Infrared Thermal Imaging During Ultrasonic Aspiration of Bone

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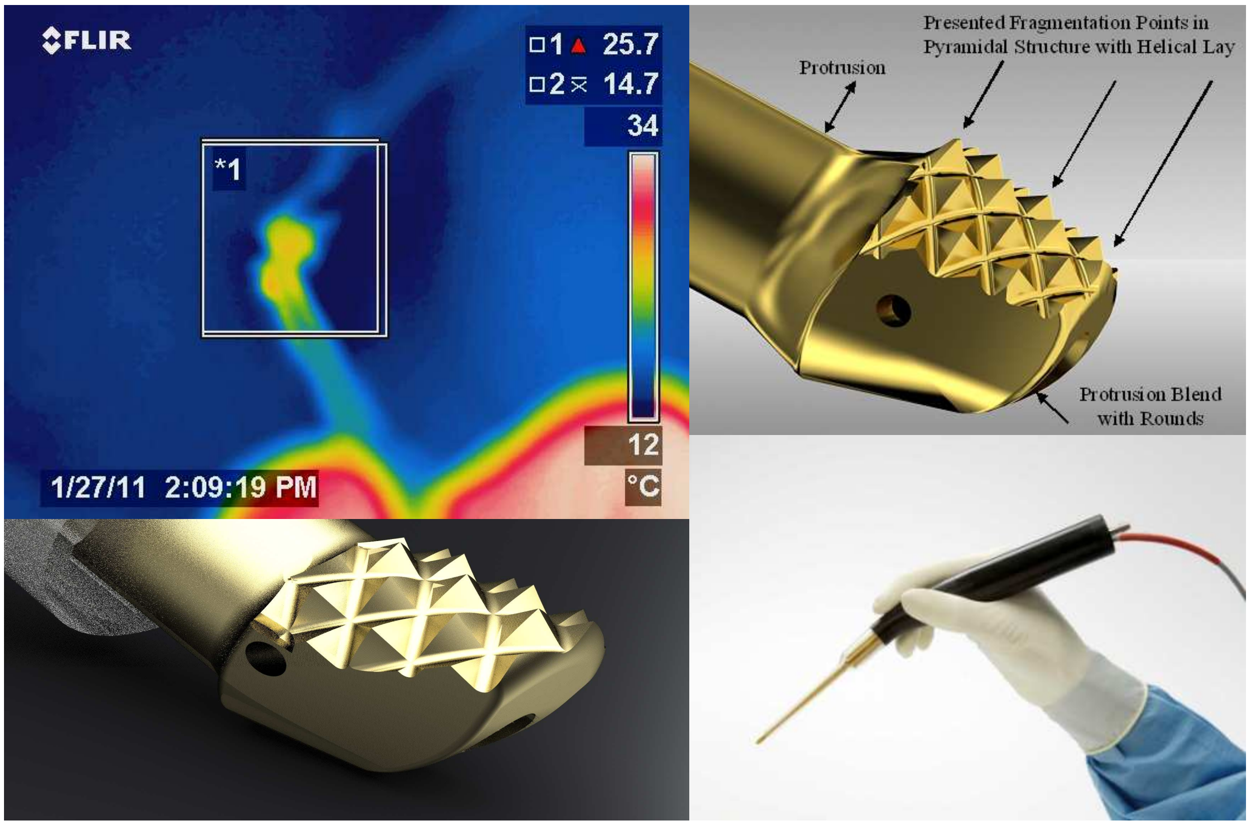

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LIMIT UNCERTAINTY

Outline:

- **Background**
  - Ultrasonic surgical aspiration
- **Ultrasonic Horns (Surgical Tips) for Bone Applications**
  - Approaches to brain tumors and aneurisms
  - Protruded surgical bone tips of improved geometry, visibility, and efficacy
- **Ultrasonic Horn Development**
  - Modified Kleesattel Gaussian (Ampulla) horn basis and references
  - 1-D physical mathematical models
  - Finite Element Method Mechanica analysis and simulation
  - Essential to modeling and simulation of complex contours and geometries
  - Stroke typically predicted with 2 % to 7 % error depending on horn complexity
  - Maintenance of allowed stress to about 1/3 of material yield strength
- **Infrared Thermal Imaging During Ultrasonic Aspiration**
  - Basis studies with developmental surgical tips
  - Cadaveric section studies and statistical analysis in representative cranium tissue
- **Summary and Conclusions**

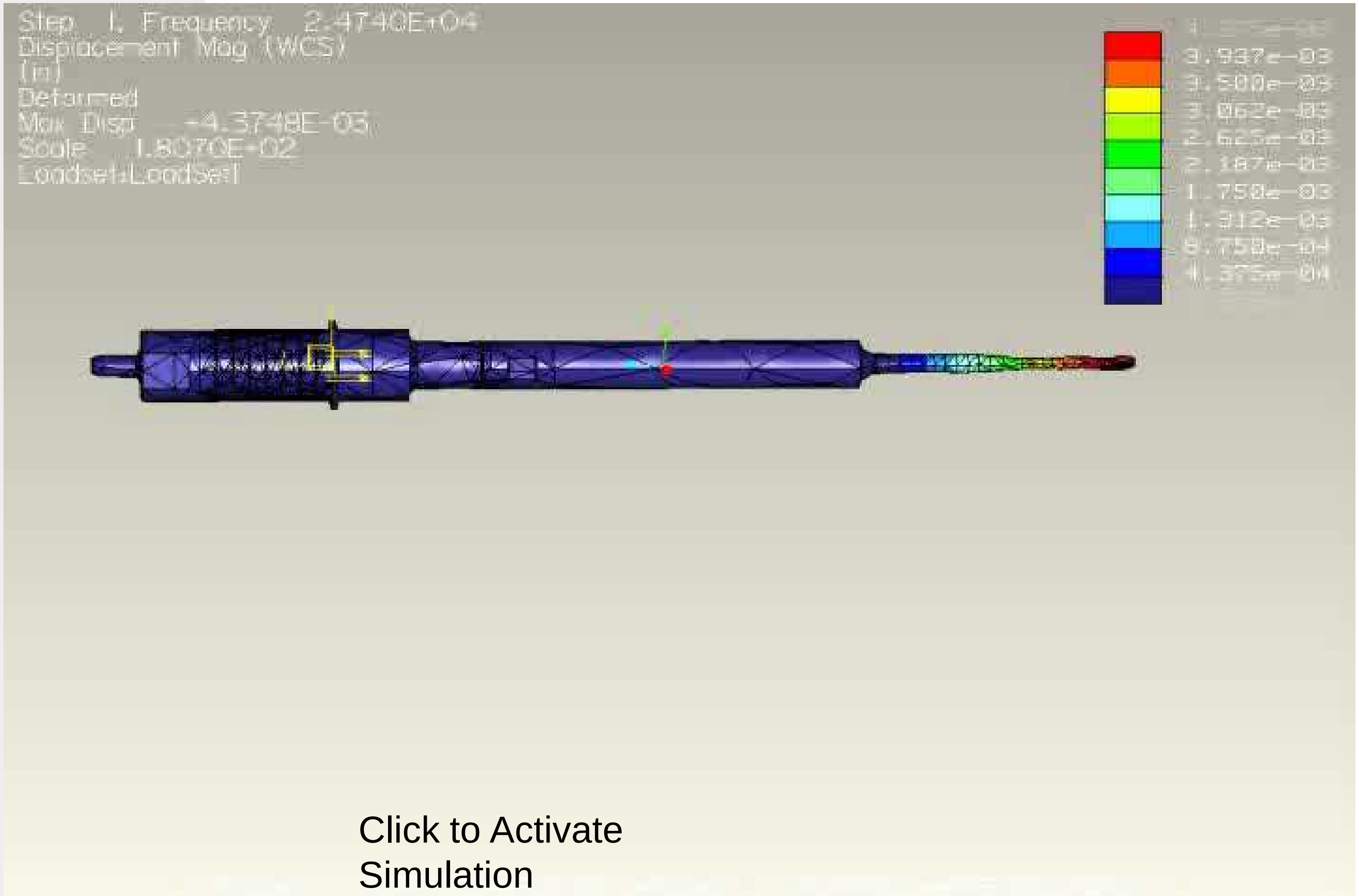
Background on Ultrasonic Surgical Aspirators

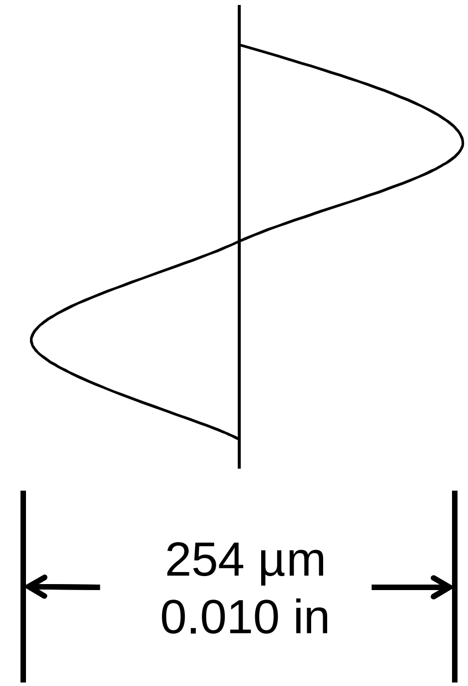
Handpieces (Transducers) and Surgical Tips (Horns)

- Removal of tumors and diseased tissue in Neurosurgery and in Liver, Orthopedic, Gynecological, and General surgery
- Employing transducers of 23 kHz to 36 kHz and horn designs more than 30 years
- Polymer irrigation flue surrounding the horn
- Continuous circuit of cooling irrigation liquid
- Dilute blood and further wet aspirated tissue
- Prevent coagulation and occlusion of central aspirating channel

Aspirating Tumor →

Mechanica Finite Element Analysis Simulation





Background on Ultrasonic Surgical Aspirators

Endoscopic-Nasal Surgery in Sphenoid Sinus Region using a Bone Tip

- Creating a cavity to aid in reduction of cranial pressure
- Removal of bone on dura
- Viewed with endoscope via second nostril

In-Progress Understanding of Ultrasound Tissue Fragmentation Mechanisms

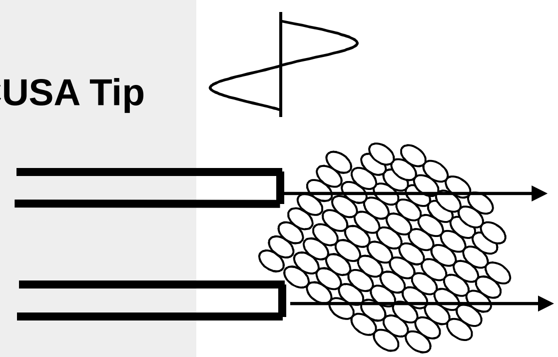
Ultrasound Tissue Interactions Commonly Described

- Momentum in mechanical impact
- Particle displacement and induced stress field
- Cavitation assisted fragmentation and emulsification

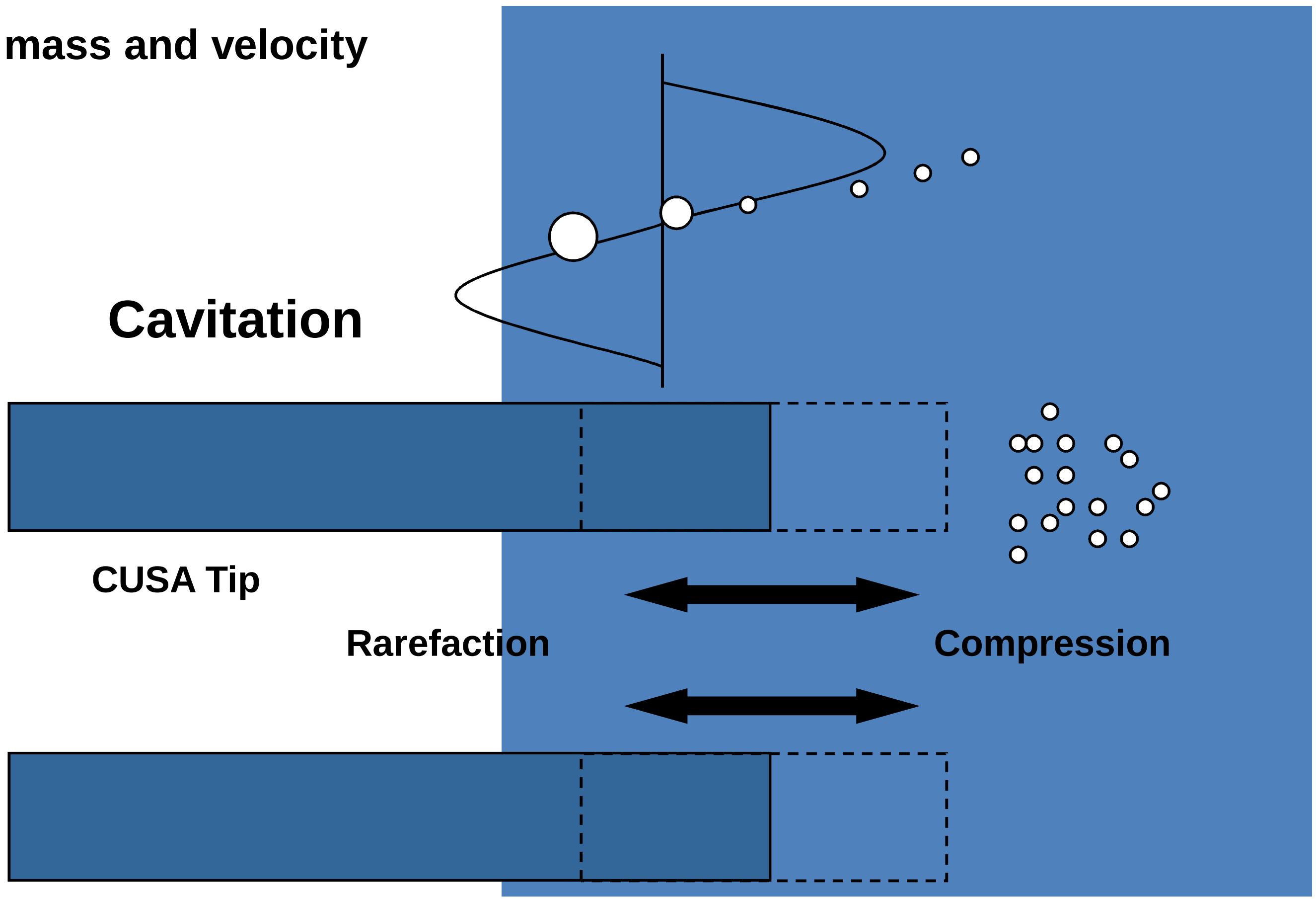
Momentum, P=mv, product of mass and velocity

