Multidimensional Analysis of Ultrasonic Surgical System Performance

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Outline

- Types of ultrasonic surgical devices
- How do typical devices operate?
  - How do we balance *safety* and *efficacy*?
- What can be measured?
  - Acoustics / Cavitation / Energy
  - Thermal Effects
  - Cutting effectiveness
- Combining results: Multidimensional analysis
- Discussion and Conclusion

Types of Ultrasonic Surgical Devices

- From " 'tripters":
  - Lithotripters
  - Histotripters
  - Lipotripters

- To scalpels

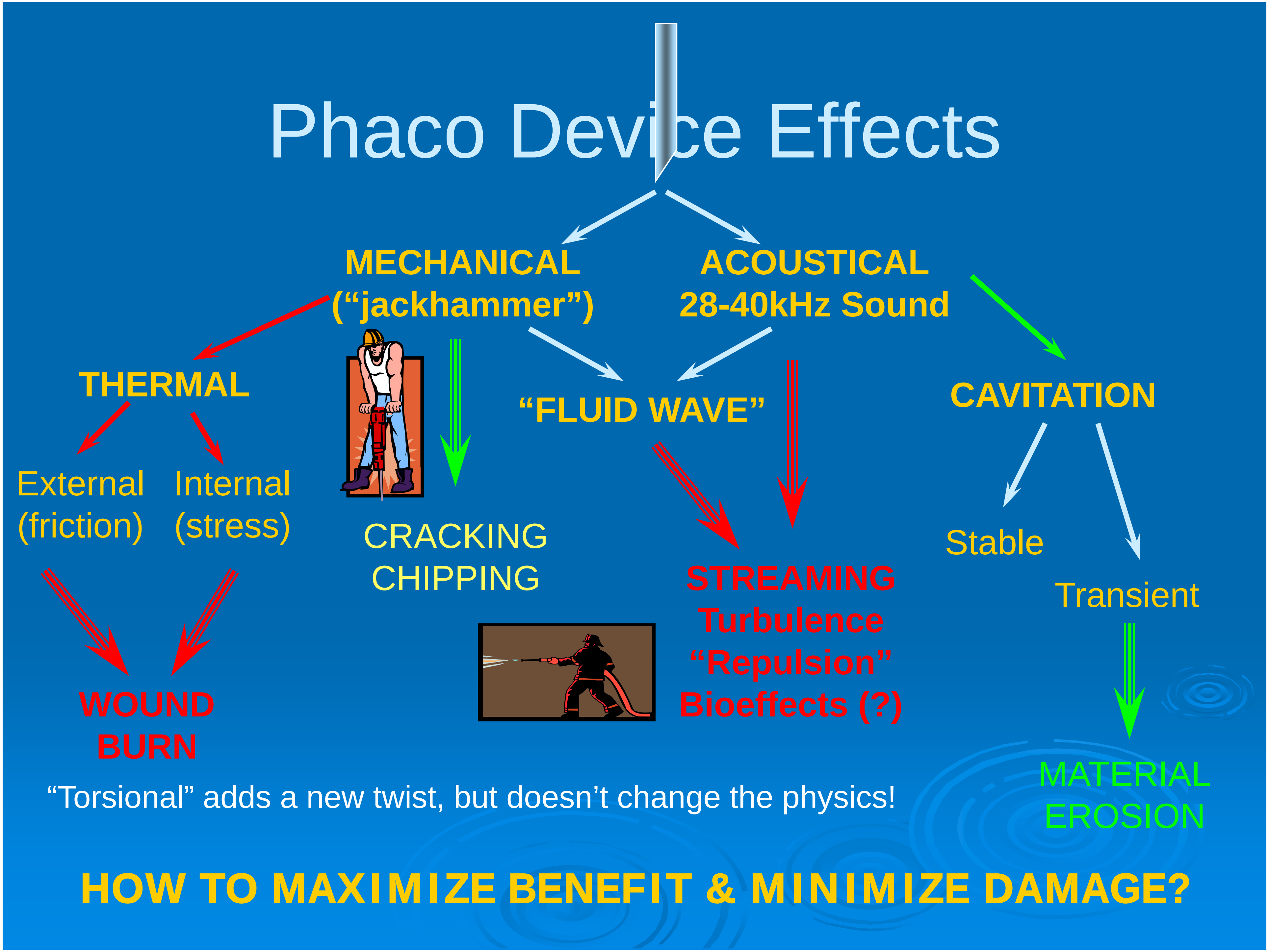
- To things in between
  - Phaco and VASERs and such, oh my!

Ultrasound's Diversity: Multiple Approaches

Monopole	← Spatial →	Focused
Pulsed	← Temporal →	Continuous
23kHz	← Frequency/Wavelength →	2.3MHz
Contact	← Intimacy →	Non-invasive
Exploited	← Heat →	Avoided
Transient	← Cavitation →	Stable

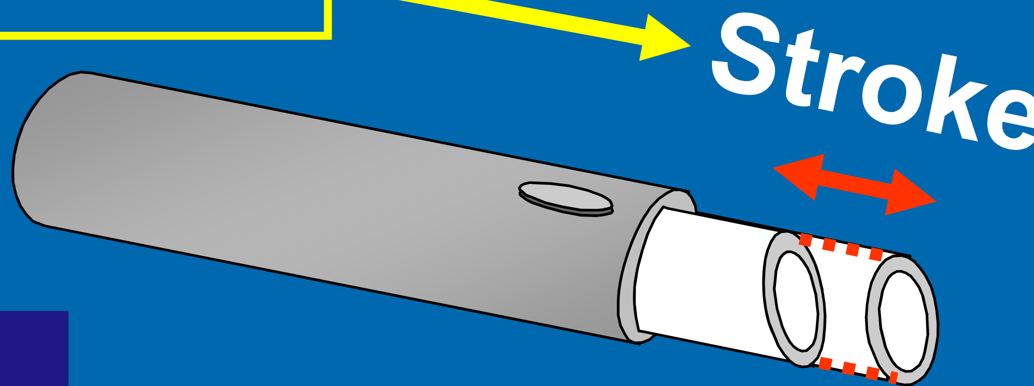
Multi-dimensional Analysis

- Examine one technology, and analyze different effects to explore interrelationships
- Attempt to:
  - Determine optimal conditions
  - Provide guidance to both designers and operators
- Phacoemulsification will be used as the primary example
- Ultrasonic Liposuction application will also be discussed briefly


Phaco Device Effects
MECHANICAL
("jackhammer")
ACOUSTICAL
28-40kHz Sound
THERMAL
External
(friction)
Internal
(stress)
WOUND
BURN
CRACKING
CHIPPING
"FLUID WAVE"
STREAMING
Turbulence
"Repulsion"
Bioeffects (?)
CAVITATION
Stable
Transient
MATERIAL
EROSION
"Torsional" adds a new twist, but doesn't change the physics!
HOW TO MAXIMIZE BENEFIT & MINIMIZE DAMAGE?

User's View of "Ultrasonic Power"

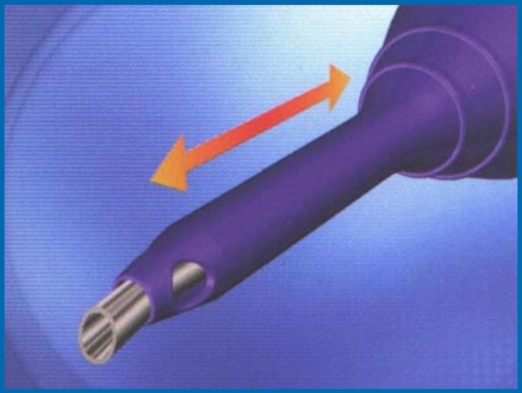
Foot Pedal Controls

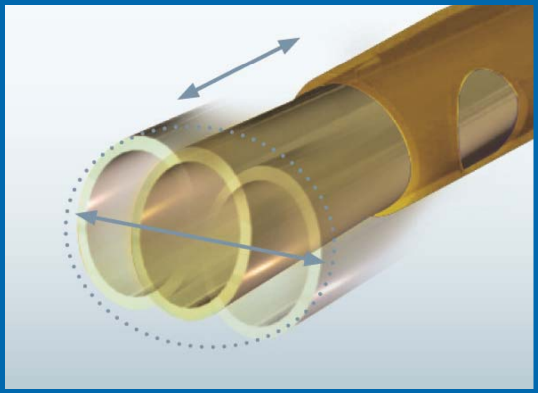


Foot pedal position controls the stroke, or movement of the tip

The machine provides a numerical indication of "% power"

What are the technologies/modes?





