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FROM SCIENCE TO PRACTICE: CONTEMPORARY APPROACHES TO SKIN, WOUND, OSTOMY, AND INCONTINENCE CARE

Health Economics: Utilizing Advanced Care Wound Products for Clinical and Cost Effectiveness

Important Pieces of the Research Puzzle

Professor Keith Harding

A Retrospective Analysis of the Cost-effectiveness of a Collagen/Oxidized Regenerated Cellulose Dressing in the Treatment of Neuropathic Diabetic Foot Ulcers

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Important Pieces of the Research Puzzle

Professor Keith Harding

Wounds and wound healing are complex and challenging for healthcare systems. In recent years, there has been an ever-increasing clamor for more research to prove that new treatments and systems of care make a difference. At the same time, awareness is growing regarding the difficulties associated with undertaking clinical research in this area — both in terms of obtaining funding and in the design of research studies. The current state of affairs can be summarized by stating that no one single piece of research is going to provide all of the evidence required to appreciate what is best for patients with a particular problem but all structured assessments of intervention add to our understanding of how to improve patient care.

The two articles in this publication contain new and novel information. Lazaro-Martinez et al examine different dressing regimens and their impact on healing in a population of patients with diabetic foot disease. Treatment including oxidized regenerated cellulose and collagen appears to make a positive difference. Although this study is not of sufficient size to prove a statistical significance, the treatment shows promise. In addition, the authors discuss a number of other outcome measures, including effectiveness and cost-effectiveness, which may be as or even more important measures

of success than complete healing. Recognition of the value of multiple potential outcome measures on patients, caregivers, and healthcare systems is long overdue and merits further thought and discussion.

Snyder et al performed a retrospective review of more than 1,000 charts of patients treated with either the cellulose-collagen product or saline-soaked gauze. After 2 months of treatment, a dramatic difference in healing and cost between the two groups of patients was noted. This study is intriguing for both the concept of the sequential use of wound treatments and the ability to demonstrate substantial cost savings.

Both studies underscore the issues clinicians and researchers must consider in understanding how to collect information, how to consider the use of products in clinical practice, and how to measure benefits of using particular treatment regimens. These studies are not intended to provide all of the answers that wound care professionals need to improve their practice but they demonstrate the need for and value of a broad base of approaches to evaluation that individually provide a small piece of the gradually forming complex picture that shows new treatments may convey many benefits. ■

A Retrospective Analysis of the Cost-effectiveness of a Collagen/Oxidized Regenerated Cellulose Dressing in the Treatment of Neuropathic Diabetic Foot Ulcers

José Luis Lázaro-Martínez, PhD; Francisco Javier Aragón-Sánchez, MD, PhD; Esther García-Morales, PhD; Juan Vicente Beneit-Montesinos, MD, PhD; and Máximo González-Jurado, PhD

Abstract

Collagen/oxidized regenerated cellulose dressings (C/ORC) have shown evidence of clinical effectiveness in the treatment of neuropathic diabetic foot ulcers (DFUs). A retrospective study to analyze cost-effectiveness was performed using results from an earlier, 6-week randomized clinical trial carried out on patients ($n = 40$) with neuropathic DFU treated with an C/ORC dressing. The patients were randomized to two groups: group 1 ($n = 20$) was treated with an C/ORC dressing and group 2 ($n = 20$), the control group, received wound care in accordance with the standard protocol in use at the authors' healthcare center. Effectiveness was defined as the percentage of patients whose wounds had healed at the end of the study. Total cost of care (including staff, ancillary supplies, dressings, and patient transport costs), the number of patients needing to treat (NNT), the mean cost, the incremental cost, and the average cost effectiveness were analyzed. NNT was 2.11 (95% CI: 1.34-4.96. $P = 0.03$). Treatment effectiveness was 63% in group 1 and 16% in group 2. Incremental cost-effectiveness was \$683.18, the amount needed to avoid nonhealing in the control group. Average cost effectiveness was \$561.48 in group 1 versus \$2,577.65 in group 2 (total cost/effectiveness in each group). Treating neuropathic ulcers with an C/ORC dressing provides an excellent cost-benefit ratio that saves an average of \$2,280.13 per patient over 6 weeks of treatment. This saving may be even greater in longer-term treatment programs and among patients with ulcers that show little tendency to heal.

Key Words: diabetic foot, cost-effectiveness analysis, metalloproteinase, wound healing

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Potential Conflicts of Interest: none disclosed

Increases in life expectancy and the growing prevalence of chronic illnesses such as diabetes mellitus are leading to increased healthcare costs.¹ Chronic wound and ulcer treatment is one of the major social and medical challenges of the 21st century. Diabetic foot, a complication of diabetes mellitus, may lead to ulceration, infection, or gangrene as a result of a combination of neuropathy, ischemia, and foot deformities; it is the principal cause of nontraumatic lower ex-

tremity amputation.² These complications come with high costs³: diabetic foot ulceration (DFU) and amputations were estimated to cost US healthcare payors \$10.9 billion in 2001.^{4,5} According to corresponding UK estimates based on the same methodology, 5% of total national health service expenditures in 2001 (£3 billion) were attributable to diabetes. The total annual cost of diabetes-related foot complications was estimated to be £252 million.⁶

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Few studies delineate the costs relevant to DFU treatments. The Eurodiale study⁷ evaluated treatment costs between September 1, 2003 and October 1, 2004 of 821 patients in a collaborative network of 14 European diabetic foot centers. According to 2005 prices, the direct and indirect costs per patient with DFU that heals was \$9,985.86, which increased to \$25,779.26 if the wound did not heal within 12 months and to \$32,406.52 if any amputation at or proximal to the ankle was required. An important element of the costs associated with the treatment of diabetic foot is the cost incurred by local treatments⁷ — specifically, dressing material, staff who performed dressing changes, and transportation, which represented approximately 20% of the total cost. Topical care with wet/dry gauze and topical antiseptic treatments has slowly been replaced with dressings that facilitate wound closure through physical and biological processes.^{8,9}