"jackhammer effect"

CUSA Tip



Stress Field



$$W = F \cdot D$$

$$P_{wr} = \frac{W}{t} = \frac{F \cdot D}{t} = F \cdot V$$

$$P = \frac{F}{S}$$

$$P_{wr} = P \cdot S \cdot V$$

$$I_0 = \frac{P_{wr}}{S} = \frac{P \cdot S \cdot V}{S}$$

$$P_{wr} = V^2 Z = (A_m \omega)^2 \rho c S$$

$$P = V Z_c$$

$$Z_c = \rho c$$

$$Z = \rho c S$$

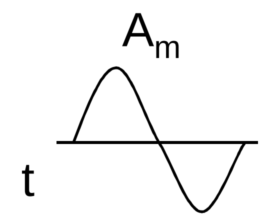
$$F = VZ$$

$$\varepsilon = A_m Sin(\omega t)$$

$$v = \frac{d}{dt}\varepsilon = A_m \omega Cos(\omega t)$$

$$a = \frac{d}{dt} v = -A_m \omega^2 Sin(\omega t)$$

$$v_{max} = A_m \omega$$



After Krautkramer, Ensminger, et al, where

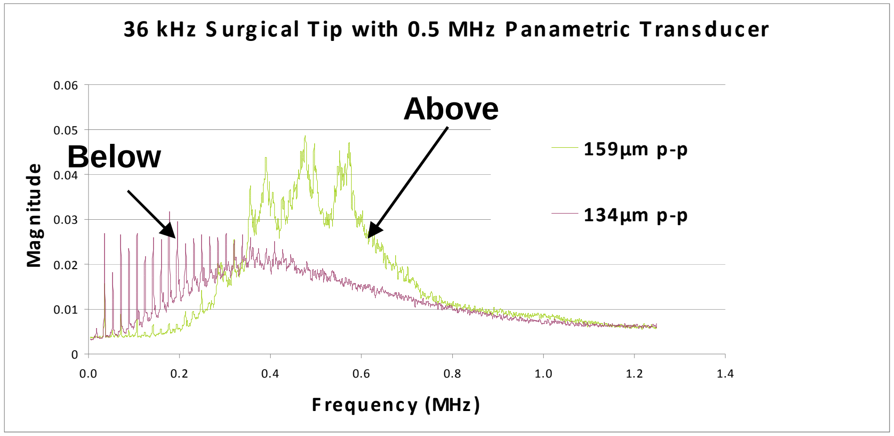
W=Work F=Force D=Distance P_{wr}=Power

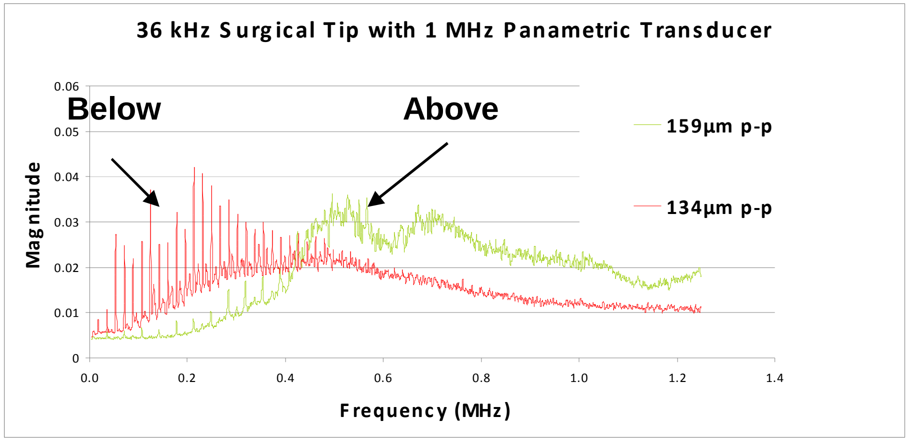
t=time V=Velocity P=Pressure S=Cross-Section Area

I_o=Intensity ρ=density ε=displacement ω= 2πf =angular frequency

f=frequency

Z_c= Characteristic Acoustic Impedance Z= Acoustic Impedance





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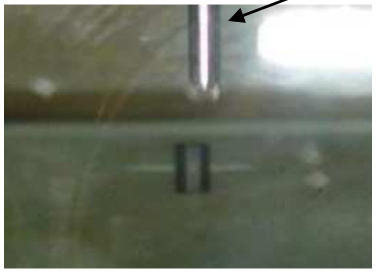


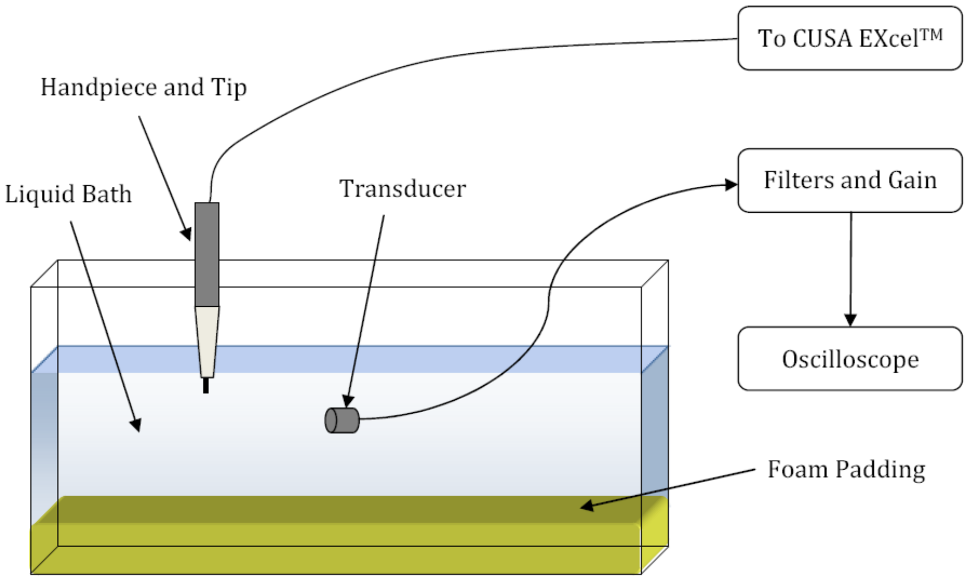
Ultrasonic Aspirator Surgical Tip in Distilled Water

Above

Broadband noise response at cavitation threshold

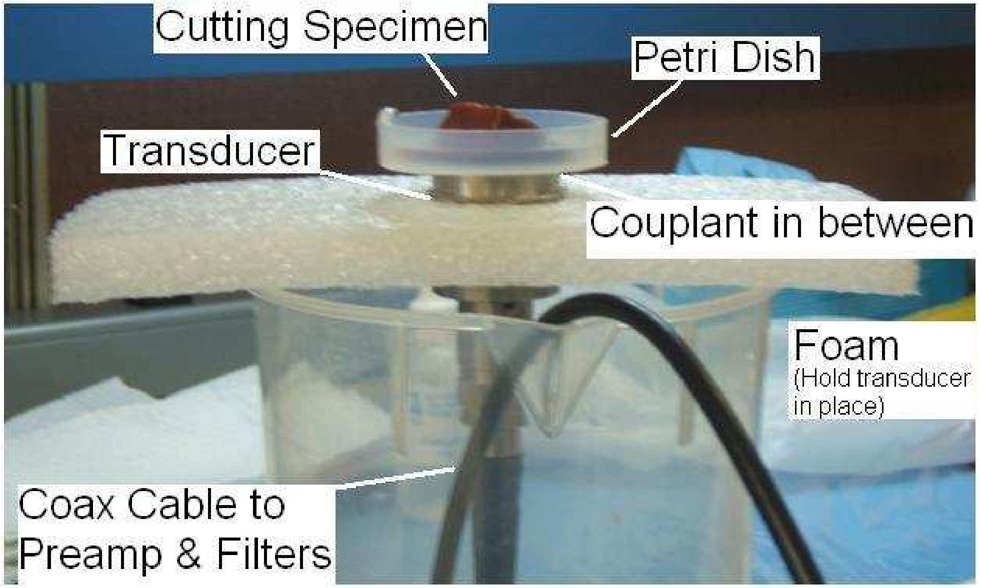
- **36 kHz resonant drive signal apparent as spikes, allowed frequencies of transducer-tip geometry and harmonics are sometimes apparent**
- **300 kHz (-6 dB) high-pass filter with spectrum magnitude averaged 100 waveforms**
- **Panametrics transducers: V301 0.5MHz/1.0 inch flat and V303 1.0MHz/0.5 inch flat**
- **Flat transducer selected for later use with tissue**
- **Broadband noise spectrum increases markedly at cavitation threshold transition**
- **Cavitation threshold is monitored with increasing surgical tip stroke peak-peak**

Instrumentation



Cavitation detection in liquid

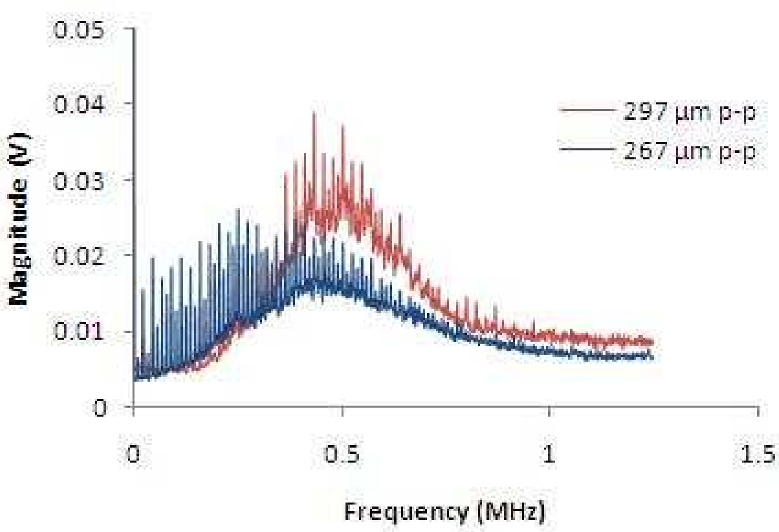
Cavitation detection in tissue



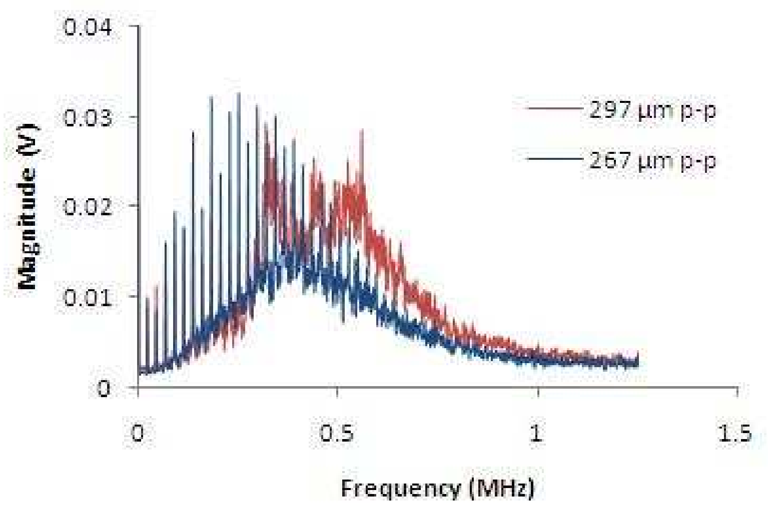
Cavitation in Tissue

- Exhibited similar “signature” to liquid
- Observed in two tissue types
- Intermittent and dynamic in tissue

23 kHz Handpiece
500 kHz transducer in liver



23kHz Handpiece
500kHz transducer in beef



Background on Ultrasonic Surgical Aspirators

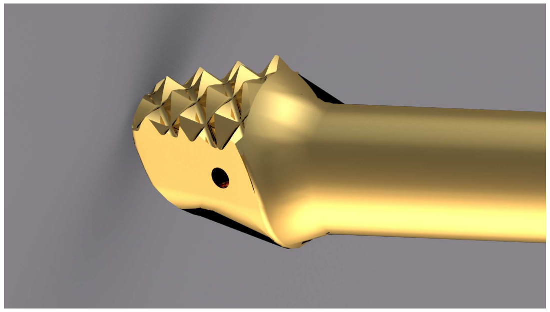
Cadaveric Section Study using a Development Bone Tip

