36 kHz Ultrasonic Surgical Horns for Endoscopic-Nasal Approaches to Brain Tumors


Integra Radionics, Burlington MA, USA
Outline:

• **Background**
  – Ultrasonic surgical aspirators and clinical applications
  – Modified Kleesattel Gaussian (Ampulla) horn basis and references

• **Generation of new horn profiles**
  – 1-D physical mathematical models

• **Solid Model FEM (Finite Element Method)**
  – 3-D Mechanica analysis and simulation
  – Essential to modeling and simulation of complex contours with asymmetric geometries
  – Half model approach utilizing constraints and a base excitation
  – Full model approach utilizing a forcing function with damping and no artificial constraints
  – Stroke typically predicted with 3 µm or 2 % error
  – SaberTip stroke predicted within 8 µm or 6.5 % error
  – Both methods of FEM analysis indicate allowed stress at or below baseline surgical horns employed for 10 years
    – Allowed stress about 1/3 yield strength of materials
    – Resonant frequency target attained in fabrication

• **Results**

• **Summary and Conclusions**
Background on Ultrasonic Surgical Aspirators

Ultrasonic Surgical Aspirators and Horns (Tips):

• Removal of tumors and diseased tissue in neurosurgery, general surgery, gynecological, liver, spine, and some orthopedic applications

• CUSA EXcel utilizing 15 horns (surgical tips) of 36 kHz and 23 kHz, and these horns have been used in surgical applications for 10 to 30 years

• Polymer irrigation flue surrounding the horn and two pre-aspiration holes located in proximity to the distal end

• Continuous circuit of cooling irrigation liquid

• Dilute blood and further wet aspirated tissue

• Prevent coagulation and occlusion
Background on Ultrasonic Surgical Aspirators

Extensive References in Planned IEEE UFFC Transactions Paper

- References on ultrasonic aspirators and endoscopic nasal approach
  - C. Kleesattel, Acustica 12[1962],322.
Extensive References in Planned IEEE UFFC Transactions Paper

• References on surgical bone tips
Extensive References in Planned IEEE UFFC Transactions Paper

- References on modeling and general applications
Newly Released Surgical Tips

- **Extended MicroTip Plus**
  - Supports the fullest extent of brain surgery through the nose in endoscopic-nasal, transsphenoidal, or neuroendoscopy approaches

- **SaberTip**
  - Cutting or abrading bone encountered given approaches to deeper regions of the brain, extending openings in bony cavities, or sectioning bone to reveal underlying surgical sites
36 kHz Extended MicroTip Plus

Extended MicroTip

Extended MicroTip Plus

121 mm

72 mm

193 mm

5.5 mm

3 mm

Extended Small Diameter Satisfies Some “Port” Surgery and Neuroendoscopy Applications

Approximately 12.5° Curved Extender

Less than 2 mm
36 kHz Ultrasonic Surgical Horns for Endoscopic-Nasal Approaches to Brain Tumors
As abrasive pad angle becomes greater, surgical tip must be angled greater to normalize to bone surface, and the 10° inverse cone is a compromise.

- Avoids protrusions and sharp edges that may present a greater hazard in insertion.
- Smooth contours and pyramids nearly fully formed but dull, like a knurl.
- Smooth contour of distal end and local major diameter of exponential aid in parting soft tissue in the approach to the surgical site.
- Pre-aspiration holes enable use in other than vertically down orientation.
- Combines bone tip functionality with an aspirating surgical tip.
Background:

- Endoscopic-Nasal Surgery in sphenoid sinus region using SaberTip
- Creating a cavity to aid in reduction of cranial pressure
- Removal of bone on dura
- Viewed with endoscope via second nostril
• Nominally, 35,750 Hz target resonant frequency
• Resonant system: core-stack, button, connecting body, and tip (horn)
Horn (Surgical Tip)

- Horn Extender
- Stepped Horn
- Gaussian
- Line of Sight
- Straight
- Flared Exponential
- Inverse Conical

36 kHz Ultrasonic Surgical Horns for Endoscopic-Nasal Approaches to Brain Tumors
After Kleesattel, where $\omega$ is angular frequency and $c$ is the acoustic velocity. Affords 60% more amplitude gain for same peak stress as exponential horn.

