“A Comparative Study of Collagen Granule Dressing Versus Conventional Dressing in Deep Wounds”

Dr. Shankar N¹, Dr. Ravindra Eligar², Dr Ramesh H³,
Dr. Narayanchandra I Hebsur⁴

( Post graduate student in General surgery, KIMS HUBLI, RAJIV GANDHI university, Karnataka, India¹. Professor Dept Of Plastic Surgery KIMS HUBLI , RAJIV GANDHI university, Karnataka, India ². Associate Professor Dept Of General Surgery KIMS HUBLI, Karnataka India ³, ⁴)

Abstract:
Introduction: Wounds can cause painful lengthy hospital stay, multiple stages of surgeries, and enormous financial burden. Biological dressings collagen granule dressing has advantage over conventional dressing in terms of non-immunogenic, non-pyrogenic, being natural, easy application and decreased days of healing.

Objectives: To compare the efficacy and safety of collagen granule dressings and conventional dressing in deep wounds in terms of reduced healing time, number of dressing, healing quality and complications.

Methods And Material: A prospective study was done between December 2012 to June 2014 in which 68 patients who presented with deep wounds were chosen by random sampling technique, and were grouped into 2 groups consisting of 34 patients.

Results: In our study it was observed that mean % of granulation tissue at 2 weeks in cases was 93.68±10.09 and in controls was 65.59±15.80. There was statistically significant difference of mean % of granulation tissue at 2 weeks among study groups(p<0.01). Mean wound bed score at 2 weeks in cases was 14.2±1.63 and in controls 10.09±2.45. There is statistically significant difference of the wound bed score at 2 weeks between the cases and controls (P<0.01).

Conclusion: Collagen granules showed faster and better healing rates among the study group

Keywords: Collagen Dressing, Deep Wounds, Wound Healing, Wound History, wound dressing.

I. Introduction

Wound Healing is a dynamic process involving soluble mediators, a variety of cells, and extracellular matrix⁵. Wound result from precise disruption of tissue by the surgeon’s knife (incision) to widespread damage of tissue (e.g. major trauma, burns). It also result from a contusion, hematoma, laceration or an abrasion. The continuity of the skin must be restored expeditiously because it plays a crucial role in maintaining homeostasis⁶.

Deep Wound are defined as wound which extending deeper, across deep fascia into muscle or deeper structure.⁷ Deep wounds are extremely complex and optimal treatment requires an understanding of nutrition, immunology, psychological issues, the physiology and the metabolic interactions among all the major organ systems. Wounds are difficult to treat includes diabetic ulcers, venous ulcers, trophic ulcers, pressure sores and necrotizing fasciitis. An ideal dressing used in the wound management should be economical, easy to apply, readily available dressing or method or coverage that will provide good pain relief, protect wound from infection, promote healing, keep moisture, be elastic, and non - antigenic and adhere well to the wound and waiting for spontaneous epithilisation and healthy granulation tissue⁸.

Among newer type of wound dressings - Biological Dressings Like Collagen create the most physiological interface between the wound surface, environment and impermeable to bacteria. Collagen, the most abundant protein in the body, plays a critical role in the successful completion of adult wound healing. Its deposition, maturation, and subsequent remodeling are essential to the functional integrity of the wound

Collagen is defined as an endogenous substance, which forms an important structural component in connective tissue and is of special importance in the skin. The importance of collagen in healing has been appreciated for many years for the simple reason that, the result of repair in wound healing is always a scar, which is composed of collagenous fibers⁹. Collagen forms molecular diversity in the body’s protein scaffold⁹.

Collagen granule dressing has better advantage over conventional dressing in terms of collagen formation with greater reduction in inflammatory cells during healing days resulting in decreased days of healing, where as conventional dressing has minimal collagen formation, high grade of inflammation during the healing days with maximum exudates formation resulting in increased days of healing. A collagen granule dressing has another advantage over conventional dressing in terms of non - immunogenic, non- pyrogenic, being natural, easy application, hypo allergic and pain free.¹⁰ This study is

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conducted to compare the efficacy of collagen granule dressing with that of conventional dressing in the management of deep wounds.