- Bone Tip aspirating hard skull
- Thermal management of bone removal
- Neurosurgeon develops “feel” for system

Developmental Ultrasonic Bone Tips

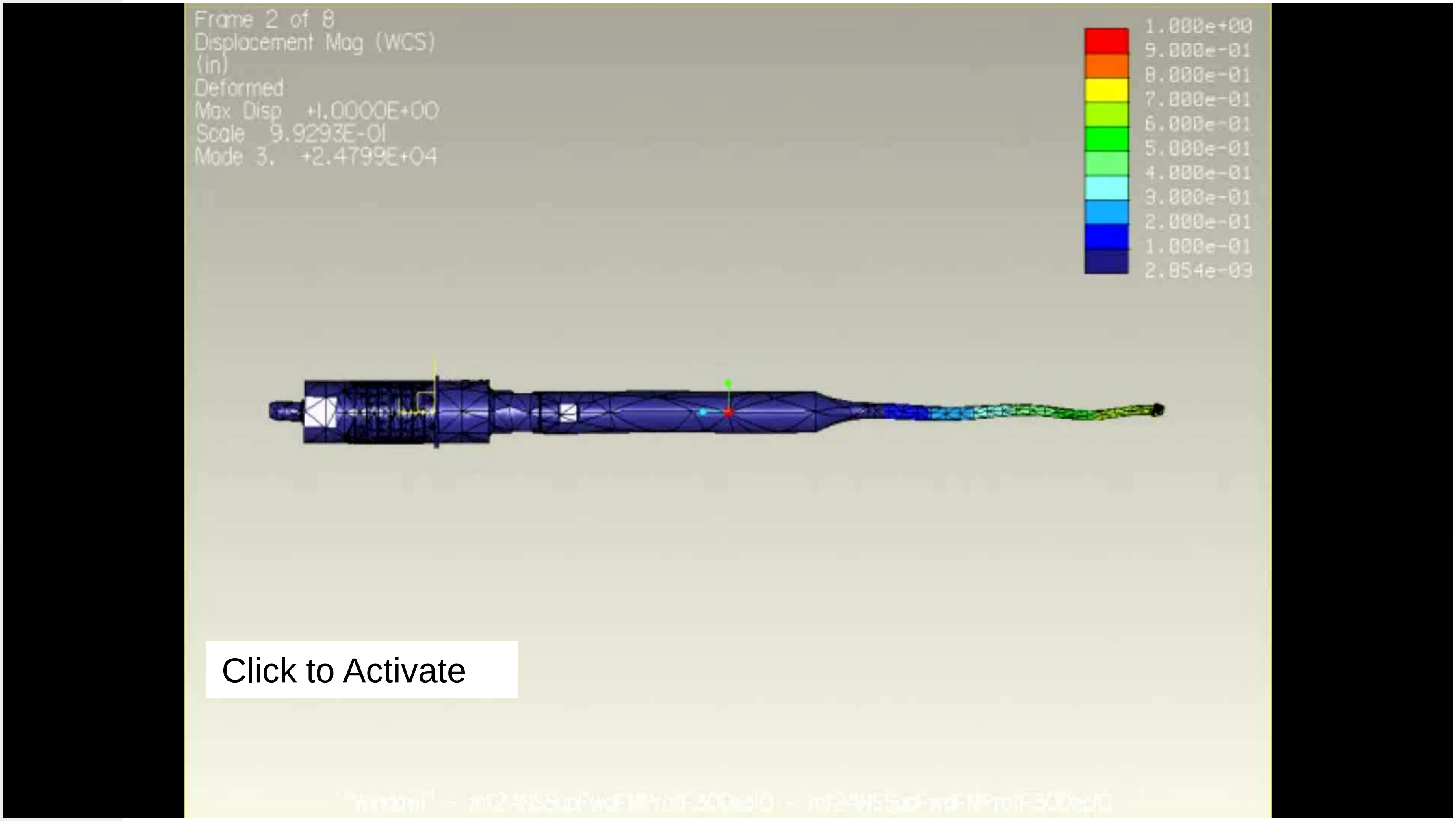
Protruded Bone Tip

- Protruded working surface for improved visibility in microscopy and endoscopy
- Relief angles to avoid any resistance to plunge cutting
- A 45° helical lay of pyramids
- Surgical tip vibrational stroke exceeding known cavitation threshold for 24 kHz ultrasound and saline irrigation liquid
- Pyramidal structure to enable interfaces with varying angled refracted longitudinal waves and stress concentration
- Reduced frictional heating
- Improved efficacy, visibility, and geometry



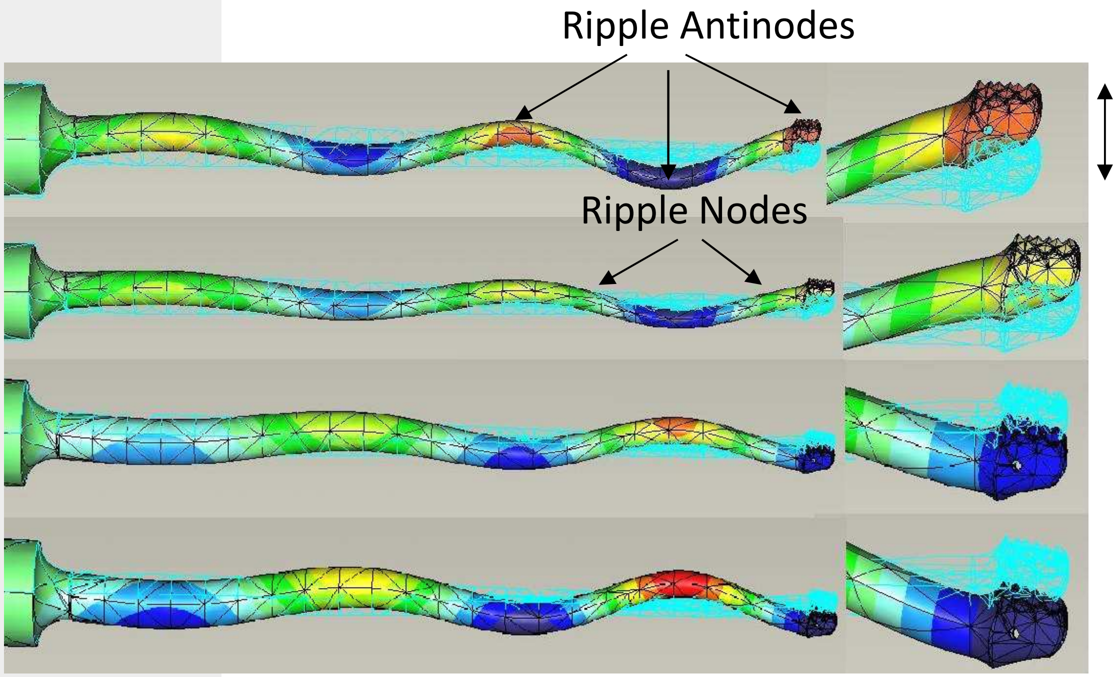
Wave Mechanics and Finite Element Method, Mechanica Simulation

Ripple, transverse motion, due to protrusion of working surface, greatly magnified



Finite Element Analysis
Developmental Surgical Tips

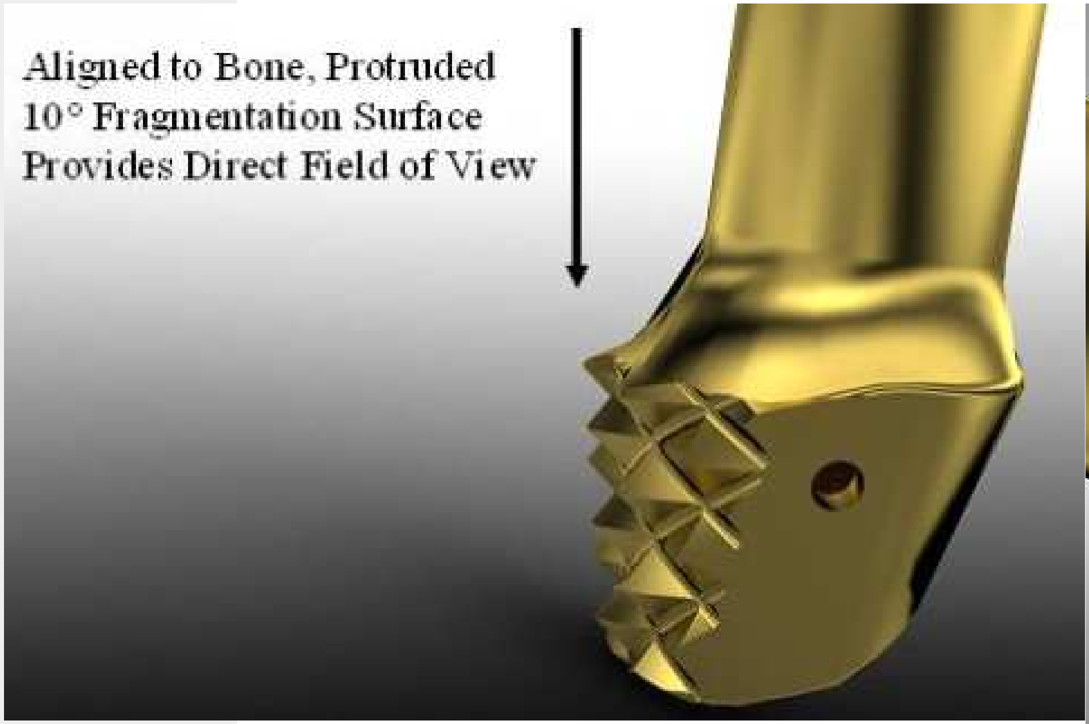
Ripple, transverse motion, greatly magnified in display

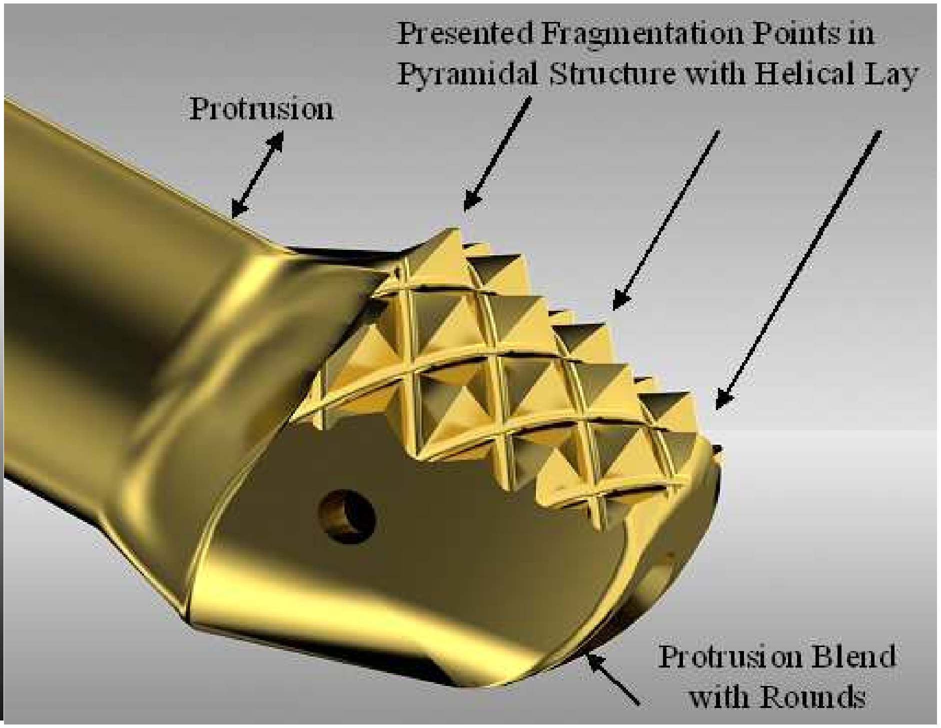


- Horn vibrates longitudinally at resonance
- Ripple, transverse motion, due to asymmetric protrusions
- Audible squealing loss of damping and cooling due to errant cavitation
- Cavitation along horn caused erosion
- Stress due to ripple and vibrational stress exceeding 345 MPa (50,000 psi)
- Premature failure of surgical tips
- Novel distal end geometry and proprietary approaches to wave mechanics managed ripple