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

36 kHz Ultrasonic Surgical Horns for Endoscopic-Nasal Approaches to Brain Tumors
Gaussian Horn Profile

36 kHz Ultrasonic Surgical Horns for Endoscopic-Nasal Approaches to Brain Tumors
Gaussian Horn Profile

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

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

\[ f_i = \frac{\omega_i}{2\pi} \]

After Klee's paper, where \( \omega \) is angular frequency, \( C_g \) is the acoustic velocity, \( L_{\text{tip}} \) is the length of the tip, and \( f_i \) is the resonant frequency.
1-D Physical-Mathematical Modeling

\[ S_g(x) = S_{g0}e^{-\frac{1}{2}\left(\frac{\omega}{c}\right)^2x^2} \]

\[ R(x) = \frac{D_c}{2} e^{\alpha \cdot x} \]

\[ R(x) = \frac{D_c}{2} \]

\[ R(x) = x\tan\theta \]
Radius Profile (mm) vs. x (mm)
FEM Solid Model - 36 kHz Transducer and SaberTip

Solid Model

- Transducer Core-Stack
- Forcing Function
- Connecting Body
- 36 kHz BoneTip Horn
- Measures
- 980 N
Design Frequency Analysis Excitation Approaches

Half Model with Base Excitation

- Half model approach utilizes constraints and a base excitation
- Constraints are needed to support analysis of the half model and to couple in a base acceleration excitation
- Constraints prevent movement of the material across the cut plane of the half model, thereby ensuring the model is not violated
- Vibration inducing acceleration is coupled to the component or assembly under evaluation via the constraints
- CUSA ultrasonic controller provides closed-loop control of the stroke of the transducer core-stack
- Displacement established at 5 µm peak (stroke of 10 µm peak-peak)
- Acceleration used in the base excitation is established to provide this magnitude of core-stack displacement
- Setting core-stack displacement can generally be accomplished on the second pass of the analysis using a simple linear adjustment
Full Model with Forcing Function

- Full model approach utilizes a forcing function with damping and no artificial constraints.
- Force employed is that magnitude of nodal force (980 N) provided by the 36 kHz transducer at 100% stroke amplitude.
- Damping in forcing function established to provide controlled magnitude of core-stack displacement 5 µm peak (stroke of 10 µm peak-peak).
- Enables full motion of the components and assembly to be evaluated independent of artificial constraints.
- Constraints could mask modes that contribute to errant motion.
- Constraints contribute to artificially high frequency in modal analysis and higher stresses: constraints make component appear stiffer.
- Half model still executed to save time in initial analysis and because design of the baseline horns utilized this approach.
- Half model indicates dominant modes (4 or 5 allowed frequencies for horns discussed) in broadband analysis (10 kHz – 50 kHz).
- Full model analysis executed with narrow band about resonance.
Design Frequency Analysis Excitation Approaches

- Transducer Core-Stack
- Forcing Function
- Connecting Body
- Full Model Forcing Function
- 36 kHz Extended Standard Tip Horn
- 980 N
- Surface Constraints
- Half Model Base Excitation
- Measures
Global Approach for Mechanica Analysis

**Half Model**
- Broadband Modal Analysis
  - Yields dominant nodes
- Design Frequency Analysis
  - Base excitation or forcing function (half force)
  - Yields peak displacements, stresses, strains, etc
  - Faster execution with narrower band (< 1 hr)
  - Iterative design-analysis
- Master Interval Analysis
  - About resonance
  - Query of displacements, stresses, strains, etc
  - Unambiguous view of interior stress concentrations, mechanical gain, etc

**Full Model – Forcing Function**
- Narrow Band Modal Analysis
  - Yields many modes for review
- Design Frequency Analysis
  - Forcing function with damping
  - Execution time (e.g., less than 2 hr)
  - Assurance of resonant peak displacement and stress data
  - At frequency steps and over analysis
  - By component and selected geometry
- Master Interval Analysis
  - About resonance, taking 3-5 hours
  - Simulation of motion, stress and strain distribution, and data query
  - Unambiguous view of mechanical gain, stress concentrations, node and anti-node locations, and confirmation of nodal forces
Design Frequency Analysis - 36 kHz SaberTip

36 kHz SaberTip - Half Model Surface Constraints

Mode of 37,362 Hz
Design Frequency Analysis - 36 kHz SaberTip

36 kHz SaberTip - Full Model, Forcing Function

von Mises Horn Stress (MPa)

Frequency (Hz)
Displacement at Resonance
Master Interval Analysis - 36 kHz SaberTip

Stress

Localized Stress

Strain

Stress
Simulation of Horn Displacement at Resonance
36 kHz Extended Standard Tip: Mechanica Simulation of Displacement

Click to Activate Simulation
36 kHz Extended Standard Tip: Mechanica Simulation of Stress

Click to Activate Simulation
Master Interval Design Frequency Analysis

- Simulations exhibiting spatial distribution of stress
- Dynamic query afforded
- Shows uniform strain of Gaussian profile
- Maintain strain over greatest Gaussian length allowed by frequency
Strain contributing to mechanical gain of the horn is low enough when encountering the stress concentrating pre-aspiration holes to keep the maximum hole stress within acceptable limits.

