Clinical Question: For adults in various health care settings, what is the effectiveness of noncontact low-frequency ultrasound therapy (aka MIST therapy) on deep tissue injury wounds?

Results: The database search was expanded to include all wounds, as the search term “deep tissue injury” yielded little-to-no results. A search of various databases and a final review of articles yielded 3 articles relevant to this clinical question (See Electronic Database Search Methodology, Page 2). The following key summary of the literature for studies involving noncontact low-frequency ultrasound (NFLU) therapy on chronic wounds is offered to provide some guidance:

- At this time, the evidence from two meta-analyses (N=444\textsuperscript{1}; N not stated\textsuperscript{3}) and one small clinical observation study (N=11) supports the adjunct use of NFLU therapy for chronic wounds\textsuperscript{1-3}
- NFLU therapy was found to be effective in reducing bacterial counts of Staphylococcus species (including MRSA) in the wound bed; no wounds demonstrated a clinical infection or adverse event\textsuperscript{2}
- NFLU therapy was associated with “remarkable consistency”\textsuperscript{1} in reducing wound area\textsuperscript{1,2}, wound volume\textsuperscript{1,2}, and wound pain for chronic wounds\textsuperscript{1}
- NFLU therapy was also associated with favorable rates of healing for chronic wounds, which ranged from 6 weeks to 5 months\textsuperscript{1,3}
- NFLU therapy demonstrated significantly faster healing rates as compared to sharp debridement\textsuperscript{3}
  - Statistically significant difference in complete healing of patients with venous stasis ulcers over a 6 month period\textsuperscript{3}
  - No difference in complete healing between NFLU therapy and sharp debridement for patients with diabetic foot ulcers\textsuperscript{3}

Limitations: The quality of the evidence is limited by several factors. There appears to be a small group of dedicated researchers investigating this important clinical issue. For this literature review, these researchers appeared as co-authors and included their own studies as part of one meta-analysis.\textsuperscript{3} Two articles\textsuperscript{1,2} and multiple studies included in the meta-analyses\textsuperscript{1,3} received financial funding from Celleration Inc., which manufactures the MIST Therapy device. The primary author for the third article is a reimbursement consultant for an unidentified NFLU company.\textsuperscript{3} Thus, an element of publication and research bias may be present. Other limitations are as follows:

- Lack of large randomized clinical trials investigating NFLU therapy versus standard wound care\textsuperscript{1-3}
- Small number of study subjects decreases the ability to generalize meta-analyses and study findings\textsuperscript{1-3}
- “Standard of care” for wound treatment varied among institutions and was not defined\textsuperscript{1,3}
- No discussion of costs associated with NFLU therapy versus current standard wound care\textsuperscript{1-3}
- Although this literature review examined chronic wounds, the Celleration Inc. website (http://www.celleration.com/medical-professionals/when-to-use-mist-therapy/) and brochure (http://www.celleration.com/wp-content/files_mf/mc67048_ebrochure.pdf) state that MIST Therapy may be used for patients with deep tissue injury (DTI), venous ulcers, diabetic foot ulcers, burns, surgical wounds, pressure ulcers, and arterial ulcers.

Clinical Options: Based on the literature, the following options are offered for consideration:

- NFLU therapy may be an effective adjunct to standard wound care for chronic wounds.\textsuperscript{1-3}
- Further evidence is needed to determine if NFLU therapy is effective for other types of wounds.

Recommendation: A systematic review using an expanded search of additional databases could provide further clarification for this medical device issue. The Kaiser Permanente Department of Clinical Analysis, Technology Assessment & Guidelines Unit, conducts systematic reviews on these types of clinical topics. (Email request and question to: scal.med-technology-agu@kp.org)
# The Effectiveness of MIST Therapy for Deep Tissue Injury Wounds

*The Effectiveness of MIST Therapy for Deep Tissue Injury Wounds: A Literature Review of the Evidence*

March 2013

**Electronic Database Search Methodology**

Literature search topic: Effectiveness of noncontact low-frequency ultrasound MIST therapy use for Deep Tissue Injury (DTI)

Date(s): March 18-21, 2013

<table>
<thead>
<tr>
<th>Database</th>
<th>Key Word(s) Used</th>
<th>Total References Identified (hits)</th>
<th>Relevant References</th>
<th>Total Duplicates</th>
<th>Articles Selected for Review</th>
<th>Articles Excluded</th>
<th>Final Total Relevant References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: PubMed Years: Open</td>
<td>noncontact low-frequency ultrasound therapy (NLFU) AND wound*</td>
<td>15</td>
<td>12</td>
<td>5 (Driver et al. 2011 Meta-analysis)</td>
<td>7</td>
<td>4 (3 case studies; 1 animal study)</td>
<td>3 (2 meta-analysis; 1 observational)</td>
</tr>
<tr>
<td>Name: PubMed Years: Open</td>
<td>ultrasonic MIST therapy AND wounds</td>
<td>9</td>
<td>4</td>
<td>4 (Driver et al. 2011 Meta-analysis)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Name: PubMed Years: Open</td>
<td>NLFU AND deep tissue injury</td>
<td>2</td>
<td>2</td>
<td>2 (PubMed)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Name: PubMed Years: Open</td>
<td>ultrasonic MIST therapy AND deep tissue injury</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Name: Cochrane Years: Open</td>
<td>NLFU AND wound*</td>
<td>3</td>
<td>3</td>
<td>2 (PubMed)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Name: Cochrane Years: Open</td>
<td>ultrasonic MIST therapy AND wounds</td>
<td>3</td>
<td>3</td>
<td>2 (PubMed)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Name: Cochrane Years: Open</td>
<td>NLFU AND deep tissue injury</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Name: Cochrane Years: Open</td>
<td>ultrasonic MIST therapy AND deep tissue injury</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**TOTALS** | 32 | 24 | 17 (duplicates across databases) | 7 | 4 | 3

