

Wound Care Study Across Skilled Nursing Facilities

2001 MedX Research



Introduction

Pressure ulcers and other chronic wounds are a common and costly problem in acute care, long-term care, and home care populations. In economic terms, the management of chronic wounds includes staff time for ongoing assessment, documentation, debridement and dressing changes and cost associated with dressing supplies, expensive surface or negative pressure devices. Complications resulting in hospitalization, surgical debridement or amputation have enormous associated economic and human ramifications. Of particular concern are the non-healing wounds that have been resistant to standard treatment.

Phototherapy, an innovative adjunctive therapy for wound care has been used in Europe, the UK, Asia and Russia for over 30 years and has Health Protection Branch (HPB) approval in Canada, with FDA clearance pending. (MedX Phototherapy has received 5 FDA clearances since July 2001). The technology is being introduced into long term care settings to decrease healing time of acute and chronic wounds. Phototherapy delivers light or photons of energy that penetrate the skin and is absorbed by the cell. This energy enhances the normal cell processes of tissue repair resulting in accelerated wound healing. The energy from the light can be delivered with either low level lasers (LLL) or superluminous diodes (SLDs).

Purpose

To evaluate the effectiveness of phototherapy combined with a standardized Wound Management Program. All residents at the facilities who met the evaluation pre-requisites were included. The majority of these residents had chronic, indolent wounds that had been unresponsive to standard therapy. For this reason no attempt was made to compare MedX Phototherapy with other forms of treatment, or to compare it to a standardized Wound Care Program.

Significance of the Evaluation

Generally, long-term care or skilled nursing facilities treat chronic wounds with conservative interventions. If these measures are unsuccessful, alternative strategies may be employed, such as the use of costly supportive surfaces or more complex dressing procedures. These alternatives often require on-going rental or purchase of high-priced supplies, e.g. VAC (vacuum assisted closure) systems or more expensive wound care dressings. In more severe cases surgical intervention such as skin grafts or amputations may be required. Therefore exploring innovative wound care strategies is an important endeavor. As well, incorporating leading edge technology into clinical practice demonstrates that long term care can be an exciting and challenging environment, especially important during significant nursing shortages. This also can communicate to families and residents an ongoing commitment to excellence.

Methods

The multi-centered trial was undertaken at six sites, two in Canada and four in the United States (at the third largest chain of Skilled Nursing Facilities in the US). The following results include 27 wounds treated over nine weeks from July to September 2001. Similar MedX Phototherapy devices, treatment protocols and inclusion/exclusion criteria were used at all sites. MedX Phototherapy devices combine both low level laser and superluminous (SLD) technologies. Stage 1 to 4 pressure ulcers, venous insufficiency ulcers and diabetic lower extremity wounds were included. Similar staff education sessions and clinical supervision were completed for all facilities.

Phototherapy is an adjunctive therapy, incorporated into a standardized Wound Management Program. Dressing orders were not altered during the 9 week study period unless the wound required changes based on the established Program.

Staff Education

All staff involved in the trial completed a prerequisite educational session. A clinical nurse specialist from MedX provided a standardized 2-hour classroom education program including basic principles of phototherapy and its physiological effects. The phototherapy procedure and how it was implemented within the Wound Management Program and hands on demonstrations and applications were covered. The process for completing the pre/post assessment tools was also reviewed.

MedX Phototherapy Protocol

Two to four joules of energy /site were used around the wound bed and one to two joules directly into the wound bed. When the wound was covered with dark eschar, four joules were used to provide additional energy to penetrate the thicker, black surface. For dark skinned residents, the dose was increased by 50% since melanin absorbs a portion of the photons. Only trained, registered staff provided the phototherapy treatments. The ordered wound dressing changes and phototherapy was provided on the following schedule:

Frequency SLD Parameters

Week 1 Daily x 5 days (based on the dressing orders thereafter)
2 joules (1 minute) wound margin
1 joule (30 seconds) wound bed
4 joules (2 minutes) eschar

Weeks 2-9 3 x weekly (until healed or end of evaluation)
2 joules (1 minute) wound margin
1 joule (30 seconds) wound bed
4 joules (2 minutes) eschar

Wound Care Trial Protocol

WOUND STAGE	DOSE (JOULES)	LOCATION
1-2 (partial thickness)	2	over reddened/open area
3-4	2-4 4-5	over wound bed around wound margin & periphery
X-Black Eschar	4-6	over & around black area

Primary and Secondary Outcome Measures

There were three primary outcome measures used to determine the rate of wound healing during the evaluation; weekly PUSH Tool 3.0 score, every two week EZ Graph™ tracings and photographs. Two secondary measures; The Staff's Impressions Survey and the staff Education Survey were completed pre and post trial.