Maximum stress in the horn is not at the pre-aspiration holes.

Master Interval Design Frequency Analysis
Master Interval Analysis - 36 kHz Extended Standard Tip

36 kHz Extended Standard Tip - Full Mode Forcing Function

- Displacement Mag (WCS)
- Stress von Mises (WCS)
36 kHz Transducer and Extended MicroTip Plus

Displacement

Localized Stress
36 kHz Transducer with Extended MicroTip Plus - Displacement

Surface Distance (mm)

Displacement (mm)
### Summary of Finite Element Analysis – 36 kHz SaberTip

<table>
<thead>
<tr>
<th></th>
<th>SaberTip Forcing Function</th>
<th>SaberTip Base Excitation Surface Constraints</th>
<th>MicroTip Forcing Function Baseline</th>
<th>MicroTip Base Excitation Surface Constraints Baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stack Displacement peak (μm)</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Stack Acceleration (m/s²)</td>
<td>272 x10³</td>
<td>295 x10³</td>
<td>267 x10³</td>
<td>287 x10³</td>
</tr>
<tr>
<td>Horn von Mises Stress (MPa)</td>
<td>252</td>
<td>317</td>
<td>252</td>
<td>319</td>
</tr>
<tr>
<td>Horn Stroke peak-peak (μm)</td>
<td>117</td>
<td>124</td>
<td>178</td>
<td>193</td>
</tr>
<tr>
<td>Horn Acceleration (m/s²)</td>
<td>3.09x10⁶</td>
<td>3.43 x10⁶</td>
<td>4.65 x10⁶</td>
<td>5.18 x10⁶</td>
</tr>
<tr>
<td>Resonant Frequency (Hz)</td>
<td>36,925</td>
<td>37,362</td>
<td>36,614</td>
<td>36,938</td>
</tr>
<tr>
<td>Input Forcing Function (N)</td>
<td>978</td>
<td>-</td>
<td>978</td>
<td>-</td>
</tr>
<tr>
<td>Input Damping (%)</td>
<td>3.483</td>
<td>-</td>
<td>2.7</td>
<td>-</td>
</tr>
<tr>
<td>Input Acceleration (m/s²)</td>
<td>-</td>
<td>192</td>
<td>-</td>
<td>275</td>
</tr>
</tbody>
</table>

### Electromechanical Data on Fabricated Horns

<table>
<thead>
<tr>
<th>Measured Results</th>
<th>Voltage (V_{RMS})</th>
<th>Current (A_{RMS})</th>
<th>Power (Watts)</th>
<th>Frequency (kHz)</th>
<th>Stroke (p-p) (µm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Horn</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extended MicroTip Baseline</td>
<td>Average</td>
<td>31</td>
<td>1.30</td>
<td>30</td>
<td>35.70</td>
</tr>
<tr>
<td></td>
<td>StdDev</td>
<td>2</td>
<td>0.07</td>
<td>2</td>
<td>0.01</td>
</tr>
<tr>
<td>SaberTip</td>
<td>Average</td>
<td>23</td>
<td>0.80</td>
<td>17</td>
<td>35.79</td>
</tr>
<tr>
<td>Initially, 50 Samples</td>
<td>StdDev</td>
<td>0.5</td>
<td>0.03</td>
<td>0.4</td>
<td>0.05</td>
</tr>
</tbody>
</table>
## Summary of Finite Element Analysis – Extended MicroTip Plus

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Stack Displacement peak (µm)</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Stack Acceleration (m/s²)</td>
<td>272 x10³</td>
<td>277 x10³</td>
<td>272 x10³</td>
<td>277 x10³</td>
</tr>
<tr>
<td>Horn von Mises Stress (MPa)</td>
<td>211</td>
<td>240</td>
<td>249</td>
<td>297</td>
</tr>
<tr>
<td>Hole von Mises Stress (MPa)</td>
<td>168</td>
<td>155</td>
<td>212</td>
<td>191</td>
</tr>
<tr>
<td>Horn Stroke peak-peak (µm)</td>
<td>142</td>
<td>147</td>
<td>142</td>
<td>147</td>
</tr>
<tr>
<td>Horn Acceleration (m/s²)</td>
<td>3.81 x10⁶</td>
<td>3.99 x10⁶</td>
<td>3.78 x10⁶</td>
<td>3.99 x10⁶</td>
</tr>
<tr>
<td>Resonant Frequency (Hz)</td>
<td>36.745</td>
<td>37.078</td>
<td>36.873</td>
<td>37.172</td>
</tr>
<tr>
<td>Input Forcing Function (N)</td>
<td>978</td>
<td>-</td>
<td>978</td>
<td>-</td>
</tr>
<tr>
<td>Input Damping (%)</td>
<td>1.755</td>
<td>-</td>
<td>2.86</td>
<td>-</td>
</tr>
<tr>
<td>Input Acceleration (m/s²)</td>
<td>-</td>
<td>1954</td>
<td>-</td>
<td>234</td>
</tr>
</tbody>
</table>