Developmental Ultrasonic Bone Tips

Bone Fragmentation Surface Top Dead Center

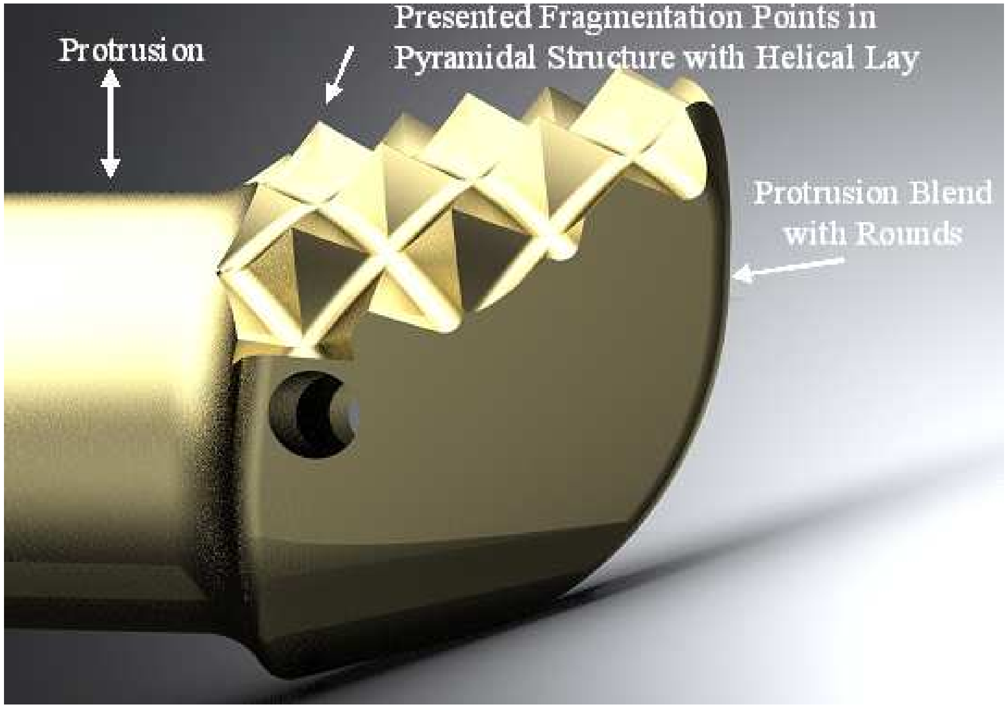




Relief exists, such that there is less resistance to cutting or cause of frictional drag and induced heating

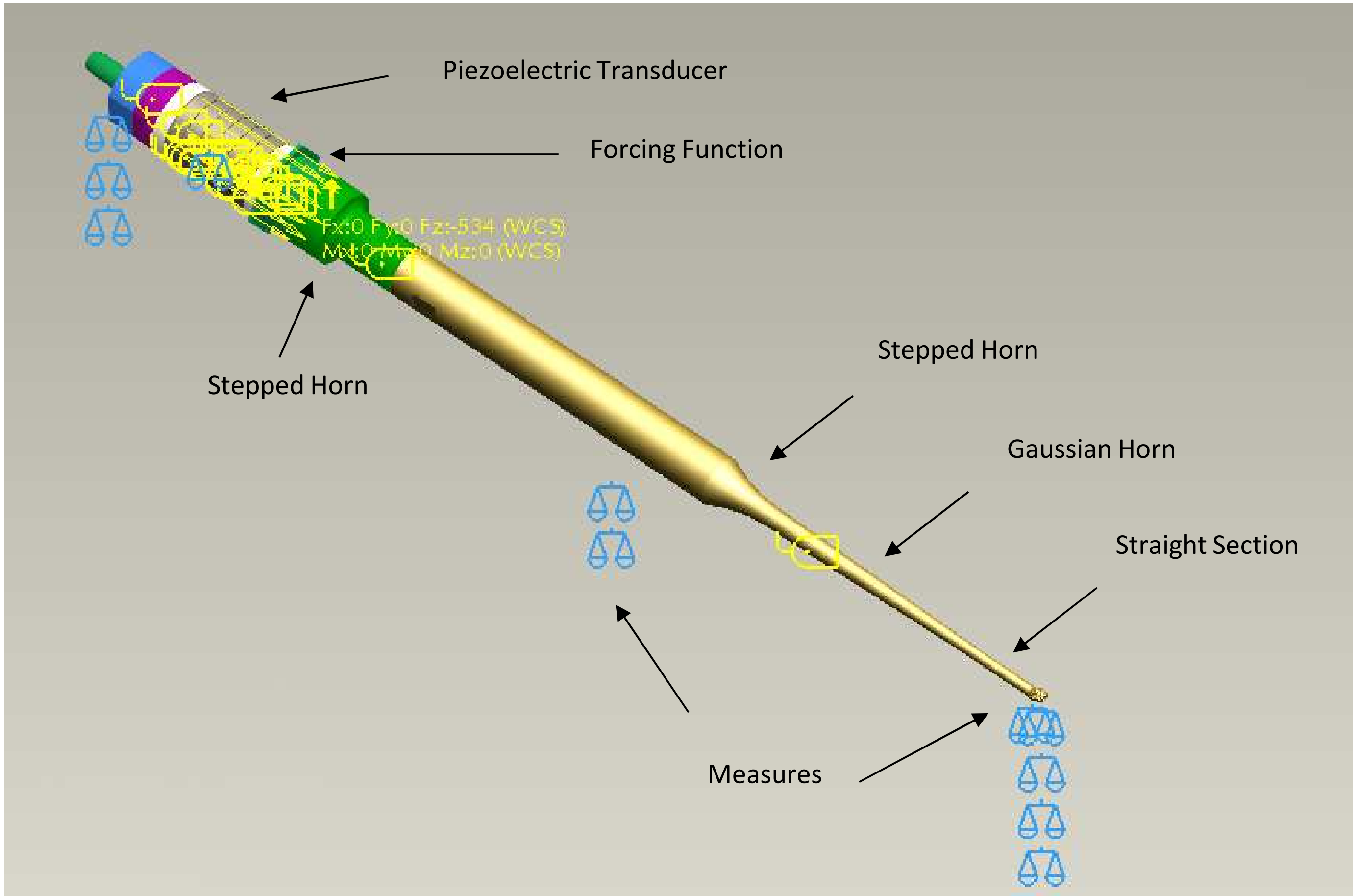
Developmental Ultrasonic Bone Tips

Bone Fragmentation Surface Up-Angled Top Dead Center



Relief exists, such that there is less resistance to cutting or cause of frictional drag and induced heating

Solid Model used for Mechanica Finite Element Analysis

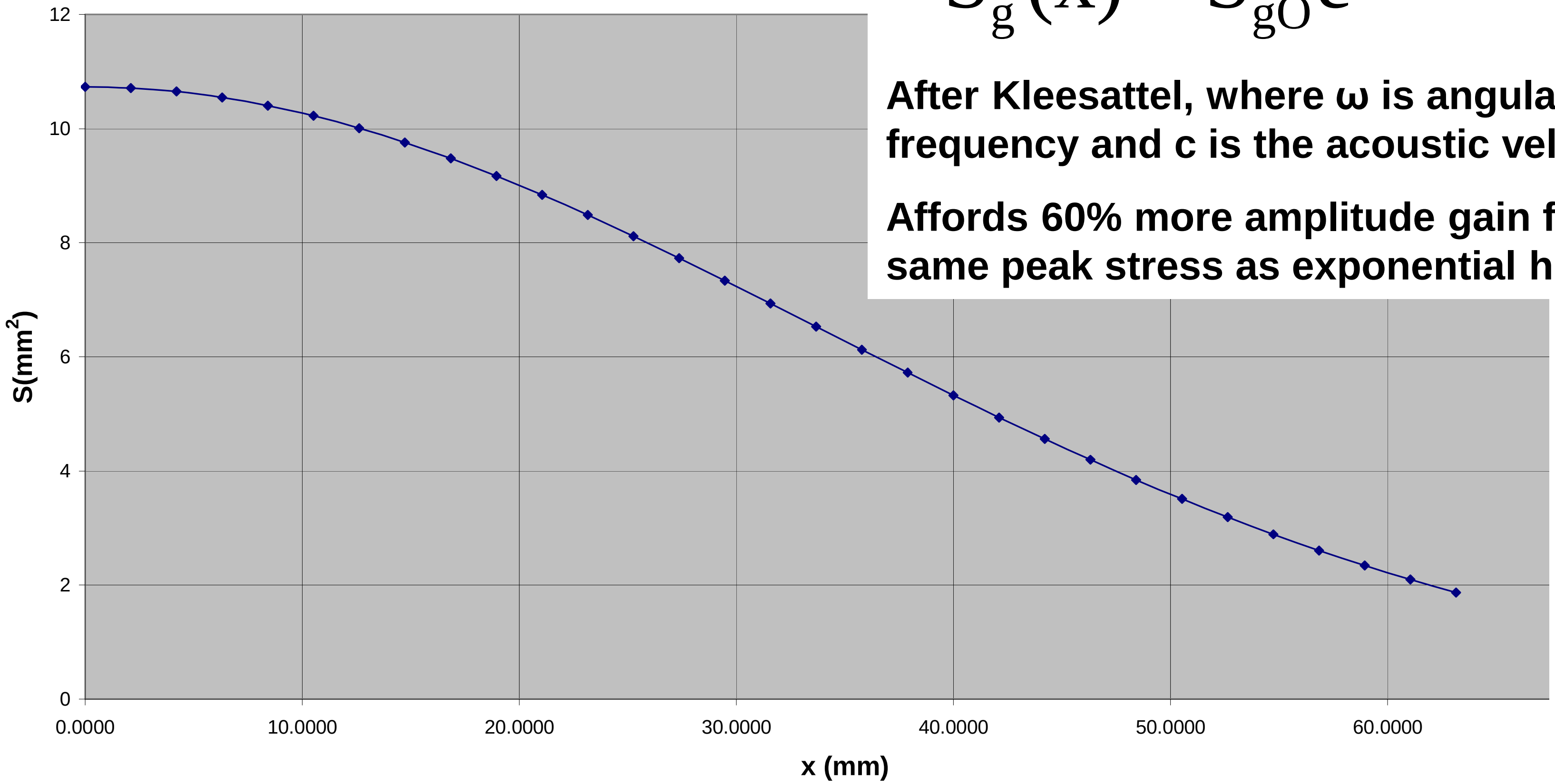


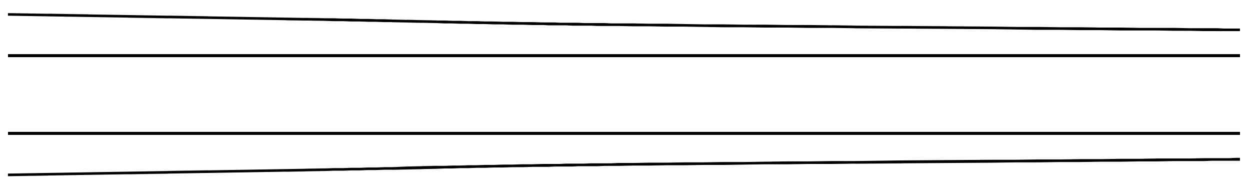
Gaussian Horn Area Function

$$S_g(x) = S_{gO} e^{-\frac{1}{2}\left(\frac{\omega}{c}\right)^2 x^2}$$

After Kleesattel, where ω is angular frequency and c is the acoustic velocity.

Affords 60% more amplitude gain for same peak stress as exponential horn.





Horn Gaussian (Ampulla) Profile

Modified Kleesattel Gaussian (Ampulla) horn basis

Gaussian Horn Profile

$$S_g(x) = S_{gO}\, e^{-\frac{1}{2}\left(\frac{\omega_i}{c_g}\right)^2 x^2}$$

Horn Gaussian (Ampulla) Profile

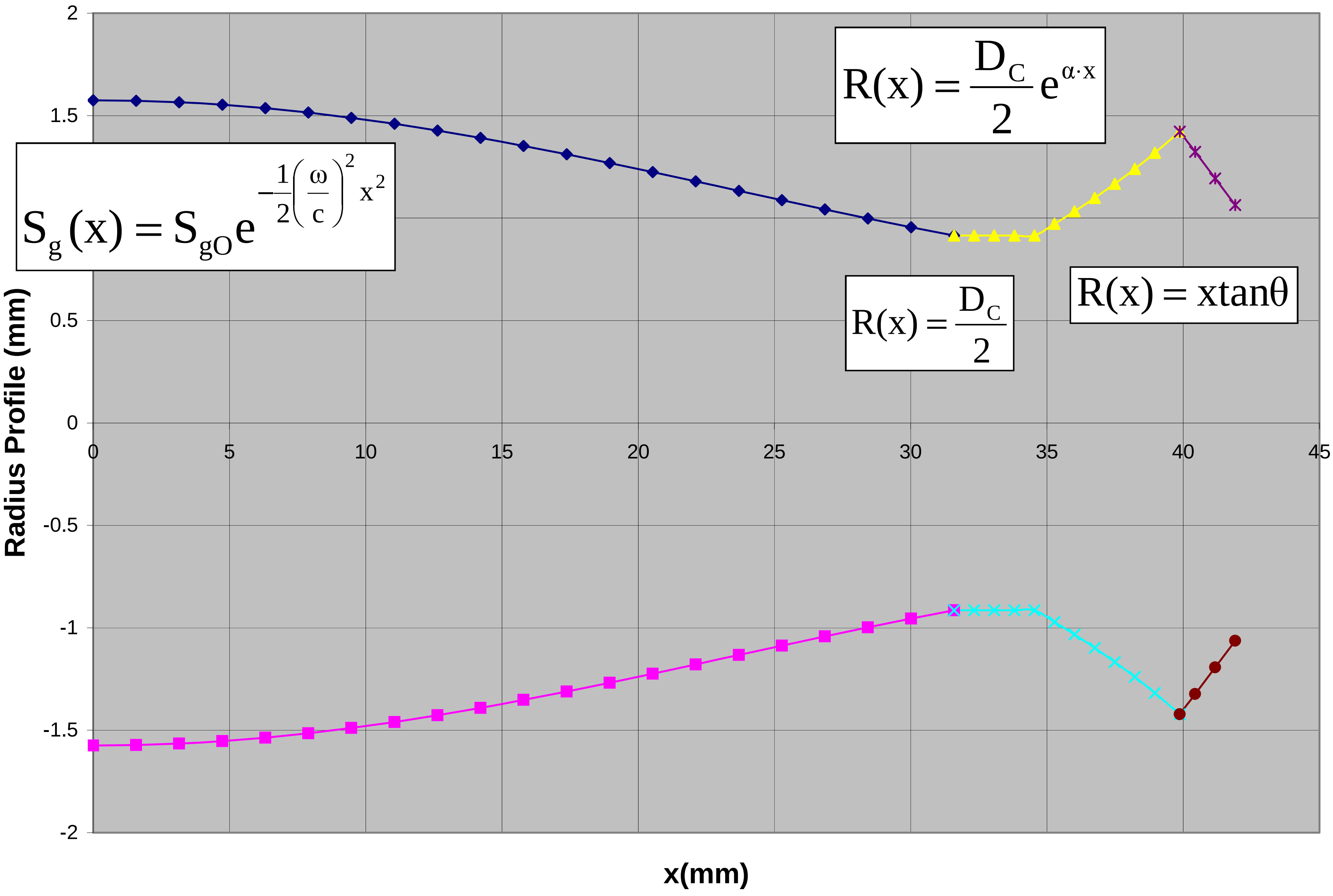
$$N = \frac{S_{gO}(\text{Area})}{S_c(\text{Area})}$$

$$\omega_i = \frac{C_g}{L_{tip}}\left(\operatorname{atan}\left(\frac{1}{\sqrt{2\ln(N)}}\right) + \sqrt{2\ln(N)}\right)$$

$$f_i = \frac{\omega_i}{2\pi}$$

After Kleesattel, where ω is angular frequency, C_g is the acoustic velocity, L_{tip} is the length of the tip, and f_i is the resonant frequency