**Inclusion Criteria:** Adults in a variety of care settings; deep tissue injury; wounds

**Exclusion Criteria:** Burns; pediatrics; experimental animal studies; case studies; opinion pieces; conference abstracts; letters to the editor

Created by Cecelia L. Crawford, RN, DNP, ©Kaiser Permanente SCAL Regional Nursing Research Program, March 29, 2013
Leveling of the Evidence

<table>
<thead>
<tr>
<th>LEVEL</th>
<th>DESCRIPTION</th>
<th>RELEVANT ARTICLES</th>
<th>ARTICLE NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Meta-analysis of multiple large sample or small sample* randomized controlled studies, or meta-synthesis of qualitative studies with results that consistently support a specific action, intervention, or treatment</td>
<td>2</td>
<td>#1, #3</td>
</tr>
<tr>
<td>B</td>
<td>Well-designed controlled studies, both randomized and nonrandomized, prospective or retrospective studies, and integrative reviews with results that consistently support a specific action, intervention, or treatment</td>
<td>1</td>
<td>#2</td>
</tr>
<tr>
<td>C</td>
<td>Qualitative studies, descriptive or correlational studies, integrative reviews, systematic reviews, or randomized controlled trials with inconsistent results</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>Peer-reviewed professional organizational standards, with clinical studies to support recommendations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E</td>
<td>Theory-based evidence from expert opinion or multiple case reports, case studies, consensus of experts, and literature reviews</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MA</td>
<td>Manufacturer’s recommendation; Anecdotes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

* A large sample has adequate power to detect the observed effect with confidence (as seen in significant Confidence Intervals). A small sample may lack confidence in the power of the desired effect (Polit & Beck, 2008)

References


Purpose/intended Audience

Because we want everyone in our communities to have the healthiest lives possible, we are making our evidence reviews available to the communities we serve to help Californians and others lead healthier lives.

Integrative reviews and evidence summaries are provided as a community service for reference purposes only, and must be used only as specified in this disclaimer. These documents are intended for use by clinicians. If you are not a clinician and are reading these documents, you should understand that the information presented is intended and designed for use by those with experience and training in managing healthcare conditions. If you have questions about them, you should seek assistance from your clinician. The information contained in the evidence reviews is not intended to constitute the practice of medicine or nursing, including telemedicine or advice nursing.

Limitations On Use

These documents have been developed to assist clinicians by providing an analytical framework for the effective evaluation and treatment of selected common problems encountered in patients. These documents are not intended to establish a protocol for all patients with a particular condition. While evidence reviews provide one approach to evaluating a problem, clinical conditions may vary significantly from individual to individual. Therefore, clinicians must exercise independent professional judgment and make decisions based upon the situation presented.

Kaiser Permanente's documents were created using an evidence-based process; however, the strength of the evidence supporting these documents differs. Because there may be differing yet reasonable interpretations of the same evidence, it is likely that more than one viewpoint on any given healthcare condition exists. Many reviews will include a range of recommendations consistent with the existing state of the evidence.

All of the Kaiser Permanente integrative reviews and evidence summaries were developed from published research and non-research evidence and do not necessarily represent the views of all clinicians in Kaiser Permanente. These documents may also include recommendations that differ from certain federal or state health care mandates.

Intellectual Property Rights

Unless stated otherwise, all of these materials are protected by copyright and should not be reproduced or altered without express written permission from Kaiser Permanente. Permission is granted to view and use these documents on single personal computers for private use within your hospital or hospital system. No portion of these materials in any form may be distributed, licensed, sold or otherwise transferred to others.

The organizations within Kaiser Permanente retain all worldwide rights, title and interest in and to the documents provided (including, but not limited to, ownership of all copyrights and other intellectual property rights therein), as well as all rights, title and interest in and to their trademarks, service marks and trade names worldwide, including any goodwill associated therewith.

2013 Kaiser Permanente Southern California Regional Nursing Research Program
Nursing.Research@kp.org
No Endorsement or Promotional Use

Any reference in these documents to a specific commercial product, process, or service by trade name, trademark, or manufacturer, does not constitute or imply an endorsement or recommendation by Kaiser Permanente. The views and opinions expressed in these documents may not be used for any advertising, promotional, or product endorsement purposes.

Disclaimer of All Warranties and Liabilities

Finally, although Kaiser Permanente believes that all of the information provided in its documents is accurate, specific recommendations derive from combining the best available evidence. Although we have sought to ensure that the documents accurately and fully reflect our view of the appropriate combination of evidence at the time of initial publication, we cannot anticipate changes and take no responsibility or assume any legal liability for the continued currency of the information or for the manner in which any person who references them may apply them to any particular patient. Kaiser Permanente does not assume any legal liability or responsibility for the completeness, clinical efficacy or value of any apparatus, product, or process described or referenced in the documents. We make no warranties regarding errors or omissions and assume no responsibility or liability for loss or damage resulting from the use of these documents.