The PUSH Tool is a standardized method of monitoring pressure ulcers and includes the following parameters; length, width, amount of exudate and tissue type. PUSH scores provided a means of tracking overall wound healing changes over time.

EZ Graph™ (a clear transparency graph material) was used for tracing wound length, width measurements, type and amount of drainage and wound descriptions. Once completed the removable backing was discarded. The wound tracings were completed at the beginning of the evaluation and at two week intervals thereafter. Pre/post comparisons determined the % of wound closure from start to completion of the study.

Photographs were taken at baseline and every 2 weeks throughout the study to document the wound healing progress allowing for comparisons between pre and post treatment for each wound in the study.

Results

Sample Description

Sixteen residents were included in the evaluation including 9 females and 7 males. Ages ranged from 76 to 97 years with a mean age of 85.1 years old. The residents had an average of 5 medical diagnoses. The sixteen residents had 27 skin areas (23 open wounds and 4 closed areas):

Chart 1-Number and Type of Wound Sites

# OF SITES (n=27)	TYPE OF WOUND	STATUS OF WOUND AREA
15	Pressure ulcers	Open wound
6	Diabetic ulcers	Open wound
2	Venous insufficiency ulcers	Open wound
4	"at risk" areas	Closed, previous wound

The 4 sites that received preventative MedX Phototherapy did not have open wounds; instead the staff deemed them "at risk" and requested to have them included. "At Risk" wounds were either acute or chronic wounds that had recently closed. Therefore, treatment was provided to decrease the likelihood of skin breakdown reoccurring.

The majority of the wounds have been acquired over 3 months prior to the Phototherapy evaluation, as demonstrated in the chart below outlining the number of wounds and length of time:

Chart 2-Number and Duration of Wounds



# OF WOUNDS (n=27)	LENGTH OF TIME
3	> 2 years
3	6-12 months
11 (9) 2 not measurable)	3-6 months
6	1-2 months
4 (preventative)	<1 month

Four of the 27 areas were treated preventatively as staff deemed them "at risk" (closed, not actual "wound"). Two ulcers located on top and/or between toes were not able to be accurately measured resulting in 21 open, measurable wounds. The majority (15/21) or 71.4%, of the wounds were chronic (≥3 months duration). Acute and chronic wounds achieved similar results of closure rates indicating that Phototherapy is effective for both types of wounds.

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The majority (61.9%) of the 21 wounds treated with MedX Phototherapy achieved significant improvement ($\geq 50\%$ wound closure) by the end of the 9-weeks of treatment. Nine (42.8%) achieved 100% wound closure, one improved by almost 44%, and two closed over 10%. The remaining 23.8% wounds demonstrated no change, but did not deteriorate during the evaluation.

Chart 3-Closure Rates at End of Evaluation

# OF OPEN WOUNDS (n=21)	% OF TOTAL NUMBER	% OF CLOSURE	TYPE OF WOUND (Acute or Chronic)
9	42.9%	100%	5 acute 4 chronic
4	19.0%	75-50%	2 acute 2 chronic
1	4.8%	≤ 50 -26%	1 chronic
2	9.5%	$\leq 25\%$	1 acute
5	23.8%	No change	1 chronic 2 acute 3 chronic

The secondary outcome measures such as the registered Staff Impressions surveys were supportive of MedX Phototherapy; stating in unit meetings that were based on their clinical experience and expertise, they observed faster wound healing rates with the phototherapy for the majority of residents. Additionally, with the 2-hour education session, staff demonstrated competence and rapidly learned how to incorporate the technology into the standardized Wound Management Program.