- Standard "Longitudinal" phaco is an in/out motion
- "Torsional" or "T-phaco" uses a twisting motion of the tip rather than a longitudinal motion (only one of the two modes can operate at a time, therefore the need to switch back and forth)
- "Transverse" or "Ellips" uses a combination of side to side and in/out simultaneously; may be used with either straight or bent tips

Inside Torsional

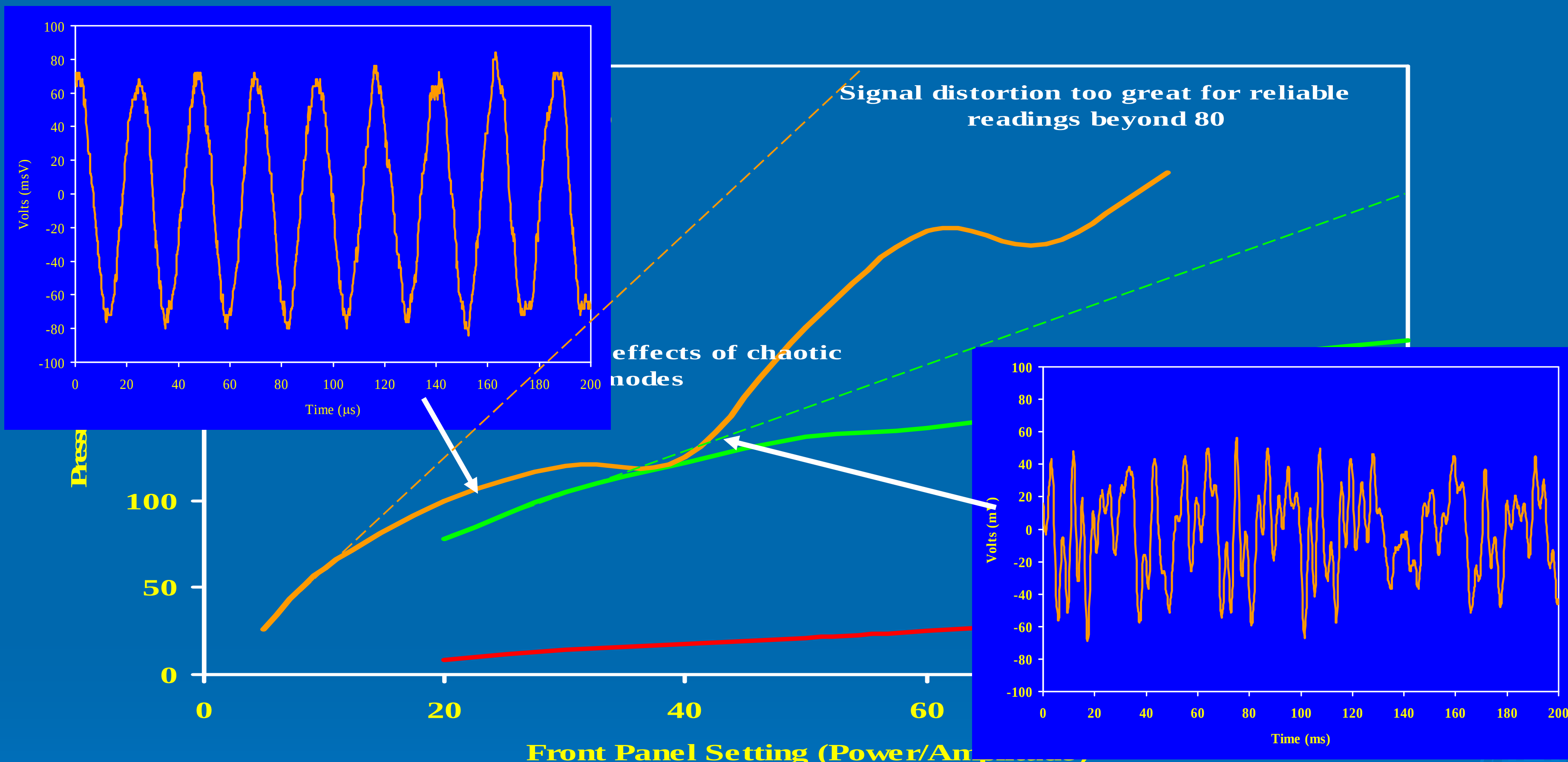
- “Torsional” uses a motional transformer within the handpiece, operating at a different resonant mode
- Only one of the two modes can operate at a time, therefore the need to switch back and forth

- We applied a suite of tests to examine output, effects, and efficacy, starting with Acoustical Output

Acoustic Output: Materials & Methods

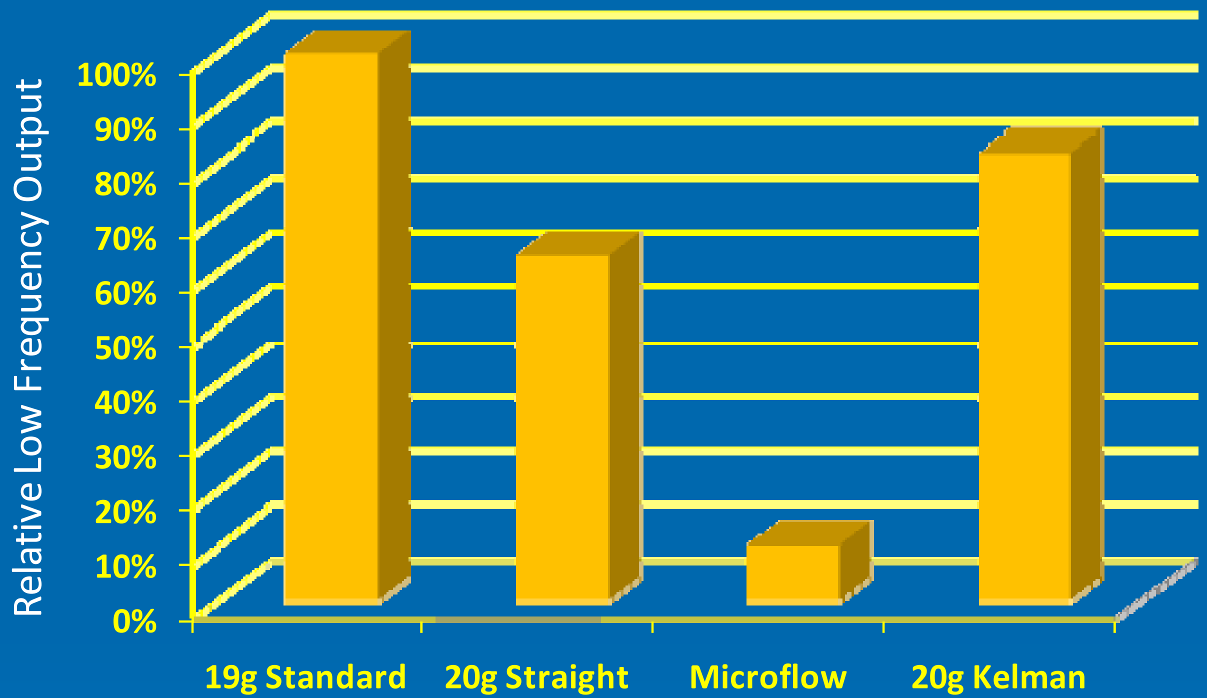
- Acoustic measurement system captures both the low frequency (handpiece drive) energy as well as the cavitational energy
- Rotational fixture allows mapping the distribution of energy, which relates to the motional direction of the tip
- Data can correlate to cutting efficiency depending upon cavitation readings

Acoustic Energy delivered from different devices



- Low frequency (linear) energy from straight needle is well controlled; difference between theory and measurement is cavitation energy
- Even when driven in “linear” (longidutinal) mode, a bent (Kelman) tip breaks into chaotic “wagging” motion; overall energy much higher
- Torsional mode generates ultrasonic energy, but less than linear

Tip Size and Shape affect output

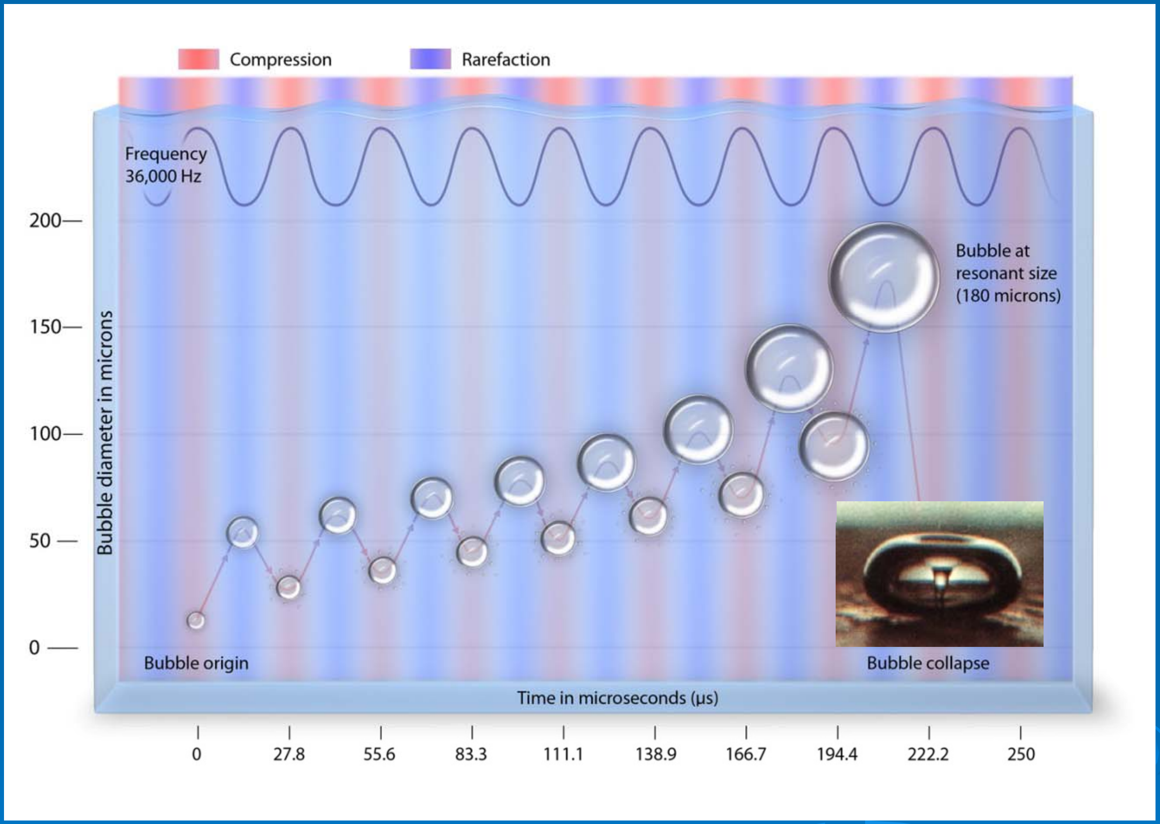


- Acoustic output directly affected by the tip size and shape
- Smaller effective area => lower output
- Bent/Kelman (squared!) tips radiate more energy for same design
- Not currently captured in any device's energy dose metric (i.e. EPT, CDE)
- However, standardization *is possible*

Ultrasound and Bubbles

- **CAVITATION** involves the creation and action of air or gas bubbles in a liquid. In this case, the tumescent fluid which is introduced into the patient contains millions of microscopic bubbles. These bubbles occur naturally because the fluid is at equilibrium pressure with the air inside the IV bag.

