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

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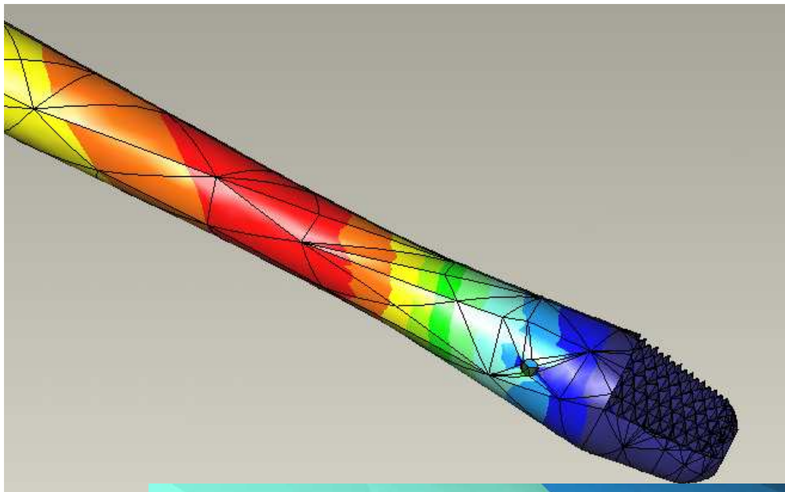

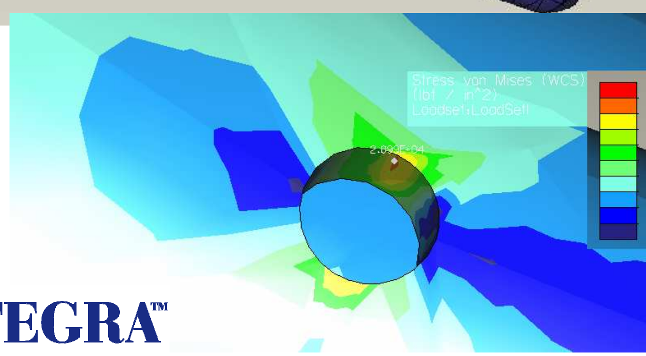

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Outline:

- **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**

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**

Extensive References in Planned IEEE UFFC Transactions Paper

- **References on ultrasonic aspirators and endoscopic nasal approach**

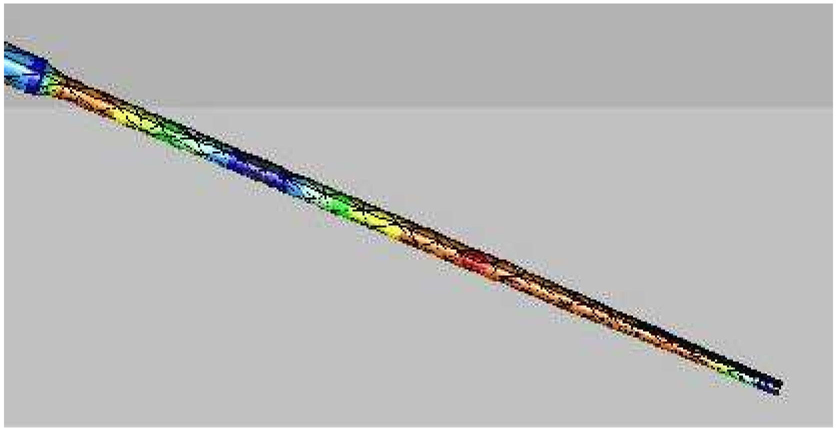
  - C. Kleesattel, Acustica 12[1962],322.
  - E. Eisner and J. S. Seager, “A Longitudinally Resonant Stub for Vibrations of Large Amplitude”, SMRE, Research Report No. 216, October, 1963, pp 1-51.
  - D. G. Wuchinick, A. Broadwin, and R. P. Anderson, “Ultrasonic Aspirator”, U.S. Patent 4 063 557, Dec. 20, 1977.
  - L. Balamuth, C. Kleesattel, and A. Kuris, “Supply and Control Apparatus for Vibratory Cutting Device”, U.S. Patent 3 213 537, Oct. 26, 1965, Original Application Dec 24, 1954, Ser. No. 477,530.
  - E. S. Flamm, J. Ransohoff, D. Wuchinich, and D. Broadwin, "A Preliminary Experience with Ultrasonic Aspiration in Neurosurgery”, Neurosurgery 2:240-245;1978.
  - R. Stoddard and A. J. Reschke, “Ultrasonic Surgical Apparatus”, U.S. Patent 6 124 017, Apr. 10, 2001.
  - G. Bromfield and J. J. Vaitekunas, “Internal Ultrasonic Tip Amplifier”, U.S. Patent 5 879 364, Mar. 9, 1999.
  - A. Kassam, C. H. Snyderman, A. Mintz, P. Gardner, and R. L. Carrau, “ Expanded endonasal approach: the rostrocaudal axis. Part I. Crista galli to the sella turcia”, Neurosurg Focus 19(1):E3, 2005.

Extensive References in Planned IEEE UFFC Transactions Paper

- **References on surgical bone tips**
  - **H. Nakagawa, S. D. Kim, J. Mizuno, Y. Ohara, and K. Ito, "Technical advantages of an ultrasonic bone curette in spinal surgery", J Neurosurg Spine, 2005 Apr;2(4):431-5.**
  - **J. D. Klopfenstein and R. F. Spetzler, "Ultrasonic Aspirator Tip Variations: Instrumentation Assessment", Barrow Neurological Institute, St. Joseph's Hospital and Medical Center, Phoenix, Arizona, Barrow Quarterly Vol. 20, No. 3, 2004.**
  - **Y. Satou, "Ultrasonic Hand Piece and Ultrasonic Horn For Use With Same", U.S. Patent 6 497 715 B2, Dec. 24, 2002.**

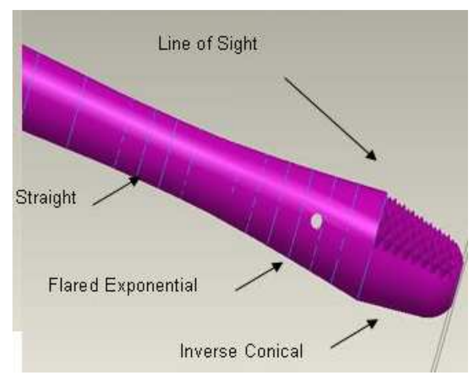
Extensive References in Planned IEEE UFFC Transactions Paper

- **References on modeling and general applications**
  - **W. P. Mason and R. F. Wick," J. Acoust. Soc. Am. 23, 209-214 (1951).**
  - **S. Sherrit, B. P. Dolgin, Y. Bar-Cohen, D. Pal, J. Kroh, and T. Peterson, "Modeling of Horns for Sonic/Ultrasonic Applications", in *Proc.* IEEE Ultrasonics Symposium, 1999, pp 647-651.**
  - **S. Sherrit, S. P. Leary, B. P. Dolgin, and Y. Bar-Cohen, "Comparison of the Mason and KLM Equivalent Circuits for Piezoelectric Resonators in Thickness Mode", in *Proc.* IEEE Ultrasonics Symposium, 1999.**
  - **L. Parrini, "New Methodology for the Design of Advanced Ultrasonic Transducers for Welding Devices", in *Proc.* IEEE Ultrasonics Symposium, 2000.**
  - **D. Ensminger, "Ultrasonics Fundamentals Technology Applications", 2nd ed., New York:Marcel Dekker, Inc, 1988.**