1-D Physical-Mathematical Modeling



Global Approach to Mechanica Analysis

Half Model Surface Constraints

- Broadband Modal Analysis
  - Yields dominant modes
- Design Frequency Analysis
  - Forcing function (halve force)
  - Yields peak displacements, stresses, strains, etc

Half Model – Symmetry Constraints

- Narrow Band Modal Analysis
- Design Frequency and Master Interval Analysis
  - Forcing function with damping
  - Excellent for iterative design
  - Simulation of motion, stress and strain distribution
  - Mechanical gain, node and anti-node locations, and nodal forces

Full Model – Forcing Function

- Narrow Band Modal Analysis
  - Yields many modes for review
- Design Frequency Analysis
  - Forcing function with damping
  - Assurance of resonant peak displacement and stress data
  - At frequency steps and over analysis
  - By component and selected geometry
- Master Interval Analysis
  - About resonance
  - Simulation of motion, without artificial constraints
  - Stress and strain distribution, and data query
  - Mechanical gain, node and anti-node locations, and confirmation of nodal forces

Pro/Mechanica is a product of Parametric Technology Corporation, Needham MA

Summary of Finite Element Analysis Developmental Surgical Tips

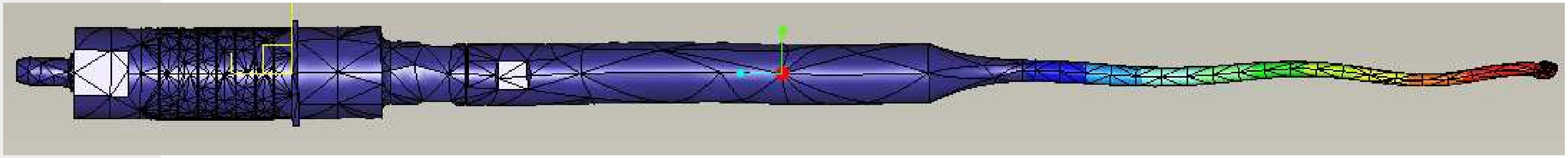
	Inverse Conical Bone Tip	Up-Angle Bone Tip	Basis BoneTip	
Input Damping (%)	0.0208	0.0163	0.0142	
Stack Displacement (µm)	3.27	3.27	3.27	**Normalized**
Horn Stroke (µm)	254	268	251	**Simulated**
Horn Stress Maximum (MPa)	276	284	266	
Horn Stress Maximum (psi)	38,680	41,280	38,550	
Resonant Frequency (Hz)	24,800	24,770	24,740	
Input Forcing Function (N)	2,380	2,380	2,380	

Electromechanical Data on Fabricated Surgical Tips

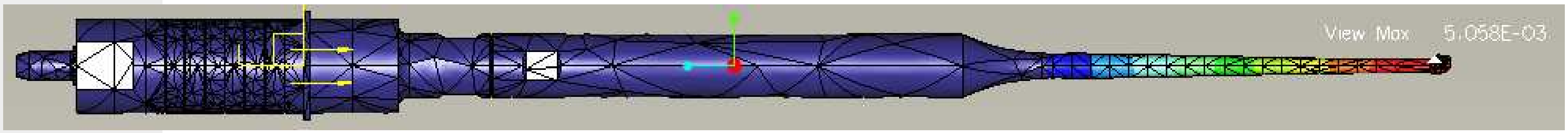
Bone Tip		**Voltage** *(V_{RMS})*	**Current** *(A_{RMS})*	**Power** *(Watts)*	**Power Factor** *(PF)*	**Frequency** *(kHz)*	**Stroke** *(in)*	**Stroke** *(µm)*	
Developmental 24 kHz Inverse Conical Bone Tip	Average	70	0.251	17	0.975	24.039	0.0093	236	**Actual**
	StdDev	8	0.006	1.98	0.016	0.046	0.0002	4	
Developmental 24 kHz Up-Angle Bone Tip	Average	71	0.250	17	0.970	23.975	0.0105	266	**Actual**
	StdDev	2	0.002	0.46	0.02	0.037	0.0002	4	
Baseline 24 kHz Bone Tip	Baseline	55	0.256	15	0.964	24.000	0.0101	256	**Actual**

Finite Element Analysis
Developmental Surgical Tips

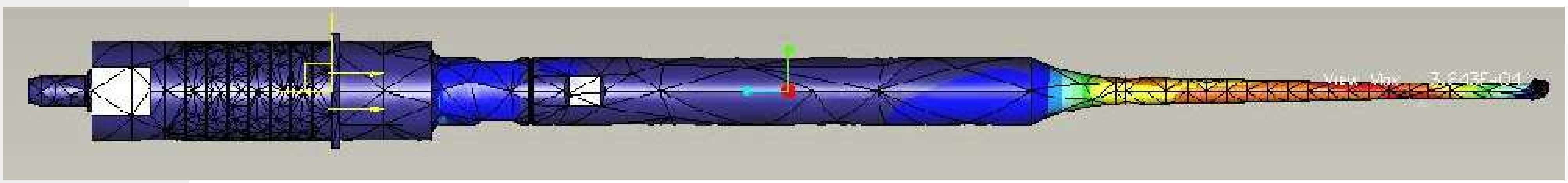
Management of Errant Ripple, Transverse Motion, and Vibrational Stress



Exaggerated display of combined motion



Surgical tip stroke 254 µm p-p (0.010 in p-p)



Transverse stress modulates longitudinal vibrational stress

Maximum stress 268 MPa (38,700 Psi) due to longitudinal vibration and transverse ripple

Developmental Bone Tip

- Eliminated objectionable audible squealing due to errant cavitation
- Minimized pitting or erosion in the metallic horn due to cavitation at ripple maxima
- Overcame loss of stability in the ultrasonic controller due to impedance change
- Eliminated loss of stroke in the surgical tip attributed to powering ripple
- Mitigated excess von Mises stresses that were concentrated at the ripple maxima
- Overcame infantile failure of horns in life-testing

Stroke Exceeds Cavitation Threshold of Saline, as low as 208 µm

Fragmentation and Abrasion

Pocine Cranium at Ultrasonics R&D Laboratory
Dr. Arle, Lahey Clinic, Burlington, MA

Clinical Studies and References Related to Potential Hazards

Clinical Studies

- K. Kim, T. Isu, R. Masumoto, M. Isobe, K. Kogure , Surgical pitfalls of an ultrasonics bone curette (Sonopet) in spinal surgery. Neurosurgery, 2006 Oct; 59(4Suppl 2).
- F. Suetsuna , S. Harata , N. Yoshimura :Influence of the ultrasonic surgical aspirator on the dura and spinal cord. An electrohistologic study. Spine 16:503-509,1991.
- W. Young, A. R. Cohen, C. D. Hunt, J. Ransohoff, Acute Physiological Effects of Ultrasonic Vibrations on Nervous Tissue, Neurosurgery, Vol. 8. No. 6, 1981.
- E. S. Flamm, J. Ransohoff, D. Wuchinich, and A. Broadwin, "A Preliminary Experience with Ultrasonic Aspiration in Neurosurgery", Neurosurgery. 2:240-245;1978.

Additional References

- International Standard, IEC 61847, Ultrasonics-Surgical Systems-Measurement and declaration of the basic output characteristics, 1998-01.
- NCRP Report No. 74, Biological Effects of Ultrasound: Mechanisms and Clinical Implications, Dec. 30, 1983.
- P. A. Ridderheim, C. von Essen C, and B. Zetterlund: Indirect injury to cranial nerves after surgery with Cavitron ultrasonic surgical aspirator (CUSA): Case report. Acta Neurochir (Wien) 89:84–86, 1987

Investigation of Potential Hazards

Considerations for Discussion

- Ultrasound is mechanical in nature and its biological effects are described in the literature based on mechanical stresses, thermal mechanisms, and cavitation
- There are at least two concerns regarding potential hazards to adjacent critical anatomy in ultrasonic aspiration: heating and propagation of ultrasound are of concern
- It is clear that excess acoustic power, such as in highly loading a surgical tip to tissue, can cause localized heating
- Less is known about the propagation of ultrasound from the surgical tip in biologic tissue and across boundaries or membranes, and its influence on specific critical anatomy

Recent Studies

- Infrared thermal imaging during ultrasonic aspiration
- Vibrating ultrasonic surgical tip temperature measurement
- Neural monitoring during ultrasonic aspiration
- Complementing ultrasound output characterization, such as pressure and intensity, and calorimetry

Technical Interaction on CUSA

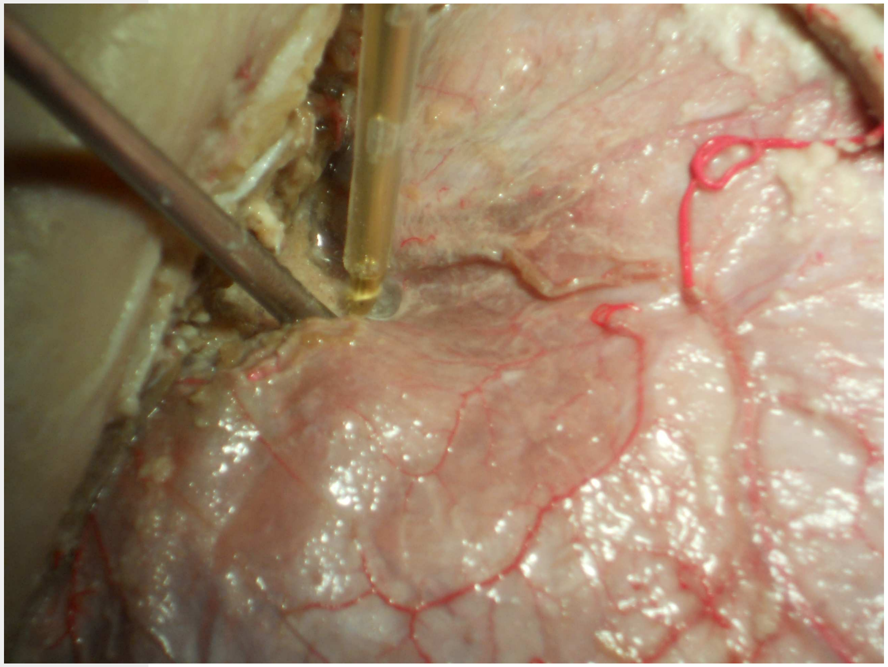
Dr. Theodore H. Schwartz of Weill Cornell Medical College and New York-Presbyterian Hospital
His Fellow Dr. Graeme Woodworth of John Hopkins, Baltimore, Maryland

- Comparison of ultrasonic bone removal and mechanical fluted and diamond drills
- Region of lesser sphenoid wing of cadaveric section
- Initial measurements conducted with infrared thermal microscopy
- An initial setup trial and 3 repeated trials of each instrument removing bone for less than 2 minutes
- Power data acquired continuously under Labview control via Yokogowa WT- 210 Digital Integrating Power Meter
- Maximum absolute temperature reading taken manually during bone removal in field of view with FLIR Infrared Camera, ThermaCAM P45HSV
- Infrared emissivity and temperature measurement validation conducted in advance for bone over range of interest

