Surgical & Dental Transducers Suitable for Single Use Applications

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Background

- Mad cow disease
  - Causal relationship between mad cow disease and human variant Creutzfeldt-Jakob (vCJD)
- Re-usable Surgical Instruments
  - Risk of contamination and transmission of the disease
  - Prion penetrates the micro structure of metal components and is known to be resistant to sterilization by steam autoclave
- Highest Risk Surgical Procedures
  - Disease affects the brain
  - Ultrasonic procedures that expose neurons to prion contamination include phacoemulsification and brain surgery using soft tissue aspirators

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Background

Marketing

- Damien Walmsley Professor of Restorative Dentistry

  "I think some patients might be prepared to pay more for teeth cleaning using a single use ultrasonic device"

- Eye Doctor

  " The average age of a woman having cataract surgery is 72 years old. The incubation period for mad cow disease is 7 years"

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Background

Market Analysis - My Perspective

- Ultrasonic Medical Device Designers/manufacturers
  - Design-in single use instruments and components whenever possible. Examples include phaco needles, scalpel waveguides, and dental scaler inserts
  - Incorporate novel and often patented design features that limit the number of uses and provide a unique interface between the control system and ultrasonic handpiece.
- Doctors and Hospitals
  - Without jeopardizing patient safety will often re-use devices and components that were originally designed for single use.
- After-market Suppliers
  - Repair OEM instruments and ultrasonic handpieces
  - Provide single use components at reduced cost

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New Technology

with the potential to influence the market

- Lead-free High Performance Piezo Ceramic LF4T
  - Toyota Inc & Denso Corp (Nature Vol 432, Nov 2004)
  - "The most successful piezoelectric materials are based on lead zirconate titanate. Environmental concerns over their lead content could disappear with the advent of a new ceramic that is lead free" (Doug Cross, Professor, Materials Research Lab, Penn State)

Piezoelectricity Property	LF4T	PZT4	Barium Titanate
Curie temperature °C	253	320	115
Coupling coefficient Kp	0.61	0.58	0.31
Charge constant d_{33} pCN^{-1}	416	295	150
Voltage constant $g_{33} 10^{-3}$ VmN^{-1}	29.9	24.5	14.3
Dielectric constant	1570	1300	1220
Mechanical Q	?	500	600

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Scope of this Presentation

The feasibility of designing a transducer with the following attributes

- Low cost
  - Materials/components
  - Labor
- Zero residual value following the medical procedure
  - Rendered inoperable should any attempt be made to steam sterilize
  - To be beyond economic repair after the single use
- Disposal
  - Transducer manufactured using environmentally friendly materials

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Comparison

High volume domestic versus specialist medical

Mentor Contour Aspirator Liposuction handpiece

Retail value $3200

Maximum power 150 watts

Withstands 300 steam autoclave cycles

Black & Decker Buzz Ultrasonic Stain Removal

Transducer Retail value approximately $10

Maximum power 10 watts

Relatively benign operational environment

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Benchmarking Performance

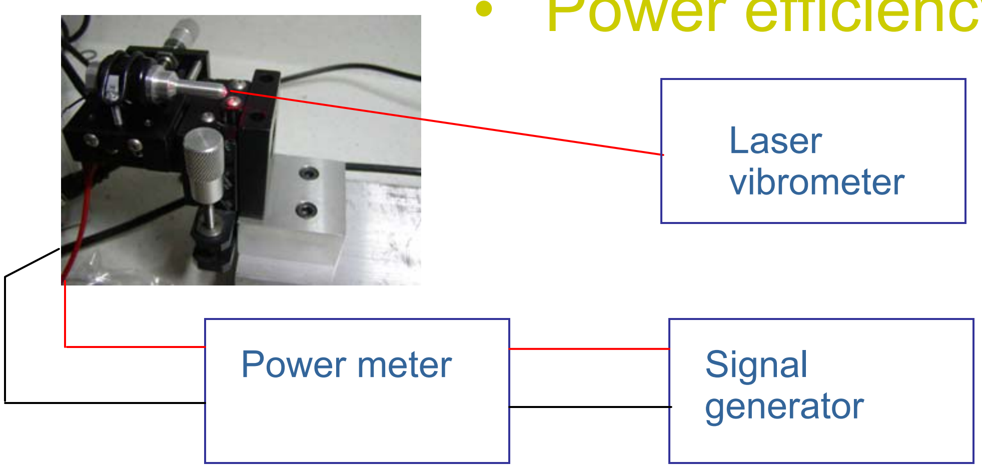
- Electro-mechanical efficiency (piezo stack heat)

  Test the transducer in the max power loaded condition at the resonant frequency, measure current I_{FP} and power.