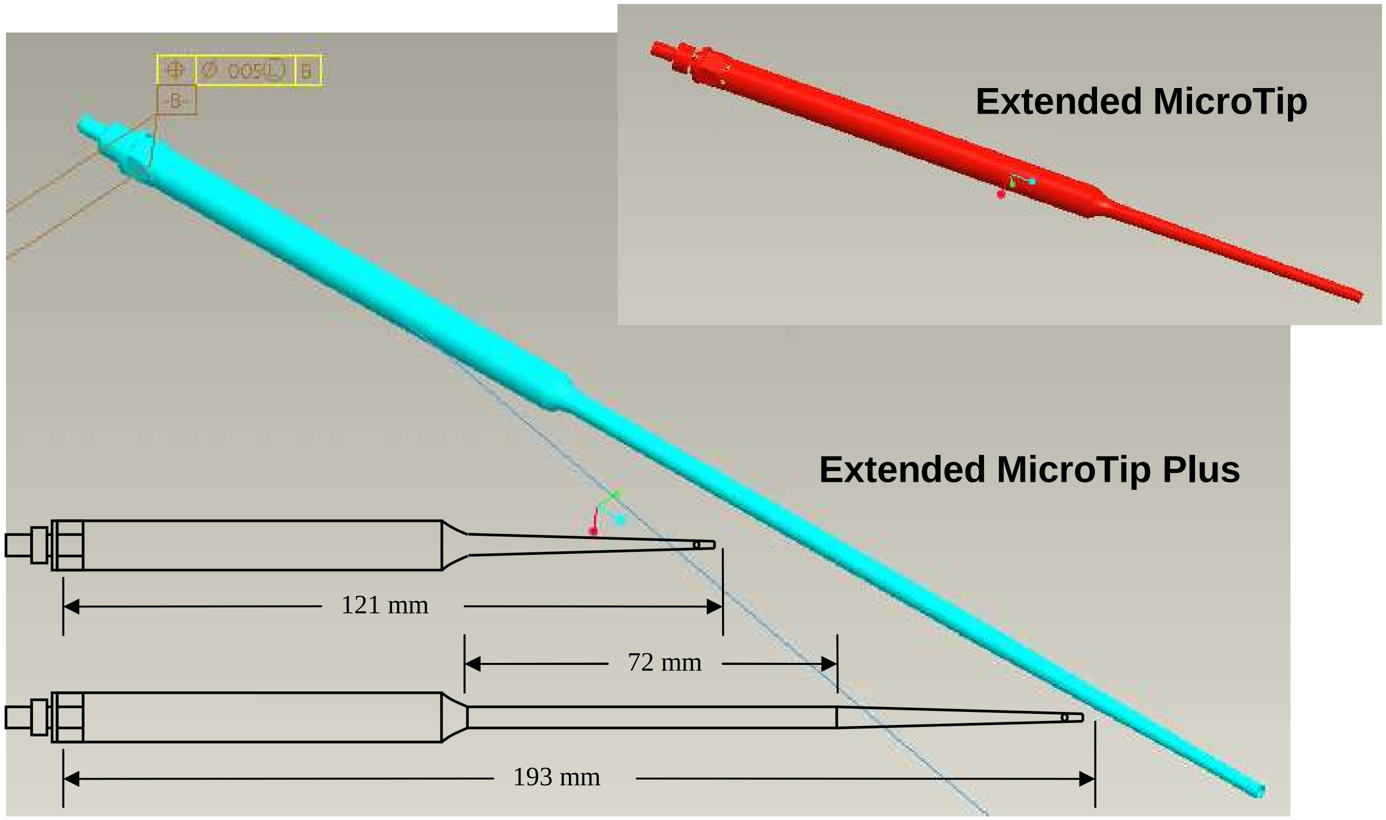


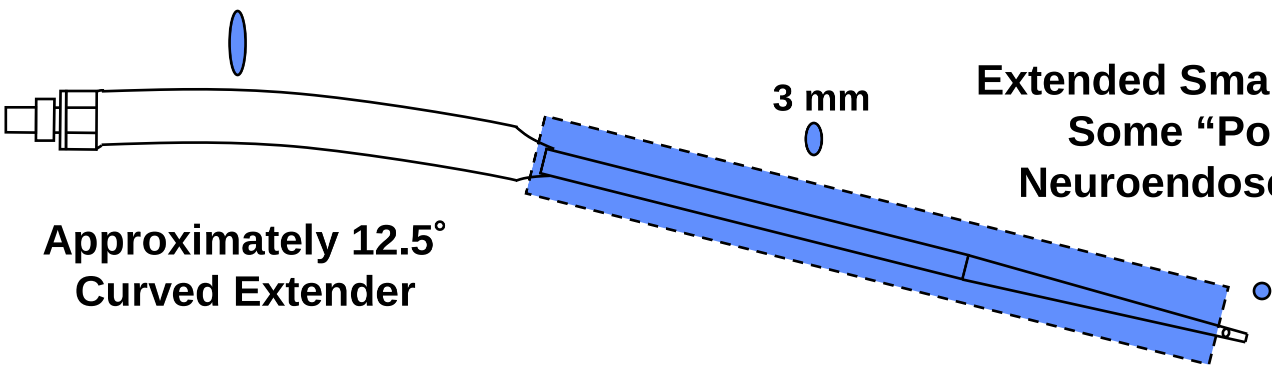
Newly Released Surgical Tips

- **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



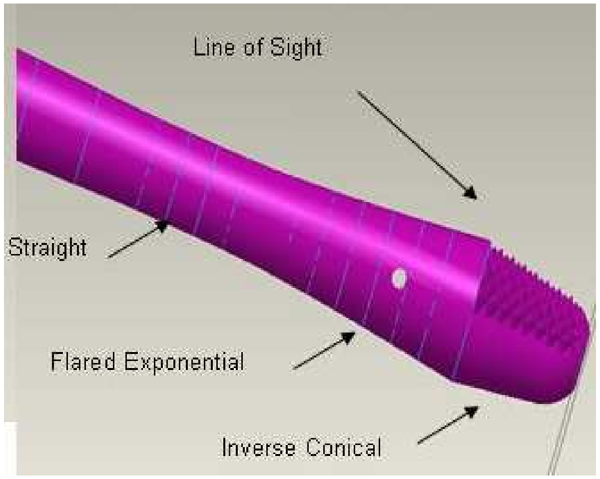


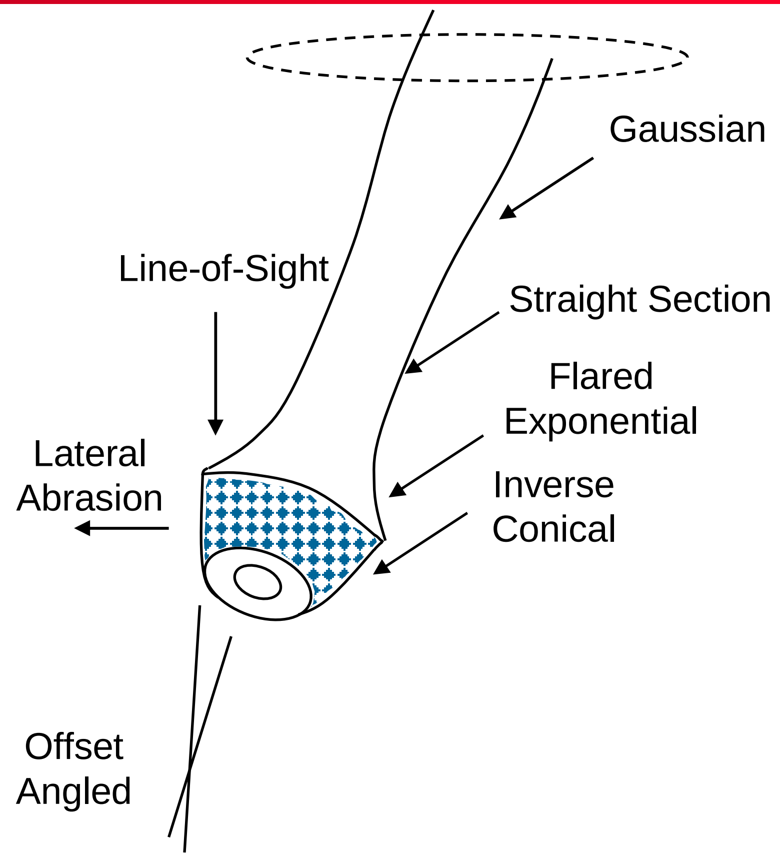
Approximately 12.5° Curved Extender

Extended Small Diameter Satisfies Some "Port" Surgery and Neuroendoscopy Applications

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

36 kHz SaberTip

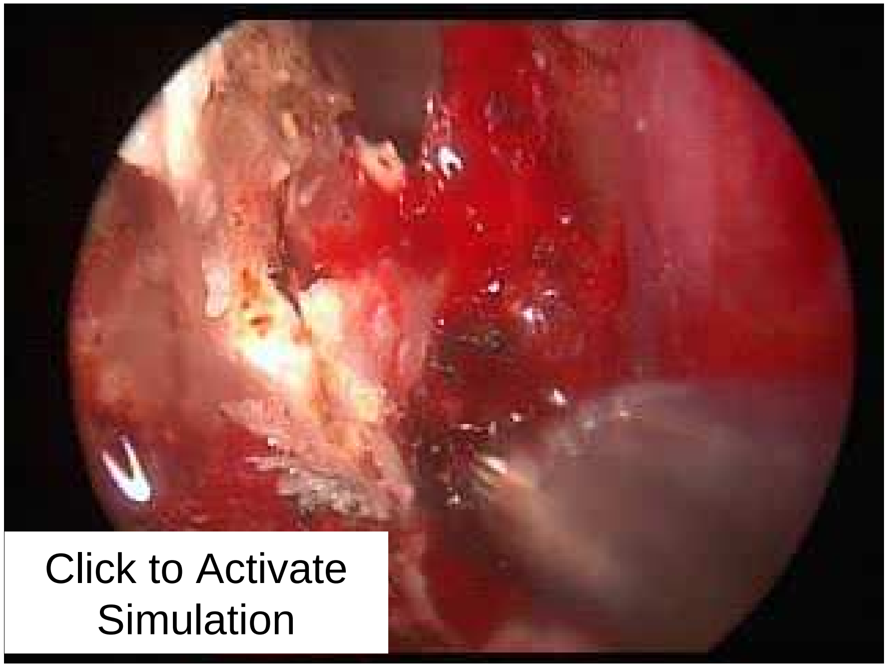


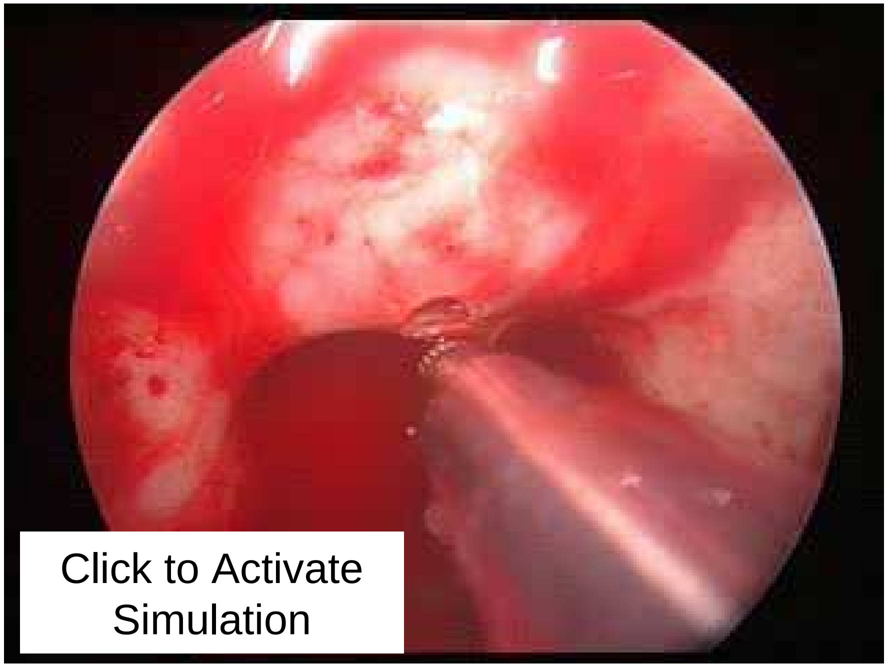


- As abrasive pad angle becomes greater, surgical tip must be angled greater to normalize to bone surface, and the 10˚ inverse cone is a compromise
- Avoids protrusions and sharp edges that may present a greater hazard in insertion
- Smooth contours and pyramids nearly fully formed but dull, like a knurl
- 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

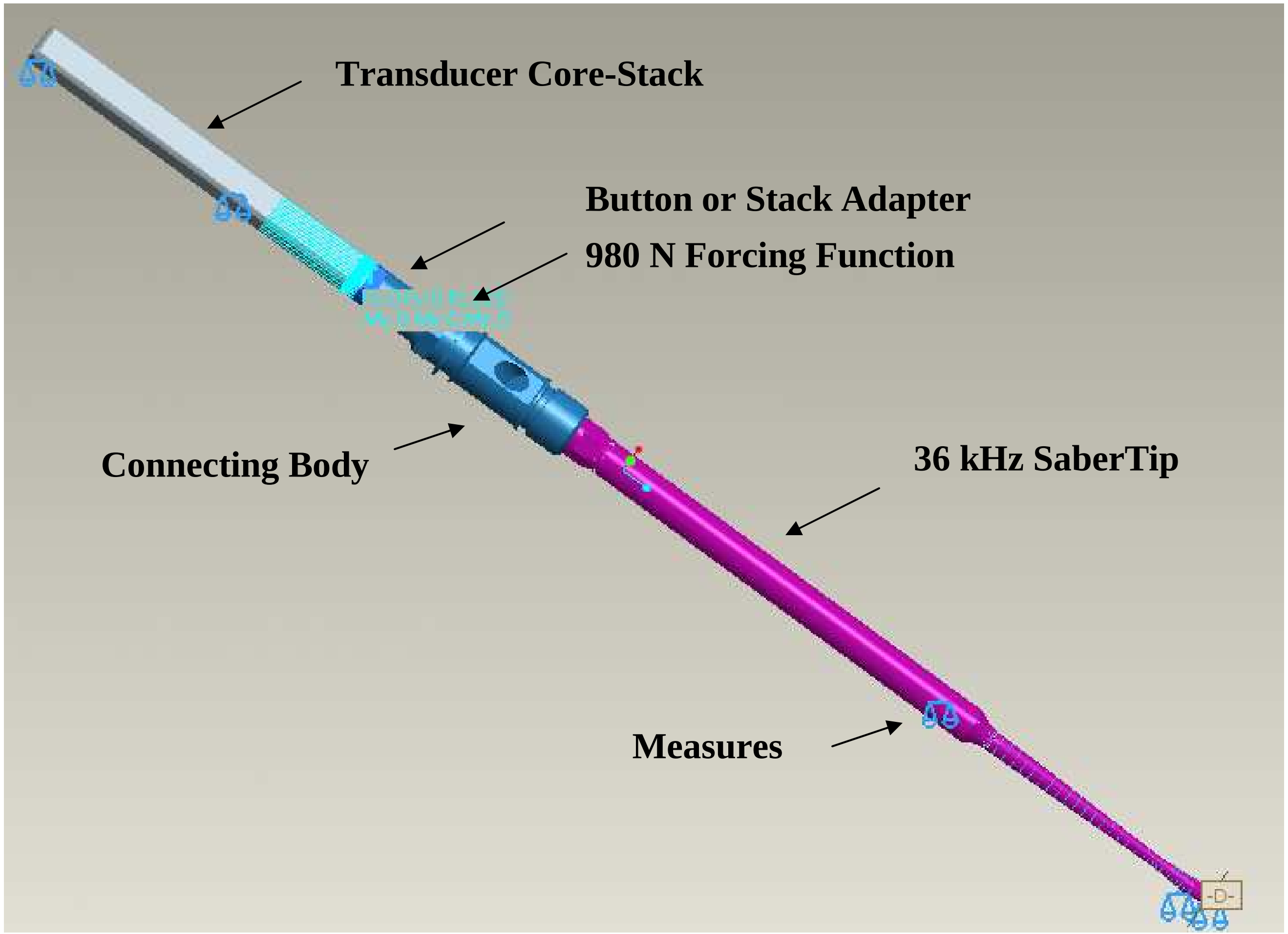
Background:

- **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**



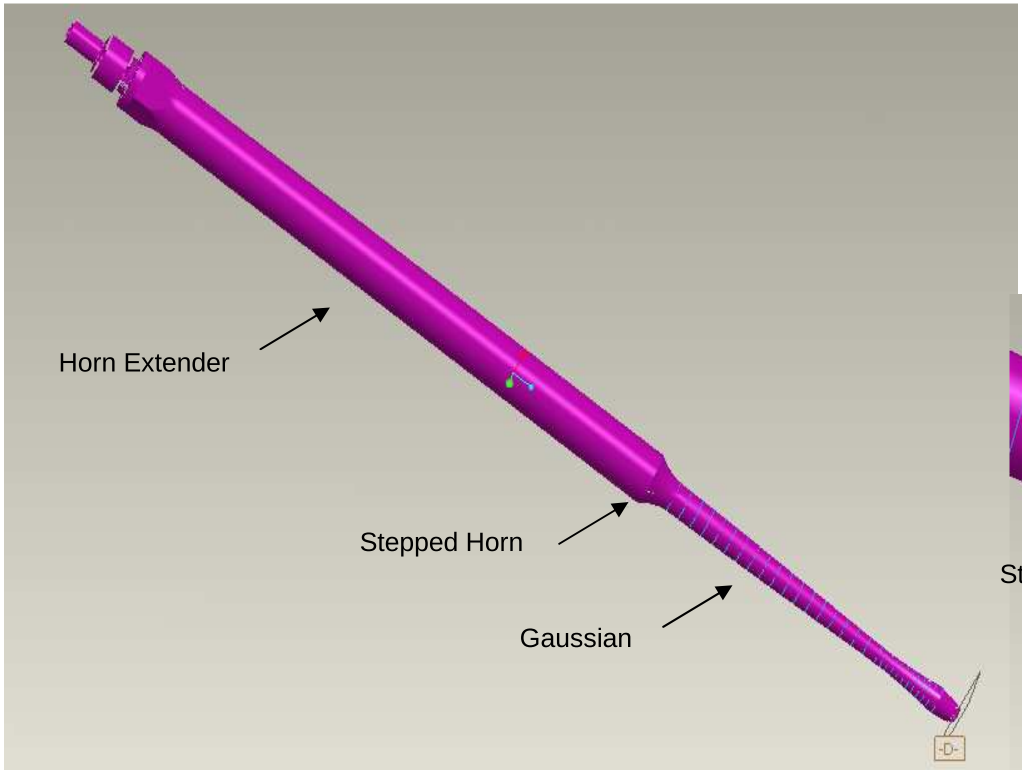


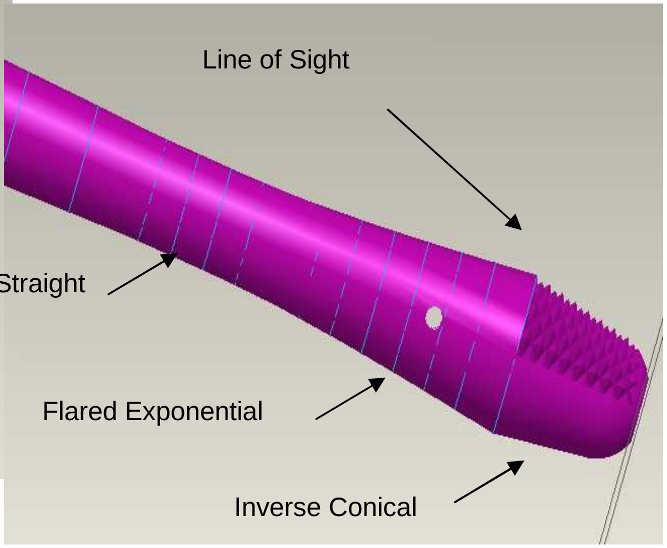
FEM Solid Model - 36 kHz Transducer



- **Nominally, 35,750 Hz target resonant frequency**
- **Resonant system: core-stack, button, connecting body, and tip (horn)**