In this area, growth factors and collagen/oxidized regenerated cellulose dressings (C/ORC) have shown evidence of effectiveness in the treatment of neuropathic DFU.¹⁰⁻¹² Previous cost-effectiveness studies have demonstrated the advantages of these new treatments. In 2002, Ghatnekar¹³ used a hypothetical cohort of patients through a Markov state transition model to estimate the probability of wounds healing, becoming infected, gangrene developing, an ulcer healing after amputation, and death. The study models the results of treatment in France, Germany, Switzerland, and the UK. The main objective of this study was to assess the effectiveness and costs of treating nonsuperficial DFU with C/ORC as part of good wound care, compared with good wound care alone. The results indicated that using C/ORC saved \$2,569.70 per patient per year in the treatment of deep DFU compared to good wound care. Other studies¹⁴ analyzed the advantages of a recombinant platelet-derived growth factor. A 1-year decision-analytic model was developed and tested

using data from a previously published controlled clinical study in involving 251 people with diabetes (124 becaplermin/127 control) and adequate vasculature presenting with an infection-free ulcer that had failed to heal despite appropriate therapy. At 20-week follow-up, an average saving of \$156 was realized, compared to the use of a placebo, at an incremental cost of \$6 for each additional day of treatment.

However, little cost-effectiveness evidence is available to guide DFU treatment. This study aims to perform a cost-effectiveness analysis using data from a previously conducted randomized clinical trial¹⁵ using C/ORC and control dressings in the management of patients with neuropathic DFU.

Material and Methods

The cost-effectiveness study was conducted using data from a previously published randomized controlled clinical study involving 40 patients with neuropathic DFU.¹⁵ Patients were randomized to treatment with an C/ORC matrix dressing (Promogran[®], Systagenix Wound Management, Gargrave, UK) ($n = 20$) or standard care ($n = 20$). Standard care consisted of 2 weeks of biocide charcoal and silver dressing (Actisorb plus 25[®]; Systagenix Wound Management, Gargrave, UK) followed by a hydroactive dressing (Tielle[®], Systagenix Wound Management, Gargrave, UK) until healed. All patients received offloading with cast-walkers and felted padding. Patient demographic and wound severity status (Texas and Wagner scales) were not significantly different at baseline with the exception of ulcer history. Ulcers in the treatment group had existed for an average of 37.9 ± 34 weeks compared to 12 ± 13.5 weeks in the control group ($P = 0.04$). At the end of the 6-week study, 12 patients in the treatment and three in the control group were healed ($P = 0.03$) (see Figure 1).

Cost-effectiveness study method. The direct costs of the healthcare services provided to both groups of patients included in the study were analyzed. Costs included staff, ancillary supplies, dressings, and patient transport costs.

Staff costs were calculated on the basis of 15-minute treatment sessions provided by a member of the nursing staff using the nursing wages in 2007 in Spanish Public Health (\$2,826.67/160 hours = \$17.66/hour). This time is considered the minimum amount required to complete a dressing change, evaluate the lesion, and reposition the offloading device.

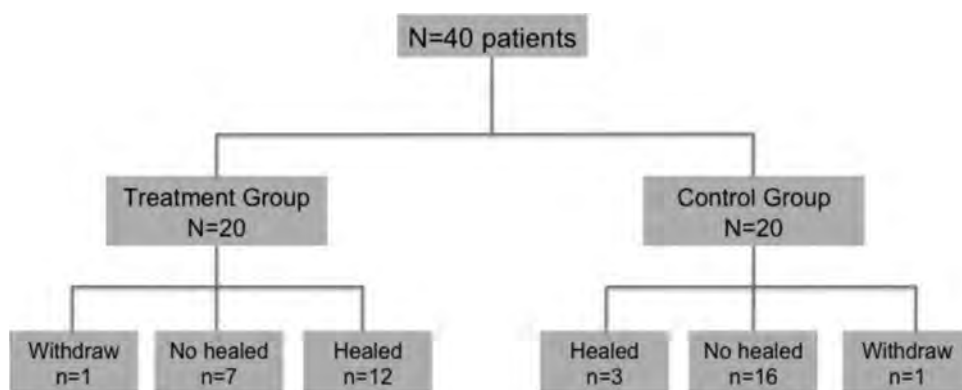


Figure 1. Patient-flow diagram during 6-week study.^a

^a Lazaro-Martinez JL, Garcia-Morales E, Benoit-Montesinos JV, Martinez-de-Jesus FR, Aragon-Sanchez FJ. [Randomized comparative trial of a collagen/oxidized regenerated cellulose dressing in the treatment of neuropathic diabetic foot ulcers]. *Cir Esp*. 2007; 82(1):27-31.

Table 1. Treatment costs

Costs	Treatment group (n=19)	Control group (n=19)	Difference
Staff costs (per visit)	\$4.30	\$4.30	-
Cost of consumables (per visit)	\$58.37	\$40.38	\$17.99
Healthcare transport cost (per visit)	\$76.44	\$76.44	-
Cost of 1 visit	\$139.18	\$121.20	\$17.98
Cost of 1 week of treatment (3 visits)	\$417.54	\$363.60	\$53.96
Cost of 6 weeks of treatment	\$2,505.38	\$2,181.60	\$323.78

Table 2. Costs of care and treatment outcomes during 6-week study

	Treatment group	Control group
Patients not healed (n/cost)	7/\$17,537.68	16/\$34,905.61
Patients healed (n/cost)	12/\$17,835.95	3/\$6,337.01
Total cost	\$35,373.3	\$41,242.63
Average cost per patient	\$1,861.76 ± \$717.91	\$2,170.65 ± \$32.75 ^a
Effectiveness (% healed)	63%	16%
Average cost effectiveness	\$561.48	\$2,577.65

^a *P* = 0.06, Student's *t* test.

