Extracorporeal shockwave treatment for chronic diabetic ulcers and wounds: a clinical perspective

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Primary AIM

To discuss and invite more research collaboration in the area of diabetic foot ulcer utilising extracorporeal shockwave treatment
Diabetic foot ulcers (DFU’s)

- Complex & complicated to manage
- Attributed to diabetic progression and changes despite glycemic control
  - Neuropathy
  - Circulatory
  - Diminished tissue synthesis / disruption to epithelialization & TGF-β transcription
  - Altered immuno-regulation & function (ie neutrophil function)
  - Infection
- Most common complication seen in DM & impacts approx. 15-25% of sufferers

Introduction

Diabetic foot ulcers (DFU’s): Underlying causes a key factor for management

- Ischaemic
- Neuropathic
- Neuroischaemic
  - Increase in incidence
  - Most commonly seen DFU’s

Introduction

## Introduction

### Diabetic foot ulcers (DFU’s): Typical etiological features

<table>
<thead>
<tr>
<th>Feature</th>
<th>Ischaemic</th>
<th>Neuropathic</th>
<th>Neuroischaemic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensation</td>
<td>Insensate</td>
<td>Painful</td>
<td>Some deg. of sensory deficit</td>
</tr>
<tr>
<td>Necrosis / Callus</td>
<td>Thick callus</td>
<td>Necrotic</td>
<td>Highly prone to necrosis with some callus present.</td>
</tr>
<tr>
<td>Wound bed</td>
<td>Granulated, pinkish, with callus present</td>
<td>Sloughy, pale, poor granulation</td>
<td>Generally poor granulation</td>
</tr>
<tr>
<td>Temp. &amp; pulse</td>
<td>Warm with bounding pulse</td>
<td>Cold with absence of pulse</td>
<td>Cold with absence of pulse</td>
</tr>
<tr>
<td>Typical location</td>
<td>Weight bearing / pressure regions</td>
<td>Tips &amp; in-between digits, lateral bor</td>
<td>Foot and toe margins</td>
</tr>
<tr>
<td>Other features</td>
<td>Dry skin</td>
<td>Non-healing</td>
<td>Non-healing + high risk of infection.</td>
</tr>
<tr>
<td>Incidence</td>
<td>10 – 20%</td>
<td>10 – 15%</td>
<td>&gt;50%</td>
</tr>
</tbody>
</table>

Diabetic foot ulcers (DFU’s): Current Management Guidelines:

- Treatment of primary and secondary disease & issues
  - Blood sugar; CVD; CAD; Habits etc.
- Improve micro & macro circulation where possible
- Wound management & infection control
  - Debridement (hydro / autolytic etc.); NPWT; biofilm detection and disruption; inflammatory control; moisture balance; antimicrobials; epithelial edge advancement
- Off load pressure regions

Aimed at amputation prevention!
Introduction

Diabetes
- Type 1
- Type 2

Comorbidity
- Neuropathy
- Ischaemia
- Impaired tissue synthesis
- Immune alteration
- Infection
- Habitual tendencies

Management Aimed at Amputation Prevention

- How effective are current strategies?
- Economic viability and sustainability?
- Are there other methods?
Extracorporeal Shockwave Treatment (ESWT)
An adjunct treatment option in the management of diabetic ulcers
ESWT

- spark discharge
- Piezo-elektric
- electromagnetic
- pneumatic

- focused
  - hard shockwave
- radial
  - soft shockwave
**Extracorporeal shock wave therapy (ESWT) for wound healing: Technology, mechanisms, and clinical efficacy**

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5. Combat Wound Initiative Program, Washington, DC, and
6. Henry M. Jackson Foundation for the Advancement of Military Medicine, Bethesda, Maryland

Outcome

Non Diab.:
- 6% not healed
- 17% missed
- 74% healed

Diabetic:
- 6% not healed
- 14% missed
- 70% healed

Healing time: 48 day from 1st ESW Tx
No of treatments: 3 – 5 sessions
Similar response in both groups