Horn (Surgical Tip)



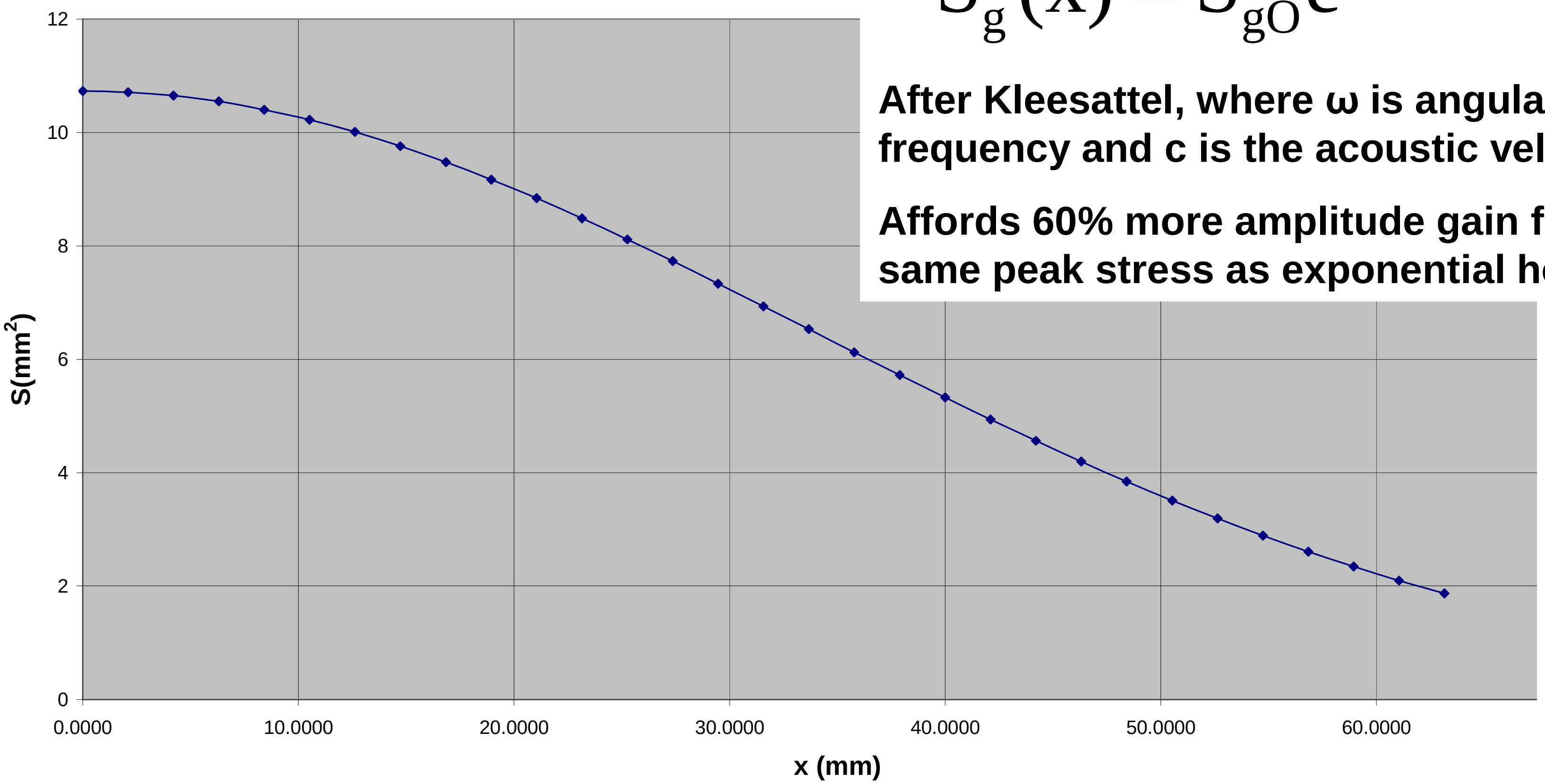


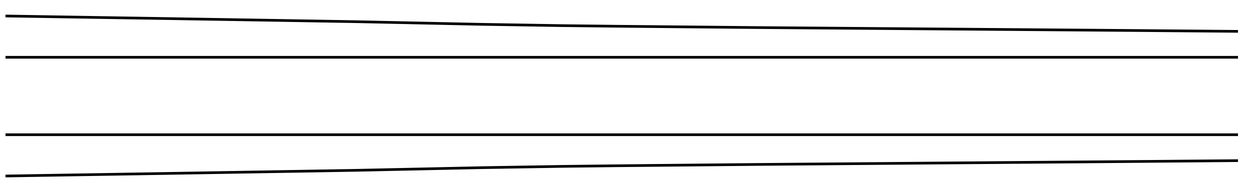
Gaussian Horn Area Function

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

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

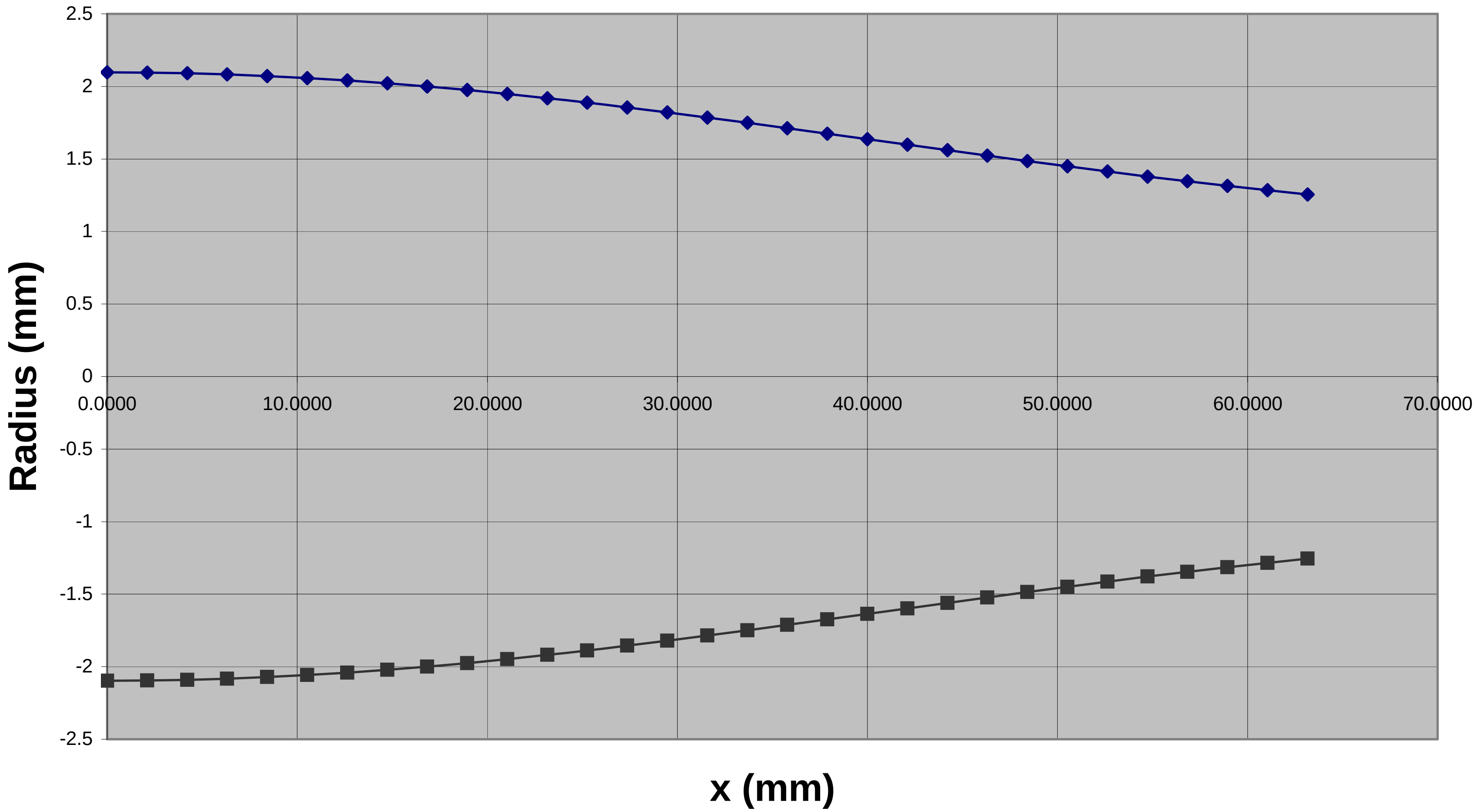
Affords 60% more amplitude gain for same peak stress as exponential horn.