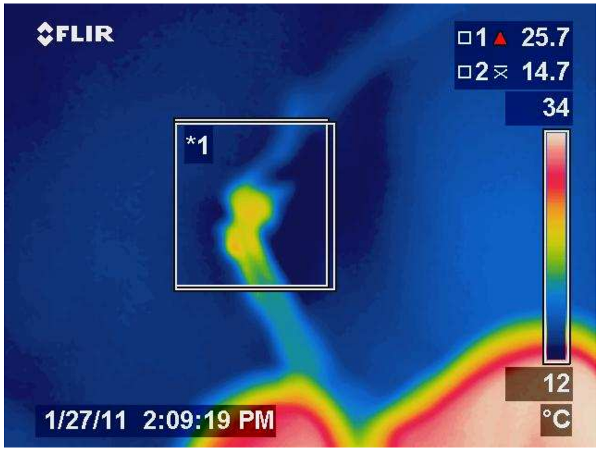
Non-contact Infrared Thermal Imaging

- Infrared thermal imaging was validated for tissue, specifically for bovine muscle, liver, and bone
- ThermaCAM P45HSV Infrared Camera from FLIR Systems Inc.
- Validation included comparing infrared measurements to surface placed and embedded miniature thermocouple measurements
- Emissivity was characterized as materials were removed from a thermal bath and cooled, such that data were obtained over the range of temperature of interest
- ASTM Standard (E1933-99a) for IR emissivity compensation uses single point contact temperature measurement and single IR temperature of dry samples at stable temperatures, as simplification
- Reference, “Bone Emissivity,” by L. D. Stumme et al, within temperature range of 37°C-60°C average emissivity was 1.01 +/- 0.034 over range of 0.94 to 1.06 for samples of human bone
- Every 0.01 the emissivity varied from true value an error of 0.1°C resulted, and this produced an error of 1.2 ° C over the range measured
- Our data for dry bone and bone wetted yielded emissivity about 1.0, with error of IR and miniature thermocouple maximum of 2.5 °C from 36°C to 60°C
- Dynamic system with bone drying over measurement and thermocouple experiencing different thermodynamics
- We plan additional work with isothermal bath and circulated saline liquid on bone to support future clinical efforts

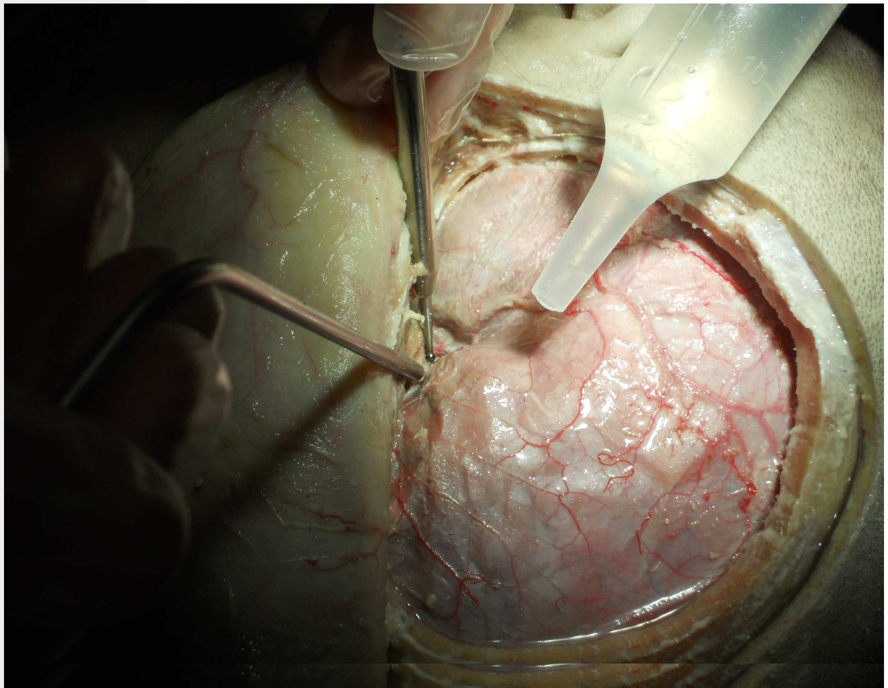
Efficacy in Ultrasonic Bone Aspiration Enables Thermal Management

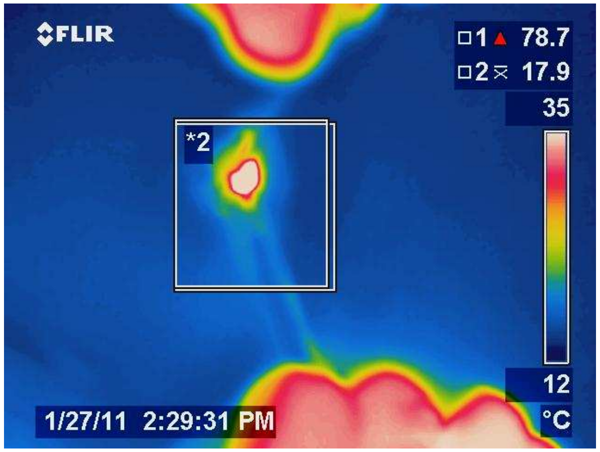


Ultrasonic Bone Tip



Application of Development Bone Tip in Sphenoid Wing



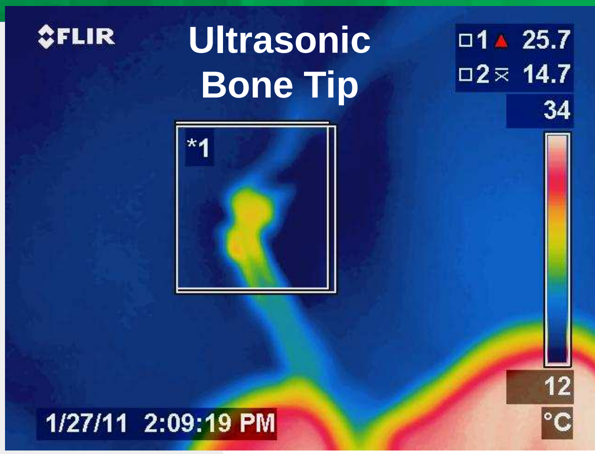


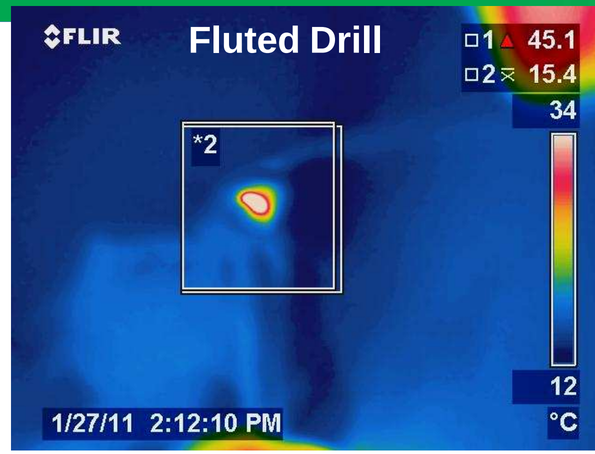
Mechanical Diamond Drill

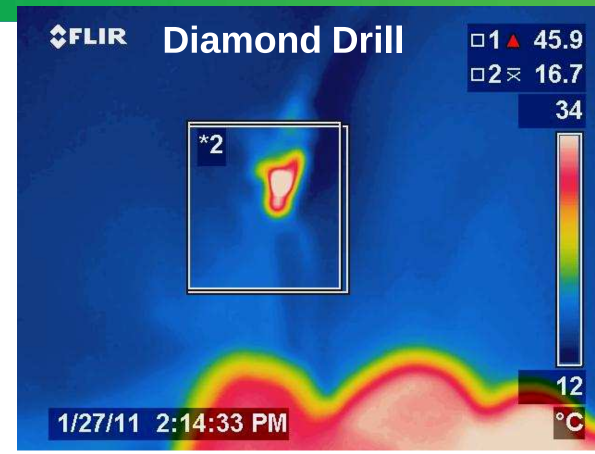
Principal concern with drill was high speed rotary cutting near critical anatomy and wind-up of tissue

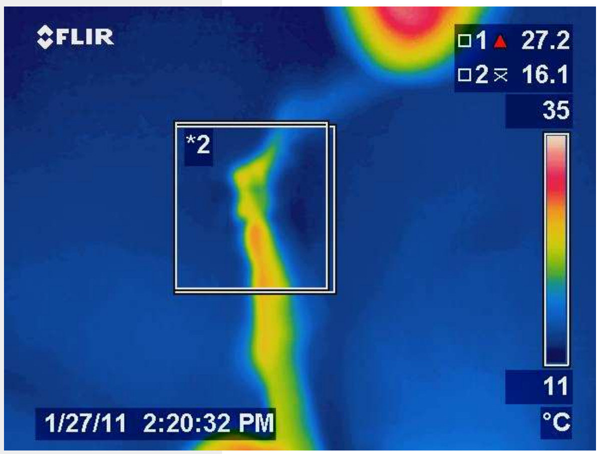
Thermal issues with mechanical drills were not expected

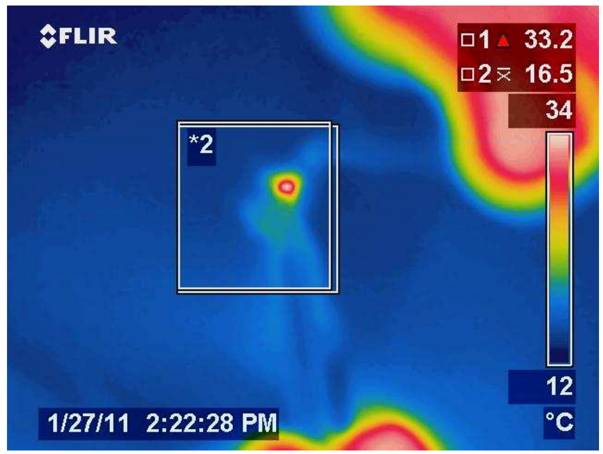
Development Bone Tip and Mechanical Drills

