Should you be using Therapeutic Ultrasound
and how can we improve our research

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Thanks

- Lenn Johns PhD - cell biologist, QU
- Sam Howard PhD – Tests & measurements, Onda Corporation
- Timothy Demchek PhD - Human tissue heating, Indian State University

Therapeutic Ultrasound

- Application of acoustic energy

- Desired outcomes
  - Tissue heating
  - Cellular response
    - Cavitation
    - Acoustic streaming
  - Alterations in cell membrane permeability
  - Up/down gene regulation
  - Activation of satellite cells

- Commonly used to treat musculoskeletal pathology
  - Physical Therapy
  - Occupational Therapy
  - Athletic Training
  - Physiatrist
  - Chiropractor

- Ceramic crystal glued onto a metal faceplate

- Some type of “plunger” introduced electricity onto the crystal
Crystal expand & contracts, generating vibrations
- Sound is nothing more than vibration in a medium

Series of Wave Interactions
Does it work?

- Cell Biology
  - Tell us yes

- Clinical trials
  - Tells us no

- Ogilve-Harris and Gilbert 1995
  - “insufficient evidence to conclude that ultrasound is an effective treatment modality for soft tissue injuries of the ankle”

- Gam and Johannsen 1995
  - the use of ultrasound in the treatment of musculoskeletal disorders is based on empirical evidence

Robertson and Baker (Physical Therapy 2001)

- reviewed 35 randomized controlled trials
  - Studied the clinical efficacy of therapeutic ultrasound
  - Of the 35 reports, only 10 met the methodological filters applied to randomized controlled trials

- Overall conclusion
  - not sufficient clinical data to support the use of therapeutic ultrasound.

- Philadelphia Panel (2001)
  - unable to demonstrate that therapeutic ultrasound had a clinically important benefit in the treatment of low back pain

- Still…
  - In spite of the lack of evidence-based clinical practice guidelines ultrasound remains a commonly used therapeutic intervention
Differences in heating

- Draper set the standard
- Kimura et al
- Merrick et al
- Holcomb & Joyce

Why is this??
US Parameters

- Total power
- Effective Radiating Area (ERA)
- Spatial Average Intensity (SAI)
- Beam Non-uniformity Ratio (BNR)

2 Possible Factors Leading to Variability in Clinical Outcomes

1) Determination of SAI  W/cm²

- Total Power
  - Display of total power –vs- actual total power produced
  - SAI variability (± 20%)

- ERA
  - group means in the software to determine SAI
  - SAI variability (± 20-25%)

2) Distribution of acoustical amplitudes

- Variability in tissue heating
Range of potential SAI values while keeping within manufacturer’s limits

- Heating rates correspond to minimum and maximum SAI values
- Digital indicator on machines reads 1.25 W/cm²
- Heating Rate °C/min in muscle (based upon Draper)

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Research Objective

- Evaluate whether significant differences exist in:
  - ERA
  - Total power
  - SAI

Experimental Design

- Mixed model design

- Independent variables
  - Manufacturer
  - Frequency

Determination of Total Power

Determination of ERA

- Both 1 and 3 MHz

- XY hydrophone scan at 5mm
  - All points that are ≥ to 5% of peak value
Calculation of SAI

- Watts/ERA = SAI = W/cm²
- Used to estimate Heating Rates

Transducer Profiling of ERA and Generation of Watts at 3 MHz

% Difference in Group Mean SAI: 3 MHz

- SAI = W/cm²
  % Difference Between
  High and Low SAI, 3 MHz

Transducer Profiling of ERA and Generation of Watts at 1 MHz

% Difference in Group Mean SAI: 1 MHz

  % Difference Between
  High and Low SAI, 1 MHz

  % Difference Between
  High and Low SAI, 1 MHz
Most Variability is tied to ERA

- Is ERA at 3 MHz related to ERA at 1 MHz?
- Is 95% ERA indicative of anything?

Why is this?