  Test transducer with tip radiating in air, adjust current to I_{FP} and tune for resonance. Measure the quiescent power.

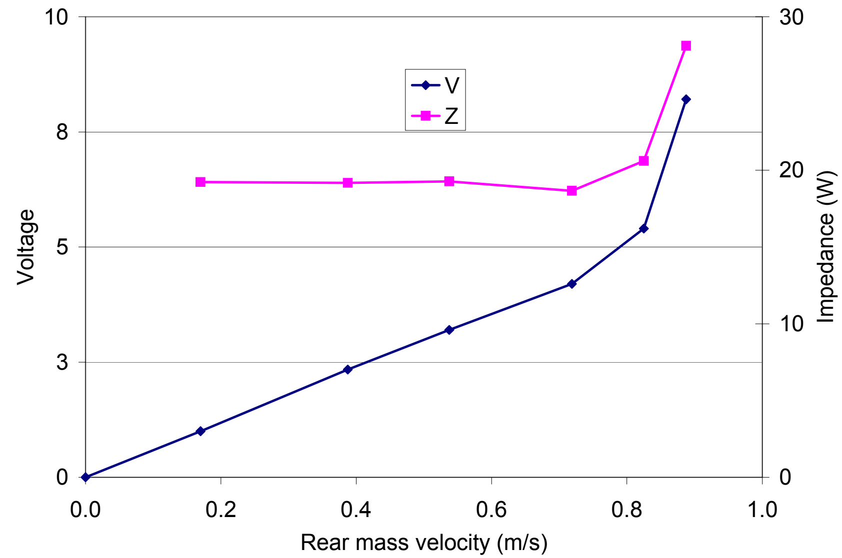
$$\text{Electro-mechanical efficiency} = \frac{\text{Max power - quiescent power}}{\text{Max Power}}$$

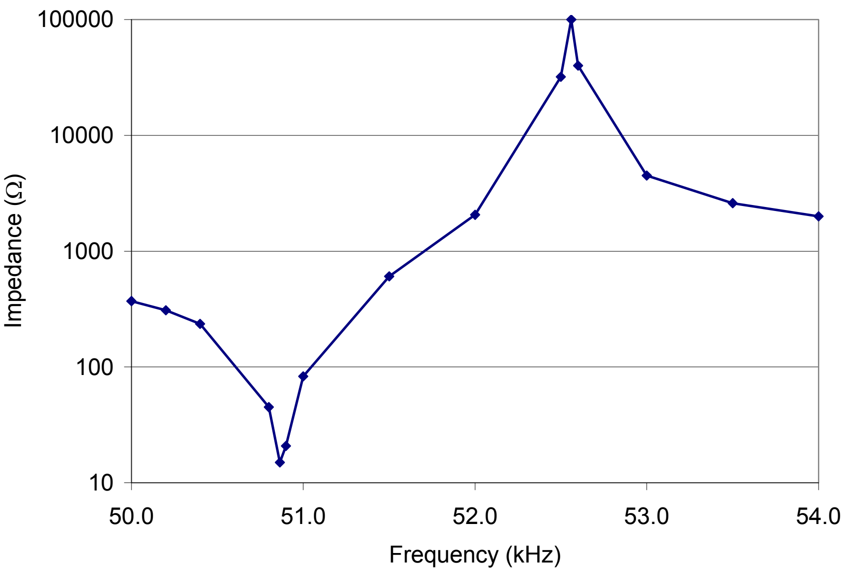
- Power efficiency (tip velocity Vs input power)



Benchmarking Performance

- Operational voltage
  - Lowest possible voltage
  - Safety - IEC, tanδ loss





- Effective coupling coefficient (f_a-f_r
  - Potential system control problems if F_a-F_r is too small