- Under the cyclic compression and rarefaction (squeezing and pulling) of the ultrasound field, the very small bubbles grow until they reach "resonant" size, at which point they collapse and the process repeats.



Cutting with sound: Bubbles and Cavitation

- The tip motion affects micro-bubbles which grow to resonance and collapse violently, emulsifying the lens
- Very high speed video (150,000fps) shows growth and collapse of cavitation cloud, and the cloud seen separating from phaco tip
- Surgical Implication:
  - Cavitation energy is highly localized and most efficient for emulsification when the lens material and the phaco tip are in extremely close proximity.
  - Only cavitation at the tip, or inside the needle, will emulsify lens material.

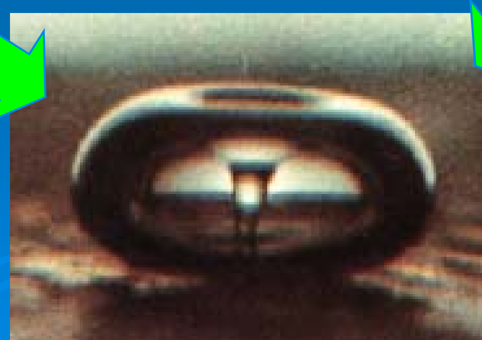
Frequency affects Cavitation Energy

28.5 KHz

40 KHz

82 Microns

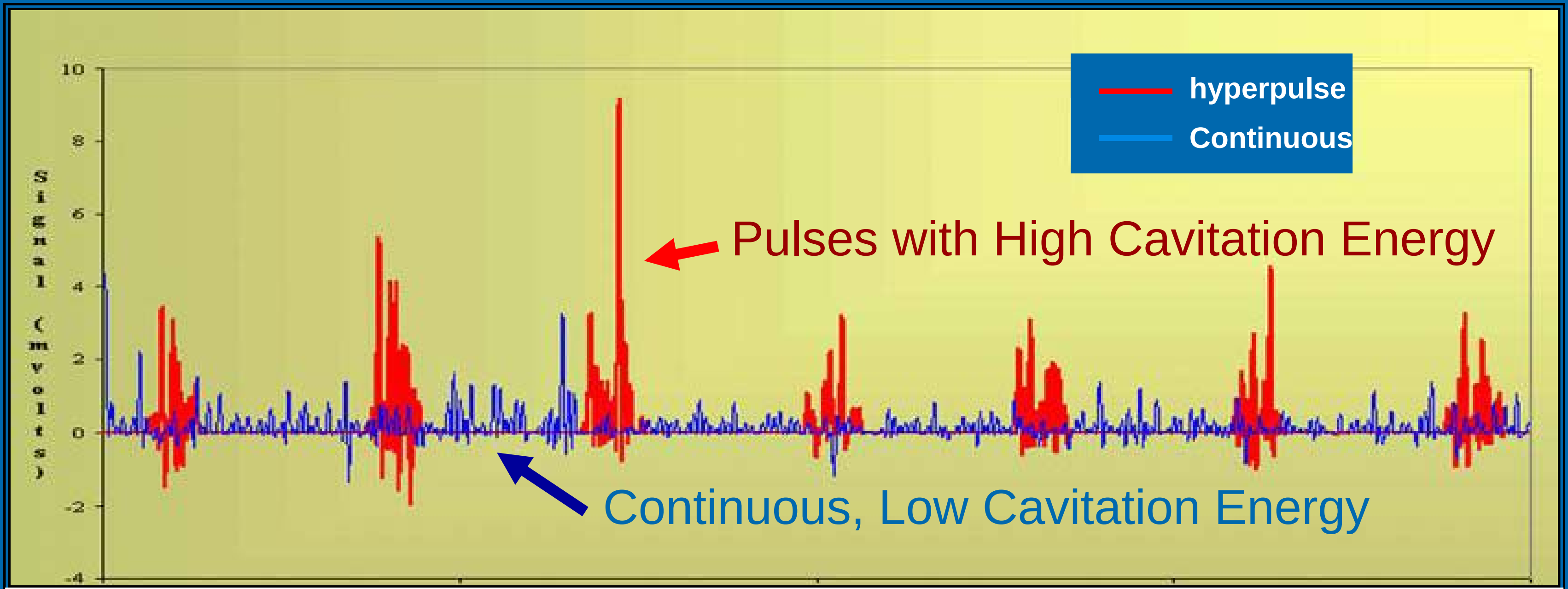
115 Microns

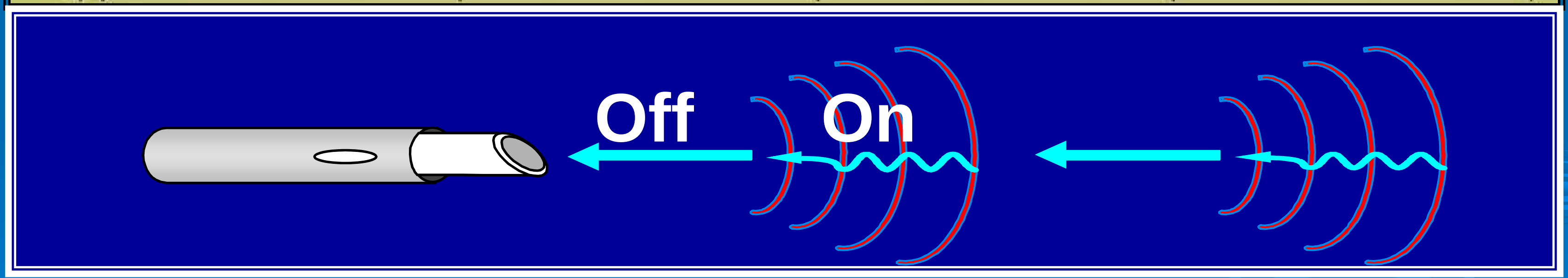


E = 2.76

E = 1.00

Hyperpulse affects Cavitation Energy



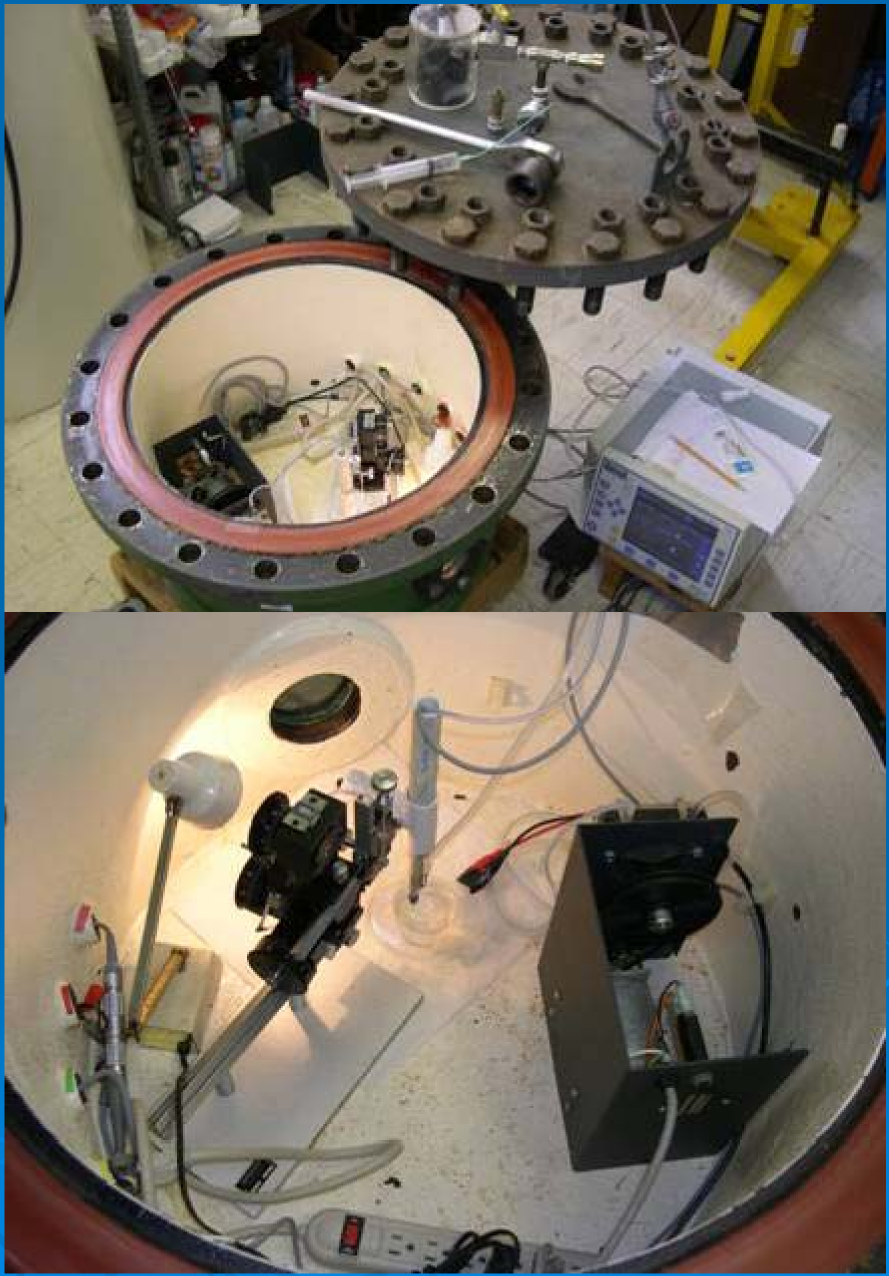


More cavitation (cutting) energy delivered with pulses than with continuous ultrasound at same power (stroke).