Table 3. Risk estimates and probability analysis for both study groups

Risk estimates		Confidence interval (CI) 95%	
		Lower	Upper
Absolute risk treatment group	0.37	0.15	0.59
Absolute risk control group	0.84	0.68	1.01
Absolute risk reduction (ARR)	0.47	0.20	0.75
Relative risk (RR)	0.44	0.24	0.81
Relative risk reduction (RRR)	0.56	0.19	0.76
Odds in treatment group	0.58		
Odds in control group	5.33		
Odds ratio (OR)	0.11	0.02	0.51

The cost of ancillary supplies included everything required for the patient's treatment session according to 2007 prices (gloves, tape, antiseptic solution, saline solution, surgical drapes, felted padding, and the like), as well as the cost of the biocide charcoal dressing with silver (Actisorb plus 25[®]; Systagenix Wound Management, Gargrave, UK), the hydroactive dressing (Tielle[®], Systagenix Wound Management, Gargrave, UK) in the control, and the C/ORC matrix dressing in the treatment group (see Table 1). Most patients were referred by their primary healthcare provider, which provided ambulance transport at a cost of \$76.44 as per 2007 Public Health Administrator agreement prices.

Costs were calculated per visit, per week (three visits), and for the 6-week duration of the study, regardless of actual length of treatment. Indirect costs relating to items such as

equipment, instruments, fixtures, and apparatus were not included. The analysis also did not include the cost of temporary offloading devices such as postoperative shoes or removable offloading boots.

Of the various types of healthcare economic analysis available, cost-effectiveness was considered most appropriate because it is most relevant to the micro-economic level of healthcare management. Its main advantage lies in the possibility of expressing effects in the same units used in clinical trials and in daily clinical practice.¹⁶ Cost-effectiveness measures used included

the number of patients needed to treat (NNT), effectiveness, average cost effectiveness, and incremental cost per patient. NNT is an epidemiological measure used in assessing the effectiveness of a healthcare intervention, typically a treatment with medication.¹⁷ The NNT is the number of patients who need to be treated in order to prevent one additional bad outcome. An NNT of 1 means everyone in the treatment group and nobody in the control group improves. The higher the NNT, the less effective the evaluated treatment. In this study, effectiveness was defined as the proportion of patients whose wounds healed. Healing was defined as complete epithelialization of the ulcer.

Data analysis. Average cost effectiveness was calculated by dividing cost by effectiveness (proportion of patients healed). Incremental cost per patient was determined by calculating the difference between cost treatment per patient in the control and treatment groups. Average were compared using the Student's *t* test for independent samples (SPSS version 15.0 for Windows, SPSS, Chicago, IL). NNT and likelihoods were calculated using the Epi Info™ version 3.5.1 program (Centers for Disease Control and Prevention, Dekalb, Georgia).

Results

During the 6-week study, the incremental cost per patient in the treatment group was \$323.78 (see Table 1). The total costs of treatment were \$35,373.63 in the treatment group and

\$41,242.63 in the control group (see Table 2). For both treatment groups combined, the average cost of treatment for patients whose ulcers healed compared with those whose ulcers did not heal was $\$1,611.52 \pm \634.35 ($n = 15$) versus $\$2,280.13 \pm \152.31 ($n = 23$) ($P < 0.001$). The average cost per patient in the treatment group was lower than the average cost per patient in the control group ($\$1,861.76 \pm \717.91 versus $\$2,170.65 \pm 32.75$, $P = 0.06$) because the ulcers healed faster and in higher proportion in treatment group (see Table 2).

The average cost effectiveness in the treatment group was $\$561.48$ compared to $\$2,577.65$ in the control group. The likelihood ratio of healing according to the treatment used is shown in Table 3. Using the treatment protocol reduced the risk of wound healing failure by 47%, and the relative risk reduction using the treatment protocol was 0.56; thus, the probability of no healing taking place was 5.3 times greater in the control group than in the treatment groups (see Table 3).

NNT was 2.11 (95% CI: 1.34-4.96, $P = 0.03$), indicating it would be necessary to manage two patients using the treatment protocol in order to avoid one case of nonhealing using the control treatment protocol. Based on the NNT value and compared to the control group, the calculated incremental effectiveness cost per patient was $\$683.18$, the amount needed to avoid nonhealing in the control group.

Discussion

Using data from the previously published study, the results regarding both NNT and the average cost effectiveness suggest that the cost benefit ratio of treating neuropathic DFU with an C/ORC matrix dressing instead of a standard protocol of care is excellent. In this study, the average cost effectiveness associated with the treatment protocol is $\$2,016.17$ less than when conventional dressings are used. An investment of $\$683.18$ resulted in an average saving of $\$1,596.95$ per patient (average cost for patients with no healing [incremental effectiveness cost]). The Eurodiale study,⁷ which calculated wound treatment costs depending on whether wounds are complicated by infection and/or ischemia and established an increment linked to the individual or combined presence of these complications, reported the cost of treating a neuropathic ulcer as $\$5,799.82$. In the current study, using direct costs only, the total cost were lower ($\$2,505.38$ in the treatment and $\$2,181.60$ in the control group). However, these direct costs were higher than the $\$4,72.82$ cited for total direct and other costs (antibiotics, offloading devices, and hospitalization) in the Eurodiale study, suggesting that nonspecialized treatment was used in the earlier research. The cost of healthcare-related transport was included in this analysis because many patients with DFU have limited mobility and require transportation. Transportation costs are high and directly related to the number of visits to the health center the patient requires before complete healing takes place.

Independent of the cost-effectiveness ratio, the cost of the treatment group protocol was lower than that of the control group ($\$35,373.63$ vs. $\$41,242.63$), with a gross saving of $\$5,868.99$, for 38 patients during 6 weeks of treatment.

The probability of healing, as reported in the original study, was 63% in the treatment and 16% in the control group during the 6 weeks of treatment even though wounds in the treatment group had existed for an average of 37.9 ± 34 weeks before study enrollment. These results are better compared with literature relationship with C/ORC dressings^{10,11} but in the current study the length of the monitoring was 6 weeks. The duration of the period of treatment could have affected the cost results because in the majority of similar studies the treatment period was longer.