Discussion

Phototherapy offers an exciting opportunity for areas deemed "at risk" of skin breakdown. The "at risk" category may include recently healed wounds, (research supports phototherapy increases tensile strength of the new tissue), or a reddened pressure point (phototherapy increases blood flow thereby potentially decreasing the effects of lack of oxygen to the area). An indirect but significant benefit of phototherapy occurs when health care aides see an innovative technology used immediately and directly on identified pressure points. This can encourage active participation and more thorough and accurate reporting. This in turn highlights the need for vigilance to prevent skin breakdown. These results demonstrate positive outcomes for the majority of these frail, elderly residents in long-term facilities. Most of these residents have a number of co-morbidity factors, often precluding wound healing (e.g. poor nutritional and fluid intake, multiple medical conditions - such as diabetes, medications, poor mobility/transfers, and incontinence.)

To address the potential question of whether the positive results of the trial are attributable to the use of MedX Phototherapy, a retrospective review of five residents with chronic wounds was undertaken. The purpose of the review was to determine the pre/post evaluation healing patterns of the chronic wounds being treated with the standardized Wound Program. The eight chronic wounds had been identified 3.5 - 9 months prior to the trial, with the majority deteriorating or slightly improving prior to the introduction of MedX Phototherapy. The PUSH scores ranged from 12-5 prior to the trial (0=closed, 20=worse score). At the end of the evaluation; five wounds were 100% healed, one was 58.7% healed, one improved initially, then the resident became ill and the wound regressed to previous size and one wound no change during study. The latter wound did heal once pressure dressings were applied post trial. This is the first time the latter venous insufficiency wounds had healed in over three years.

Additionally a retrospective analysis of 'high intensity funding' for supplies and labor costs was completed for these eight wounds. An estimated \$940 was saved monthly for dressing supplies, supportive mattresses and covers and VAC (vacuum assisted closure) rental costs. Also, an estimated 180 nursing hours were saved monthly, approximately \$2340 (180 x \$13) for a total estimated cost saving of \$3280 per month for these eight chronic wounds. Since no significant wound deterioration occurred requiring hospitalization, this potentially may have added substantial cost savings.

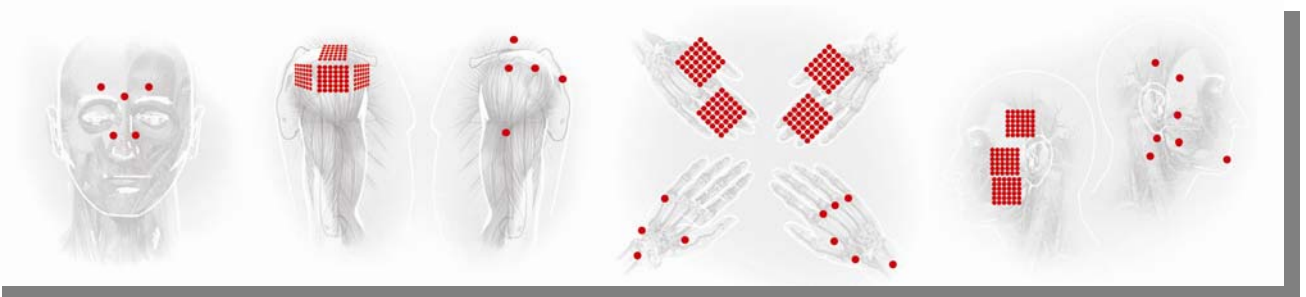
Once the 9 week trial was completed, MedX Phototherapy treatments were stopped. When some of the wounds began to deteriorate, MedX Phototherapy was re-initiated. Post trial follow-up demonstrated that many of these wounds healed, indicating that nine weeks may not be sufficient time to heal Stage 3 to 4 wounds. A number of the wounds continued to heal initially without phototherapy, but reached a plateau, requiring light stimulation to continue the healing process.

Conclusion

Overall, the results of the trial demonstrate positive objective and subjective clinical outcomes. Similar to the literature, there were no negative effects of MedX Phototherapy. When considering the risk/benefit, the results demonstrate:

- positive clinical outcomes, in acute and chronic wounds
- no wound deterioration beyond pre-treatment level
- no negative consequence of MedX Phototherapy
- potential significant savings > both in staff time and supplies and equipment
- improved quality of life for indolent conditions
- an innovative option for these difficult-to-treat wounds
- extremely "doable" by staff and easily incorporated into a wound care protocol

Therefore, the evaluation results indicate that MedX Phototherapy is a clinically effective adjunct to a Wound Care Program for residents living in skilled nursing facilities and long-term care with no negative consequences. Additionally, the staff quickly learned the principles and use of MedX Phototherapy, rapidly and willingly incorporating the technology into their wound care clinical practice.



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