II. Materials And Methods

Source Of Data:
Data was collected from all patients with deep wounds, who were admitted during period of December 2012 to November 2014 for study considering the inclusion and exclusion criteria. A total of 68 indoor surgical ward patients with deep wounds were considered for the study. Selection of the patients were done randomly. Cases were allocated randomly into test group and control group, test group treated with collagen granule dressing and control group treated with conventional dressing. Groups were done taking into account the confounding factors, which are matched.

Study Type: Prospective Randomized Controlled Study
Method Of Collection Of Data:
Information was collected through predesigned pretested proforma for each patient. All patients were interviewed as per the Proforma and a complete clinical examination was done.

Sample Size:
A total of 68 indoor surgical ward patients with deep wounds were considered for the study. Selection of the patients were done randomly. Where 34 patients were selected under Collagen dressing studies and the rest 34 patients selected under conventional dressing studies.

Statistical Tests:
The collected data will be evaluated using appropriate statistical methods. Unpaired students “t” test and Chi Square test were used to find out the statistical significance. A “p”<0.05 was taken as significant.

Patient’s Demography

<table>
<thead>
<tr>
<th>AGE IN YEARS</th>
<th>CASES</th>
<th>CONTROLS</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;20</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>21-30</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>31-40</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>41-50</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>51-60</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>&gt;60</td>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td>TOTAL</td>
<td>34</td>
<td>34</td>
</tr>
</tbody>
</table>

MEAN AGE ±SD 43.88±18.05 50.41±15.38

“t” Value -1.605
P VALUE 0.261

Observation: In this study, the Mean age of the patients ranged from 14 to 80 years. Mean age is 43.88 ±18.05 years in cases and 50.41±15.38 years in controls. The difference in mean age between cases and controls was not statistically significant (p=0.261)

Table 2: Showing Distribution Of Wound Bed Score At 2 Wk

<table>
<thead>
<tr>
<th>WBS AT 2WK</th>
<th>CASES</th>
<th>%</th>
<th>CONTROL</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>5-8</td>
<td>0</td>
<td>0</td>
<td>13</td>
<td>38.2</td>
</tr>
<tr>
<td>9-12</td>
<td>7</td>
<td>20.6</td>
<td>15</td>
<td>44.1</td>
</tr>
<tr>
<td>13-16</td>
<td>27</td>
<td>79.4</td>
<td>6</td>
<td>17.6</td>
</tr>
</tbody>
</table>

MEAN±SD 14.2±1.63 10.09±2.45

“t” Value 8.202
P VALUE <0.01

Observation: Mean WBS at 2 weeks in cases was 14.2±1.63 and in controls 10.09±2.45. There is statistically significant difference of the wound bed score - WBS at 2 weeks between the cases and controls (P<0.01)

Table 3: Mean WBS Initial And At The End Of 2 Weeks

<table>
<thead>
<tr>
<th>WBS</th>
<th>CASES MEAN±SD</th>
<th>CONTROLS MEAN±SD</th>
<th>P VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>INITIAL</td>
<td>4.82±1.37</td>
<td>5.50±1.58</td>
<td>0.060</td>
</tr>
<tr>
<td>2 WEEKS</td>
<td>14.2±1.63</td>
<td>10.09±2.45</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

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Observation: Mean initial WBS in cases was 4.82±1.37 and in controls 5.50±1.58. There is no statistically significant difference of the initial wound bed score- WBS (p=0.060). Mean WBS at 2 weeks in cases was 14.2±1.63 and in controls 10.09±2.45. There is statistically significant difference of the wound bed score- WBS at 2 weeks between the cases and controls (P<0.01).

<table>
<thead>
<tr>
<th>Table 4: Mean Percentage Of Granulation Tissue At 2 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>CASES</td>
</tr>
<tr>
<td>CONTROLS</td>
</tr>
</tbody>
</table>

Observation: Mean % of granulation tissue at 2 weeks in cases was 93.68±10.09 and in controls was 65.59±15.80. There was statistically significant difference of mean % of granulation tissue at 2 weeks among study groups(p<0.01).