Limitations

Results of the Ghatnekar's study¹³ indicated that using C/ORC saved $\$2,569.70$ per patient per year in the treatment of deep DFU compared to good wound care. Current study results show these savings may be higher but study comparisons are limited by the two different cost calculation methods used. However, the principle limitation of this study is that the results can be compared only to studies using the same cost-effectiveness model and a different topical treatment option. Also, patients in this study were seen in a referral center for diabetic foot treatment, where patients are managed using an integrated treatment model, with offloading of the ulcer a key element in neuropathic wound treatment. This could have affected the results. For example, it has been shown that offloading procedures are not always implemented in the treatment of these patients. A prospective study¹⁸ involving 1,232 patients with DFU showed that 77% of patients were not using offloading devices or were using an inappropriate method of pressure redistribution.

It is extremely important to bear in mind that the effectiveness of this treatment depends on correct use of dressings, correct offloading of the ulcer, and correct diagnosis of any potential complications involved (ischemia and/or infection).^{15,19} The incremental cost per day of treatment was $\$7.70$, similar to the amount reported from a 2003 study by Sibbald¹⁴ of daily applications of recombinant platelet derived growth factor.

The lack of cost-effectiveness studies analyzing new treatments for DFU means that purchasing decisions relating to dressings for localized treatment are occasionally based only on the incremental cost of the treatments. The current study results indicate that investment in effective localized treatments may reduce the cost of treatment. Additional studies, using larger sample sizes, comparing different treatment modalities, and including other variables such as indirect costs will provide much-needed knowledge in the field of cost-effectiveness for DFU treatment.

Conclusion

A retrospective cost-effectiveness study demonstrates that use of an effective wound dressing has the potential to reduce the cost of treatment and, compared to standard of care alone, to save patients and payors substantially on care costs. In order to increase knowledge in the field of cost-effectiveness for DFU treatment, additional studies with larger samples and comparing different alternative treatments are needed. ■

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A Retrospective Study of Sequential Therapy with Advanced Wound Care Products versus Saline Gauze Dressings: Comparing Healing and Cost

Robert J. Snyder, DPM, CWS; Deborah Richter, RN, CWCA; and Mary Ellen Hill, PT

Abstract

Treating chronic wounds often creates daunting medical and financial challenges — perhaps, in part, because no standard-of-care algorithms have been universally accepted for the provision of care. In a retrospective chart study of patients receiving home care services, researchers compared the results on lower extremity wound healing of using sequential therapy comprising advanced wound care products (collagen/oxidized regenerated cellulose [C/ORC] and collagen/oxidized regenerated cellulose + silver/ORC [C/ORC/silver]) versus saline-soaked gauze. Nine hundred, seventy-four (974) persons fit the inclusion criteria; 873 had received C/ORC and C/ORC/silver and 101 had received the saline gauze treatment. Demographics were comparable in both groups with regard to age (range 55 to 80 years) and wound type (trauma leading to chronic ulcers, pressure ulcers, neuropathic ulcers in persons with diabetes, postsurgical ulcers, locally infected ulcers, and venous leg ulcers). After 2 months' treatment, 95% of the C/ORC and C/ORC/silver-treated wounds closed at a total cost of \$2,145, compared to 7.2% of the saline gauze-treated group at a total cost of \$7,350; 43% of saline-treated wounds healed by 6 months at a total cost of \$22,050. The additional expense incurred was for nursing costs, due mainly to the need for more frequent dressing changes. When compared to saline gauze dressings, sequential therapies and advanced wound care products may reduce the frequency of nursing visits and optimize wound healing time, subsequently reducing healthcare costs; thus, underscoring the need for a paradigm shift in the standard of care for the treatment of chronic wounds in the home care environment.

Key Words: chronic wounds, advanced care therapy, home health care, healthcare cost, standard wound care, health economics

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Chronic wounds represent a significant medical problem and create huge financial burdens on healthcare systems globally. Despite the daunting implications of this medical dilemma, no standard-of-care algorithms have been universally accepted. Topical treatments often are chosen on the basis of local traditions.¹ Wet-to-dry gauze dressings are the most widely used primary dressing material in the US² and may be erroneously considered a standard of care; in a review of the literature, Ovington³ notes that impeded healing due to local tissue cooling, disruption of angiogenesis by dressing removal,

and increased infection risk from frequent dressing changes, strikethrough, and prolonged inflammation represent good reasons to abandon this traditional dressing technique. The benefits of moist wound healing are well documented but in practice the use of gauze, particularly as a wet-to-dry dressing, does not ensure a moist wound environment.⁴

Collagen/oxidized regenerated cellulose (C/ORC) has been shown *in vitro* to reduce elastase, plasmin, and metalloproteinase activity in chronic wound exudate in patients with diabetes.⁵ Results from randomized controlled trials involving

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patients with venous leg ulcers⁶ and diabetic foot ulcers^{7,8} have provided evidence that C/ORC decreases protease activity in wound exudates and can accelerate healing rates of venous leg ulcers.⁹ A randomized, prospective controlled clinical trial¹⁰ involving wounds treated with C/ORC demonstrated better tissue regeneration and faster time to complete healing when compared to wounds treated with good wound care alone.

Silver appears to positively effect wound healing, providing antimicrobial and anti-inflammatory benefits to healing. A review of the literature¹¹ reveals that unlike silver nitrate and silver sulfadiazine, which require repeated applications, new technologies allow for consistent silver delivery over time while maintaining broad-spectrum antimicrobial activity against yeasts, molds, and bacteria, including

methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant *Enterococci* (VRE). A randomized controlled pilot study by Lanzara et al¹² involving 30 patients with difficult-to-heal venous leg ulcers showed that 12 weeks of wound treatment using C/ORC and C/ORC/silver and compression substantially reduced ulcer size compared to control treatment with moist wound healing and compression alone. However, antiseptics such as silver were not designed to be utilized indefinitely. A review of the literature¹³ revealed that eliminating silver in favor of other advanced wound products that re-balance the wound microenvironment may move wound progression from preparation to closure — using an C/ORC and C/ORC/silver protocol has shown the ability to reduce protease activity, scavenge free radicals, and control bacterial levels, thereby breaking the vicious circle of inflammation and stimulating healing (see Figure 1).