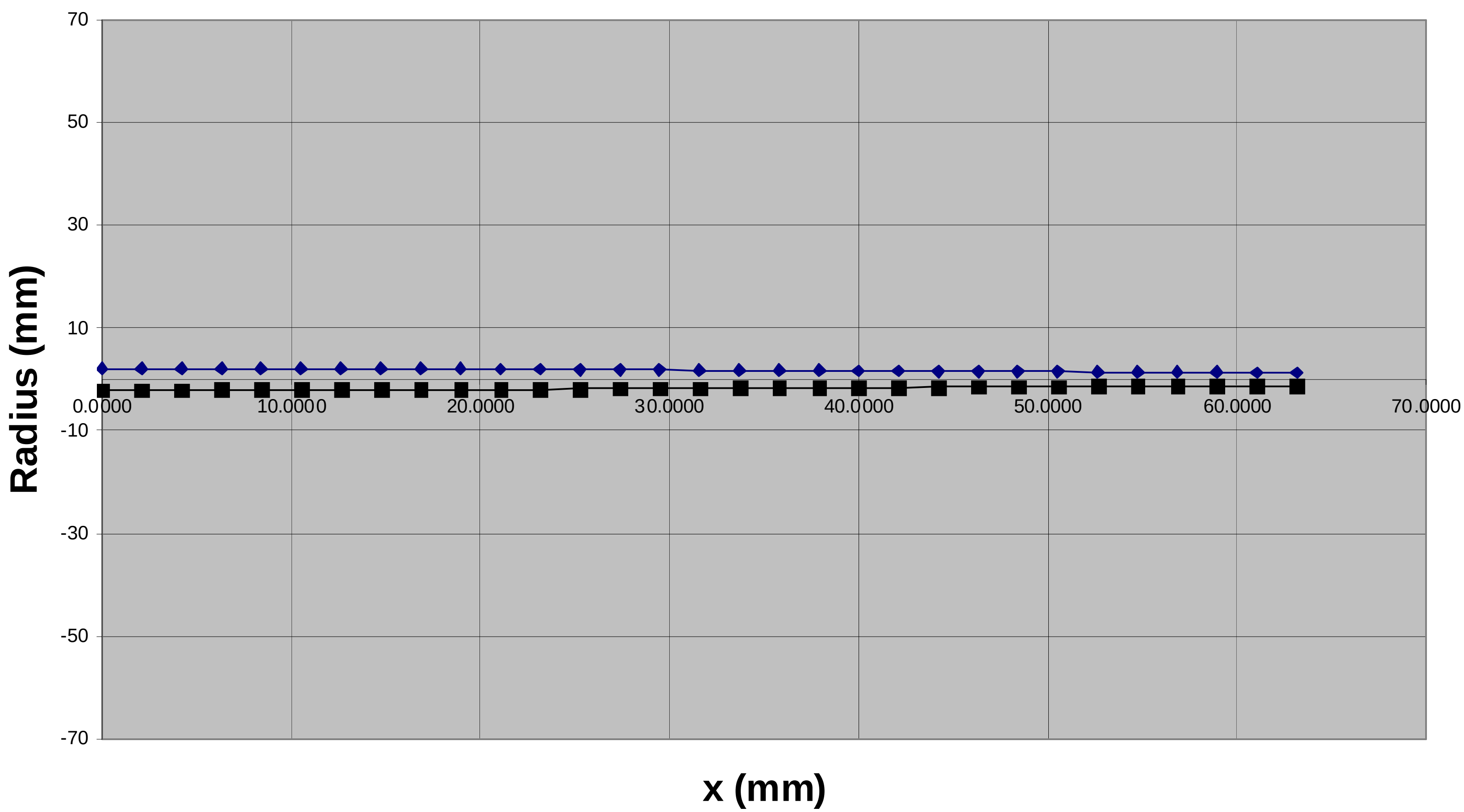


Horn Gaussian (Ampulla) Profile

Gaussian Horn Profile



Gaussian Horn Profile



Gaussian Horn Profile

Horn Gaussian (Ampulla) Profile

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

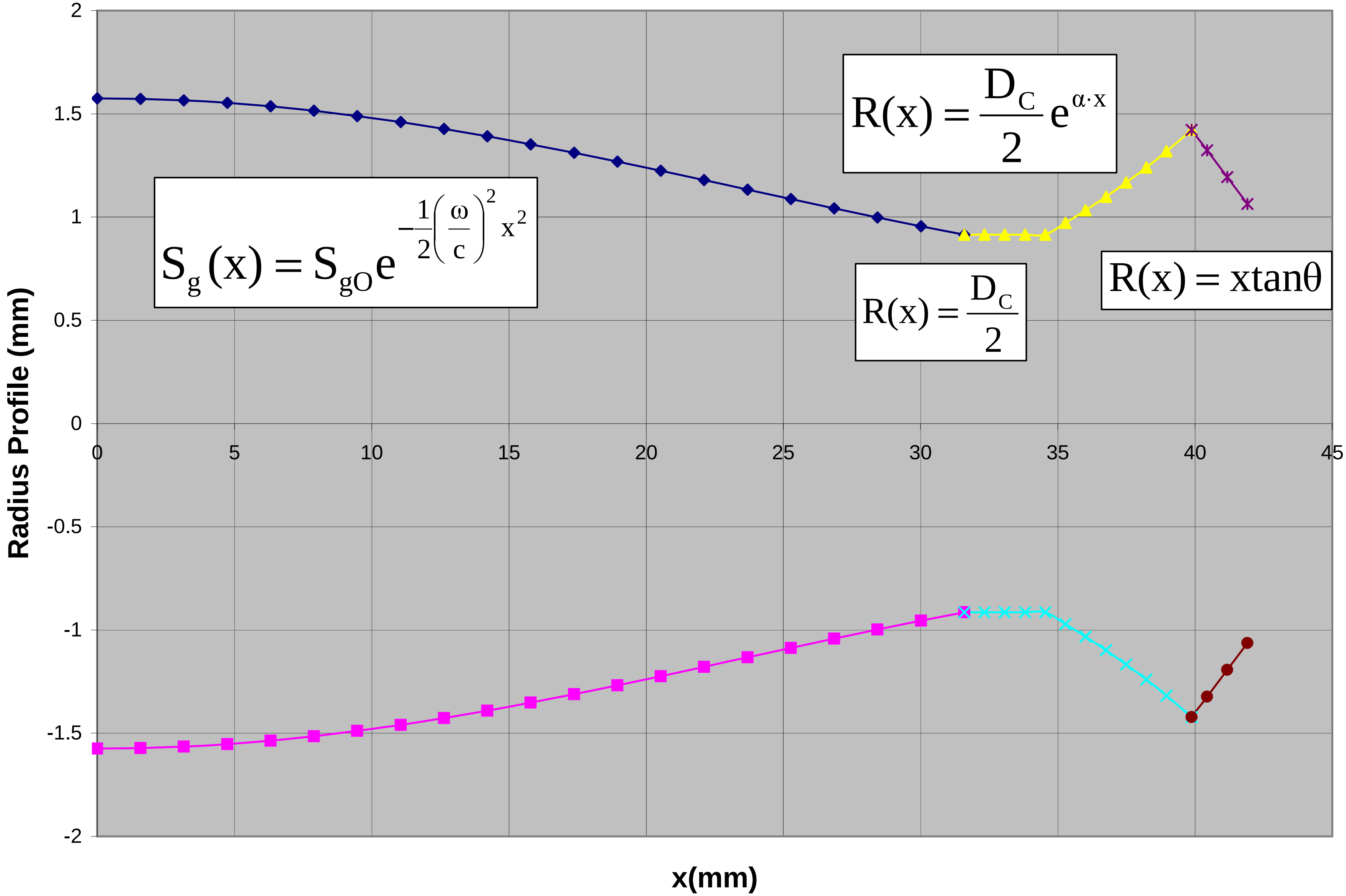
$$N = \frac{S_{gO}(\text{Area})}{S_c(\text{Area})}$$

