Treatment of Ischemic Wounds with Non-Contact, Low Frequency Ultrasound: The Mayo Clinic Experience

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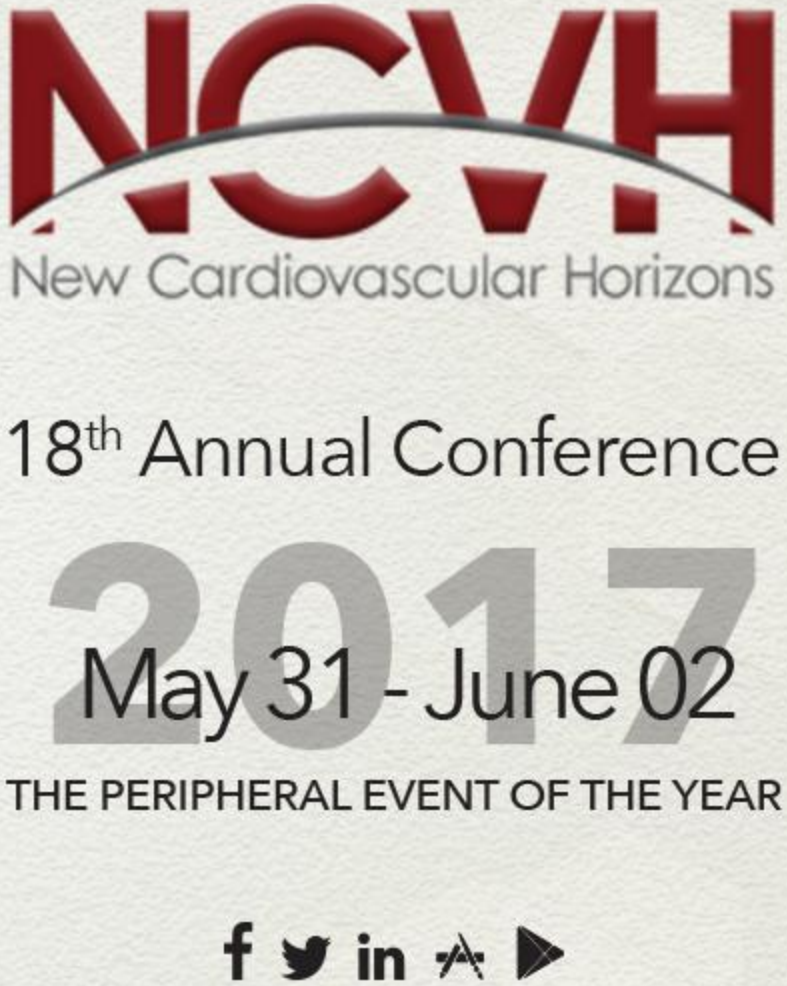


DISCLOSURE

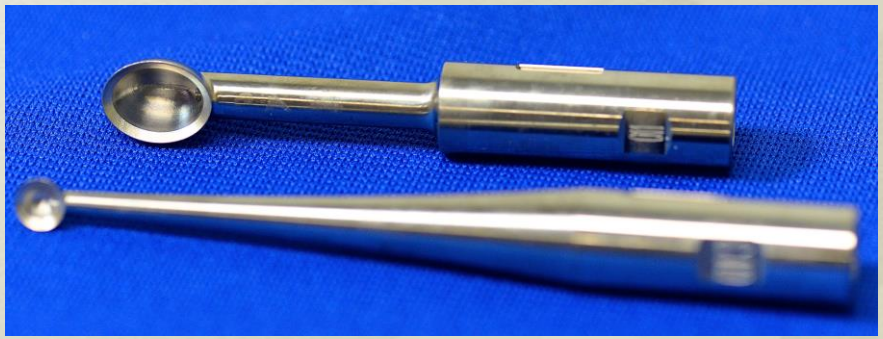
- NONE

Low Frequency Ultrasound

- kHz (35 – 40 kHz
- Non-contact and contact systems
- Saline solution is atomized at the transducer tip (55 -60 micron particle)
- Acoustic streaming carries the small particles the wound surface
- Cavitation at the surface occurs


Arobella


Applicator
Channel for tubing management
Ultrasound will not start without applicator in place
Applicator with integrated tubing for saline delivery
Easy and intuitive set up and use



Acute and Chronic Wounds

- Ischemic
- Neuropathic
- Venous
- Pressure
- Post Surgical Wounds
- Burns
- Traumatic
- Infectious
- Radiation