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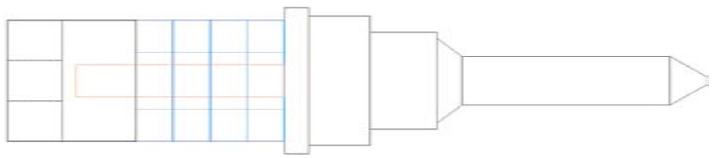
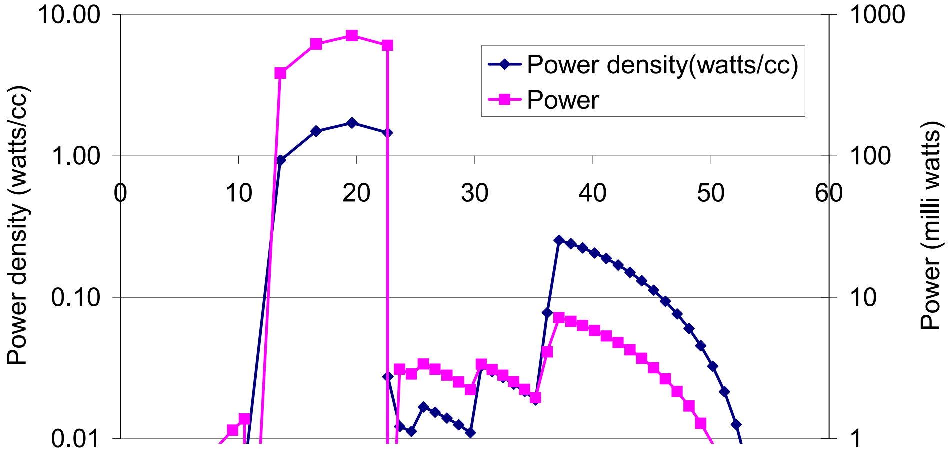
Benchmarking Piezo Stack Performance

- Medical/dental transducer design limitation
  - Typically cyclic stress within the piezo stack
    - Problems associated with bias stress and bias stress bleed-off
    - Heat generated by the piezo elements and their joints
- Piezo/Joint losses
  - Combined value (mechanical Q) can be determined from measured data and “best-fit” with PiezoTran analysis software



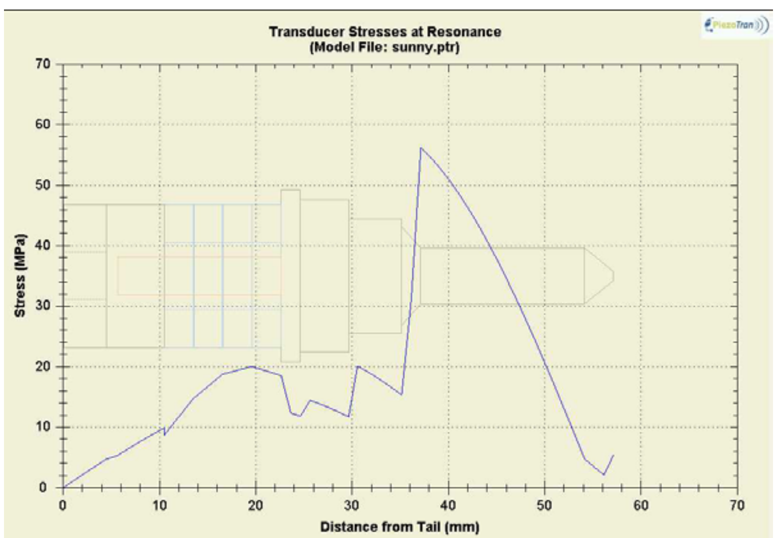
Relates to a maximum safe power condition where the stack temperature is limited to 60 ◦C



Transducer: Critical Design Analysis

Node does not coincide with the mounting flange

Ratio of horn tip to rear mass displacements could be improved if rear mass was made from steel instead of aluminum



For an aluminum horn the ratio of the horn step stress to the max. piezo stress should be approximately 4.4 : 1.

For this design the ratio is 2.75 : 1

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Piezo Stack: Critical Design Analysis

- Joint losses: compare with PI proprietary method

4 Navy Type I Rings 15 mm X 6 mm X 3 mm
Mechanical Q of piezo/joint combination = 130

40 kHz test transducer with Stainless steel end masses

4 Navy Type I rings 10 mm X 5 mm X 2 mm
Mechanical Q of piezo/joint combination = 166

- Piezo material loss

4 Navy Type III Rings 9.5 mm X 5 mm X 2 mm
Mechanical Q of piezo/joint combination = 300

4 Navy Type I rings 10 mm X 5 mm X 2 mm
Mechanical Q of piezo/joint combination = 166

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Design Evolution and Optimization

- Evolving this transducer design for phacoemulsification
  - Step 1: Change to 4 Navy III rings 10mm X 5mm X 2mm (no additional cost)
  - Step 2: Change horn geometry, change rear mass to stainless steel, provide a central aspiration lumen through the horn, bolt, and rear mass
  - Step 3: Attach a titanium needle
  - Step 4: Enclose in a housing with irrigation (Note the Buzz system/handpiece includes an irrigation lumen)