Any therapy chosen for the treatment of chronic wounds should be clinically effective at a reasonable cost. A cost-effectiveness analysis¹⁴ demonstrated that diabetic foot wound therapy involving C/ORC may be more cost effective and provide more benefits when compared to treatment of these wounds with good wound care alone using saline gauze used as a primary dressing.

To assess the clinical and cost effectiveness of sequential use of advanced wound care products, a retrospective chart analysis was conducted. Using data extracted from the records of home care patients, the effects on wound closure (ie, skin reepithelialization without drainage or need for dressing) and cost of care (treatment costs and volume of nursing visits) of using C/ORC products as part of sequential therapy versus daily use of saline-soaked gauze dressing were compared.

Methods

Patients. The charts of 1,165 patients under the care of Comprehensive Home Care of Broward (CHCB), southeastern Florida, with lower extremity chronic wounds (at least 30 days but no longer than 12 months in duration) treated in 2007 were reviewed retrospectively. The chart reviews were conducted internally by an appropriately trained wound care nurse and physical therapist designated by CHCB.

Institutional Review Board (IRB) approval was not required. However, this research study was monitored and sanctioned by the Ethics and Compliance Committee of CHCB.

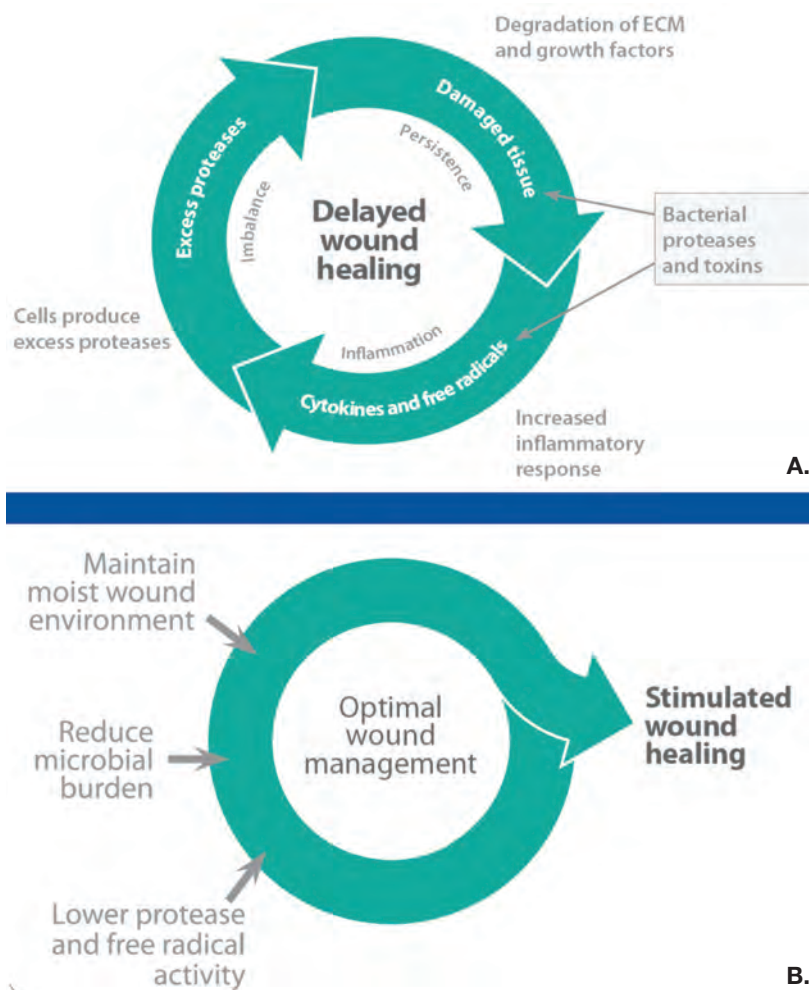


Figure 1. A) Theoretical Model: Cullen's cycle — the vicious circle of delayed wound healing B) Theoretical Model: Breaking out of the circle to encourage healing. With permission from Breda Cullen, Systangenix Wound Management.

Data mining procedure. Retrospective analysis was predicated upon a search of the database of CHCB for diagnosis codes (ICD-9). Charts of patients receiving palliative care or using negative pressure wound therapy (NPWT) or human skin equivalents and patients with severe ischemia, atypical wounds, and a hiatus in treatment of more than 1 month were excluded. Based on information in the charts, patients were divided into two groups: group A received sequential therapy using C/ORC/silver and C/ORC (Promogran[®] Matrix Wound Dressing and Promogran Prisma[®] Wound Balancing Matrix (Systagenix Wound Management, Gargrave, UK) and group B received saline gauze dressings.

Sequential therapy. Sequential therapy represents a treatment philosophy — ie, when wound appearance changes, it may be appropriate to change the type of dressing used to ensure dressing properties rebalance the wound environment and support healing in an appropriate manner.

For wounds in both groups showing local wound infection at the commencement of therapy, treatment was initiated with topical antimicrobial/antiseptic dressings such as hydro-alginate antimicrobial dressing with silver (Silvercel[®], Systagenix Wound Management, Gargrave, UK) or with cadexomer iodine along with culture-driven systemic antibiotics, if necessary. In keeping with the sequential therapy model, these treatments were discontinued in favor of more appropriate protocols when signs and symptoms of infection cleared. Infection was defined clinically based on the presence of purulent secretions or at least two signs and symptoms of inflammation.¹⁵

Group A patients receiving sequential therapy were initially treated with C/ORC/silver to decrease the bacterial bioburden and to prepare the wound bed for further treatment. When the wound improved clinically (usually within 2 to 3 weeks) C/ORC was used to continue treatment of these wounds, restore the balance within the wound microenvironment, and promote closure.

Group B patients were provided saline-moistened dressings changed daily and covered with dry sterile dressings.