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

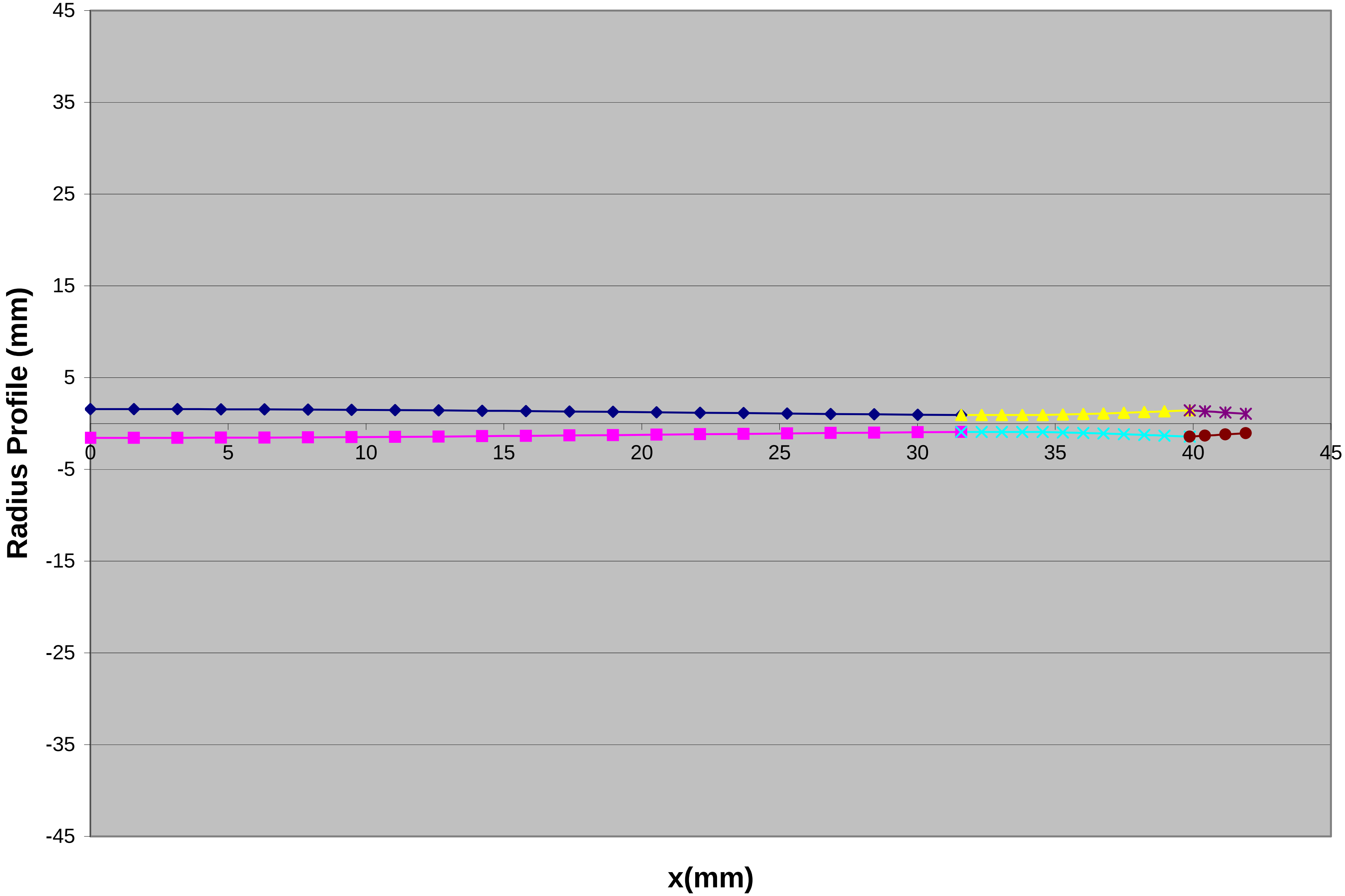
$$f_i = \frac{\omega_i}{2\pi}$$

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

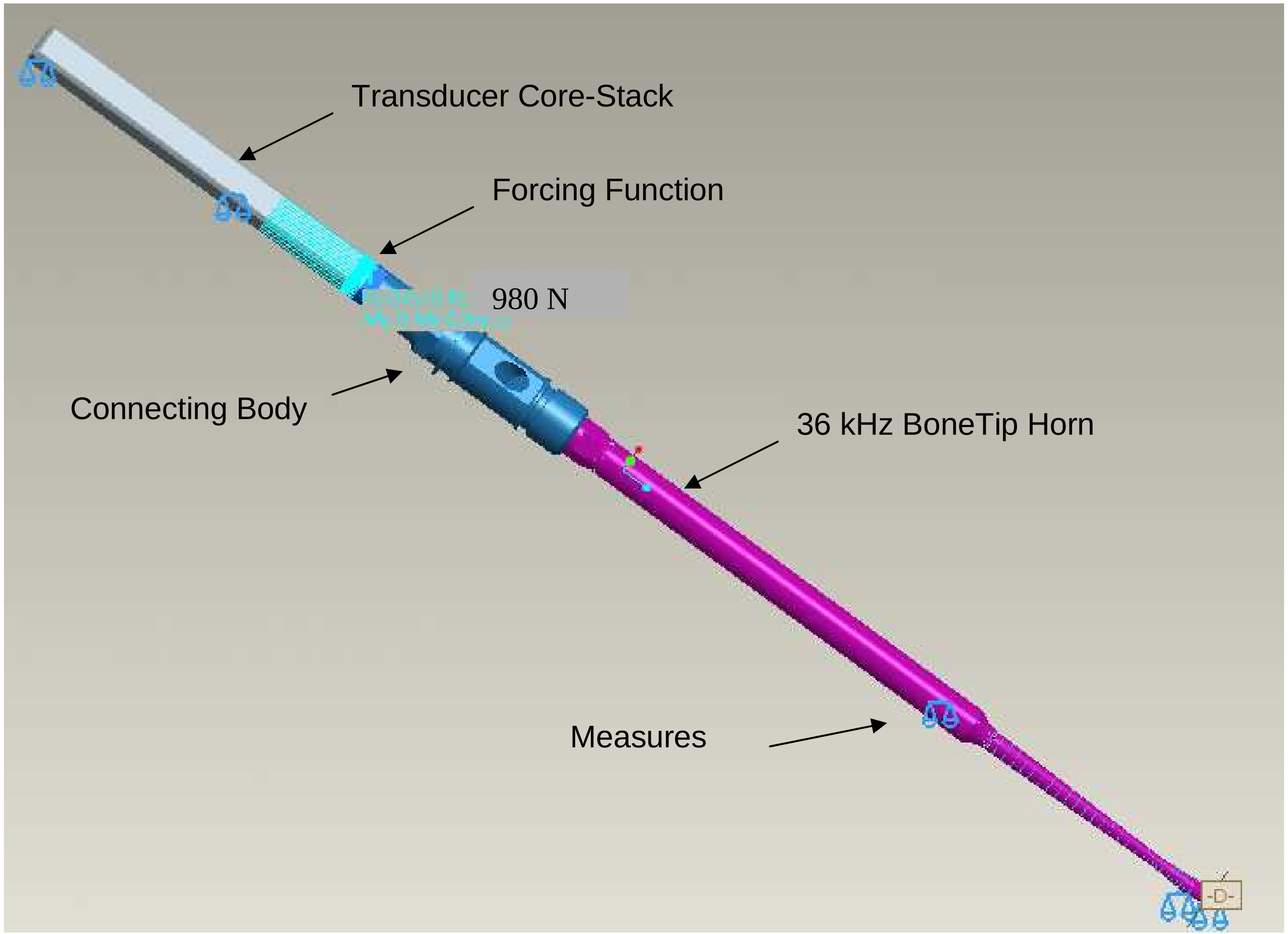


1-D Physical-Mathematical Modeling



FEM Solid Model - 36 kHz Transducer and SaberTip

Solid Model



Design Frequency Analysis Excitation Approaches

Half Model with Base Excitation

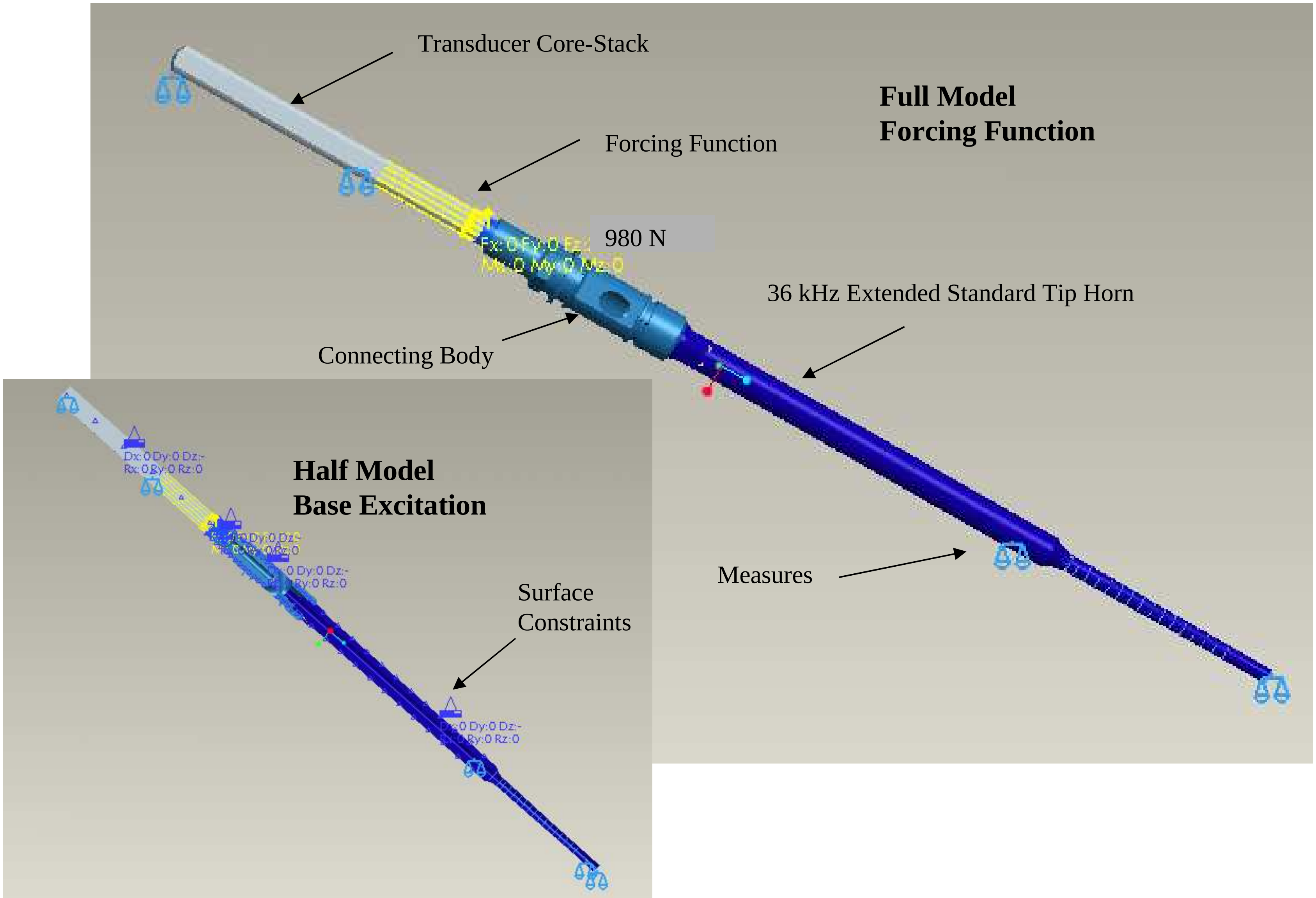
- **Half model approach utilizes constraints and a base excitation**
- **Constraints are needed to support analysis of the half model and to couple in a base acceleration excitation**
- **Constraints prevent movement of the material across the cut plane of the half model, thereby ensuring the model is 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**

Design Frequency Analysis Excitation Approaches

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



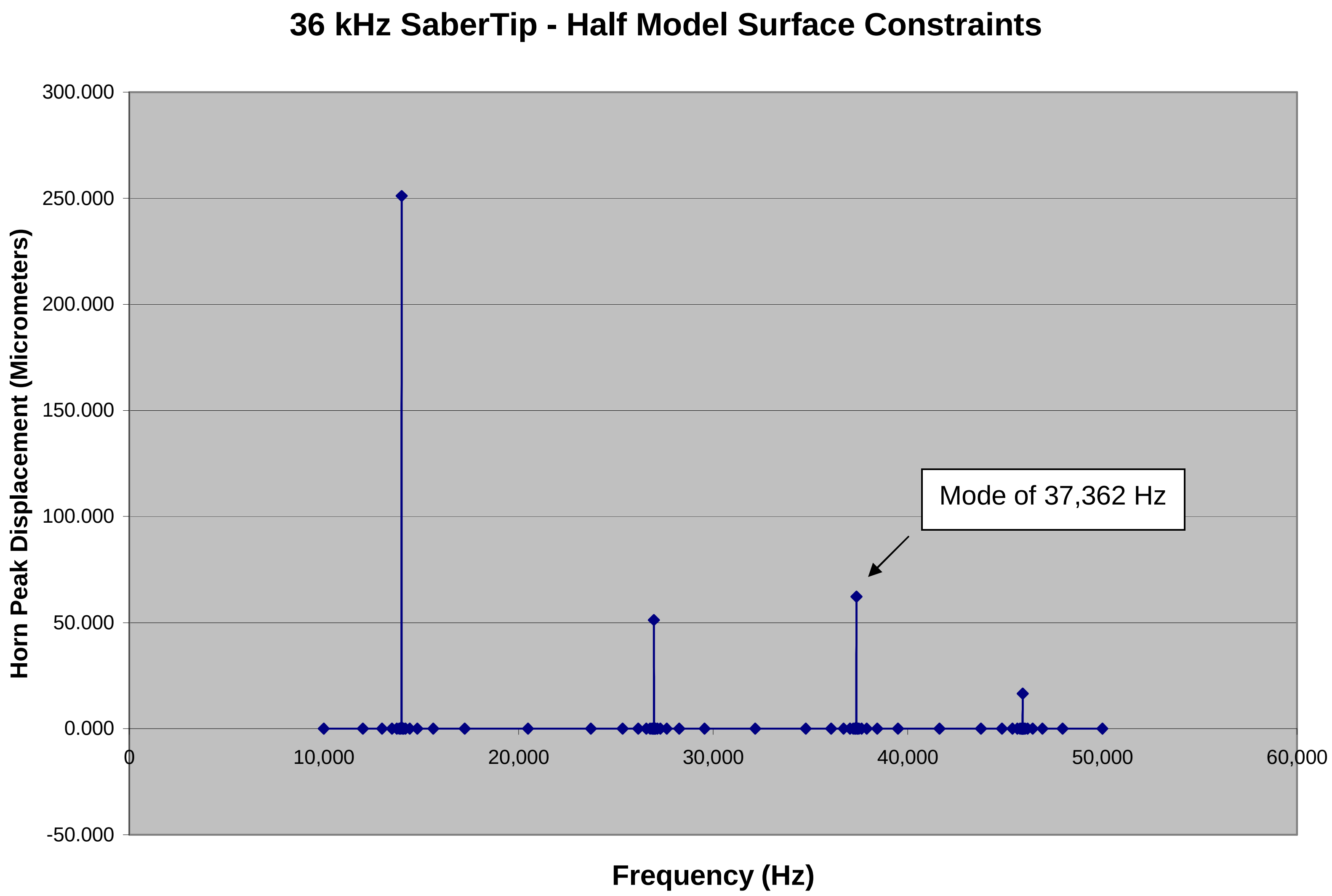
Half Model

- Broadband Modal Analysis
  - Yields dominant nodes
- Design Frequency Analysis
  - Base excitation or forcing function (halve 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

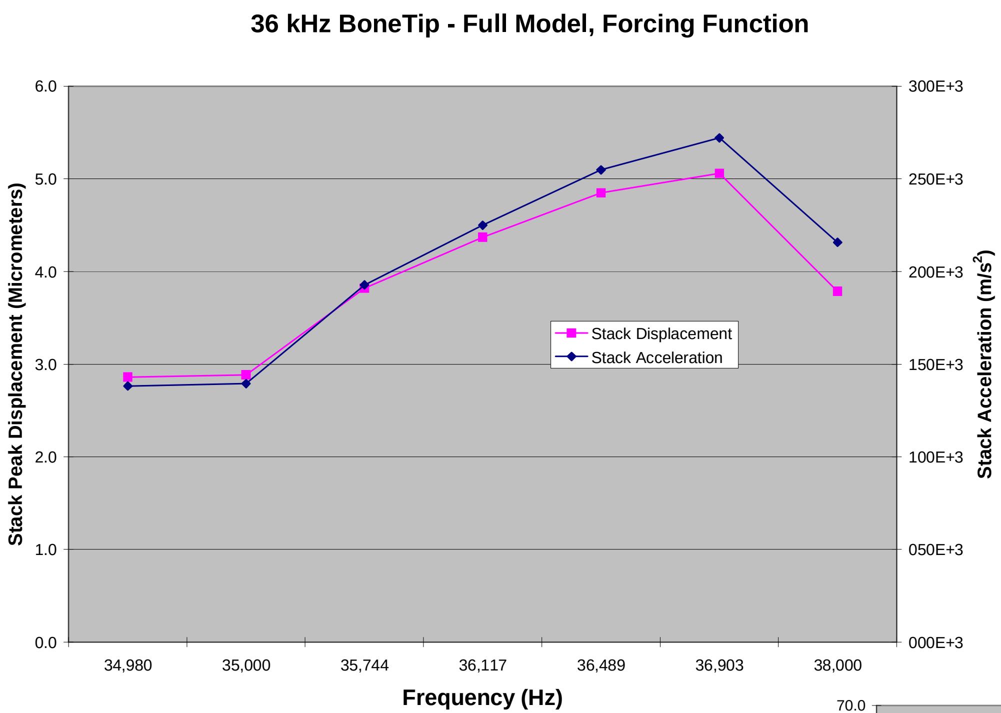
Full Model – Forcing Function

- 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

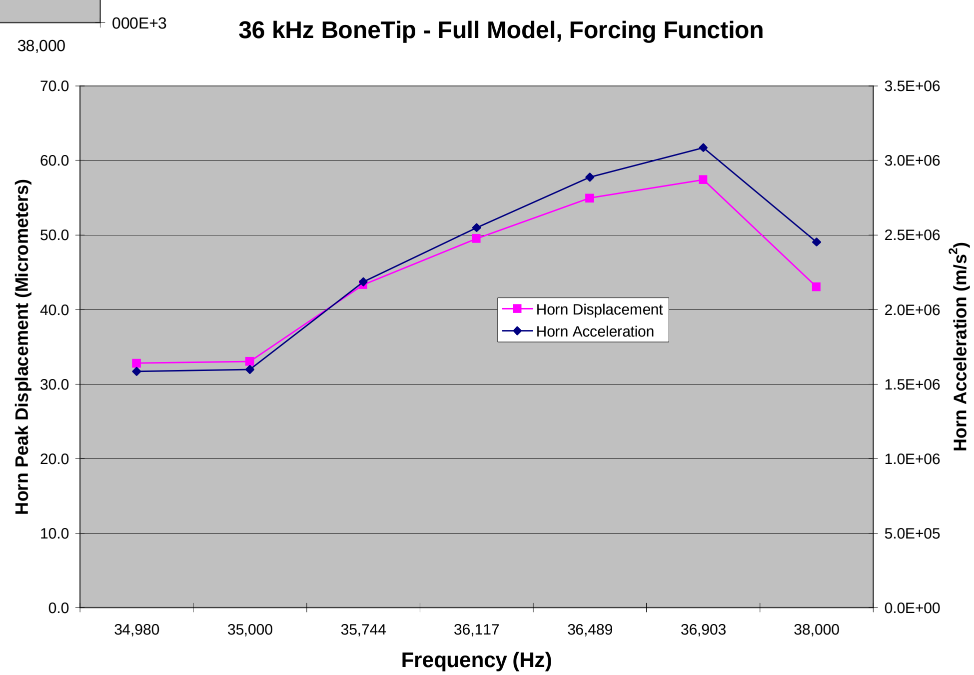
Design Frequency Analysis - 36 kHz SaberTip