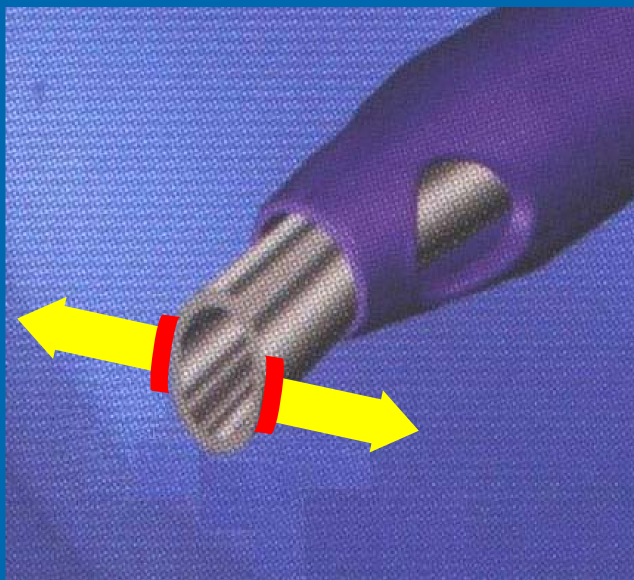
Accentuating cavitation conditions reduces total ultrasound delivered for same or better cutting effectiveness

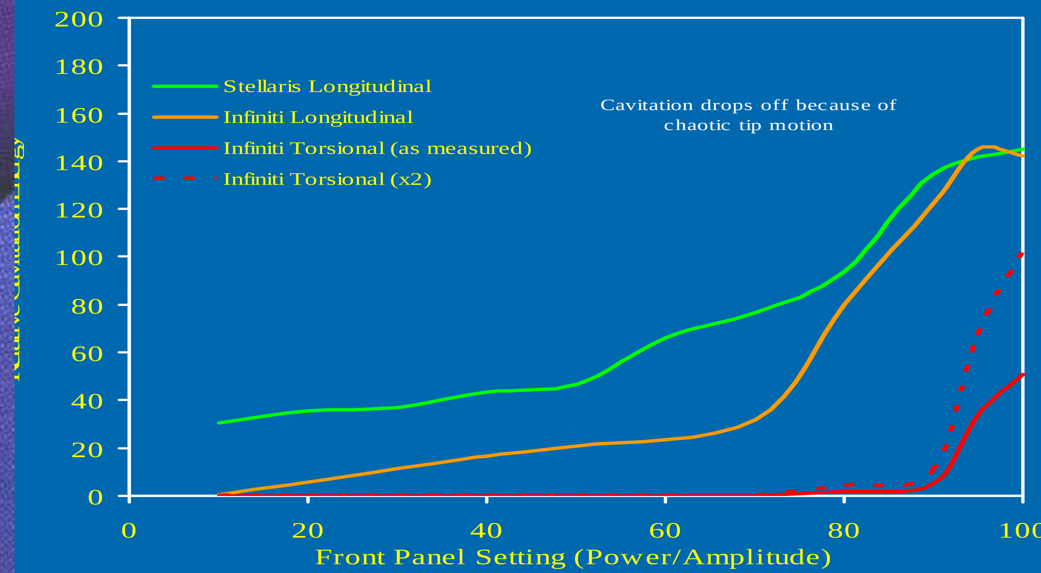
Confirming Cavitation

- Custom high pressure tank capable of +10 atmospheres overpressure
  - Large enough to contain handpiece, roller pump
  - Special electrical feed through
  - Sighting porthole to view experiment
- Results proved cavitation was necessary for efficient cutting



Cavitation Analysis



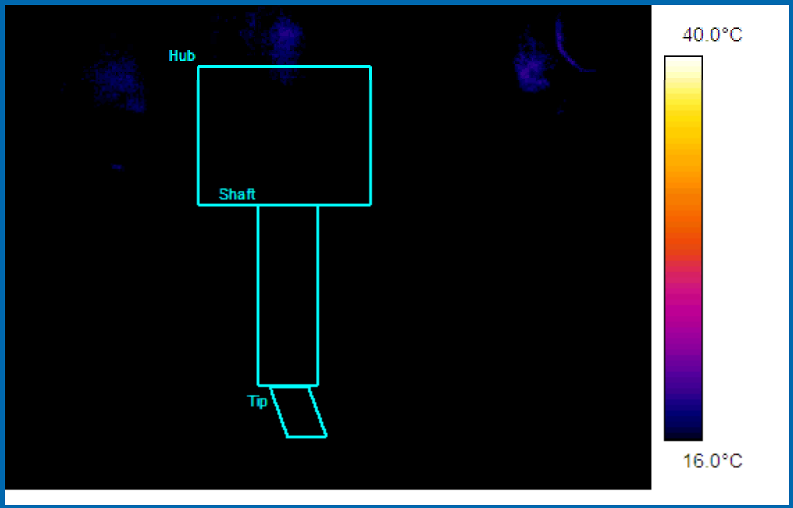


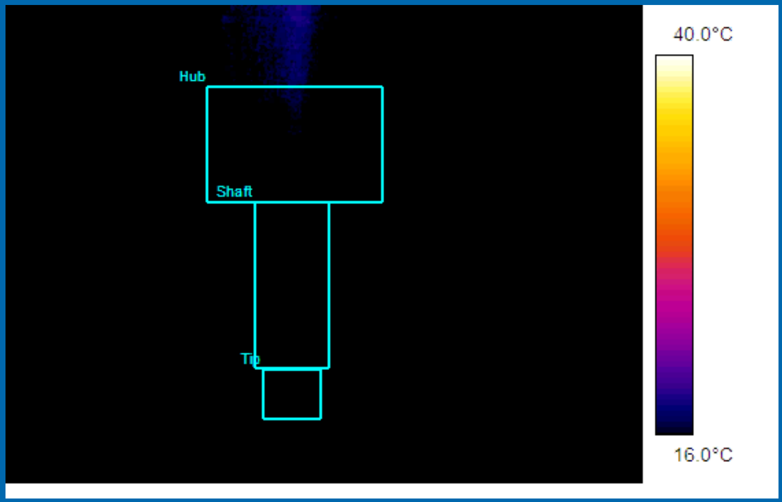
- Longitudinal mode creates cavitation in the forward annular region
- In torsional, cavitation is generated at the sides of the tip
- Torsional mode generates cavitation, but only at the highest (>95%) setting: exactly matches the manufacturer's recommendations
- However, this cavitation does not erode lens material within the tip, which can lead to clogging

Final comments on Cavitation

- Cavitation concentrates the acoustical energy of the tip into a very small scale, so that the energy is delivered just to the cataract, causing emulsification
- Tuning the energy delivery can improve the overall safety (by reducing unwanted or harmful effects) while increasing efficiency of emulsification
  - Hyperpulse sequences accentuate Transient Cavitation
  - Drive frequency also matters (23kHz better 38kHz)
  - Tip configuration affects acoustic dose and cavitation
  - “Torsional” phaco produces cavitation on sides, but only at highest settings, and suffers from clogging
- Now move on to thermal effects

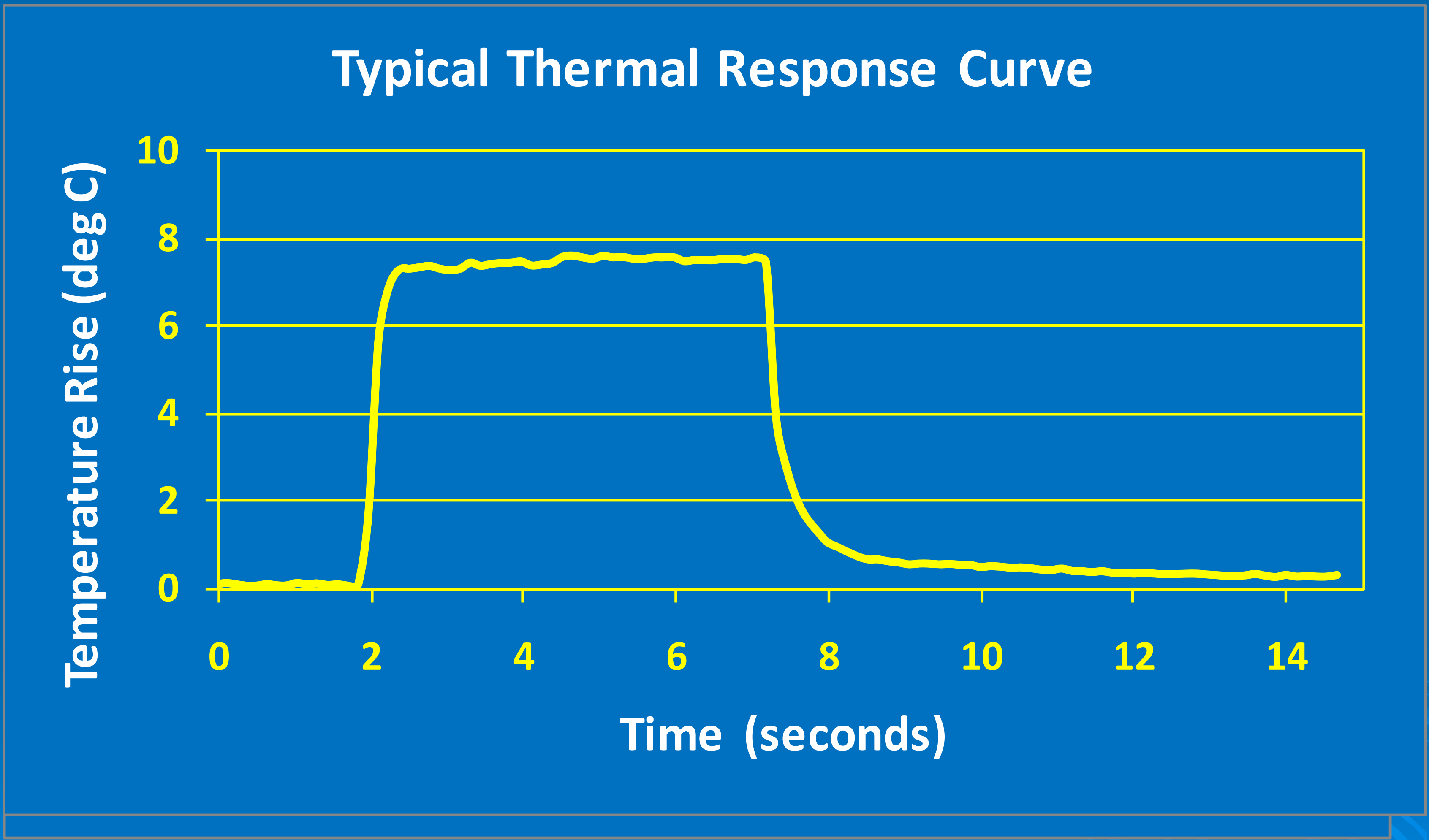
Thermal Comparison: IR Imaging of longitudinal and torsional





