ActiveNeedle Technology for Safe Needle Intervention

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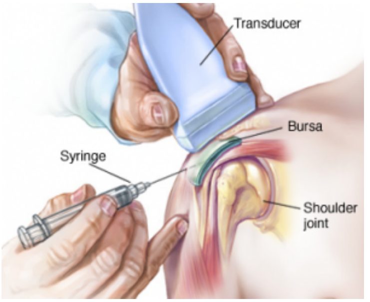
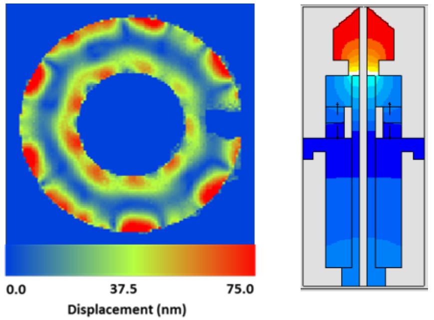
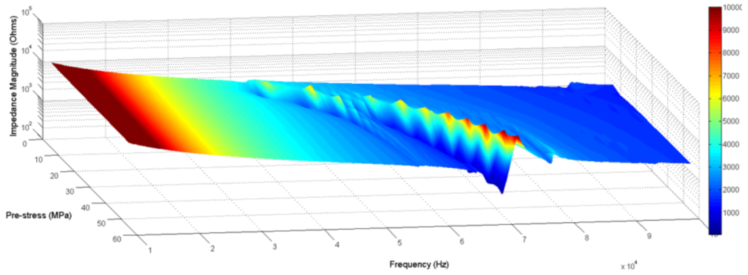
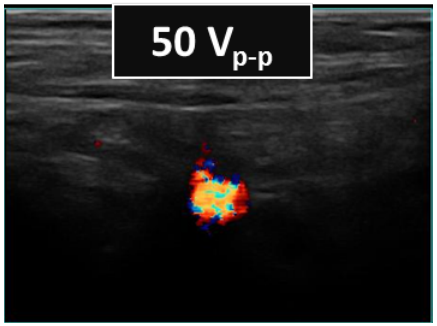
Presentation Outline

- **Background**
- **Objectives**
- **PZT vs Mn:PIN-PMN-PT Devices**
- **Experimental Studies**
- **Summary**
- **Acknowledgement**