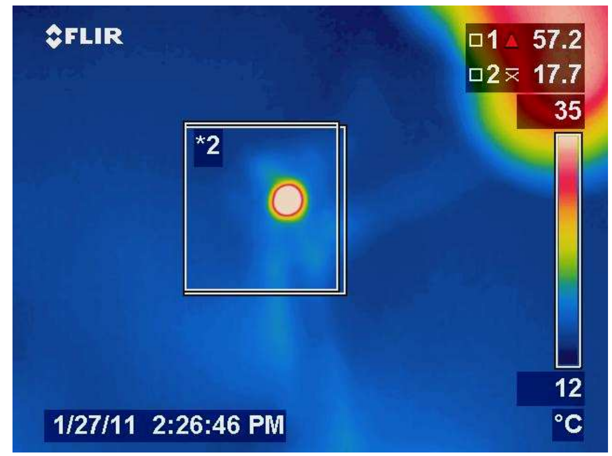


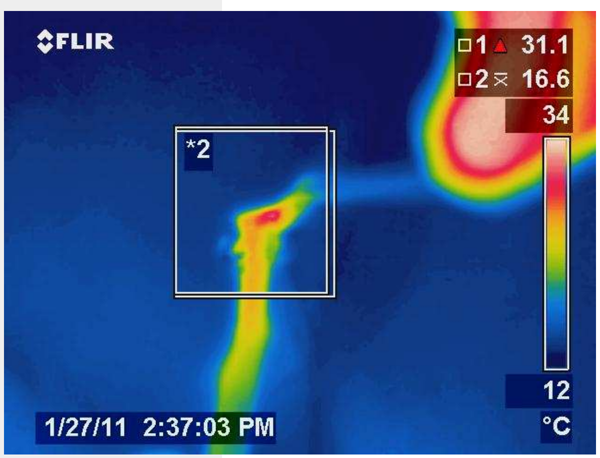


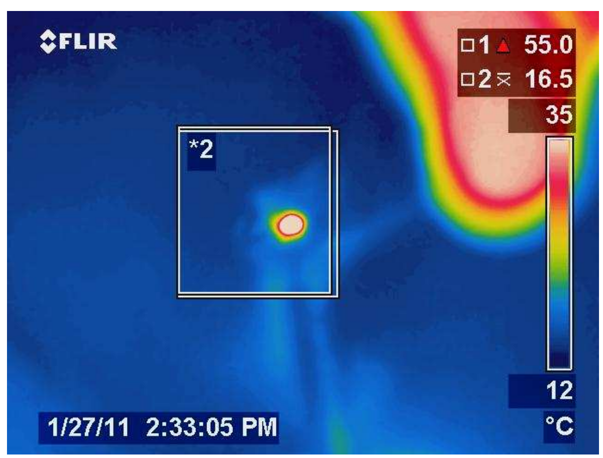


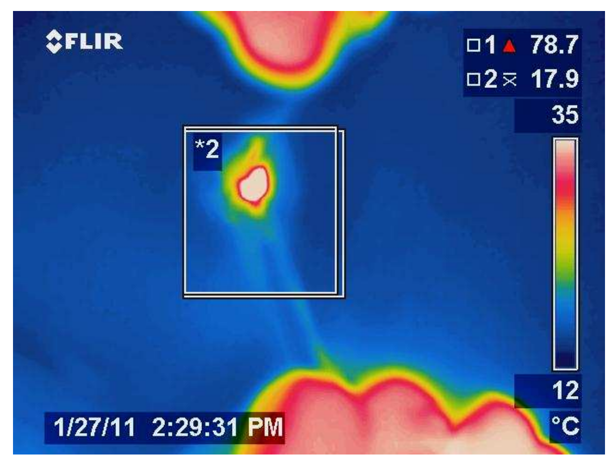












Tabulated Thermal Data

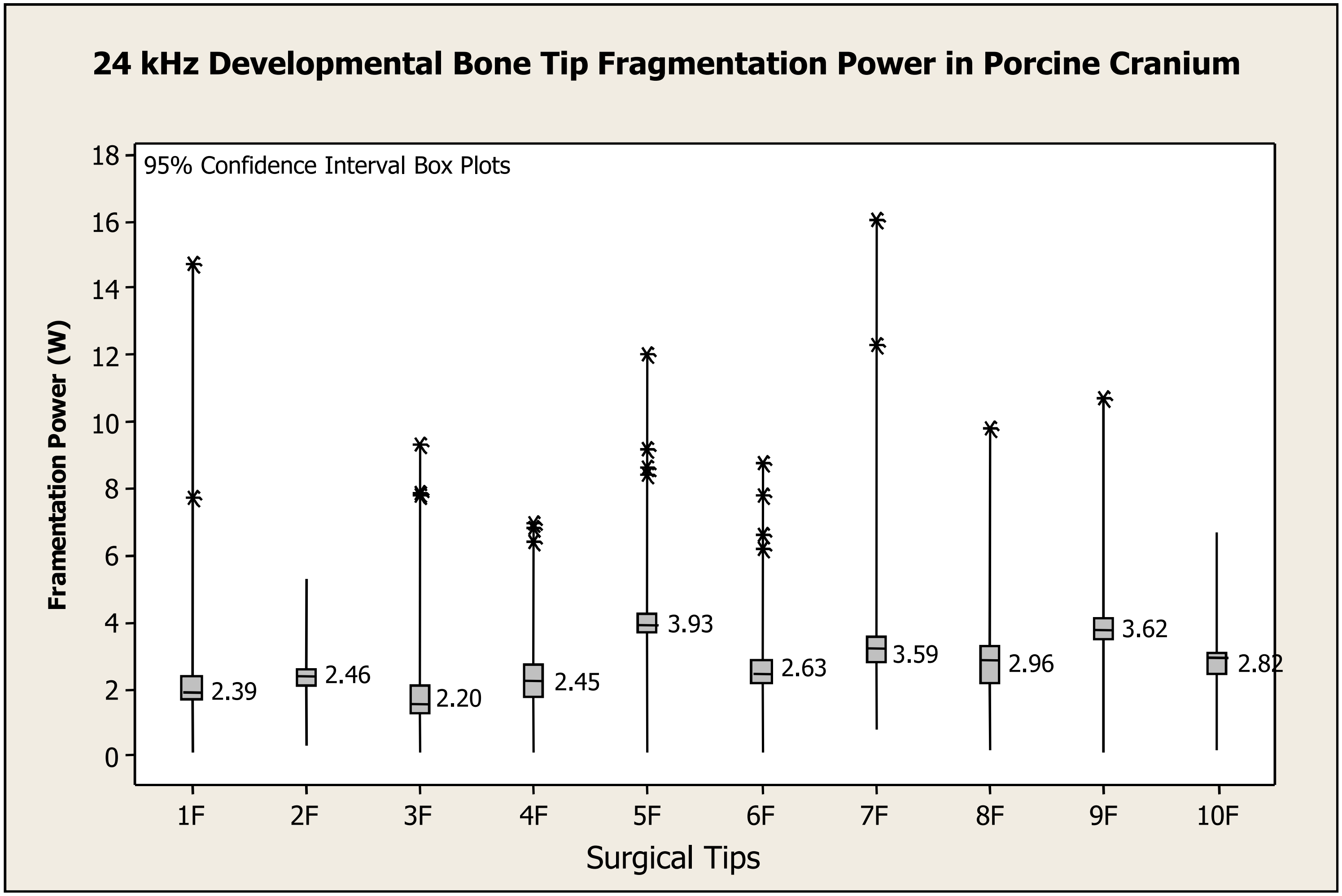
Maximum Absolute Temperature during Bone Removal			
	Trial A (°C)	Trial B (°C)	Trial C (°C)
Ultrasonic Bone Tip	24.6	24.8	24.2
	25.6	27.0	31.1
	24.0	27.2	26.5
Fluted Drill	45.0	29.9	39.4
	45.9	33.2	28.1
	69.4	33.2	55.0
	44.2		50.7
			35.7
Diamond Drill	37.4	49.0	26.4
	40.3	22.8	59.3
	45.0	57.1	45.5
	45.0	46.0	78.5
		47.8	

- Maximum absolute temperature data recorded in field of bone removal for 3 trials in lesser sphenoid wing of cadaver section
- Data are extracted from manually recorded images
- A criteria discussed in bone necrosis in drilling is temperature exceeding 56°C for 10 seconds, reference, Pearce et al. Basis study is believed to be Moritz et al, showing irreversible damage at 56°C for 10 seconds and necrosis at same temperature at about 20 seconds.
- In some applications of removing bone, necrosis is of less concern

Technical Discussion on Cadaveric Section Study

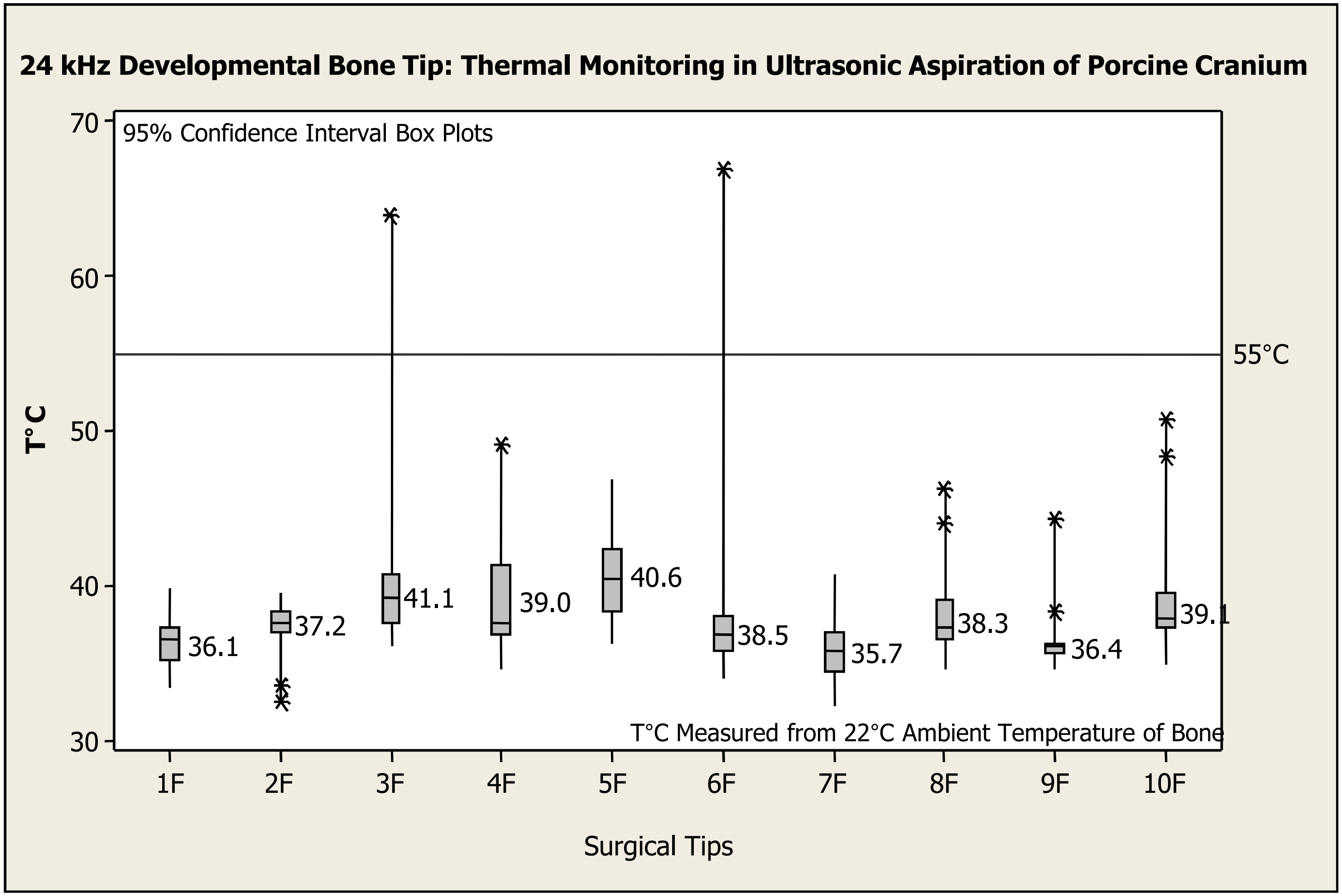
- Ultrasonic bone tip had lower temperature than mechanical fluted and diamond drills in precision bone removal studied
- Surface thermal spread will continue to be monitored, but extent of thermal rise is associated with heated irrigation liquid, and is below normal body temperature
- It should be noted, precision removal, where trained surgeon limits loading and thermal hazard was monitored, and this is consistent with instructions for use
- Maximum fragmentation power measured in precision ultrasonic bone removal in cadaveric section was less than 6 Watts
- Results indicate a safe practice could be developed in the present application
- Of course, each application and proximity to sensitive critical anatomy would have to be considered and further developed by the surgeon
- A more statistical approach needed given sparse bone tissue in sphenoid wing and investigation of thermal rise contribution to body temperature is of interest

Data from Testing in Integra Neurosurgery Ultrasonics Lab



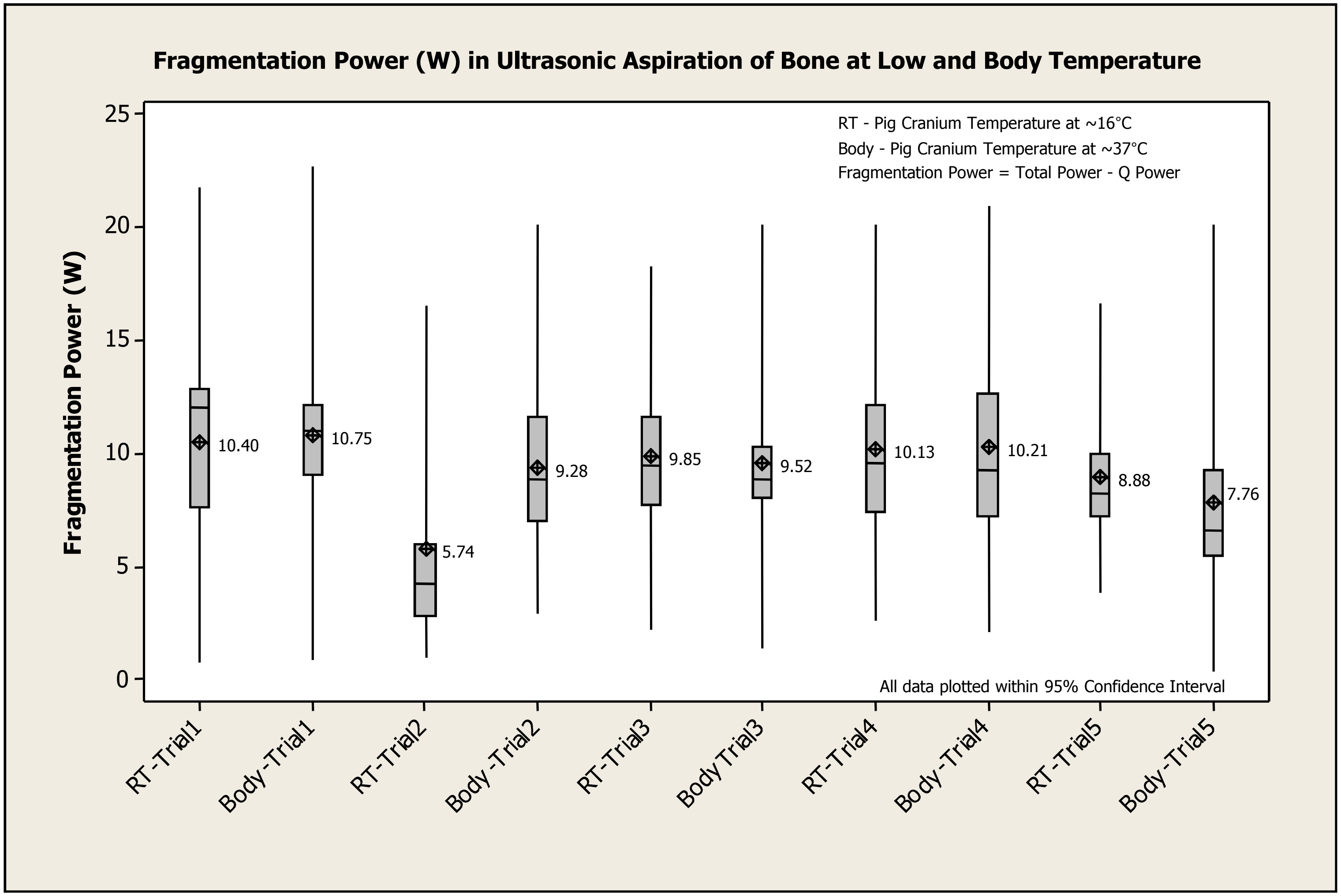
- Power measured for 10 developmental 24 kHz Bone Tips fragmenting porcine cranium
- Data points within the box represent 95% confidence interval
- Two minutes of bone aspiration per sample, with 1 measurement per second
- Mean power measured less than 4 Watts
- Elevated power measurements, shown as outliers with an asterisk, are of 1 second duration, and correspond to excess loading