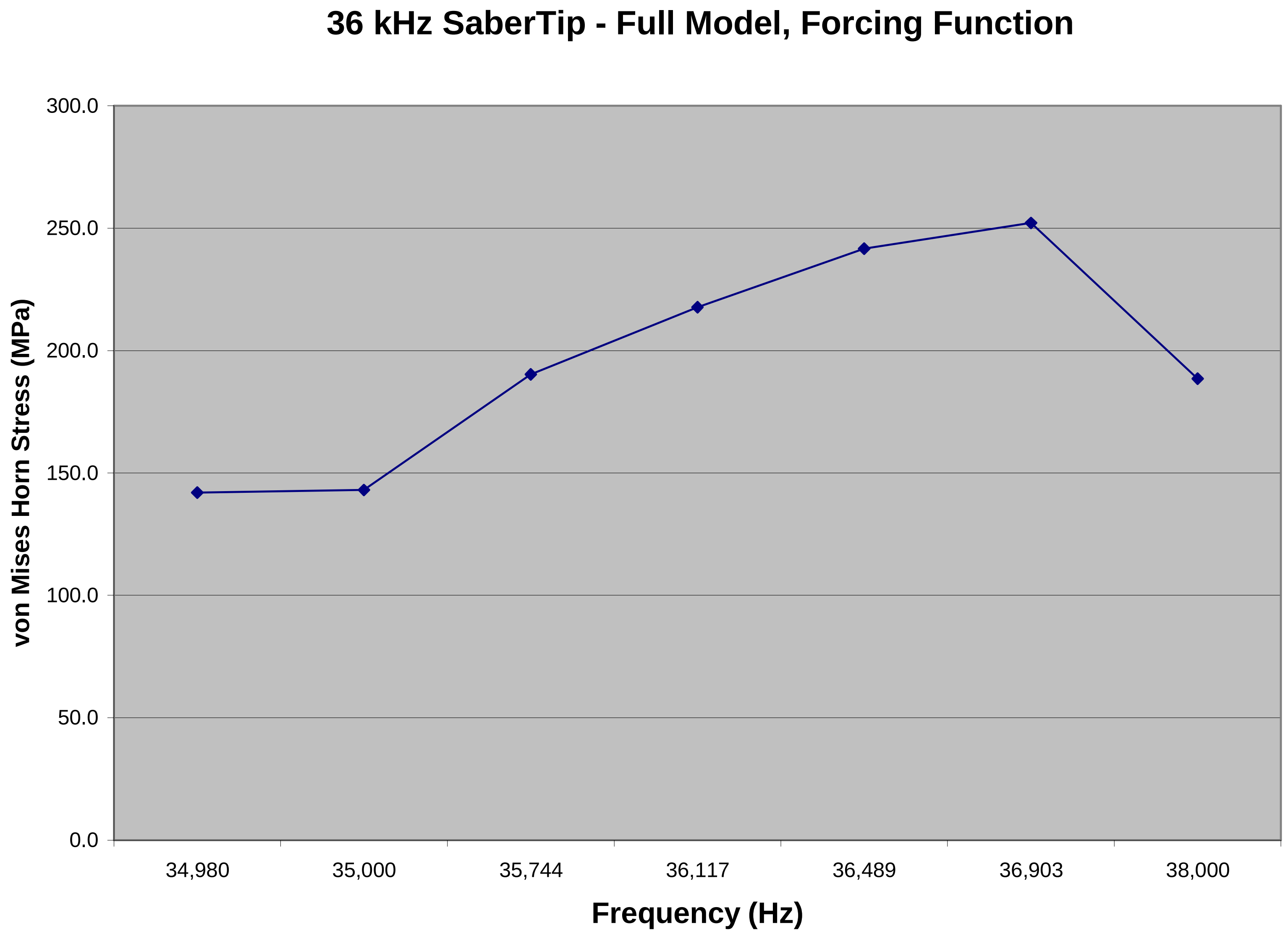
Magnetostrictive Stack Input



Horn Output

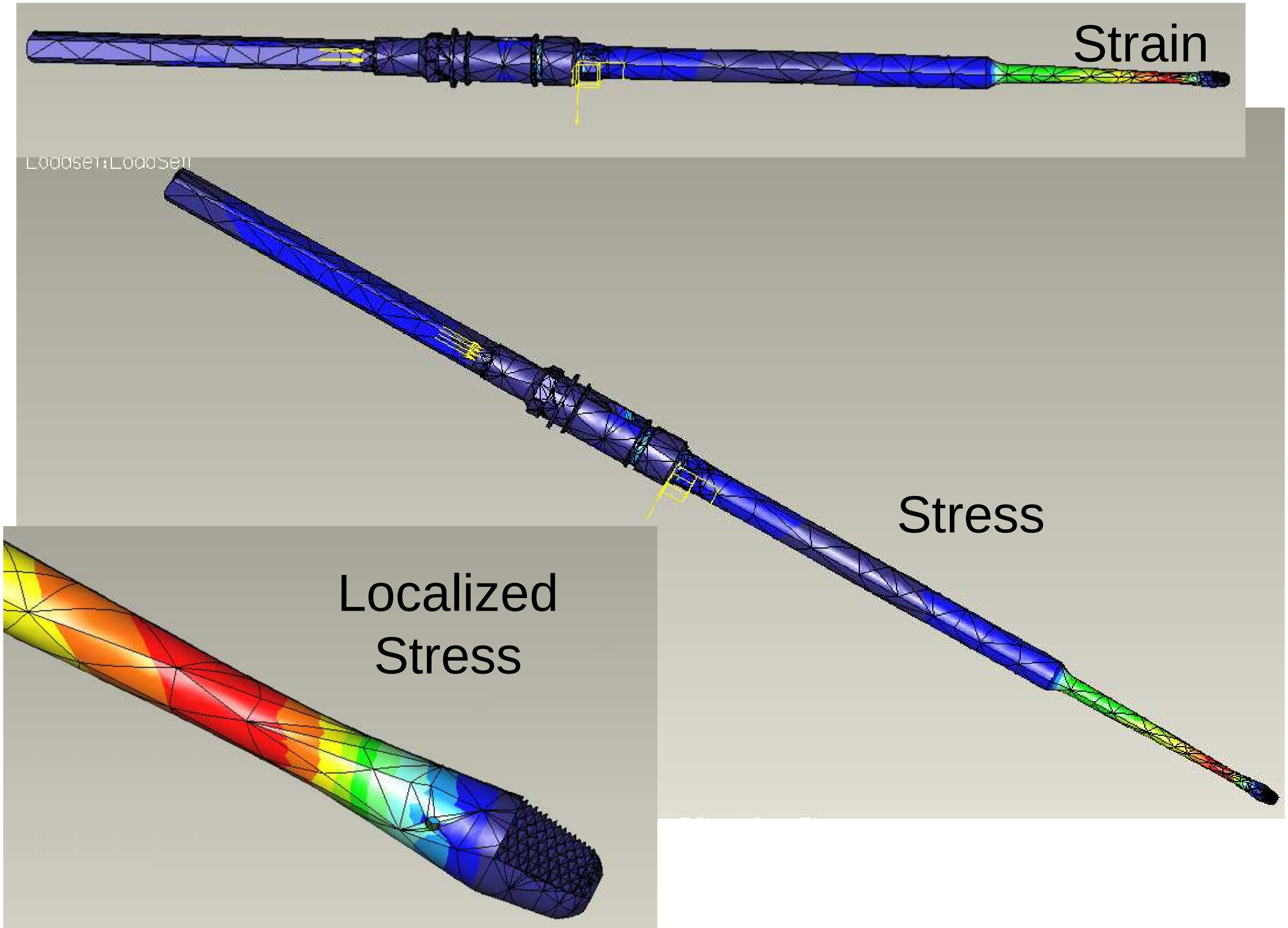


Design Frequency Analysis - 36 kHz SaberTip

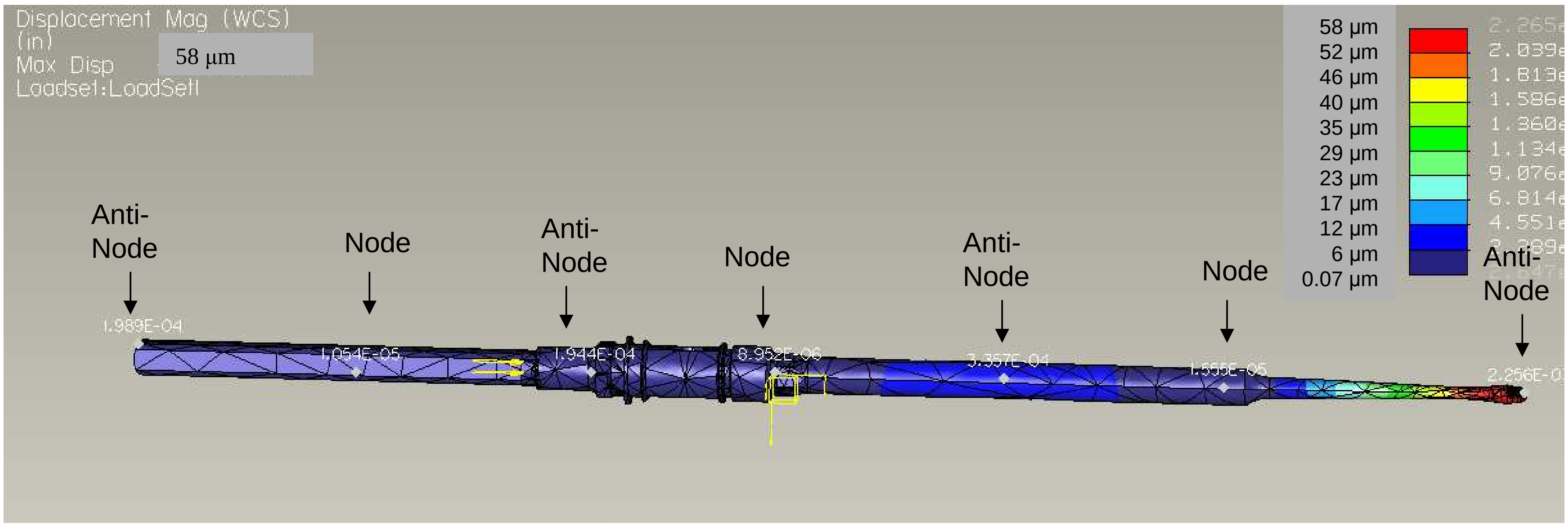


Displacement at Resonance

Master Interval Analysis - 36 kHz SaberTip

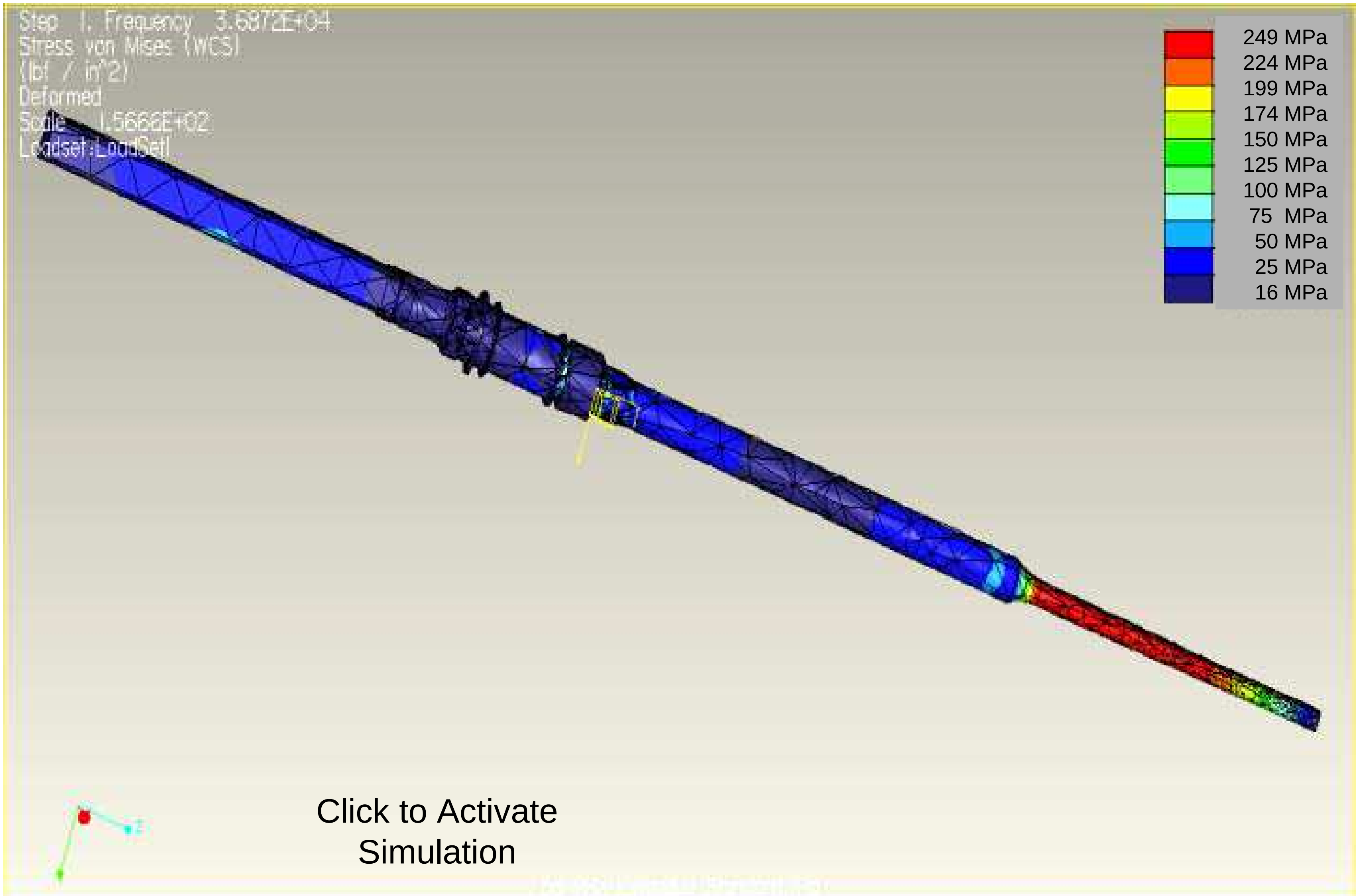


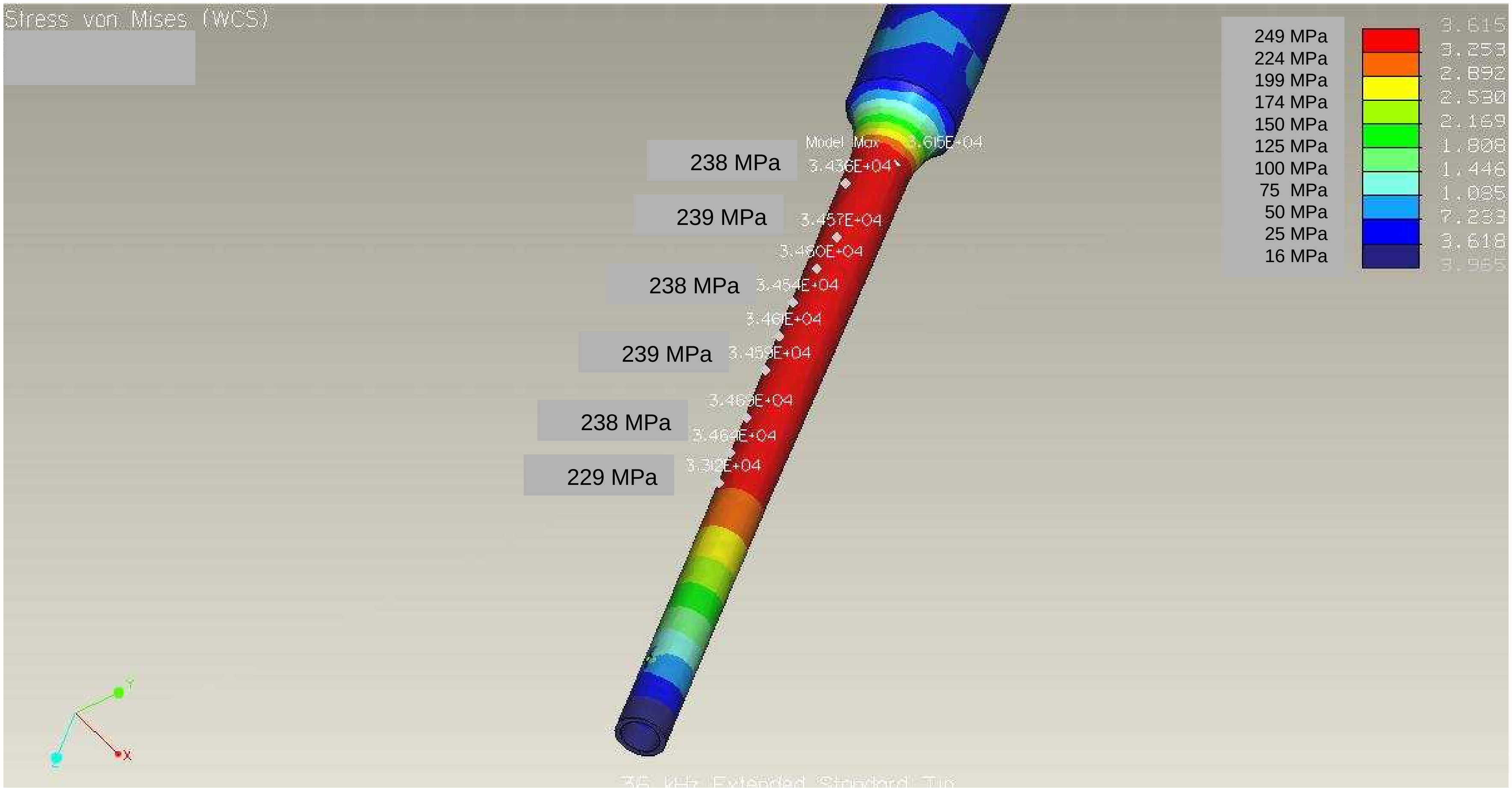
Simulation of Horn Displacement at Resonance



