960 which revolutionized wound care. This led to further research in this direction leading to influx of many products .People have tried various non conventional topical agents in wound healing such as aleo vera, antacids, benzoyl per-oxide, collagen,gentian violet, impregnated gauze, insulin, mercurochrome oxygen therapy, sugar and vinegar. Each claiming a better wound healing rate than the others. As the concept of outcome based medicine evolved, the need for better wound dressing modality became more acute.

Now wound dressing systems were compared not only on the basis of the rate of granulation tissue formed or the rate of wound healing but also on the cost and duration of hospital stay of the patient which was considered as a measure of the morbidity of the patient.

The study comprises minimum of 30 patients as gauze dressing group, and minimum of 30 patients as TENS group and minimum of 30 patients as collagen particle dressing + TENS group, with diabetic foot ulcers secondary to type 1 and type2 diabetes mellitus.

Among the patients who have undergone TENS dressing the mean score on the pain scale was 3.5 compared to 6 for gauze dressing group and 4 for TENS + collagen particle dressing. The result showing statistical significance with P value being 0.0001. Of the TENS group 68% required 1 to 5 dressings where as among the patients in gauze dressing group 58% required more than 12 dressings and collagen particle dressing + TENS group 60% required 1 to 5 dressings showing statistically significant P value 0.0001. The mean duration for hospital stay for the patients who were in TENS group was 20.5 compared to 26.5 in gauze group and 19 in collagen particle + TENS group. The result shows statistically significant P value = 0.0001. For the patients who were in TENS group the mean duration of antibiotics administered were 21.3 days compared to 29.5 days for gauze dressing room and 21.67 days for collagen particle + TENS group with P = 0.008. The patients who had undergone TENS dressings 1 patient (5%) required further disarticulation / amputation to control the disease. Where as in gauze dressing group 4 patients (14%) required further disarticulation/ amputation and 1 patient (5%) for collagen particles + TENS group required further amputation with P=0.31. The mean hospital stay for TENS group 6141whereas it is 8332 for gauze dressing group and 6575 for collagen particle + TENS group with P=0.02.

This study can be compared to Ludenberg TCM et al which is a control study of effect of electrical nerves stimulation was performed in conjunction with standard treatment for healing diabetic ulcers on 64 patients divided randomly in to 2 groups. The results shows the healing wounds after 12 weeks in TENS group was on an average 61% of the initial size and the gauze group was 41% of the initial size.

In the present study TENS is applied daily for 20 minutes 100-150V; alternative current 100HZ, 100MS is similar to Ludenberg TCM.

This study can be compared to Donghue V M, etal study which evaluated the impact of collagen wound dressing on healing or reduction in wound area of foot ulcers in people with diabetics. The result shows no statistical significant wound area reduction or complete healing.

It is possible that the improvement in the healing of ulcers seen in the present study reflects the effect of increased blood flow. However additional studies are needed to identify the mechanisms involved in the promotion of healing with TENS and to determine the stimulus variables that most efficaciously accelerate tissue repair. TENS is easy to apply and can be used by the patient at home following instructions from a medical doctor.

**Future trends:**

The important areas where significant advances has occurred in chronic wound care are the development of wound dressing systems, which stimulate wound healing process by improved

granulation tissue formation and the development of permanent composite skin replacement in the form of genetically engineered keratinocyte culture techniques and growth factors. The main problem of the latter technique is that it is still in the experimental phase and will not be available to common man in the near future.[30,74]

Extensive research is going on in the development of artificial skin substitutes by combining cultured keratinocytes with artificially formed dermal analogues, namely Integra, AleoDerm, polygalactin mesh, human allogenic dermis etc., which has immense potential. It is only a matter of time before a successful approach to the management of diabetic wounds is devised.

**CONCLUSION**

The present study compares the efficacy of collagen particle dressings, TENS (Transcutaneous Electrical Nerve Stimulation) and gauze dressings in the healing of diabetic ulcers has shown that the patients who has undergone TENS dressings had

- Significant lesser pain
- Shorter duration of hospital stay
- Lesser no. of dressings
- Required lesser doses of antibiotics
- Lesser economic burden on the patients
- Greater limb salvage rate

**When compared to gauze dressings**

The study comparing TENS and TENS+ collagen particle groups has shown that there was no significant change in pain, duration of hospital stay, number of dressings required, number of patients requiring amputations / disarticulation and total cost of hospital stay. Hence this study has shown that collagen particle has no role in the healing of diabetic foot ulcers.

TENS is also easy to apply and can be used by patients at home following instructions from the doctors, which makes the patients have shorter hospital stay and lesser economic burden.

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