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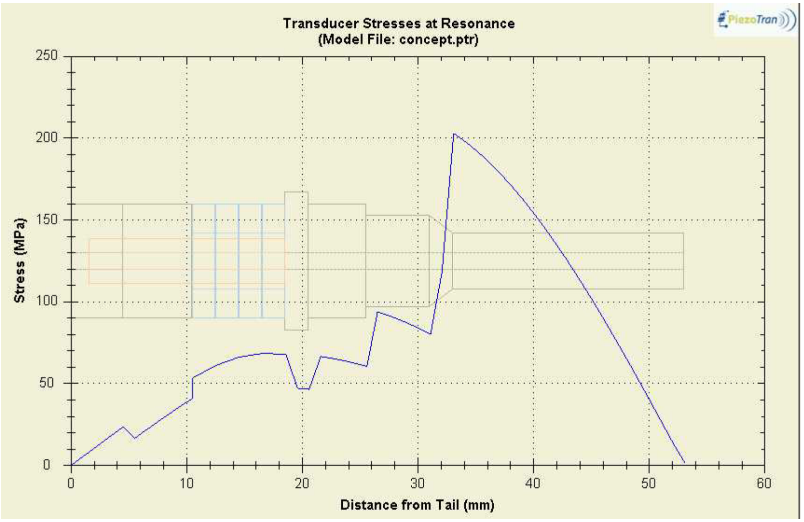
Predicted Performance of Low-cost Phaco Transducer

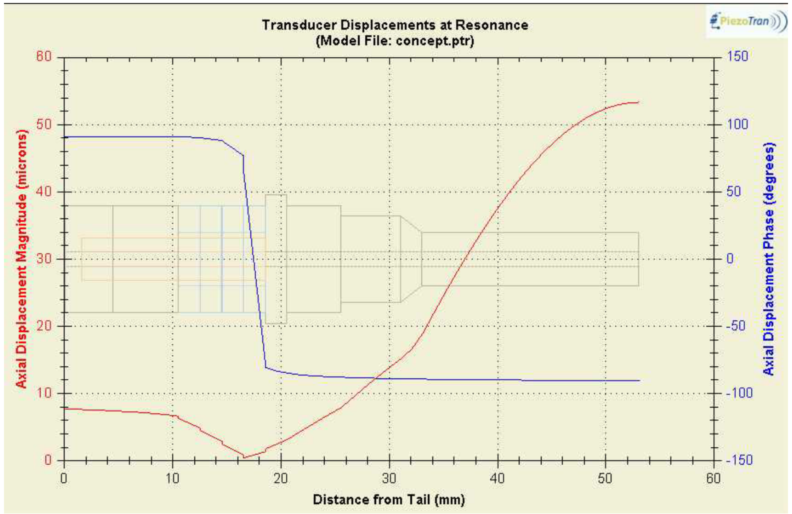


Cyclic stress in aluminum horn limited to 200 MPa p-p

Note that the max cyclic stress for a titanium horn would be 400 MPa.

High cyclic stress in piezo will require high bias stress of about 50 MPa (OK for single use)

High cyclic stress in piezo will require cooling by the aspiration fluid



Adding a titanium needle at the tip of the horn will increase the stroke by about 15% to 60 μm p-p. The resonant frequency with needle attached will be approximately 45 kHz

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Low-cost Phaco Transducer:

Estimated to cost between 50% and 100% more than the Buzz transducer

- Aluminum Horn
    - Stroke limited by cyclic stress
    - Changing to titanium would increase horn cost by a factor of 2
    - Would need some form of protective coating
- Piezo
    - Mating surfaces would need to be lapped flat before applying the silvered electrode
- Bias bolt
    - Customized stainless steel component with aspiration port drilled through the center
- Rear mass
    - Stainless steel

Single Use Transducer Design

- Rendered inoperable after steam sterilization
  - Fabricated using piezo materials that have a low Curie temperature < 200°C
  - Piezo stack compressed using an epoxy bonding method having a Tg < 100°C
- Permanent end effector/tool attachment
  - Using a self locking taper
- Disposal
  - Fabricated from materials that will not cause harm to the environment (Lead-free piezo)

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Piezo for Single Use Transducers

Piezoelectricity Property	LF4T	PZT4	Barium Titanate
Curie temperature °C	253	320	115
Coupling coefficient Kp	0.61	0.58	0.31
Charge constant d_{33} pCN^{-1}	416	295	150
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Dielectric constant	1570	1300	1220
Mechanical Q	?	500	600