36 kHz Extended Standard Tip: Mechanica Simulation of Displacement

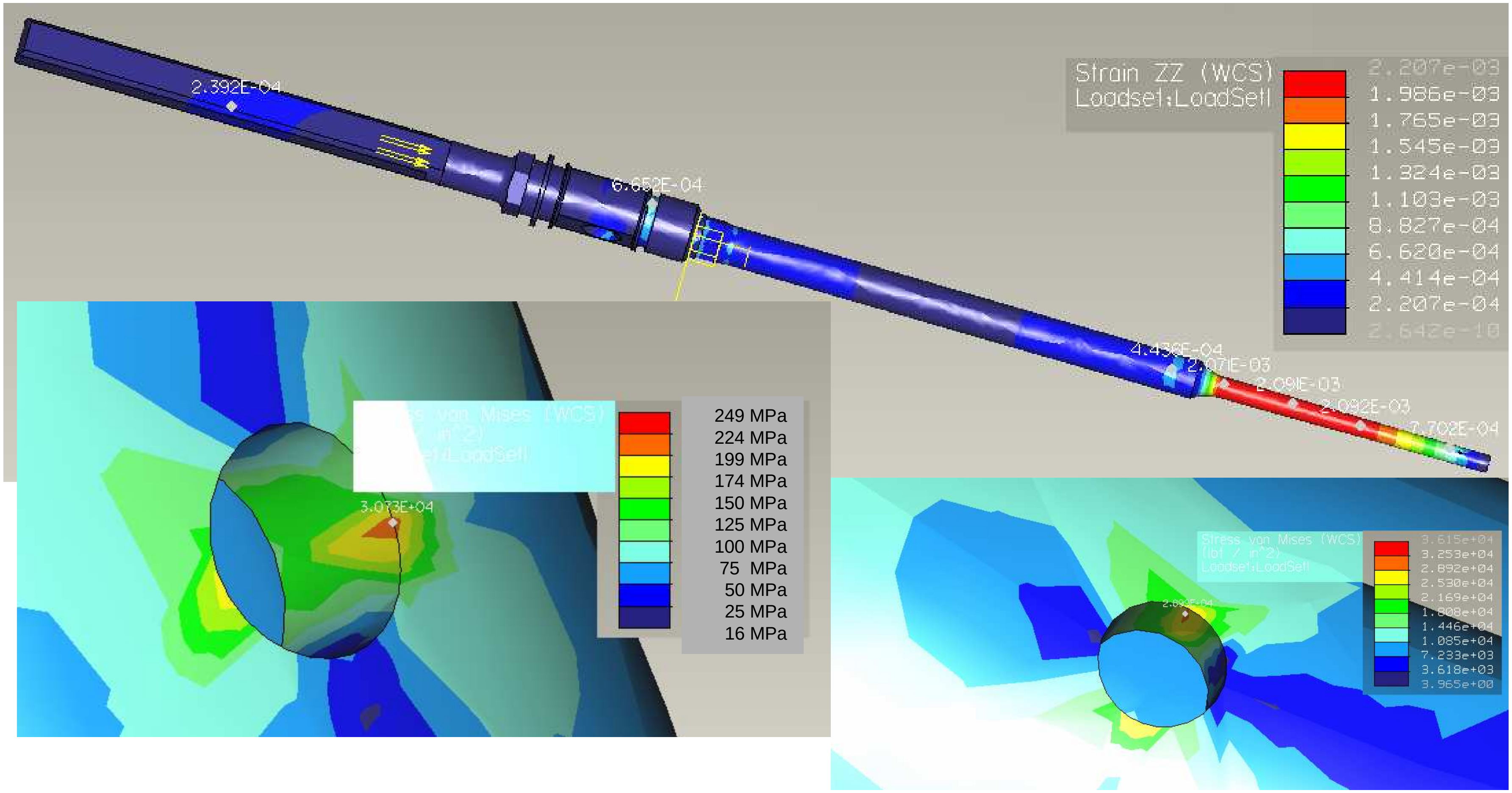
36 kHz Extended Standard Tip: Mechanica Simulation of Stress





Master Interval Design Frequency Analysis

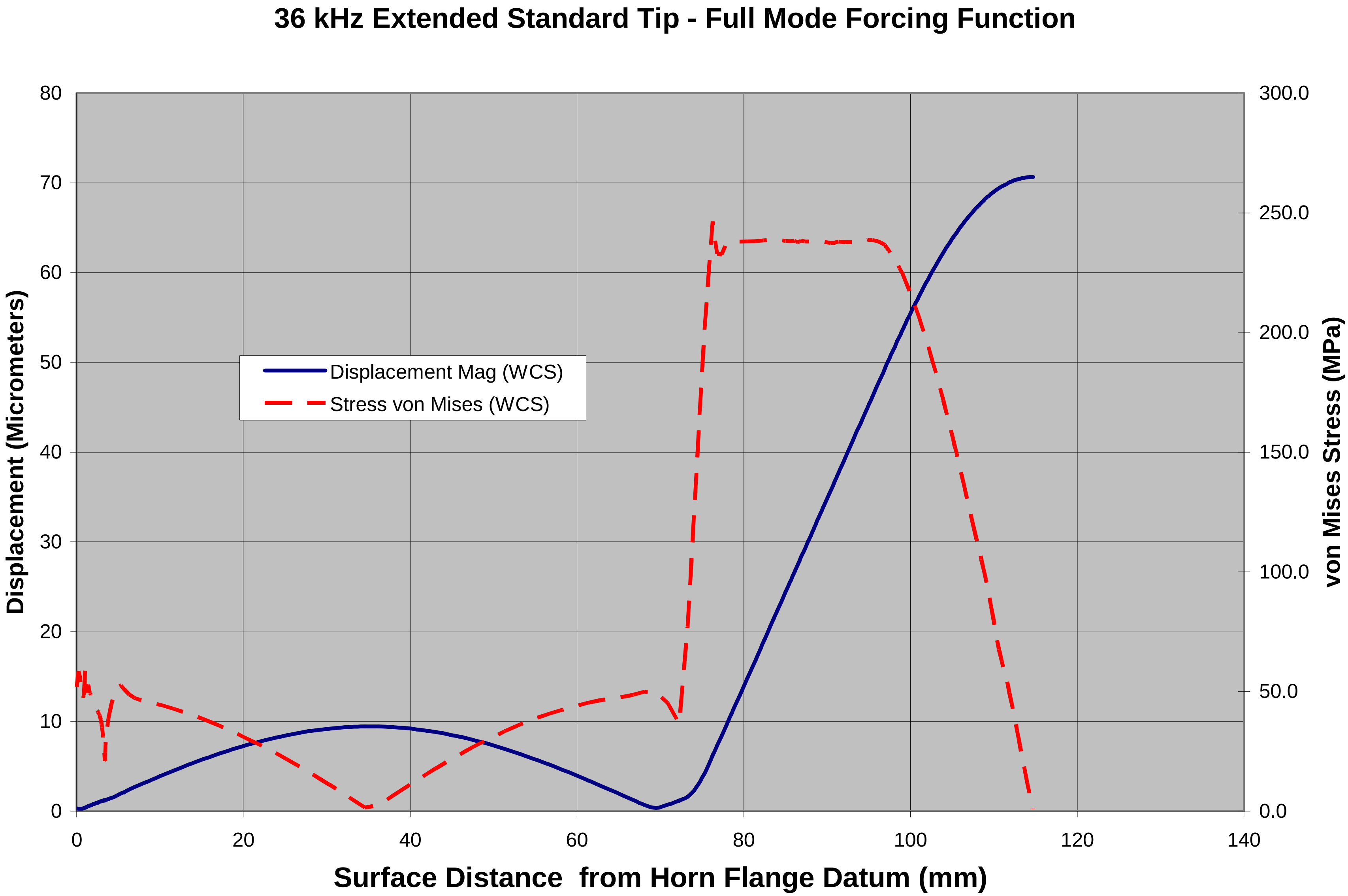
- **Simulations exhibiting spatial distribution of stress**
- **Dynamic query afforded**
- **Shows uniform strain of Gaussian profile**
- **Maintain strain over greatest Gaussian length allowed by frequency**