Sequential wound care protocol. C/ORC/silver and C/ORC dressing change frequency adhered to manufacturer's guidelines. These wounds and dressing were prepared as follows:

- Debridement when necessary, followed by wound site irrigation in accordance with standard protocols.
- For wounds with little or no exudate, C/ORC/silver and C/ORC were hydrated with saline. The dressings could be pressed on if needed to break the surface tension and help facilitate hydration.

For dressing application:

- The dressing was cut or torn to the size of the wound and applied directly to the wound bed
- After hydration through exposure to wound exudates or saline, the dressings became gelatinous, creating intimate contact with the wound surface.

- The dressing is biodegradable and will be absorbed into the body over time
- To maintain a moist wound environment, these dressings must be covered with a semi-occlusive dressing.

Dressing change and removal:

- Applied daily or per physician recommendation
- Frequency of application depended on level of exudate
- It was not necessary to remove any residual material during dressing changes.

Patients in sequential therapy Group A had been provided nursing visits daily for 1 week, reduced to three times/week during week two, and then further reduced to once per week thereafter, when feasible.

In each case, the principles of wound bed preparation (debridement, infection, and moisture control, and wound edge preparation) and disease-specific wound management protocols were followed in both Groups A and B — eg, neuropathic ulcers in persons with diabetes were treated with strict metabolic control, weekly debridement and offloading; venous leg ulcer patients were treated with appropriate compression.^{16,17}

Wound healing assessment. All ulcers were photographed on admission, then monthly, to provide a visual record of any changes in appearance. In review of the database, healing progress was assessed weekly by measuring wound length, width, and depth via planimetry; however, these data, as well as patient demographics relating to secondary underlying comorbidities (eg, renal disease, anemia, and diabetes) unless otherwise captured as a specific ulcer group (eg, neuropathic ulcer in persons with diabetes) could not be gleaned retrospectively; therefore, they were not included.

The effects of sequential treatment utilizing C/ORC/silver and C/ORC were measured by determining complete wound closure, defined as skin reepithelialization without drainage or dressing requirement. Results were compared with complete wound closure results of Group B of patients treated with saline gauze dressings applied daily.

It is standard policy for CHCB to monitor safety via constant surveillance for adverse events during treatment; this was reflected in the charts and data reviewed.

Calculation of treatment costs. Dressing costs were based on the average purchase price to the agency (CHCB). The C/ORC dressings were priced at \$10.00/dressing; gauze and saline were calculated at \$2.50/dressing. The cost of each home nursing visit in both groups was \$120.

Statistical analysis. Data involving average material costs (eg, gloves, saline, gauze, C/ORC/silver, C/ORC, dry sterile dressing, tape), nursing costs (taking vital signs; wound evaluation, measurements, and photos when necessary; dressing changes; and charting), and number of wounds healed in the

Table 1. Retrospective cost analysis: saline gauze and sequential therapy treatment

	Saline gauze treatment	Sequential treatment with advanced wound care dressings
Frequency of dressing change	Daily	Daily or as required
Dressings costs per dressing change ^a	\$ 2.50	\$ 10
Material costs for 2 months ^b	\$ 150	\$ 165
Costs for 1 nursing visit	\$ 120	\$ 120
Costs of nursing for 2 months	\$ 7,200	\$ 1,980
Costs of 2 months of care	\$ 7,350	\$ 2,145
Wound healing (complete wound closure)	7.2%	95.0%

^a Average material costs included gloves, saline, gauze, C/ORC/silver and C/ORC, dry sterile dressing, tape)

^b Average nursing costs included taking vital signs; wound evaluation, measurements, and photos when necessary; dressing changes; and charting

measured time frames were extracted to a spreadsheet and analysis performed using Sigma Plot (10.0 version). Confidence intervals (CI, 98%), standard deviations (SD), and variance were calculated for each group at 2 months and 6 months. The level of significance was considered to be $P < 0.05$.

Results

Nine hundred, seventy-four (974) persons fit the inclusion criteria; 873 had received C/ORC/silver and C/ORC and 101 received saline gauze treatment. The majority of treated patients in both groups was elderly (average age 70 years; range of 55 to 80 years). A random sampling of the data revealed wound sizes ranged from 1 cm² to 12cm². Group A included 463 trauma leading to chronic wounds (53%), 192 pressure ulcers (22%), 102 diabetic foot ulcers (11%), 78 postsurgical wounds (9%), 30 locally infected wounds (4%), and eight venous leg ulcers (1%). Group B included 53 trauma leading to chronic wounds (53%), 22 pressure ulcers (22%), 12 diabetic foot ulcers (12%), nine postsurgical wounds (8%), four locally infected wounds (4%), and one venous leg ulcer (1%).

Wound healing. In group A, 95.0% of the wounds achieved complete wound closure in 38.6 days (95% CI; SD 4.62; variance 21.33; population SD 4.54567; variance population SD 20.66). During the same time period, 7.2% patients in group B achieved complete wound closure (95% CI; SD 0.72; variance 0.52; population SD 0.66; variance population SD 0.44); after 6 months of treatment, a total of 43% of group B wounds achieved complete wound closure (95% CI; SD 4.25; variance SD 18.07; population SD 4.09; variance population SD 16.7).

Local infection not apparent on initial evaluation and thus presumed to have occurred during the treatment phase was the only adverse effect observed. However, this condition

was classified as mild to moderate and presented in <1% of patients in each group.

Treatment costs. In Group A, average material costs per dressing change were \$10 and the average number of nursing visits per home care admission was 16.5; as a result, dressing material costs through complete wound closure were averaged at \$165. Costs for each nursing visit were \$120; therefore, nursing costs for 16.5 visits, until wounds were completely healed, came to \$1,980. Combining the two expenses (clinician and supplies), the average total costs per

patient of sequential therapy with advanced wound care products for 2 months of care was \$2,145.00. In this group, 95% of wounds achieved full closure.

In Group B, average material average costs per dressing change were \$2.50. Dressing material costs for 2 months of treatment averaged \$150 and costs for nursing visits for 2 months of treatment were \$7,200. The average cost per each nursing visit was \$120; therefore, average total costs of treatment for 2 months per patient was \$ 7,350, with only 7.2% of wounds showing complete wound closure. Even after 6 months of treatment, only 43% of wounds achieved complete wound closure, at a cost of \$22,050 (see Table 1).