Patient Photographs:

III. Discussion

Wound healing is a complex process involving a number of chemical and biological events. Collagen serves as the key extracellular component for repair and remodeling of skin tissue. As a biomaterial, collagen offers several advantages over traditional dressings, growth hormones and biological coverings. The use of collagen as a drug delivery system is very comprehensive and diverse. Collagen can be extracted into an aqueous solution and molded into various forms of delivery systems. Due to its excellent biocompatibility and safety, the use of collagen in biomedical application has been rapidly growing and widely expanding to bioengineering areas.

Collagen appears to be a good material for use as a biomedical implantable device and is used to form a matrix for regenerating tissue outside of the body, for example in regenerating skin for use in burns treatment, but increasingly it is also used in the development of other tissues offering the prospect of growing replacements for damaged organs. Collagen membranes are also chemotactic for regenerative cells and may enhance the migration and attachment of fibroblasts through its space-making ability.

Present study is a prospective study regarding collagen dressing versus conventional dressing. It was conducted between December 2012 to November 2014 in which 68 patients who presented with deep wounds of various etiologies were chosen by random sampling technique, and were grouped into two groups consisting of 34 patients each to show the efficacy of collagen dressing. Comparing present study with 3 other randomized control trails.

In a study conducted by Veves, 276 patients with diabetic foot ulcer, after 12 weeks of treatment, 51 (37.0%) Promogran- a collagen/oxidized regenerated cellulose dressing-treated patients had complete wound closure as compared to 39 (28.3%) patients of control group (moistened gauze), but this difference was not statistically significant (P=0.12). In this study, author found an overall benefit of collagen on the rate of wound healing compared with moistened gauze.

Omkar Singh study reveals that regarding Collagen Dressing Versus Conventional Dressings in 120 patients with chronic wounds of varied aetiologies and with mean age 43.7yrs, with two weeks of treatment, 60% of the ‘collagen group’ wounds and only 42% of the ‘conventional group’ wounds were sterile (P=0.03). Healthy granulation tissue appeared earlier over collagen-dressed wounds than over conventionally treated wounds (P=0.03). After eight weeks, 52 (87%) of ‘collagen group’ wounds and 48 (80%) of ‘conventional group’ wounds were >75% healed (P=0.21). Eight patients in the ‘collagen group’ and 12 in the ‘conventional group’ needed partial split-skin grafting (P=0.04). Collagen-treated patients enjoyed early and more subjective mobility. No significant better results in terms of completeness of healing of burn and chronic wounds between collagen dressing and conventional dressing were found. Collagen dressing, however, may avoid the need of skin grafting, and provides additional advantage of patients’ compliance and comfort.
In another study by Harish Rao regarding collagen dressings versus conventional dressings in wound healing of 100 patients with diabetic foot ulcer. In 75 patients collagen dressing was applied, whereas conventional dressing in 25 patients. On enrollment, the median wound size was 33.5 cm² in collagen dressing group and 48 cm² in conventional dressing group. Healing time (4.02 ± 0.59 Vs 7.6 ±1.38), duration of antibiotic therapy (15.12±4.55 Vs 24.08± 6.5) and mean follow up period (2.40 ± 0.61 Vs 2.96 ± 1.2) were significantly less in collagen dressing group as compared to conventional dressing group (P<0.001). No adverse event was reported in both the groups. Collagen dressing is safe and effective in the treatment of foot ulcer and significantly reduces healing time, duration of antibiotic therapy and follow up time.

The present study made a comparison between the collagen dressing and conventional dressing. The efficacy and wound healing capacity of both the methods were gauged using suitable statistical test. The study revealed some interesting results.

The study constituted a total of 68 participants. The Age of the patients ranged from 14 to 80 years. Mean age was 43.88 ±18.05 years in cases and 50.41±15.38 years in controls. The difference in mean age between cases and controls was not statistically significant (p>0.05). Similar findings were obtained from the studies in the past (Singh O, Rao S).

Majority of the participants in the study were males in both the case and the control group. The difference in sex distribution of case and controls was not statistically significant (p>0.05). The results were similar to studies done in the past where the male dominance was seen in the sample size (Singh O, Rao S). This could be because males are more prone to traumatic wounds and the prevalence of diabetes is also known to be higher in middle-aged males.