Note: PZT4 contains lead and is included in the table above for comparison purposes

- LF 4T
    - New material still being developed. Suitable for single use as the properties will probably degrade rapidly if subjected to autoclave temperatures with bias stress applied .
- Barium Titanate
    - Superceded by PZT 40 years ago.
    - Pros: cost, low curie temperature and relatively high mechanical Q
    - Cons: Low coupling coefficient, d_{33} and g_{33}

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Transducer Performance Implications of Using Barium Titanate

Test Transducer # 1

4 barium titanate rings

9.5 mm X 4.4 mm X 2.54mm

Lapped flat using1500 grit

Bias stress 37 MPa

Test Transducer # 2

4 PZT 8

9.5 mm X 5.0 mm X 2mm

Lapped flat using1500 grit

Bias stress 35 MPa

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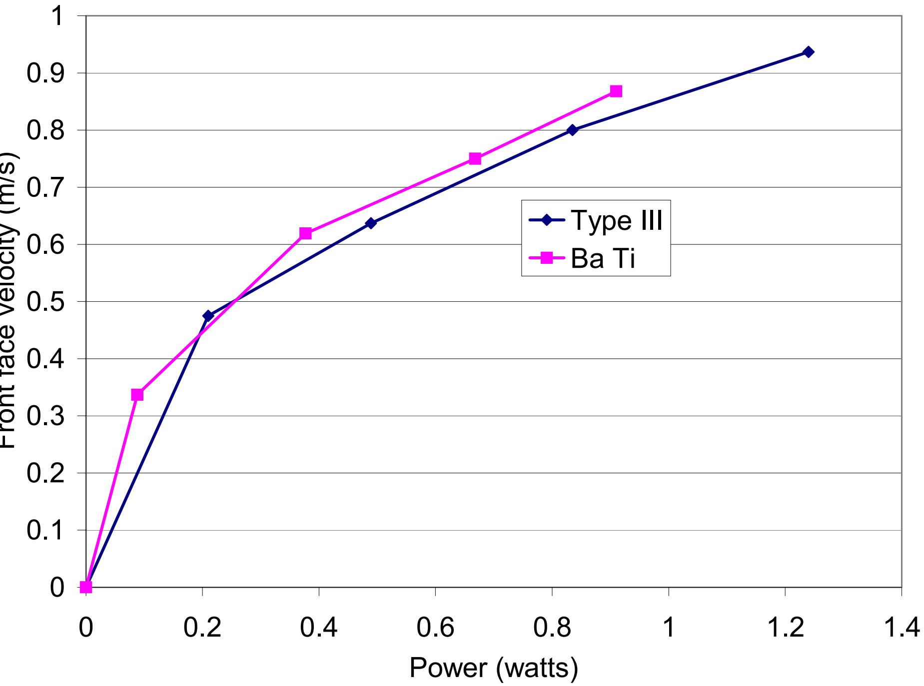
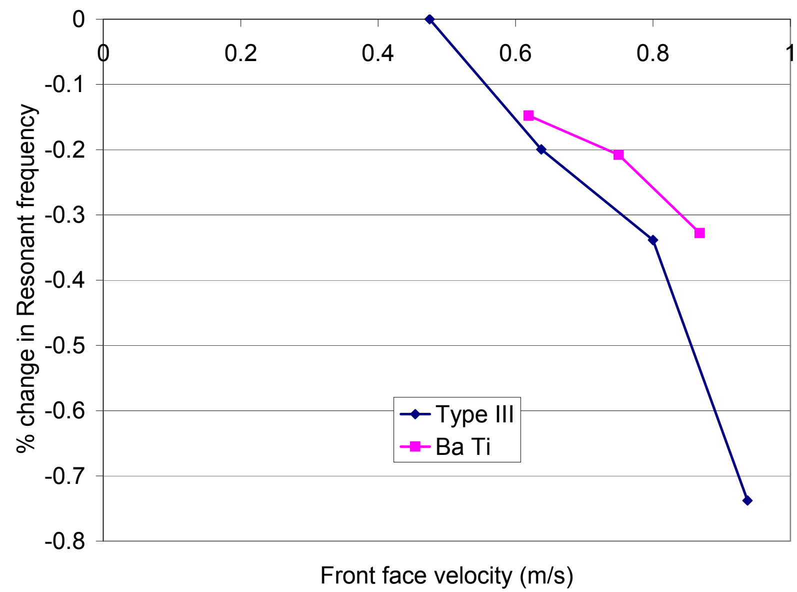
Performance Comparison