## Electromechanical Data on Fabricated Horns

<table>
<thead>
<tr>
<th>Measured Results</th>
<th>Voltage (V_{RMS})</th>
<th>Current (A_{RMS})</th>
<th>Power (Watts)</th>
<th>Frequency (kHz)</th>
<th>Stroke (p-p) (µm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Horn</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extended MicroTip Plus</td>
<td>Average</td>
<td>34</td>
<td>1.31</td>
<td>32</td>
<td>35.78</td>
</tr>
<tr>
<td>Initially, 21 Samples</td>
<td>StdDev</td>
<td>1</td>
<td>0.01</td>
<td>1</td>
<td>0.04</td>
</tr>
<tr>
<td>Extended Standard Tip</td>
<td>Average</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>35.75</td>
</tr>
<tr>
<td>Production data only</td>
<td>StdDev</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
Gaussian Profiles – Known Frequency Shift

\[ \omega_i = \frac{C_g}{L_{tip}} \left( \tan \left( \frac{1}{\sqrt{2\ln(N)}} \right) + \sqrt{2\ln(N)} \right), \quad f_i = \frac{\omega_i}{2\pi}, \quad N = \frac{S_{gO}(\text{Area})}{S_c(\text{Area})} \]

Frequency Adjustments

<table>
<thead>
<tr>
<th>Profile</th>
<th>Frequency Adjustments</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>-200 Hz</td>
</tr>
<tr>
<td>B</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>35,750 Hz</td>
</tr>
<tr>
<td>D</td>
<td></td>
</tr>
<tr>
<td>E</td>
<td>+250 Hz</td>
</tr>
<tr>
<td>F</td>
<td></td>
</tr>
<tr>
<td>G</td>
<td></td>
</tr>
<tr>
<td>H</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td></td>
</tr>
<tr>
<td>J</td>
<td></td>
</tr>
</tbody>
</table>

Mechanica Results

<table>
<thead>
<tr>
<th></th>
<th>SaberTip Forcing Function</th>
<th>Extended MicroTip Plus Forcing Function</th>
<th>Extended Standard Tip Forcing Function</th>
<th>Extended Micro Tip Forcing Function Baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resonant Frequency (Hz)</td>
<td>36,925</td>
<td>36,745</td>
<td>36,873</td>
<td>36,614</td>
</tr>
</tbody>
</table>

- Frequency “shift” expected
  - Designed for resonance at 100% amplitude and quiescent operating conditions
  - FEM results more comparable to low-power spectrum analysis of system
  - Reduction in stiffness at quiescent operating point, incomplete model of joint compliance, geometry, case attachments, elastic properties, etc
- Consistency for transducers and “family” of horns supports prediction for initial manufacturing, as noted for the four 36 kHz examples shown and also in 23 kHz prototypes
- Multiple profiles afford adjustments and support known titanium material properties variance
- Complete FEM at extremes of profiles and modal frequency analysis for all columns
Summary:

- Solid Model FEM (Finite Element Method)
  - Stroke typically predicted with 3 µm or 2 % error
  - SaberTip stroke predicted within 8 µm or 6.5 % error
  - Both methods of FEM analysis indicate allowed stress at or below baseline surgical horns employed for 10 years
  - Allowed stress about 1/3 yield strength of materials
  - Resonant frequency target attained in fabrication with aid of FEM results and known frequency shift

- Extensive successful verification and validation testing
  - Surgical tips released in April of 2006
Background:

- Endoscopic-Nasal Surgery in sphenoid sinus region using surgical bone tip
- Creating a cavity to aid in reduction of cranial pressure
- Removal of bone on dura

36 kHz Ultrasonic Surgical Horns for Endoscopic-Nasal Approaches to Brain Tumors
Acknowledgements

• University of Pittsburgh Medical Center
  – Dr. Amin Kassam (Co-inventor of horns described), Dr. Ricardo L. Carrau, Dr. Carl H. Snyderman, Dr. Paul Gardner, and Dr. Arlan Mintz
  – Development, Endoscopic-Nasal courses and conferences, cadaveric-section testing, and clinical and surgical interactions

• UVA Medical Center
  – Dr. Jane, Dr. Han, and Dr. Ashok for assistance in initial bone cutting cadaveric-section efforts

• Integra Radionics
  – Peter Gould and CUSA Tips Team for laboratory efforts, operations, and regulatory efforts
  – Zach Leber, Chris von Jako, and Peter Colgan for direction and continued support throughout the course of this work