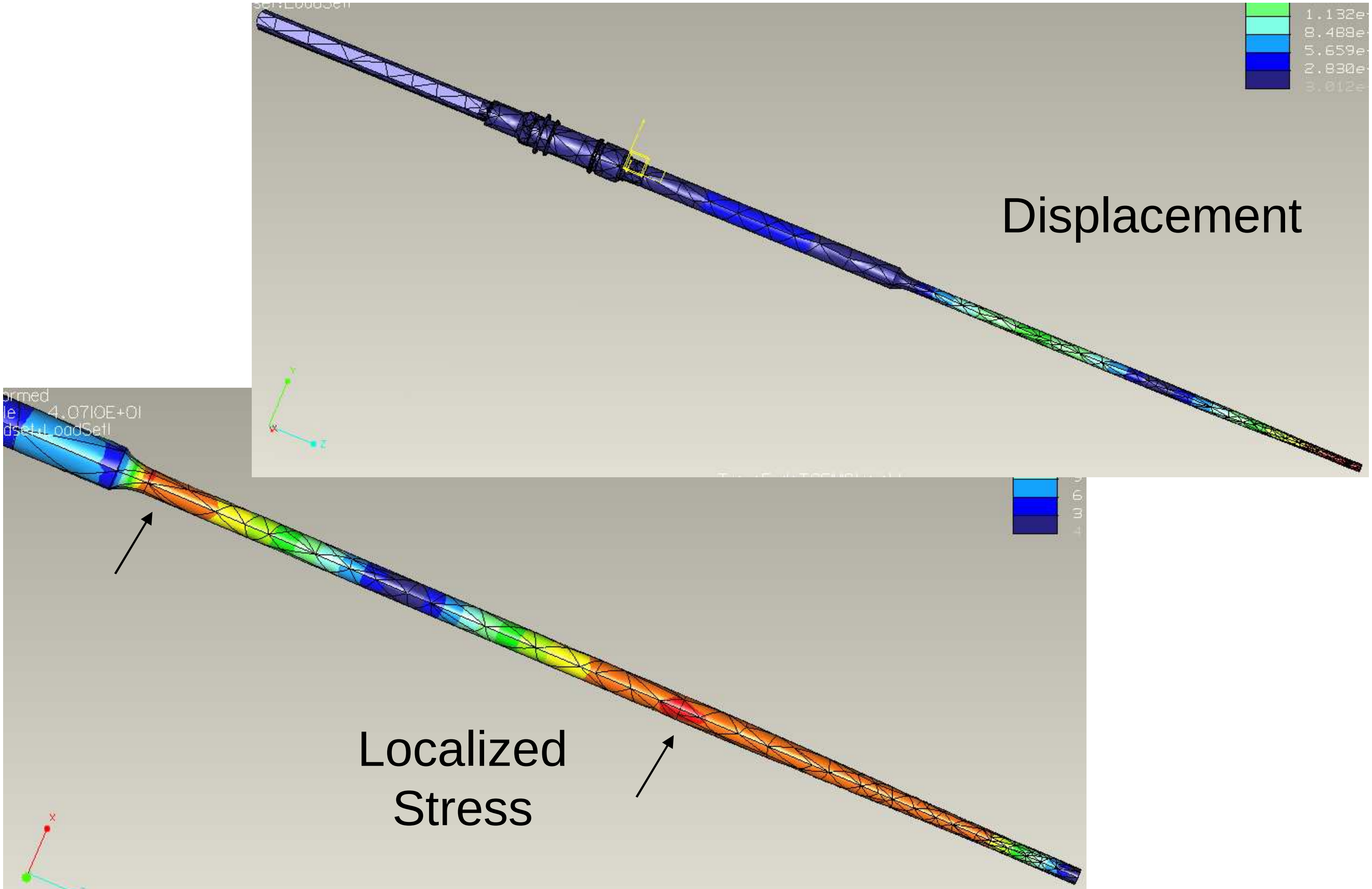
Master Interval Design Frequency Analysis

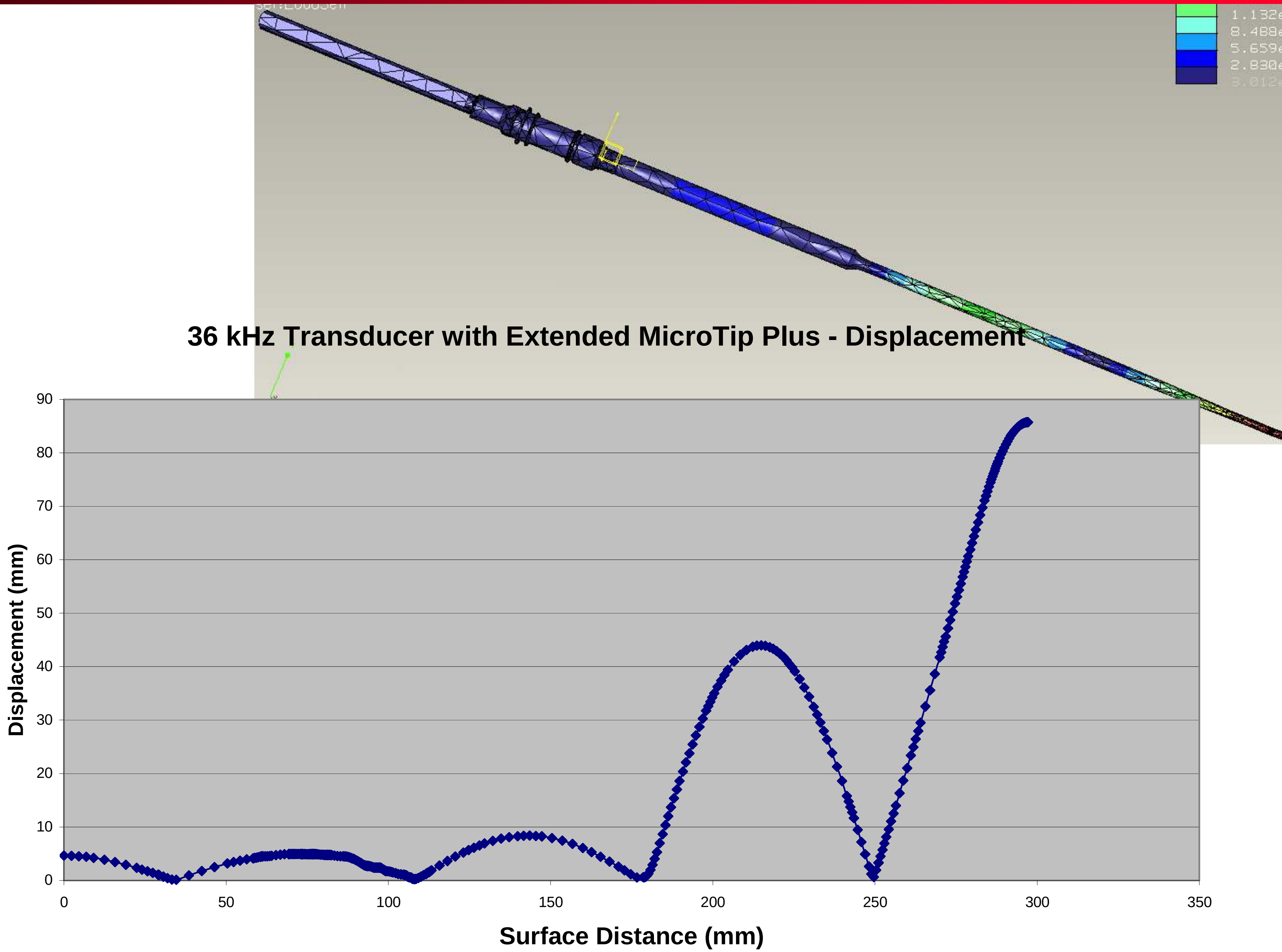
- **Strain contributing to mechanical gain of the horn is low enough when encountering the stress concentrating pre-aspiration holes to keep the maximum hole stress within acceptable limits**
- **Maximum stress in the horn is not at the pre-aspiration holes**

Master Interval Analysis - 36 kHz Extended Standard Tip



36 kHz Transducer and Extended MicroTip Plus




1.132e
8.488e
5.659e
2.830e
36 kHz Transducer with Extended MicroTip Plus - Displacement
Displacement (mm)
Surface Distance (mm)
0
10
20
30
40
50
60
70
80
90
0
50
100
150
200
250
300
350

Summary of Finite Element Analysis – 36 kHz SaberTip

	SaberTip Forcing Function	SaberTip Base Excitation Surface Constraints	MicroTip Forcing Function Baseline	MicroTip Base Excitation Surface Constraints Baseline	
Stack Displacement peak (μm)	5	5	5	5	← **Normalized**
Stack Acceleration (m/s^2)	272 x10^3	295 x10^3	267 x10^3	287 x10^3	
Horn von Mises Stress (MPa)	252	317	252	319	← **Maintained**
Horn Stroke peak-peak (μm)	**117**	124	**178**	193	← **Simulated**
Horn Acceleration (m/s^2)	3.09x10^6	3.43 x10^6	4.65 x10^6	5.18 x10^6	
Resonant Frequency (Hz)	36,925	37,362	36,614	36,938	
Input Forcing Function (N)	978	-	978	-	
Input Damping (%)	3.483	-	2.7	-	
Input Acceleration (m/s^2)	-	192	-	275	

Electromechanical Data on Fabricated Horns

Measured Results		Voltage	Current	Power	Frequency	Stroke (p-p)	
Horn		(V_{RMS})	(A_{RMS})	(Watts)	(kHz)	(μm)	
Extended MicroTip Baseline	Average	31	1.30	30	35.70	**178**	← **Actual**
	StdDev	2	0.07	2	0.01	2.5	
SaberTip	Average	23	0.80	17	35.79	**125**	← **Actual**
Initially, 50 Samples	StdDev	0.5	0.03	0.4	0.05	0.4	

Summary of Finite Element Analysis – Extended MicroTip Plus

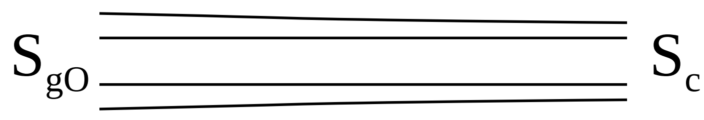
	Extended MicroTip Plus Forcing Function	Extended MicroTip Plus Base Excitation Surface Constraints	Extended Standard Tip Forcing Function	Extended Standard Tip Base Excitation Surface Constraints	
Stack Displacement peak (µm)	5	5	5	5	← **Normalized**
Stack Acceleration (m/s^2)	272 $x10^3$	277 $x10^3$	272 $x10^3$	277 $x10^3$	
Horn von Mises Stress (MPa)	211	240	249	297	← **Maintained**
Hole von Mises Stress (MPa)	168	155	212	191	
Horn Stroke peak-peak (µm)	**142**	147	**142**	147	← **Simulated**
Horn Acceleration (m/s^2)	3.81 $x10^6$	3.99 $x10^6$	3.78 $x10^6$	3.99 $x10^6$	
Resonant Frequency (Hz)	36,745	37,078	36,873	37,172	
Input Forcing Function (N)	978	-	978	-	
Input Damping (%)	1.755	-	2.86	-	
Input Acceleration (m/s^2)	-	1954	-	234	

Electromechanical Data on Fabricated Horns

Measured Results		Voltage	Current	Power	Frequency	Stroke (p-p)	
Horn		(V_{RMS})	(A_{RMS})	(Watts)	(kHz)	(µm)	
Extended MicroTip Plus	Average	34	1.31	32	35.78	**145**	← **Actual**
Initially, 21 Samples	StdDev	1	0.01	1	0.04	2.54	
Extended Standard Tip	Average	-	-	-	35.75	**145**	← **Actual**
Production data only	StdDev	-	-	-	-	-	

Gaussian Profiles – Known Frequency Shift

$$\omega_i = \frac{C_g}{L_{tip}}\left(\operatorname{atan}\left(\frac{1}{\sqrt{2\ln(N)}}\right) + \sqrt{2\ln(N)}\right) \qquad f_i = \frac{\omega_i}{2\pi} \qquad N = \frac{S_{gO}(\text{Area})}{S_c(\text{Area})}$$



Frequency Adjustments			<<< Minus 50 Hz			Plus 50 Hz >>>				
	A	B	C	D	E	F	G	H	I	J
	Profile	Profile	Profile	Profile	Profile	Profile	Profile	Profile	Profile	Profile
	- 200 HZ				35,750 HZ					+250 HZ

Mechanica Results	SaberTip Forcing Function	Extended MicroTip Plus Forcing Function	Extended Standard Tip Forcing Function	Extended Micro Tip Forcing Function Baseline
Resonant Frequency (Hz)	36,925	36,745	36,873	36,614

- **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

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