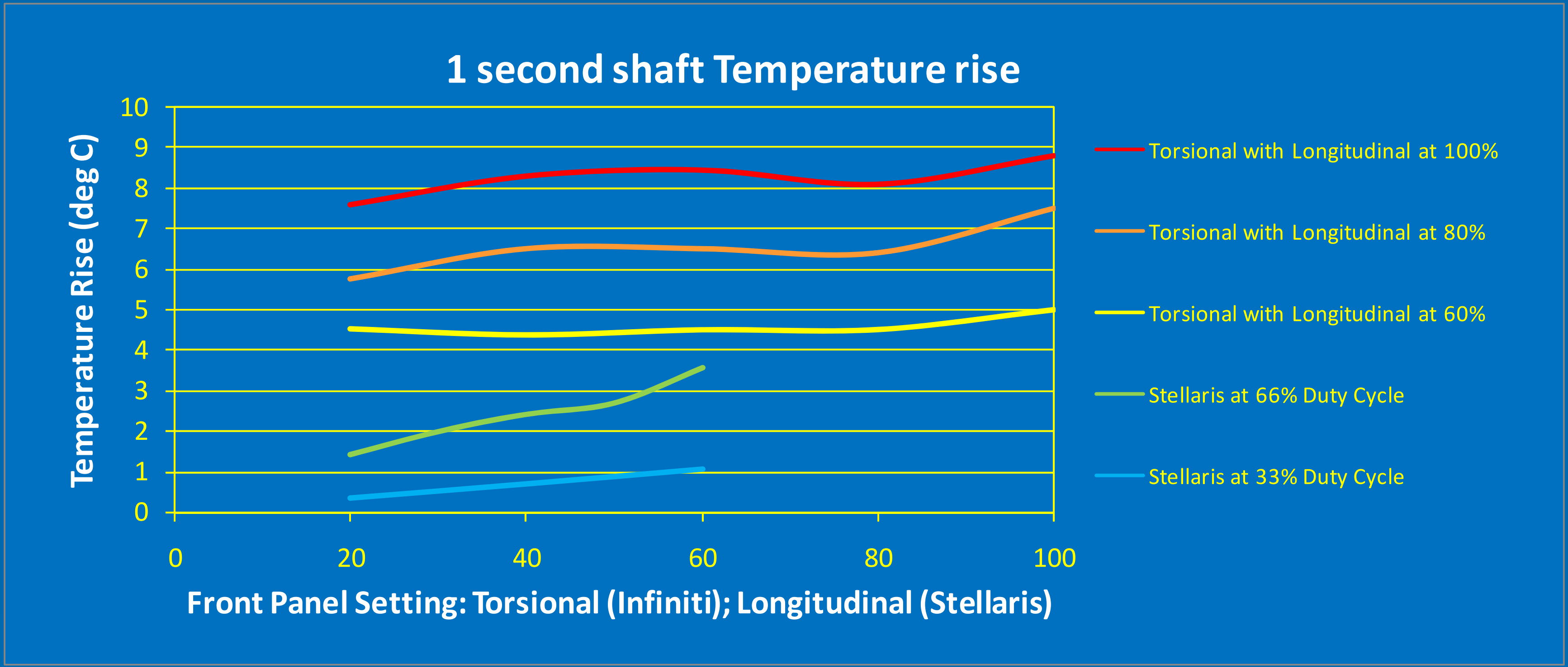
- High resolution InfraRed imaging of longitudinal and Torsional action; identical I/A rates, 19g needles
- Torsional only; Longitudinal only; and 80%/20% Torsional/Long. mix
- Images show 5 seconds of on time, with rapid rise in temperature, then a slower cool down; temperature data sampled 7.5 times/second
- The maximum temperature in the hub, shaft, and tip regions was recorded for each run; multiple runs taken for each condition
- Left hand image is torsional mode; right hand image is longitudinal mode
- Note where point heat source appears in each image

Results



- Consistent temperature results, tip always coolest
- Significant difference in rise time and 1 second thermal analysis
- Occlusion caused additional rise, although more slowly

Results: Thermal Rise Comparison



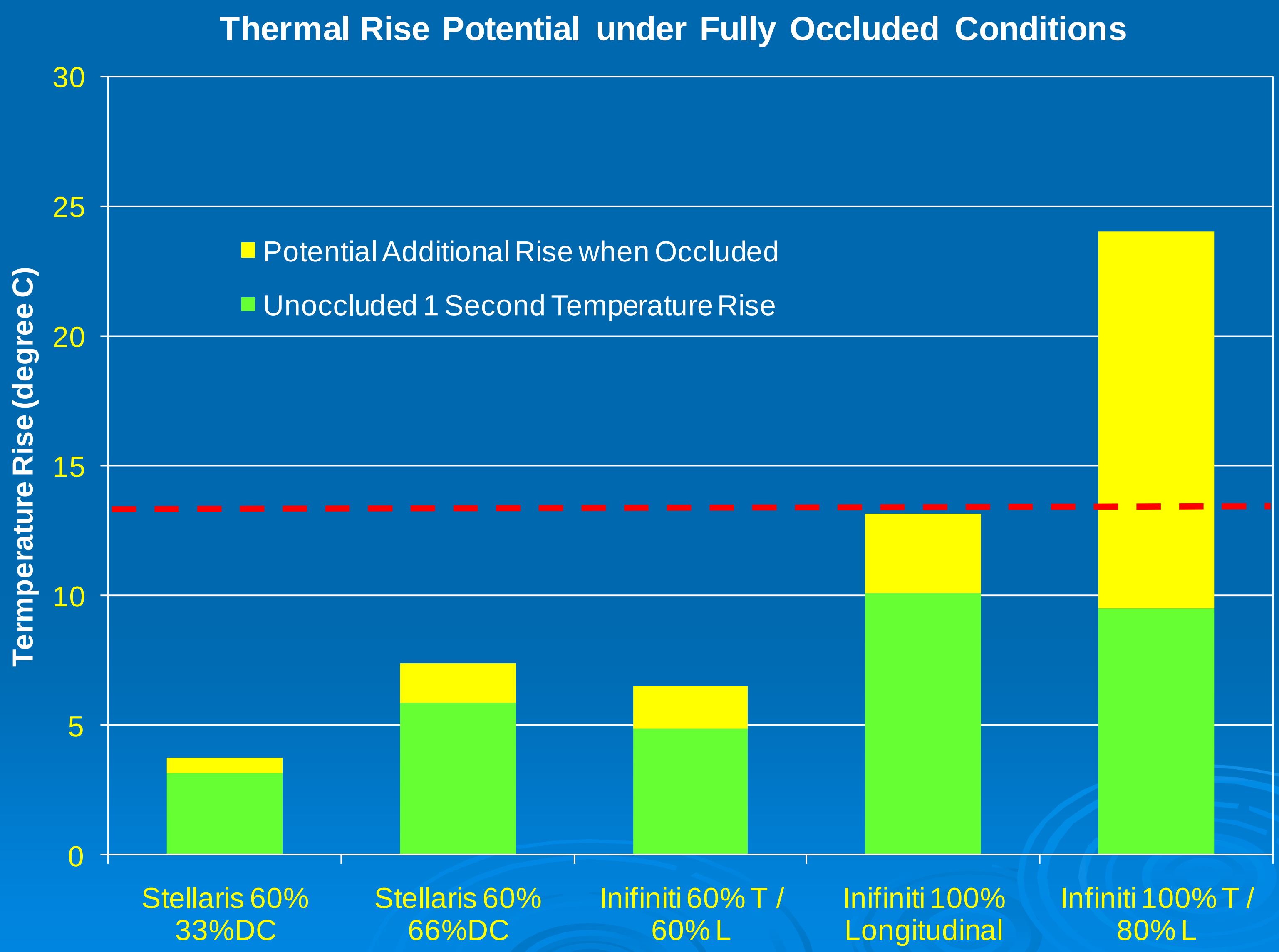
- Longitudinal mode generates heat due to friction with the sheath, and some internal losses at the hub transition
- Torsional mode creates heat within the shaft because of the internal stresses induced by the torsional motion, irrespective of friction.
- The heat from internal stress is essentially right at the wound location
- Hyperpulse reduces unwanted thermal rise

Heat Source: Internal Shaft Stress

- Torsional mode creates heat within the shaft because of the internal stresses induced by the torsional motion, irrespective of friction.