Outcome: Superficial Tissue Perfusion

Baseline

7 days post ESWT

Outcome: Case file

Baseline
0.7cm x 1cm

2nd month post ESWT
Outcome: Case file

Baseline

52 days post ESWT (4 sessions)

Moretti, Notarnicola, Baggio et al. 2008 – Ref 36
Treatment of diabetic foot ulcers: A comparative study of extracorporeal shockwave therapy and hyperbaric oxygen therapy

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### Table 3 – The overall clinical results.

<table>
<thead>
<tr>
<th>Ulcer status</th>
<th>ESWT</th>
<th>HBOT</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>After one course of treatment</td>
<td>(N = 44)</td>
<td>(N = 40)</td>
<td></td>
</tr>
<tr>
<td>Completely healed ulcers</td>
<td>57% (24 of 44)</td>
<td>25% (10 of 40)</td>
<td>0.003</td>
</tr>
<tr>
<td>≥50% improved ulcers</td>
<td>32% (14 of 44)</td>
<td>15% (6 of 40)</td>
<td>0.071</td>
</tr>
<tr>
<td>Unchanged ulcers</td>
<td>11% (5 of 44)</td>
<td>60% (24 of 40)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Worsened ulcers</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>After second course of treatment</td>
<td>(N = 14)</td>
<td>(N = 17)</td>
<td></td>
</tr>
<tr>
<td>Completely healed ulcers</td>
<td>50% (7 of 14)</td>
<td>6% (1 of 17)</td>
<td>0.005</td>
</tr>
<tr>
<td>≥50% improved ulcers</td>
<td>43% (6 of 14)</td>
<td>47% (8 of 17)</td>
<td>0.815</td>
</tr>
<tr>
<td>Unchanged ulcers</td>
<td>7% (1 of 14)</td>
<td>47% (8 of 17)</td>
<td>0.015</td>
</tr>
<tr>
<td>Worsened ulcers</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

N: Numbers of foot.  

P-Values: comparison between the ESWT group and the HBOT group.
Outcome: Perfusion Status

Significant increase in perfusion status in ESWT vs HBOT

Outcome: Histological Features

Significant increase in cell proliferation, concentration and activity in ESWT vs HBOT

Baseline

Post ESWT

Electrohydraulic shockwave field:

- Ellisoidal (Blue)
- Parbolic (Yellow)
- Focused / diffused
- High / Soft-intensity
- Narrow / wide therapeutic zone
ESWT: Impact on Human Tissue

ESWT Acoustic Stimulus

Intracellular & extracellular modulation and factoring

eNOS, VEGF, PCNA stimulus & modulation

Endothelial cell migration, hypoxic correction, inflammation modulation, cell proliferation

Homeostatic restorative regulation & return

References: 16 - 45
**ESWT: Safety & Efficacy**

Rationale for further investigation & implementation for DFU’s

- Systemically neutral
- Safe
- Hypoxic & Ischaemic correction
- Neuro modulation
- Inflammation modulation
- Tissue synthesis promotion
- High rate of resolution
- Low number of Tx
- Economically viable

References: 16 - 45
Welcome

We welcome you to join us in collaborative research in diabetes and other areas of interest.

We can help establish a regional ESWT Society

Collaborate with member institutions and members of the ISMST

Welcome to our 19th International Scientific Congress in Malaysia

19th International Congress of the ISMST 2016
International Society for Medical Shockwave Treatment

KUCHING, SARAWAK MALAYISA
14 - 16 July 2016
Reference


Craig K, d’Agostino M, Poratt D & Walker M. Original hypothesis: Extracorporeal shockwaves as a homeostatic autoimmune restorative treatment (HART) for Type 1 diabetes mellitus. Med Hypotheses. 2014;83(1); 250 – 253.


Contact for research collaboration & information

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