EVALUATION OF MECHANISMS OF ACTION OF A HYDROCONDUCTIVE DRESSING FOR CHRONIC WOUNDS

Diane Ochs, RN,[1] M Georgina Uberti, MD, [1] Guillermo A Donate, DPM,[1] Melissa Abercrombie, DPM,[1] Rudolph J Mannari, PA-C,[1]
Martin C Robson, MD,[2] Wyatt G Payne, MD[1,2]
[1]Institute for Tissue Regeneration, Repair, and Rehabilitation, Bay Pines VA Healthcare System, Bay Pines FL
[2]University of South Florida Division of Plastic Surgery, Tampa FL

ABSTRACT

Nine Million people in the US will suffer from chronic wounds each year. Treatment cost estimates are up to 14 billion dollars. Standard treatment for chronic wounds includes wound bed preparation followed by wound closure. Recently, a hydroconductive dressing with two types of absorbent cross-section structure might be able to perform the functions of wound bed preparation. This dressing creates the ability to actively move large volumes of fluid and other debris from wounds. Mechanisms of action and benefits in wound healing have not yet been elucidated. The purposes of this study are to 1) evaluate the dressing's role of decreasing the tissue level of bacteria in wounds; 2) determine if bacteria are drawn into the test dressing; 3) evaluate levels of MMP-9 and MMP-1 from treated wounds; and 4) evaluate the effect of the dressing to decrease wound size. Photographs and digital planimetry were utilized to document and follow wound size and character. Drawtex dressing was applied to the wound surface 2x/week. Wound biopsies were obtained to determine quantitative and qualitative culture, and MMP-9 and MMP-1 levels. Wound dressings were analyzed for bacteria type and amount, and for cytokine types and amounts. A sample patient data is presented.

INTRODUCTION

Nine million people in the US will suffer from chronic wounds such as diabetic foot ulcers (DFU), venous stasis ulcers (VSU), or pressure ulcers (PU) each year. The treatment costs of these wounds will be 11-14 billion dollars in 2011 and is estimated to be 20 billion dollars by 2016. The standard treatment for chronic wounds has been wound bed preparation by debridement of necrotic tissue, decreasing excessive wound exudate, decreasing bacterial level, removal of deleterious chemical mediators, and wound closure. Recently, a hydroconductive dressing (Drawtex) has been designed with two types of absorbent cross-section structure and has been reported to assist in wound bed preparation. This dressing creates the ability to actively move large volumes of fluid and other debris from chronic wounds. The exact mechanism of action and benefits in wound healing have not been elucidated.

STUDY PURPOSE

1) Evaluate the dressing's role to decrease the quantitative tissue level of bacteria in wounds

2) Determine if the tissue bacteria are drawn into the test dressing

3) Evaluate the ability of the dressing to remove deleterious substances such as MMP-9 and MMP-1 from chronic wounds

4) Evaluate the effect of the dressing to decrease wound size and improve wound appearance

METHODS

Chronic wounds were treated with the hydroconductive dressing (Drawtex). For each wound, standardized photographs and tracings for digital planimetry were obtained on Day 0. A biopsy for quantitative and qualitative bacteriology was obtained. Also a biopsy was obtained from the wound for cytokine analysis using ELISA technique. The wounds were treated with Drawtex dressing applied to the wound surface with a cover dressing appropriate for the specific chronic wound type (DFU vs. VSU vs. PU). In instances of extremely exudative wounds of wound with deep cavities, two layers of Drawtex was utilized. The dressings were changed twice weekly. At alternate dressing changes, samples of dressing, and wound tissue biopsies were harvested for serial analyses of quantitative and qualitative bacteriology and ELISA cytokines. Wounds were photographed and traced for serial wound measurements and quality analysis. Serial analysis was repeated for four weeks or until wound closure, whichever occurred first.

Determinations were made for 1) decrease in bacterial levels; 2) change in cytokines (MMP-9, MMP-1) ; 3) presence and quantification of cytokines in the dressing; 4) rate of decrease in wound size; and 5) qualitative assessment of wound appearance

RESULTS

To date, 9 patients have been studied including DFUs, VSU, and PUs. Tissue bacterial levels ranged as high as 10^6 colony forming units (CFUs) / gram of wound tissue. Bacterial levels in the Drawtex dressings ranged from 10^3 to 10^4 CFUs/sq cm of dressing. MMP-1 levels in the tissue tended to decrease as levels increased in the Drawtex dressings. MMP-9 levels similarly tended to decrease slightly as the MMP-9 level appeared in the Drawtex dressings.

An example of these cases is this patient with a DFU (Table 1). Bacterial levels in the wound tissue decreased from 10^6 CFU/gm wound tissue to $< 10^2$ CFUs/gm wound tissue. The bacteria appeared to be drawn into the Drawtex dressings. MMP-1 tissue levels decreased from 2.649 pg/µg of protein to 0.696 pg/µg. MMP-9 tissue levels decreased slightly. The levels of MMP-1 and MMP-9 in the Drawtex dressings increased .

TABLE 1

	Tissue CFUs/gm	Drawtex CFUs/ sq cm	Tissue MMP-1 pg/ug protein	Drawtex MMP-1 pg/ug protein	Tissue MMP-9 pg/ug protein	Drawtex MMP-9 pg/ug protein	Wound Size sq cm
Day 0	10^6		2.649		22.38		2.5

Day 7	10^5	10^3	-------	0.471	22.28	------	1.8
Day 14	10^4	10^4	0.685	0.510	23.26	19.86	1.7
Day 21	$<10^2$	10^4	0.860	0.529	22.20	16.66	1.7
Day 28	$<10^2$	10^4	0.696	0.962	21.78	21.64	1.8

DFU Day 0

DFU Day 14

DISCUSSION AND CONCLUSIONS

Drawtex hydroconductive dressings appear to have the ability to decrease tissue bacterial levels and to decrease deleterious cytokines in chronic wounds. This interval report appears to indicate that clinical results with Drawtex mimic experimental animal results. These data suggest that Drawtex may be an effective adjuvant for debridement of chronic wounds, and that it may have a role in wound bed preparation.

ACKNOWLEDGMENTS/DISCLAIMERS

This material is the result of work supported with resources and the use of facilities at the Bay Pines VA Healthcare System, Department of Veterans Affairs
The contents of this work do not represent the views of the Department of Veterans Affairs or the United States Government
Supported by funding from SteadMed Medical, Inc.
Dr. Robson is a consultant for SteadMed Medical, Inc.;