Data from Testing in Integra Neurosurgery Ultrasonics Lab



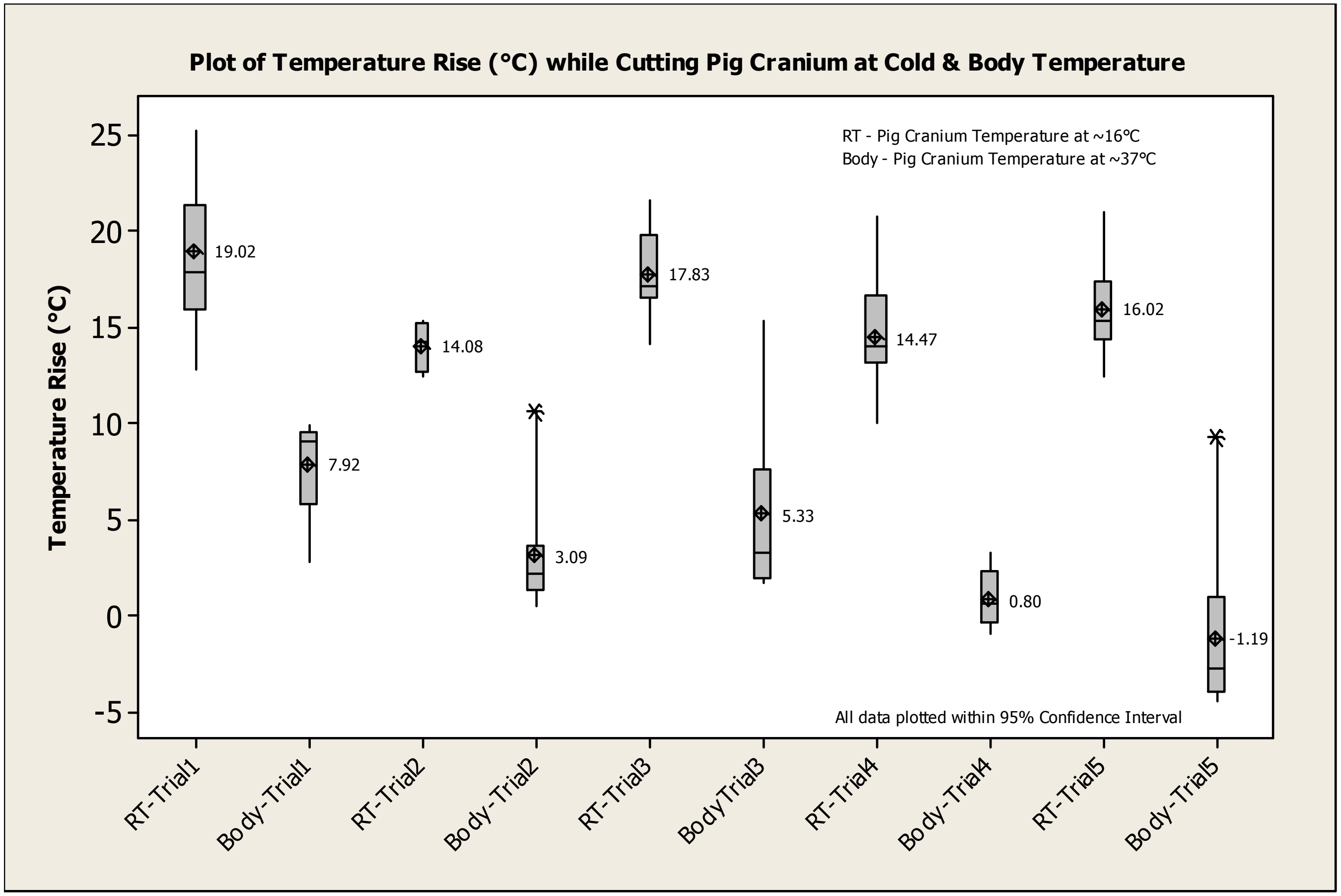
- Absolute temperature measurement based on non-contact infrared thermal monitoring
- Mean temperature at surgical site less than 41.1°C for developmental 24 kHz Bone Tips
- Two occurrences above 55°C, believed to correspond to excessive loading
- Box represents 95% confidence interval and those indicated with asterisk are outliers
- One thermal image every 6 seconds, or 20 measurements per 2 minutes of bone aspiration

Data from Testing in Integra Neurosurgery Ultrasonics Lab

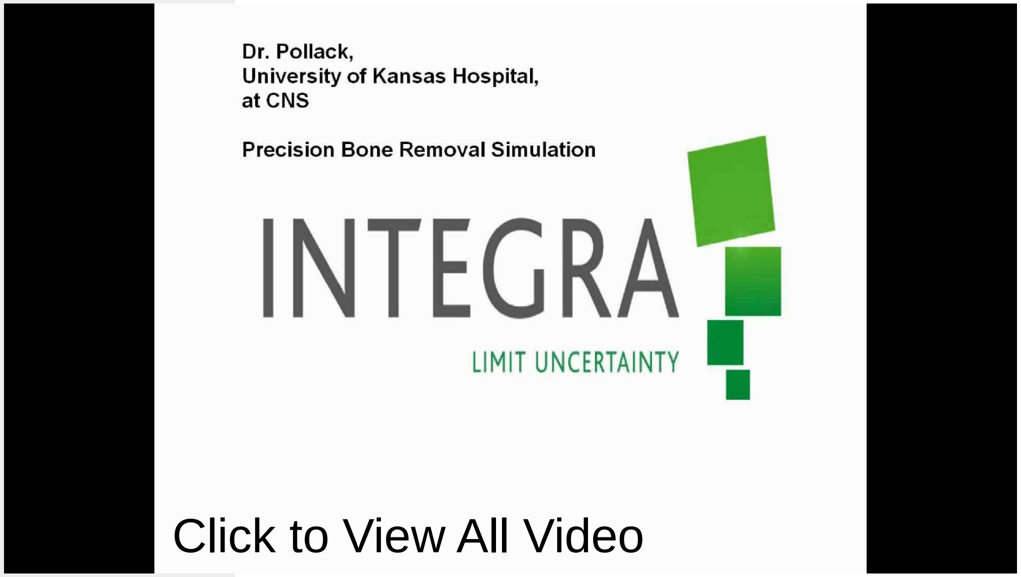


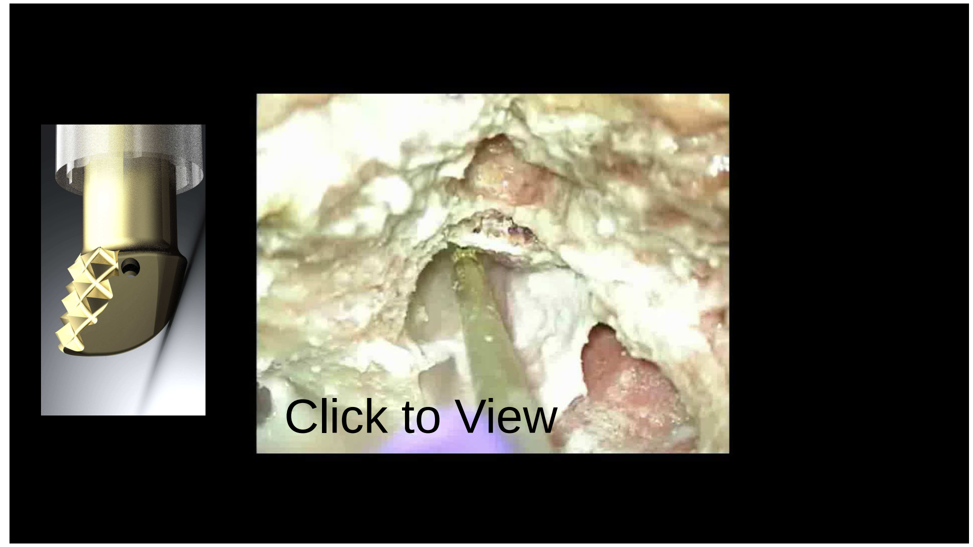
- Thermal rise and power monitored in repeated trials using the 24 kHz Development Bone Tip with porcine cranium starting at low temperature and body temperature
- Similar ultrasonic power observed in fragmentation for two thermal starting conditions

Data from Testing in Integra Neurosurgery Ultrasonics Lab



- Thermal rise monitored in repeated trials using the 24 kHz Development Bone Tip with porcine cranium starting at low temperature and body temperature
- Thermal rise with similar ultrasonic power is less significant at body temperature than when starting at lower temperatures
- Thermal rise quantified is not strictly additive to body temperature: an important result in support of future testing and reporting

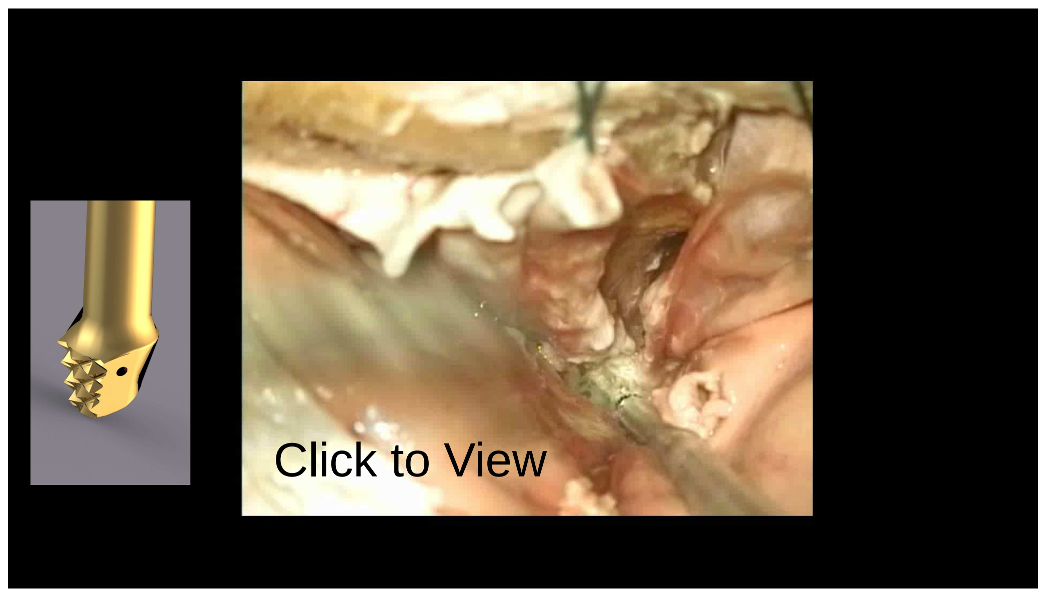




Bone Ridges and Opening in Periorbital Bone
Dr. Padalino, SUNY Upstate Medical University

Anterior Clinoid Process Bone Removal

Dr. Deshaies, SUNY Upstate Medical University



Reference, Wikipedia and they reference Gray's Anatomy

Infrared Thermal Imaging During Ultrasonic Aspiration of Bone

Summary:

- Background
- Ultrasonic Horns (Surgical Tips) for Bone Applications
  - Improved geometry, visibility, and efficacy
- Ultrasonic Horn Development
  - Stroke typically predicted with 2 % to 7 % error depending on horn complexity
  - Maintenance of allowed stress to about 1/3 of material yield strength
- Infrared Thermal Imaging During Ultrasonic Aspiration
  - Ultrasonic bone tip had lower temperature than mechanical fluted and diamond drills in precision bone removal studied
  - It should be noted, precision removal, where trained surgeon limits loading and thermal hazard was monitored, and this is consistent with instructions for use
- Coupled with statistical treatment of data in further testing, results indicated a safe practice could be developed
- Of course, each application and proximity to sensitive critical anatomy would have to be considered and further developed by the surgeon

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Infrared Thermal Imaging During Ultrasonic Aspiration of Bone

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Viscoelastic Tissue Fragmentation

Rupture and Failure of Viscoelastic Materials

- Reference J.D. Ferry, Viscoelastic Properties of Polymers
  - Hookean solids, stress is proportional to strain, but independent of strain rate
  - Viscous liquids, stress directly proportional to rate of strain, but independent of strain itself
  - Viscoelastic materials typically have a time-dependent stress-strain relationship
  - To induce rupture of viscoelastic material, subject it to high tensile or shear stress, and shear with high strain rates and high velocity gradients
- Reference Y.C. Fung, Biomechanics
  - Biologic tissues are viscoelastic
  - Collagen is basic structural element of soft and hard tissue
  - Fibrils, organized in bundles of fibers, and fibers to tissue
  - Disc nucleus pulposus, Type II collagen cartilage like tissue
  - Elastin is nearly linearly elastic, e.g., ligament flavum of spine is mostly elastic
  - Source of elasticity must be decrease of entropy or increase in internal energy
- Reference C. R. Hill, J. C. Bamber, and G. R. ter Haar, Physical Principles of Medical Ultrasonics
  - Bamber references J.D. Ferry and discusses simplified Voigt model combining stress due to bulk modulus, E, or shear modulus, G, and strain ,ε, ($\sigma=\varepsilon E$ or $\sigma_s=\varepsilon G$) and stress due to viscous loss, where η is viscosity ($\sigma=\eta d\varepsilon/dt$ or $\sigma_s=\eta_s d\varepsilon/dt$), but acknowledges over simplification

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