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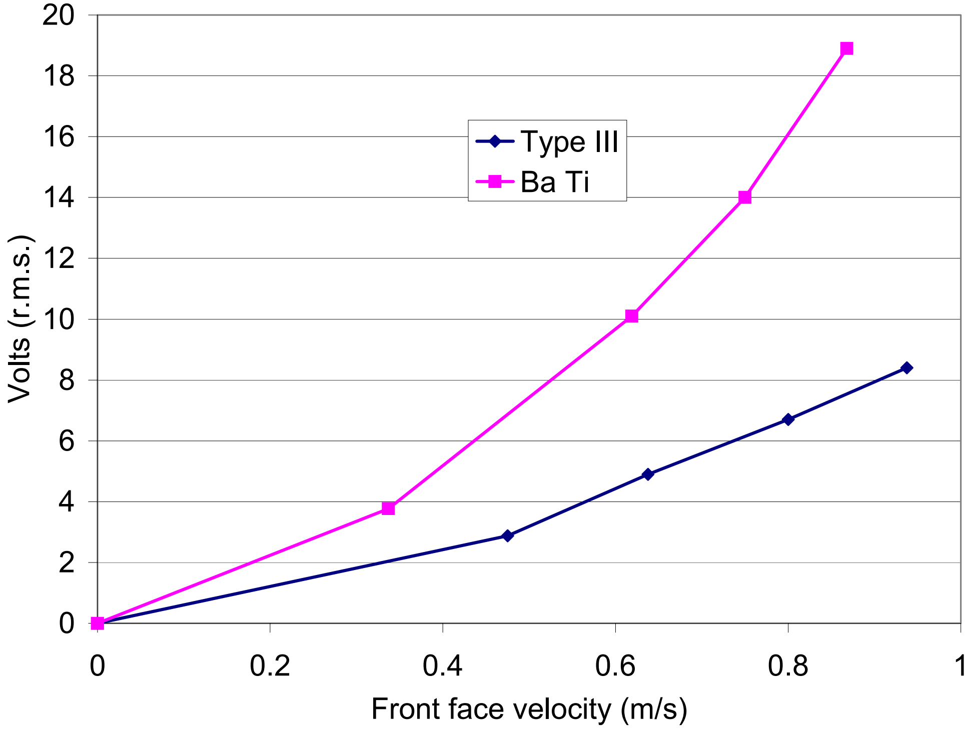
Performance Comparison



Note: Barium titanate rings were 2.54mm thick and the Type III rings were 2mm thick. For valid comparison the Ba Ti volts need to be reduced and the actual ratio is approximately 2:1.