The study revealed that the participants presented with various wounds. However, post debridement wounds were the most common in both case and control group followed by post traumatic wound. Majority of the wounds were present in the lower limbs, followed by upper limb, chest and abdomen.

The wound duration in the cases and control groups were not found to be statistically significant (p>0.05). The mean duration of wound in cases was 28±68.37 days and 29.94±42.58 days in control group.

The study also compared the wound size between the cases and controls. The study findings revealed that there was a statistical significance between the wound sizes of cases and controls at 4 weeks (p<0.05). However there was no statistical significance noticed between the wound size between the case and control groups at initiation, 2 weeks and 12 weeks (p>0.05). The mean ulcer size was also compared between the study groups. The study reported that the mean ulcer size in case and control groups were 167 cm² and 147 cm² respectively. This was higher as compared to the findings of Harish Rao and Veves studies.

The WBS was also compared between the cases and control group at initiation and 2 weeks. The study revealed that the mean initial WBS was 4.82±1.37 in cases and 5.50±1.58 in controls. There was no statistically significance noticed between the two group as per the initial WBS (P>0.05). However the mean WBS at 2 weeks was 14.2±1.63 in cases and 10.09±2.45 in controls. There was statistically significant difference noticed between the cases and control groups (P<0.01).

Granulation tissue formation was also compared between the case and the control group in the study. It was noticed that the mean percentage of granulation tissue formation at 2 weeks in cases was 93±10.09 and that of control was 65.59±15.80. There was statistically significant difference noticed between the two study groups (p<0.01).

Majority of wounds showed more than 90% granulation tissue at 2 weeks among cases and 51-60% among controls. Also, Majority (17) of wounds healed by wound contracture in cases followed by skin grafting and majority (21) by split skin grafting among control group.

The percentage of wound size reduction was also compared between the cases and controls in 2 weeks. Though there was no statistically difference that was recorded between the groups based on the percentage of wound size reduction, the cases group recorded a higher percentage of reduction in wound size compared to the control group. The case group in the study recorded 100% in wound size compared to 93% in the control group. Similar differences were noticed in the previous studies (Veves et al).

The study highlighted some important distinctions between the use of collagen in wound healing and conventional methods. The study marked essential benefits in the healing procedure by use of collagen. However, further in-depth attempts are needed in order to make a robust case of newer form of wound dressing/healing.

Limitations Of The Study.
1. This study was conducted only for 12 weeks.
2. The wound was studied in only two dimensions.
3. Observer and patient were not blinded increasing the risk of bias.
4. Wound volume measurement rather than area would have been a more accurate approach of judging results.
The study, in spite of its shortcomings, does indicate that topical application collagen particles is more effective than conventional dressing therapy in healing a deep wound and that it has the potential to be a useful and safe adjunct to wound healing.

IV. Conclusion

With the use of collagen granule dressings in comparison with the control group (normal saline group) for the treatment of deep wounds, the following conclusions were derived.

1. Collagen granules showed faster and better healing rates among the study group
2. Area reduction was statistically significant in the study group
3. There was no adverse effects or reactions seen when collagen were applied over the wound
4. Venous ulcer healed completely with collagen granule dressing

Acknowledgements

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References

Foot Ulcers. ISRN Endocrinology: Arman Zaharil Mat Saad, Teng Lye Khoo, and Ahmad Sukari Halim.

Apparatus And Method For Deformed Areas Of Skin. Jane I. Kundin, Appl' No" 503'067 Jun. 10, 1983

Dressing in the management of diabetic foot ulcers. Donaghue VM, Purna Sai K., Mary Babu. Collagen Based Dressings

SRB’s text book of surgery, 4th edition page no 3


Dr. Harish Rao, Dr. Ashwin Pai, Dr. Irshad Hussein, Dr. Hs Shankar Ram, Dr.Sheila R Pai, and Dr. Shobha Pai. A Comparative Study

Human Biosciences, Inc. 940 Clopper Road Gaithersburg, Md 20878, 2006:169.


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