Discussion

The data mined as part of a retrospective chart review of patients with lower extremity wounds managed either with sequential therapy using C/ORC or saline gauze dressings demonstrated that sequential therapy provides better healing and cost outcomes than using saline-soaked gauze. Despite decades of strong evidence that saline gauze dressings fail to create an appropriate wound healing environment, they still remain the most widely used dressings in the US and often are employed inappropriately.³ In related research, Margolis et al¹⁸ evaluated the rate of neuropathic ulcer healing by two endpoints (12 weeks and 20 weeks) in 10 control groups (n = 622) from prospective clinical trials via meta-analysis; control groups used good wound care, which included debridement and offloading and either saline-moistened gauze or placebo gel and gauze. Among the 450 patients in the 12-week group, weighted mean healing rates were 24.2% (19.5% to 28.8%) and among the 172 in the 20-week group, healing rates were 30.9% (95% CI 26.6% to 35.1%). These poor healing rates elucidate the challenges of healing chronic wounds despite appropriate conservative wound management (including saline gauze

dressing) and proliferate the notion that advanced wound care products may be considered more costly and are often unavailable to the clinician, especially in the acute hospital setting where patients may be admitted only for a few days. As such, advanced wound therapies often are not utilized but may be required to treat ulcers that fail to progress with good wound care alone. Research¹⁷ shows that when a wound fails to progress by at least 50% in the first 4 weeks despite implementation of disease-specific therapies, it is unlikely it will heal in 12 weeks. Therefore, when good wound care does not produce a desired result, advanced therapies should be considered.

Impediments to healing. Chronic wounds fail to follow the normal pattern of wound repair; the pathogenesis of chronic wounds is characterized by persistent inflammation and an imbalance in protease/protease-inhibitor levels.¹⁹ Persistent inflammation and ongoing proteolysis of matrix proteins, such as fibronectin, laminin, various collagens, and low levels of growth factors and growth factor receptors impede granulation and epithelialization in chronic wounds.^{20,21} In addition, a review of the literature²²⁻²⁴ reveals that a high percentage of wounds with delayed healing have bacterial biofilms that host antibodies, inflammatory cells, antibiotics, and disinfectants cannot eradicate.

Sequential therapy.

The importance of wound bed preparation. Knowing these biochemical variables, many wound care specialists have embraced moist wound healing and the recent concept of wound bed preparation (WBP) as the underpinning in facilitating healing. Falanga²⁵ defined this hypothesis as the management of a wound in order to accelerate endogenous healing or to facilitate the effectiveness of other therapeutic measures. This model extends the holistic approach to wound management, removing barriers to healing, establishing healthy granulation tissue, and stimulating a well-vascularized wound bed. An understanding of wound healing science and inherent differences between acute and chronic wounds remain mandatory in facilitating these changes and making appropriate treatment choices.¹⁶

WBP combines a number of important concepts, including debridement, treatment of infection, management of moisture balance, and wound edge preparation. This methodology fosters removal of healing impediments while initiating the repair process and restoring healthy granulation tissue over time. This encourages the sequential use of therapeutic products in order to reduce infection and bacterial bioburden, rebalance wound biochemistry, and encourage growth factor production while stimulating wound edge epithelialization and addressing senescent cells. Treatment with saline gauze remains ineffective in this regard.³

The role of timing, products, and cost. In a review of the literature, Frantz and Gardner²⁶ hypothesize that changes in wound care must be based on changing wound parameters,

as well as timely, complete, and accurate wound assessment. This review represents the foundation for sequential use of products and therapies appropriate to the changing wound environment. A literature review by Hanson¹ concluded that if a wound can be re-dressed at longer intervals and if healing can occur more quickly, advanced product usage can be cost effective; Metzger's²⁷ review of the literature found that "best practice" wound management included moist wound healing and the use of advanced products that promote efficient use of nursing time. Similarly, Horch et al's²⁸ review of the literature found that despite higher daily costs, some alternative wound therapies turn out to be more cost efficient when all economic factors are considered. A qualitative study involving 65 professionals conducted by Armstrong and Price²⁹ revealed that barriers to the use of modern products did not appear to be associated with availability or knowledge and experience of use — cost was the most frequently cited barrier. Although it is true that modern dressing products have a higher unit cost, they require fewer changes than gauze, making them more cost effective. If other issues, such as time to healing and quality of life, are included, cost effectiveness should be a major force for change.³

C/ORC/silver. The product used in the current contains 1% silver ORC salt, which equates to a release of 0.25% ionic silver. When compared to other available silver dressings, this would be considered a "low-dose" vehicle; however, the product has been shown to provide significant reductions in bacterial counts in a standard *in vitro* assay of antimicrobial activity without harming host cells *in vitro*.³⁰ In a pilot randomized controlled study with 30 venous leg ulcer patients, Lanzara et al¹² demonstrated that 12 weeks of treatment of wounds with C/ORC/silver resulted in ulcer size reduction.

The use of low- versus high-dose silver is controversial. In results of a literature review, Drosou et al³¹ postulate that the strongest argument against the use of antiseptics in wounds is that these substances, using primarily *in vitro* models, may be cytotoxic to cells essential to wound healing; however, this cytotoxicity appears to be concentration-dependant. Several antiseptics in low concentrations may not be cytotoxic, although they retain their antibacterial activity *in vitro*; for example, silver ions at low parts per million (ppm) concentrations have been shown to be bactericidal against most planktonic bacteria.³² However, *in vitro* research does not always correlate to the patients' bedside and most treatment strategies still remain intuitive. It remains likely that a higher dose of silver, such as those used in the initial phase of treatment in this study, may be required in the presence of overt infection. Additional *in vivo* research is needed to further investigate this issue.