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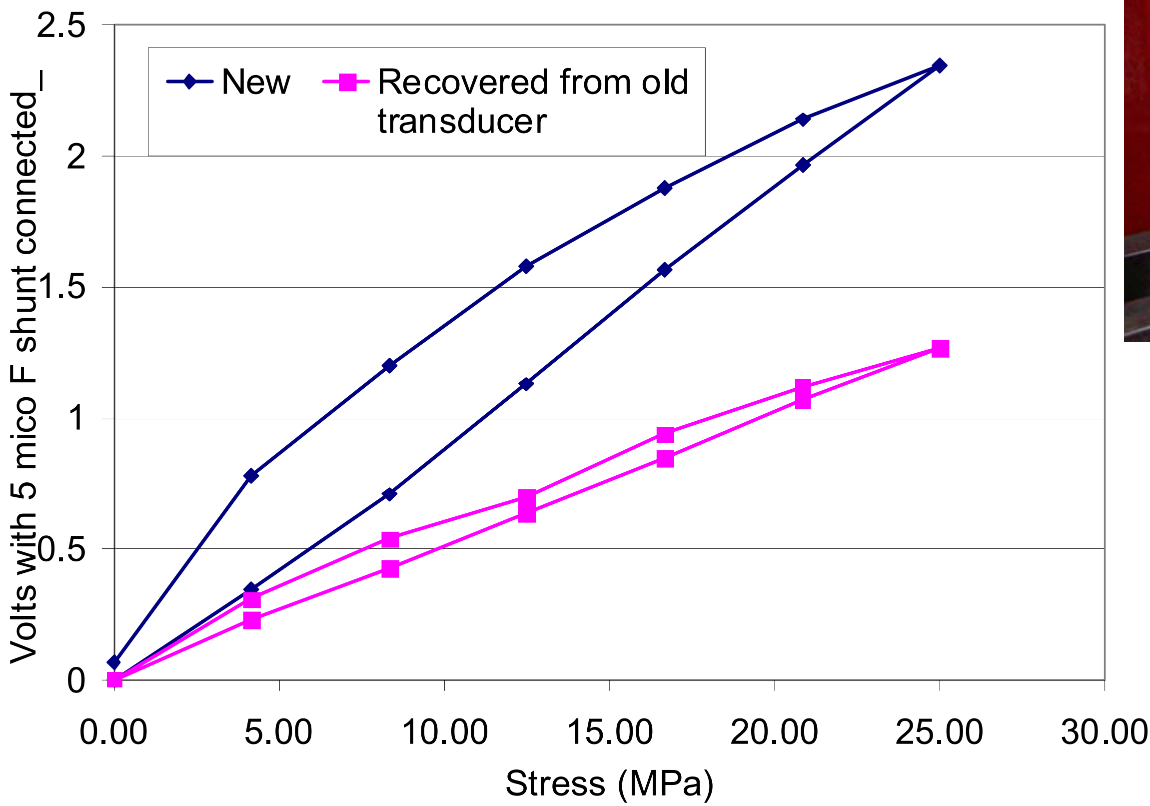
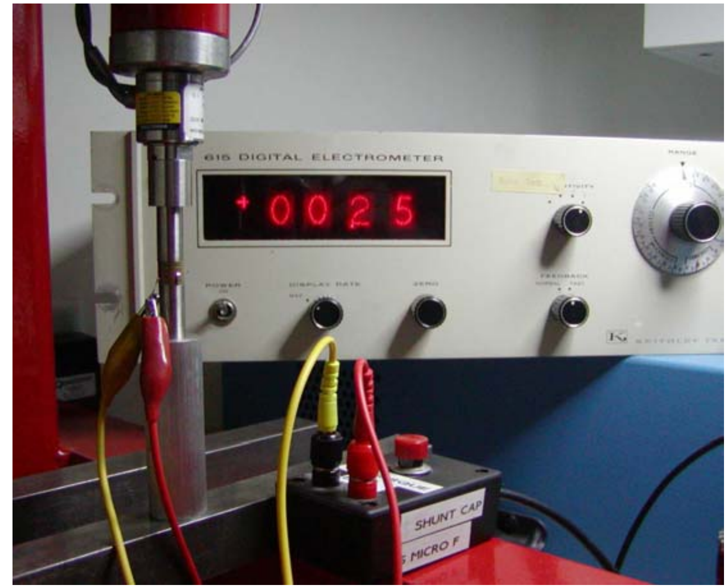
Performance Comparison

With end-of-life re-usable Type III PZT transducer





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Piezo Properties Comparison

Old multiple use type III PZT versus Single-use BaTi O_3

Piezoelectricity Property	Type III	$BaTiO_3$
Curie temperature °C	320	115
Coupling coefficient Kp	0.55	0.31
Charge constant d_{33} pCN^{-1}	245	150
Voltage constant g_{33} 10^{-3} VmN^{-1}	25	14.3
(Stansfield 10 day nominal values)		

- Old Re-usable Transducer
  - Initial stack bias stress = 60 MPa
  - Multiple steam a/c cycles
  - g_{33} degrades to $14x10^{-3}VmN^{-1}$
- Single Use Transducer
  - Initial stack bias stress = 25 MPa
  - 1000 day + aged piezo
  - g_{33} degrades to $10.5x10^{-3}VmN^{-1}$

Note: g_{33} data relates to PiezoTran "best fit" computer model of the transducers in air at low power

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Novel Single-use Transducer Design Features

- Transducer assembly method
  - Piezo stack compressed using an epoxy bonding method having a Tg < 100°C

- Permanent end effector/tool attachment
  - Using a self locking taper Transducer