- On screen "power" for Torsional mode has been based on the assumption of frictional heating alone
- However, the heat from internal stress rises quickly with torsional amplitude, much more quickly than the "power" indicates to the user

Occlusion Analysis

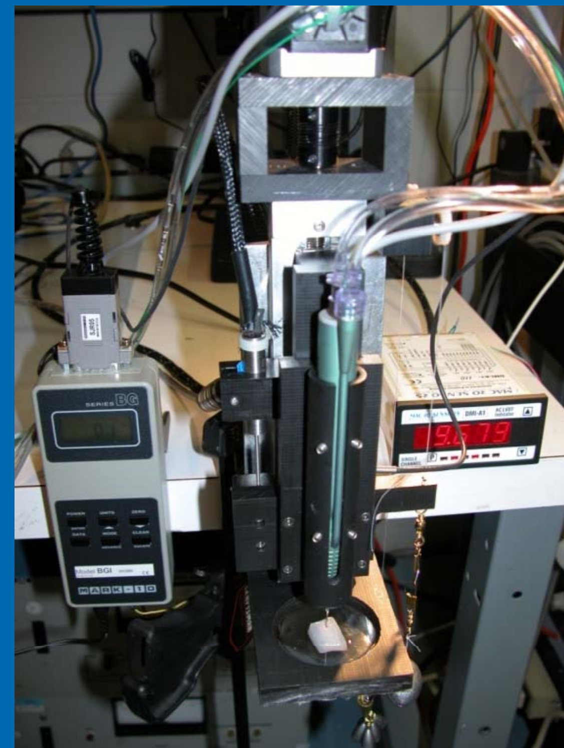


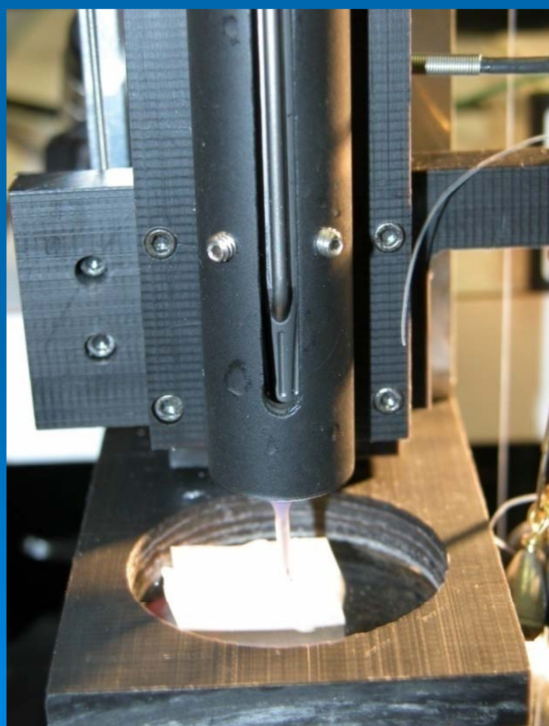
Thermal results summary

- For typical clinical settings:
  - Lower frequency longitudinal motion had low measured temperature rise, especially at the 33% duty cycle setting; Torsional showed a significant rise, especially at the recommended 100% longitudinal mix
  - For longitudinal, the hub region was the heat source, outside the surgical field; for Torsional, the shaft itself was the primary heat source, right at the wound location.
  - The on-screen “power” metric was a very poor indicator of potential thermal effect, with a 4x temperature span for the same indicated value
  - Additional recent work showed that Torsional, when occluded, could exceed 50C, which can cause collagen damage and tissue necrosis
- Final topic to consider is cutting efficiency

Measuring Cutting: Materials & Methods

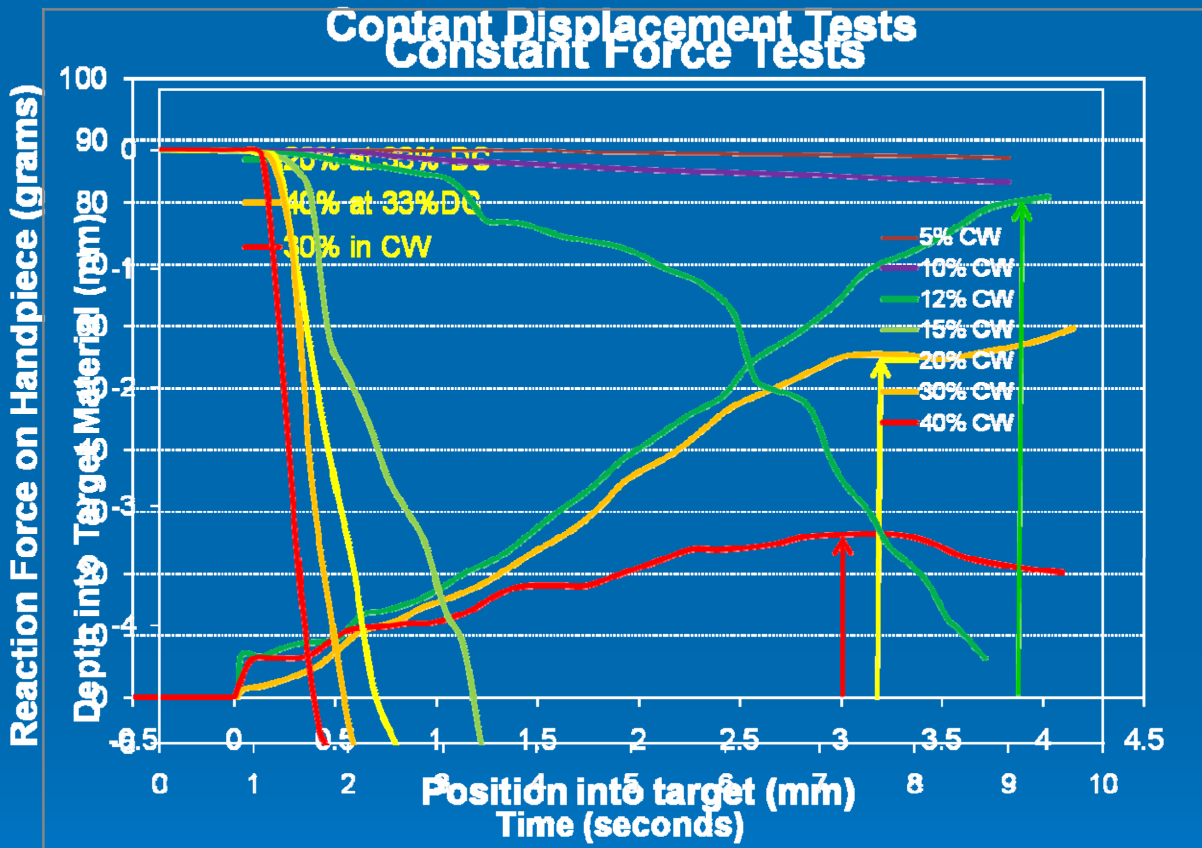
- Custom cutting force system
- Full computer control of motor and high resolution acquisition of position and force data for analysis
- Simulated lens target material
- Constant force (60g weight), measure displacement as a function of time





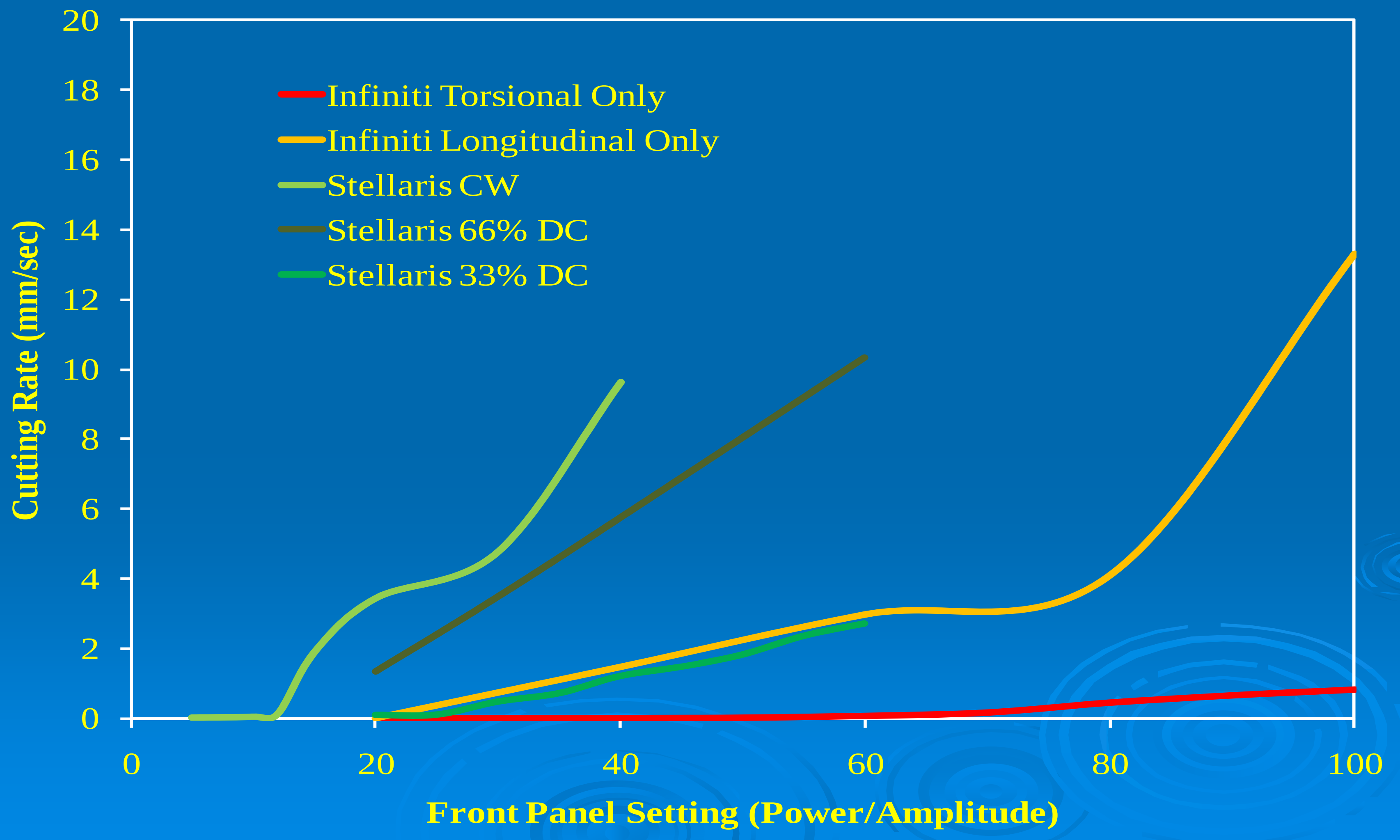
- Fluid rates maintained at 30cc/min
- Straight tip longitudinal, bent forTorsinal
- 10 second experiment; initial 2 seconds to establish position baseline; systems then run for 8 second foot pedal time
- Systems operated over a range of settings