Cost-effectiveness. The current study helps dispel several myths regarding the effectiveness and cost benefits of saline gauze dressing. It is clear from this study that saline gauze is ineffective; healing rates are abysmal even at 6

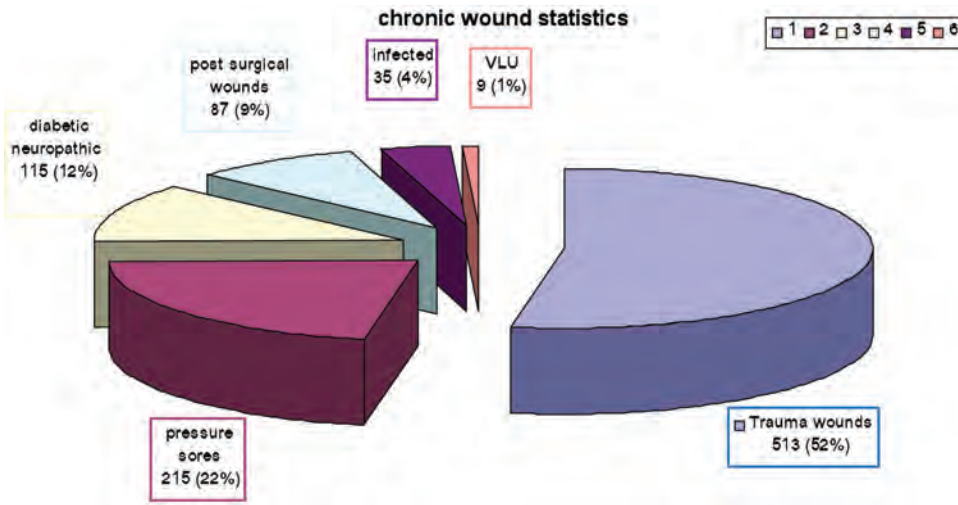


Figure 2. Statistics of chronic wounds treated in 2007 at the Comprehensive Home Care of Broward (CHCB).

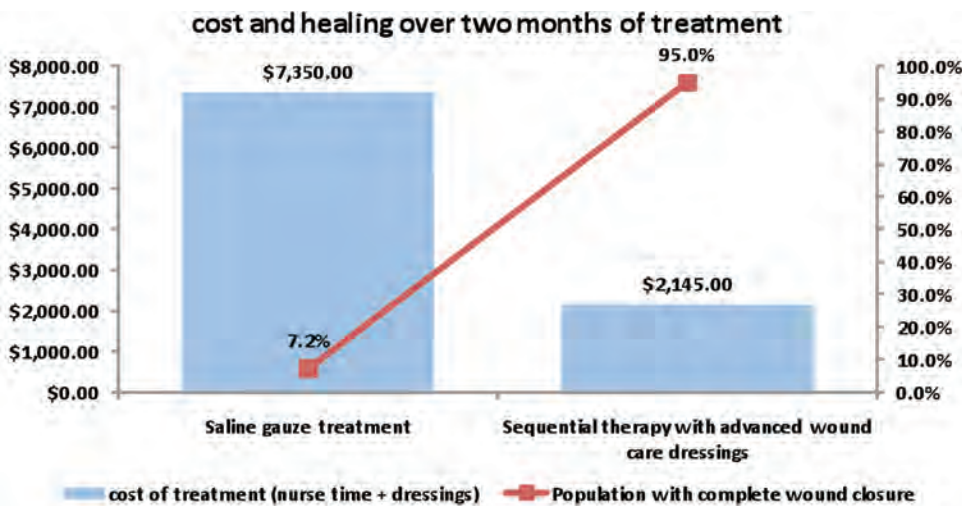


Figure 3. Cost and healing over 2 months of treatment.

months. Additionally, although the actual gauze product is inexpensive, based on the labor intensity of daily usage, it is not cost efficient and in fact represents one of the most expensive therapies available: the cost of 2 months of treatment utilizing saline gauze dressing was \$7,350 and only 7.2% of persons using it achieved complete, versus \$2,145 in the sequential therapy group where 95.0% achieved complete healing (see Figure 3).

These results are similar to those observed in a randomized controlled trial by Nisi et al³³ (n = 80) in which pressure ulcers treated with C/ORC dressings were compared to controls treated with conventional dressings; in this study, the C/ORC dressings-treated group showed a lower mean healing time, a

greater frequency of complete healing, and cost-effectiveness when compared to controls.

Limitations

Although this study has shown advanced wound care products to be cost-effective in that they can decrease nursing visits and augment healing by aiding in wound preparation and closure as part of a sequential therapy model, potential gaps in the presented study may have affected outcomes. Most obviously, saline-soaked gauze may not have represented the best comparator, despite its frequent use by clinicians. Also, results were not compared to what is known about other moist wound dressings such as hydrogels and alginates; additional research is ongoing in this regard. Furthermore, the cohort of patients in the saline gauze group was small when compared to those in the advanced therapy group and may have created bias. Historical controls from well-managed and powered randomized control trials could have been utilized to establish parity between the two groups. Additionally, in

light of the large cohort of patients in the traumatic wounds category, it is likely that some of these patients may have been misdiagnosed and should have been recorded as venous leg ulcers, for example; this would have made a more appropriate demographic consistent with patterns of wound etiologies in the general population. Finally, data concerning secondary underlying comorbidities (eg, renal disease, anemia, and diabetes) in addition to relating to a specific ulcer type studied such as diabetic foot ulcers, were not captured retrospectively; these conditions may have an impact on wound healing and inclusion could have culminated in a more comprehensive review of the data sets presented.

Conclusions

Despite the limitations of this retrospective study, the analysis of data shows that utilizing advanced wound care products such as C/ORC/silver and C/ORC in lower extremity ulcers applied sequentially may better optimize wound healing when compared to saline gauze and may reduce the frequency of nursing visits and subsequent healthcare costs. The data suggest that treatment with saline gauze dressing applied daily may be 10 times more costly than advanced therapies and provide fewer benefits. These results should foster a change in practice away from “traditional” saline gauze dressings and encourage a paradigm shift in the standard of care for the treatment of chronic lower extremity wounds in the home care environment, with potential far-reaching implications in the global wound care community. ■

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