- Each transducer resonates at a particular frequency determined by the thickness of the crystal and the frequency of the driving AC.
- In multi-frequency transducer, the thickness of the crystal can be optimized for only one treatment frequency.
- The second treatment frequency must be obtained by manipulating the frequency of the AC current that drives the crystal.
- Therefore a manufacturer optimizes to a particular treatment frequency.

Why 95% ERA?

ERA can be measured at any value we choose

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Variability in US Field

- Traditional
  - BNR
    - Can be measured planar
    - Can be measured axial

Is BNR an adequate descriptor of the entire acoustic field

PAMBNR

Primary Objective

- Develop Novel Method
  - WHOLE FIELD characterization
  - Not dependent on BNR and ERA

- Generate General Beam Profiles of Multiple Manufacturers

Schlieren Image

- Describes the interaction of light and sound
  - Optical index of refraction
  - Shows field variations

Schlieren Set-up

- Schlieren images were captured at 1 and 3MHz
  - intensity of 0.1W/cm², a method shown to be valid and reliable
- Analysis of Schlieren images
  - lateral beam profiles
  - 1cm increments over a distance of 7cm from the transducer surface

- Reporting beam width (cm)
  - 40% and 80% of the beam’s relative intensity

3 MHz: General Images
3 MHz: Beam Widths at 80% RI
3 MHz: Beam Widths at 40% RI

Beam Width at 3 MHz

- Main effects for manufacturer include:
  - Mettler
    - Significantly larger than all other manufacturers (P<0.001)
  - Omnisound
    - Significantly smaller than all other manufacturers (P=0.005 – 0.001)

1 MHz: General Images
1 MHz: Beam Widths at 80% RI
1 MHz: Beam Widths at 40% RI

Beam Width at 1 MHz

- Main effects for manufacturer include:
  - Both Rich-Mar and Dynatronics
    - Significantly larger than all other manufacturers (P<0.001)
  - Mettler
    - Significantly smaller than all other manufacturers (P<0.001)
  - Chattanooga
    - Significantly smaller than Omnisound (P=0.009)
Conclusions

- Beam width variability exists between manufacturers
- A large beam width at 3 MHz does not guarantee a large beam width at 1 MHz
- Lateral beam profiles may aid in:
  - Predicting distribution of heating within sound fields
  - Explaining variability in treatment outcomes

Follow-up

- Examine the variation in ultrasound field construction within manufacturer
  - Determine if different manufacturers have different degrees of variability
- Compare degree of variation along Z axis
- Compare degree of variation at different % RI

DV

- Variation Index (VI)
  - \[ \text{Absolute value (data point mean – data point/data point mean)} \times 100 \]
- Represent each point as a % deviation from the manufacturer group mean

Consistent / Inconsistent

- Mettler - Consistent
- Excel - Consistent
- Richmar - Inconsistent
- Omnisound - Inconsistent
- Excel - consistent
- Richmar - consistent
- Omnisound - inconsistent
Do these differences in beam width mean anything??

Conclusions- **beam width variability:**

- Exists within manufacturers
- I
- s greater in some manufacturers
- Is greater when defining the areas of higher relative intensity

**Conclusions**

- Consistency at 1 Mhz ≠ Consistency at 3 Mhz
  - some crystals/manufacturers may be better suited for treatment at a specific frequency rather than both frequencies

- Lateral beam profiles provide us with information regarding the possible distribution of heating within sound fields
  - Explaining variability in recently reported treatment outcomes?

**Why are there differences??**

- Crystal properties
- Crystal adhesions techniques
- Transducer technologies

**How can we document energy distribution??**

- Heating rates in vivo
  - Place thermistor into people
  - IRB Approval
  - How many thermistors can you place?

- Thermal imaging??
Thermal imaging

- Optotherm

Prior to Clinical Trials

- Determine True ERA & SAI
- Determine appropriate beam width/energy density
- Adjust Treatment area equally
- Develop a good injury model

Thank you