Examples of Recorded Data

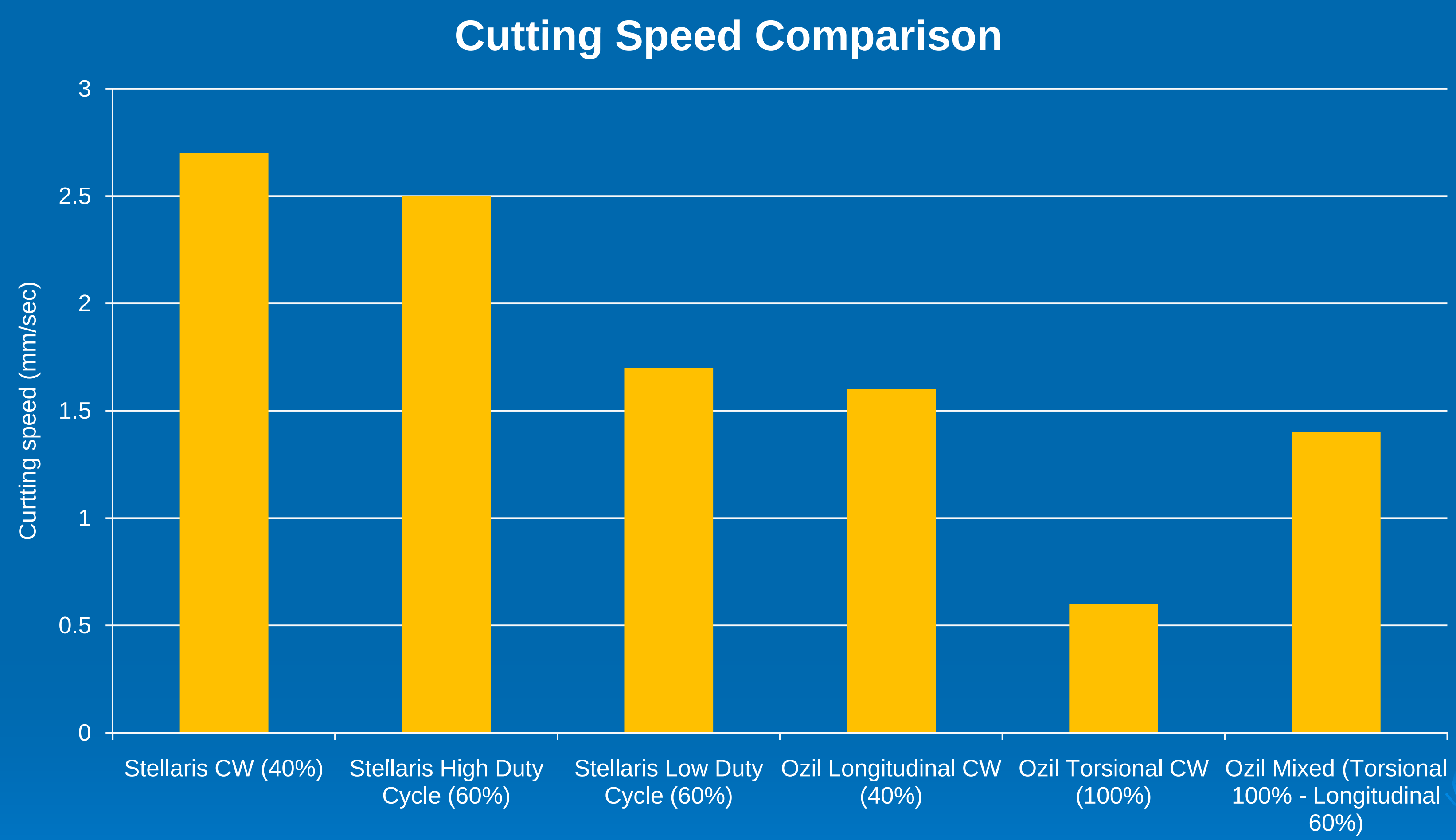


- Constant displacement experiments show the “resistance” or “feel” of the handpiece when engaging the lens; area under curve is “work”
- However, the constant force tests better mimic the surgeon’s action
- Constant force test show trends in effectiveness with system and setting

Cutting Rate as a function of setting



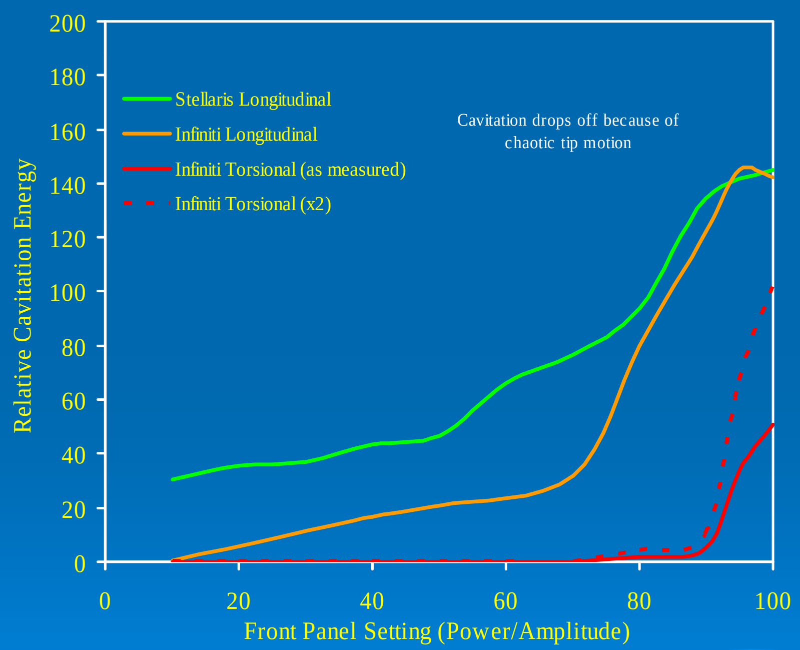
Results:



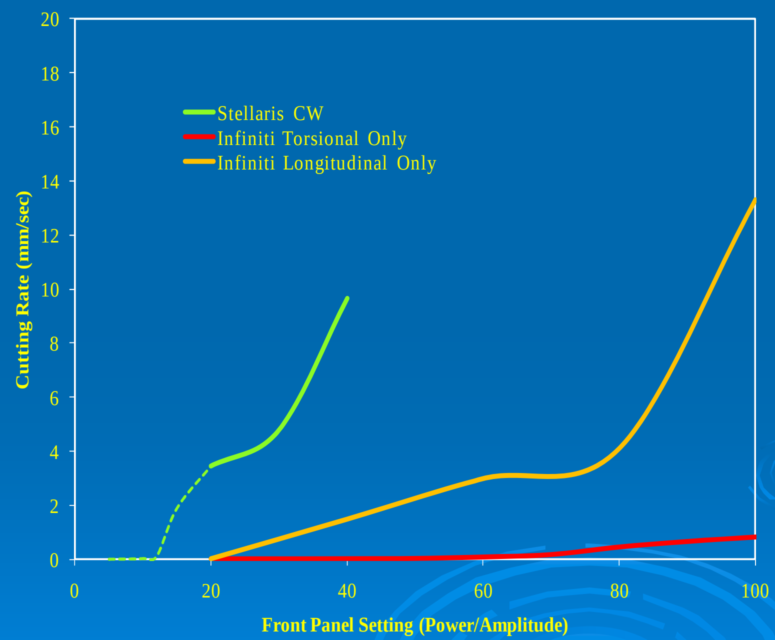
- Torsional only was the least effective; Lower frequency longitudinal CW was the most
- Longitudinal in hyperpulse had good effectiveness
- Torsional mixed mode shows influence of longitudinal