Treatment of Ischemic Wounds with Noncontact Low-Frequency Ultrasound:

The Mayo Clinic Experience (2004 – 2006)

- Prospective, randomized, open-label study
- Parallel group, controlled trial
- Patients had ischemic wounds of at least 8 weeks duration (foot, ankle, leg)
- $TcPO_2 \leq 40$ mmHg

Background

- Noncontact low-frequency ultrasound (LFU) has been shown to be an effective method in the treatment of chronic foot ulcerations
- The purpose of this study was to evaluate the clinical role of LFU in the treatment of non-healing leg and foot ulcers associated with chronic critical limb ischemia (CCLI)
- Option for care prior to and post revascularization in CCLI

Methods

- The study was performed in a multidisciplinary vascular wound healing clinic
- Two groups:
  - Group 1: 35 patients using LFU as part of their SOC
  - Group 2: 35 patients with SOC treatment alone
- Outcomes considered favorable if the wound reduced by 50% or greater
- Both arms of the study were treated for 12 weeks
- LFU treatment was 3 times per week for a 5 minute duration
- SOC treatment was daily dressing changes, hydrogel

Patient Characteristics	LFU Therapy (n=35)	Standard of Care (n=35)
Age, median (range), years	74 (72.2-76.5)	76 (73.4-81.2)
Men, no. (%)	28 (80)	26 (74)
Coronary artery disease, no. (%)	26 (74)	27 (77)
Prior revascularization, no. (%)	24 (69)	28 (80)
Diabetes mellitus, no. (%)	22 (63)	23 (66)
Insulin dependent	12 (55)	9 (36)
Non-insulin dependent	10 (29)	14 (56)
Glycosylated hemoglobin (≤ 8%), no. (%)	16 (73)	20 (80)
Median (range)	7 (6.72-7.85)	6.9 (6.2-7.98)
Hypertension, no. (%)	26 (74)	30 (86)
Dyslipidemia, no. (%)	29 (83)	27 (77)
No. (%) treated with statins	22 (63)	25 (71)
Smoking, no. (%)		
Current	5 (14)	4 (11)
Former	26 (74)	22 (63)
Never	4 (11)	9 (26)
Chronic renal failure		
Serum creatinine, median (range)	1.2 (1.1-1.8)	1.2 (1.17-1.85)
No. (%) on hemodialysis	3 (8)	4 (11)
Osteomyelitis, no. (%)	4 (11)	5 (14)

No statistically significant differences observed between treatment groups.

Baseline Arterial Status

	LFU Therapy (n=35)	Standard of Care (n=35)
Supine $TcPO_2$, no. (%)		
0-20 mm Hg	11 (31)	15 (43)
21-40 mm Hg	24 (69)	20 (57)
Dependent $TcPO_2$, no. (%)		
0-20 mm Hg	12 (34)	19 (54)
21-40 mm Hg	23 (66)	16 (46)
Ankle-brachial index, median (range)	0.72 (0.66-0.8)	0.73 (0.65-0.81)
Prior arterial reconstruction, no. (%)	27 (77)	26 (74)
Femoro-popliteal bypass, no. (%)	4 (15)	6 (23)
Femoro-distal bypass, no. (%)	15 (56)	10 (38)

No statistically significant differences observed between treatment groups.
$TcPO_2$ = transcutaneous oximetry pressure

ANALYSIS OF $TcPO_2$ WITH DEPENDENCY BASED ON POSITIVE OR NEGATIVE WOUND HEALING OUTCOME AFTER 12 WEEKS OF TREATMENT

	LFU (n=35)	**SOC (n=35)**	***P* Value**
Positive outcome (>50% healing in 12 weeks) – no. (%)	22 (63)	10 (29)	*P* <0.001
$TcPO_2$ with dependency – no. (%)			
< 20 mm Hg	1 (0.05)	0 (0)	NS
20 to 40 mm Hg	21 (96)	10 (52)	NS
Negative outcome (<50% healing in 12 weeks) – no. (%)	13 (37)	25 (71)	*P* <0.01
$TcPO_2$ with dependency – no. (%)			
< 20 mm Hg	11 (85)	19 (76)	NS
20 to 40 mm Hg	2 (15)	6 (24)	NS

Conclusion

- Non-contact low frequency ultrasound therapy is safe and effective in CCLI patient population
- Non-contact LFU therapy assisted in stabilizing the ischemic wound while the patient is medically managed prior to further interventional procedure for limb salvage
- Significant improvement in wound healing when MIST Therapy is added to the standard of care in patients with CCLI

Thank you