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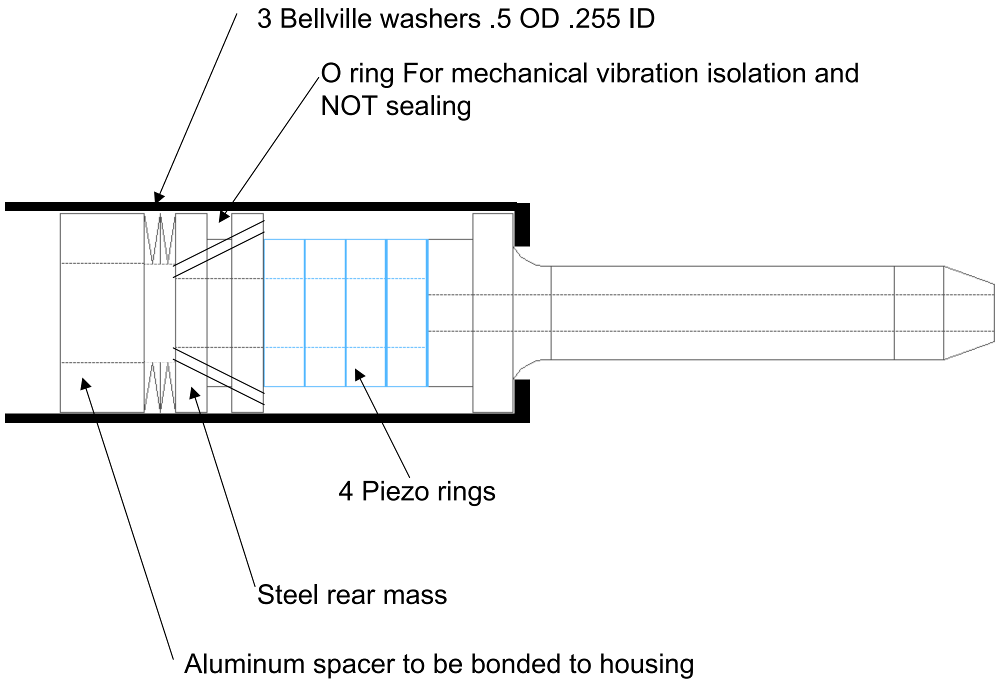
Single-use Transducer Assembly

Phaco Transducer Assembly



Novel Design Features:

Belleville washers replace the center bias bolt and de-couple the rear mass

Aluminum spacer at the rear can either be bonded to the housing or can be screwed into the housing

Test data with needle attached and using barium titanate rings:

Fr = 41720 Hz, Zmin = 10kΩ* , Cap = 953 pF

* Piezo not lapped flat

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Single-use Transducer Assembly

Conventional design using Barium Titanate Rings

Titanium Horn

4 Barium Titanate rings lapped flat

Stainless steel rear mass

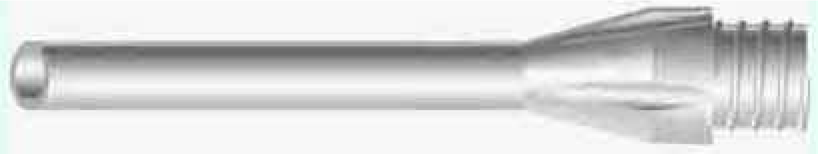
HP Impedance Analyzer Test Data

With needle attached: Fr = 46.040 kHz, Zmin = 2.6 kΩ, Cap =779 pF

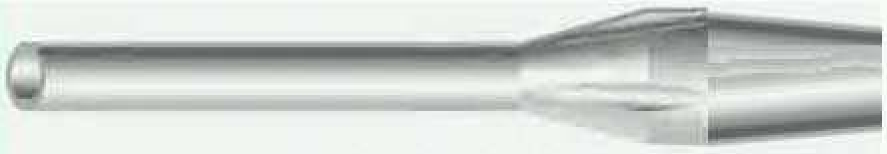
Without needle attached: Fr = 61.340 kHz, Zmin = 1.5 kΩ, Cap =779 pF

Permanent Tool Attachment

- Replace screw threads



- With self-locking taper



  - Taper angle < 16 °
  - Reduces cyclic stress losses associated with screw threads

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Conclusions

- Low-cost (Phaco transducer)
    - US Market: Handpiece retail cost approximately $5000, typically used 500 times, cost per procedure $30 (including cleaning and sterilization, and single use needle)
    - Cost goal of $30 would only be achievable with reduced stroke and manufacture in a country with low labor cost
- Single-use
    - LF 4T has similar characteristics to PZT and therefore has the potential to be substituted into existing designs.
    - New transducer designs could be optimized to use Barium Titanate. They would operate at high voltage and have lower (Fr - Fa)

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- Piezo Innovations
  - This research has been internally funded by PI and is protected by a number of provisional patent applications.
    - The Barium Titanate rings were supplied free of charge by Morgan Electro Ceramics

- References

David Wuchinich. “A practical evaluation of elastic power loss in harmonically strained structures”, oral presentation to the Ultrasonic Industry Association Meeting May 15, 1998 King of Prussia, Pennsylvania).

Underwater Electroacoustic Transducers by D. Stansfield published by Peninsula Publishing

M. J. Earwicker, Mathematical Modelling of Piezoelectric Transducers, and Sean Winterer for developing the PiezoTran software based on this model

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