Example of Multidimensional Analysis: Linking Cavitation and Cutting

Results from Cavitation Measurements

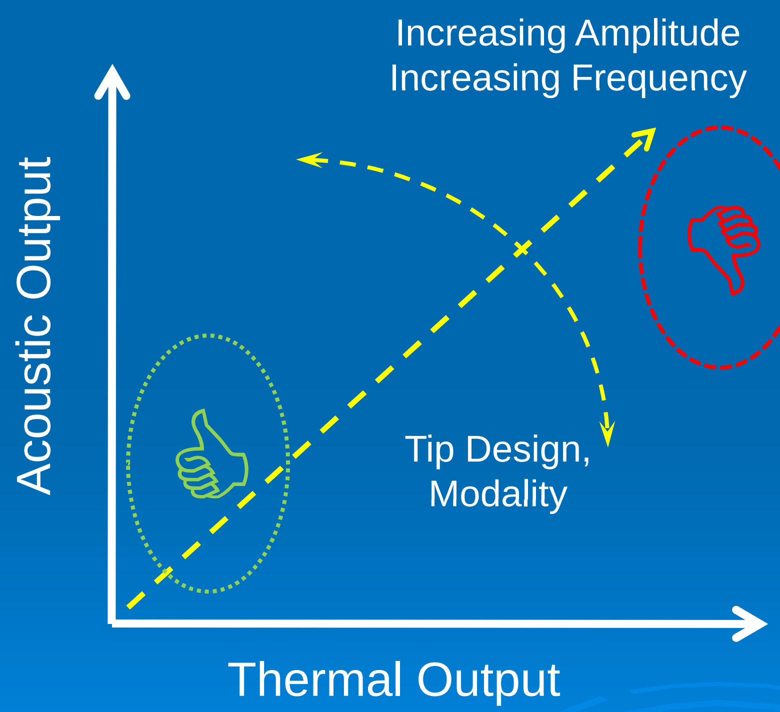


Results from Cutting Force Measurements

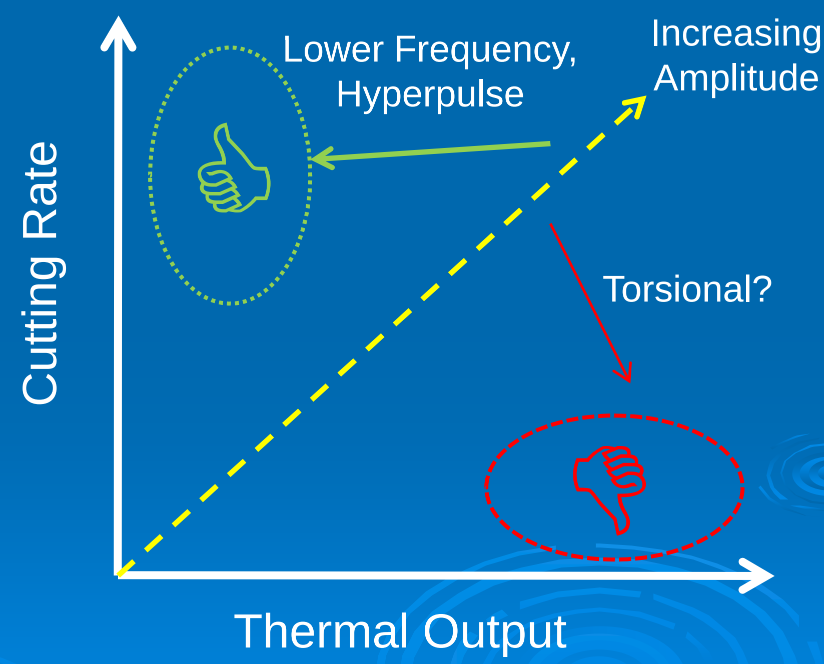


Combining Performance Metrics

Compare Thermal Output & Acoustic Effects (repulsion, streaming)



Compare Thermal Output & Cutting Rate



But different clinical need can lead to a different analysis… for example liposuction application

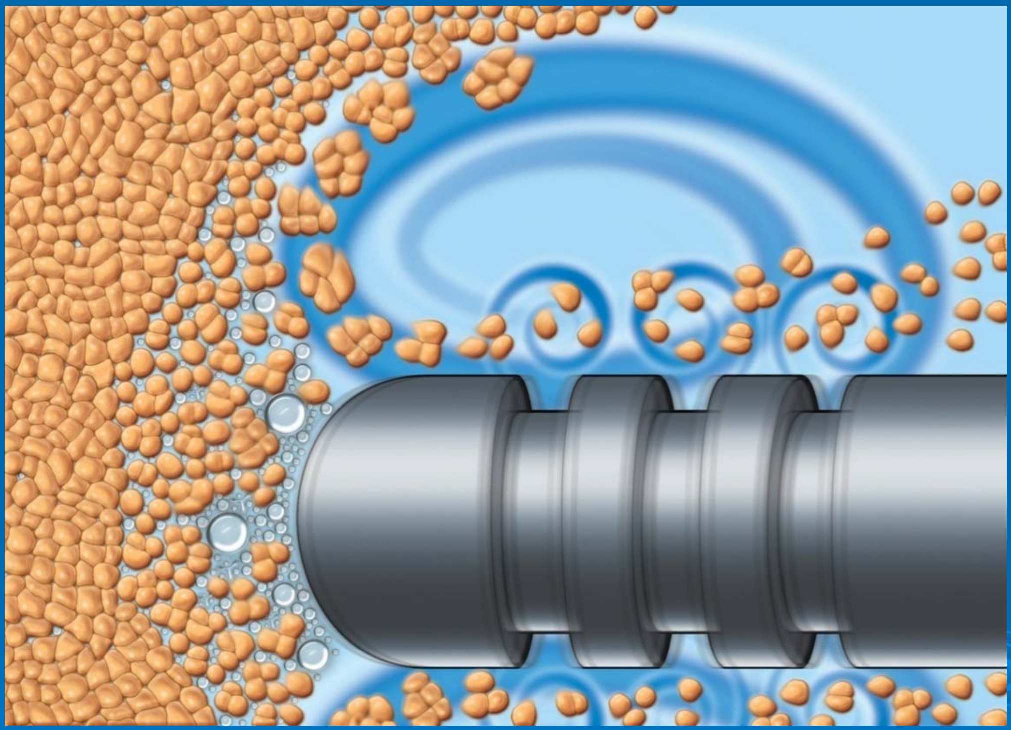
Compare phaco with the goals of ultrasound surgery for liposuction

- Rather than emulsification, goal is to remove fat cells, with minimal damage to patient or to cells (fat transfer)
- Requires shift in amplitude and frequency counter to those used in phacoemulsification

System Name	Frequency (Hz)	Probe Area (cm^2)	Vibration Amplitude (μm)
Mentor	27,000	0.017	145
Lysonix	22,500	.02	132
SMEI	20,000	.011	240
VASER	36,000	.011	75

Create a suspension of fat cells

- Once the fat is loosened from the tissue matrix, it is mixed with the infiltration fluid to form a **Suspension**, that is, a thorough mixture of cells and fluid.
- This is done through **Acoustic Streaming**, which are powerful fluid forces caused by ultrasound energy.
- In the region around the vibrating tip, these forces cause intense localized swirling to further break up the fat into small clusters of cells. The clusters are well suited for Autologus Fat Transfer.



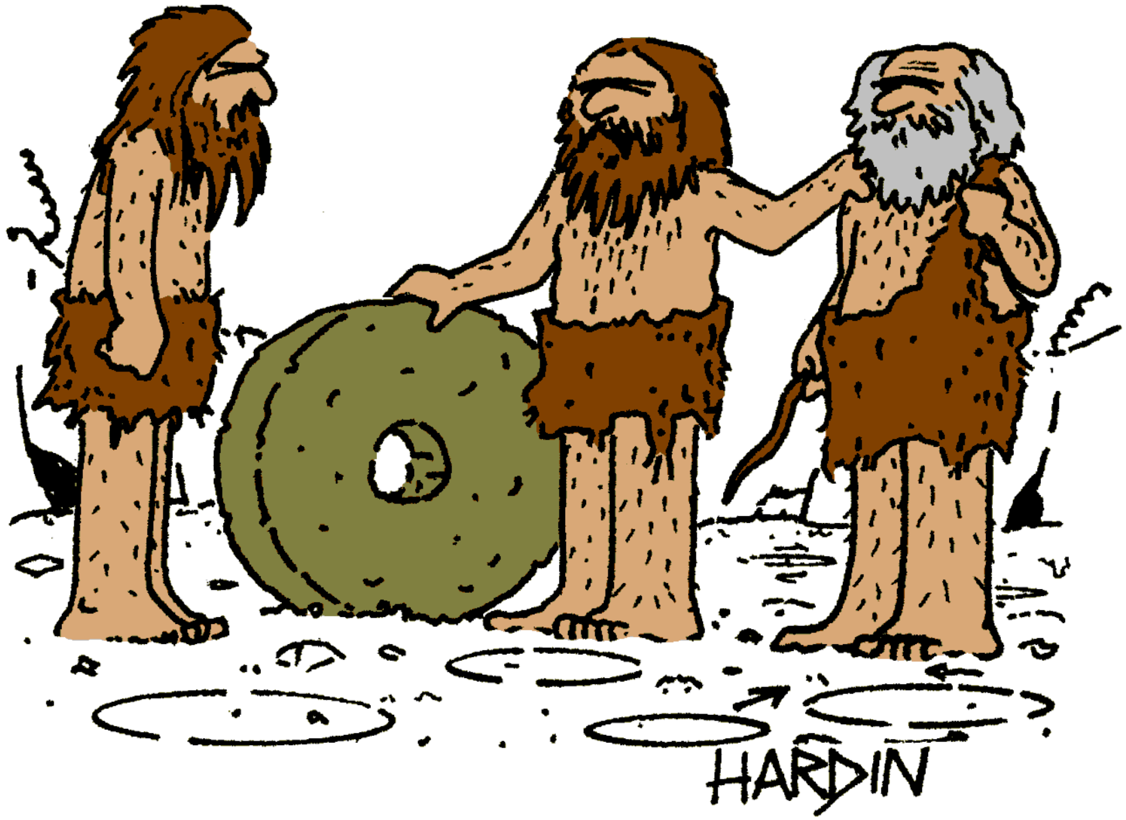
Thus Liposuction requires a different analysis with different parameters

Where do we go from here?

- Multi-dimensional analysis: Combining Acoustic energy, cutting, thermal characteristics, and ???
- Despite the marketing, basic physics still apply
  - For example, don't get all twisted up about Torsional
- Better information on current modes
  - New measurements and simulations
  - Attempt to account for all energy domains
- Provide users with meaningful metrics
  - Derive energy in equivalent Joules
  - Compare data between machines, tips, modes
  - Goal will be on-screen "power" values, replacing "EPT", "Avg Power" and "CDE"
  - Allow for better understanding of energy input and clinical outcome

Summary

- Ultrasound is an amazing technology applicable to a wide range of medical applications, including diagnostic, therapeutic, surgical (and cosmetic)
- Work over the past 20 years has allowed for a better understanding of the mechanisms behind ultrasound surgical technologies
- By combining information from different test methodologies, we can develop a holistic approach to device design and use



"To be honest, I never would have invented the wheel if not for Urg's groundbreaking theoretical work with the circle."

Thank You!

Acknowledgments: Bausch &Lomb, Abbot Medical Optics, Terry Devine, MD, Swarthmore College, University of Washington Omnisonics Medical Technologies