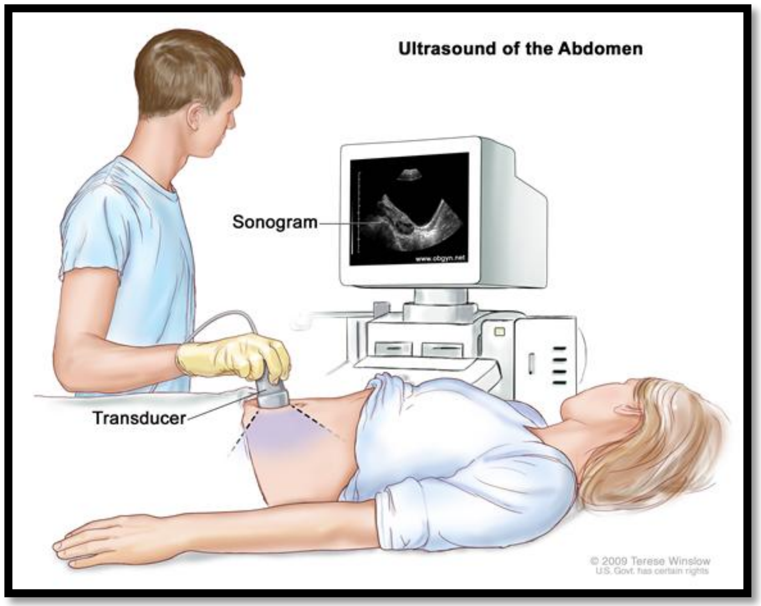






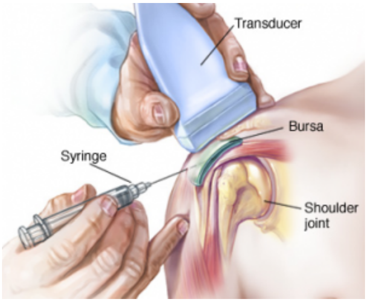
BACKGROUND

Unmet Clinical Need

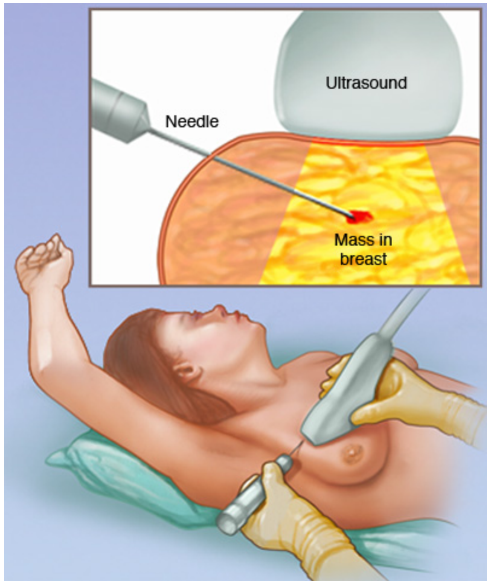


Source: www.nibib.nih.gov/science-education

Source: www.nysora.com



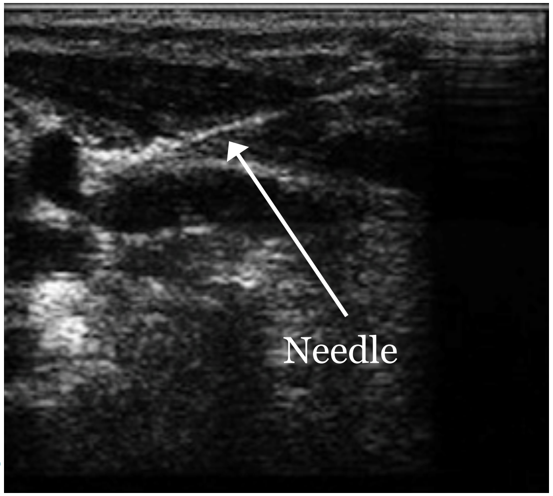
Source: www.sportsandpain.co.nz



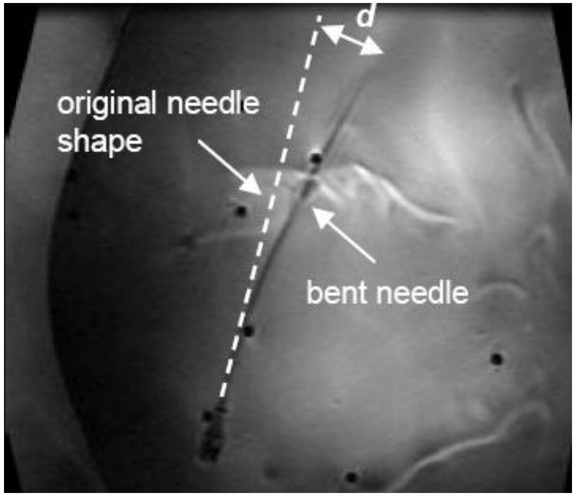
Source: www.sparrow.org/HealthLibrary

Unmet clinical need: To **improve accuracy and safety** by reducing needle placement errors

Unmet Clinical Need



An Example of Poor Tip Visibility
J Emerg Med. 2009 Nov;37(4):403-8



An Example of Needle Tip Deflection
http://www.bdml.stanford.edu

40M needle based procedures conducted each year in the USA alone

- **Nerve Damage:** 1 in 10 patients report numbness
- **Repeat Biopsy:** Inadequate biopsies in 2 in 10 cases
- **Increased Cost:** $20 for every minute in the operation room

Needle misplacement costs over $ 1 Billion p.a. (www.inneroptic.com)

Solution – ActiveNeedle

A **award winning** device for precision needle targeting (WO 2014140556 A1, 2014)

Pre-clinical Prototype

Needle Actuating Device in Operation

Potential Clinical Benefits

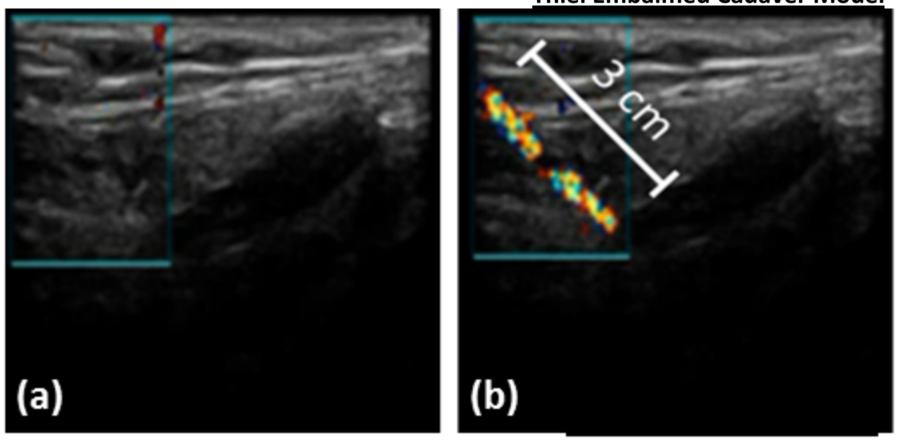
Increased Visibility: Especially at angles steeper than 45˚

Reduced Deflection: Especially at depths deeper than 3 cm

Reduced Pain/Trauma: Better penetration through tissue interfaces

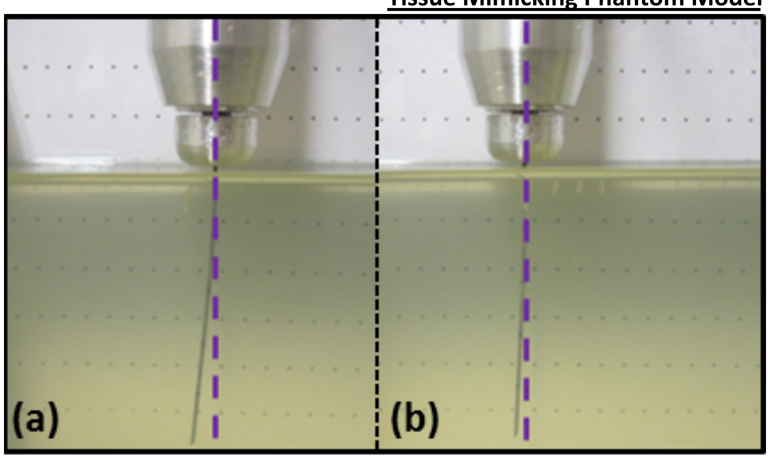
Solution – ActiveNeedle

Thiel Embalmed Cadaver Model



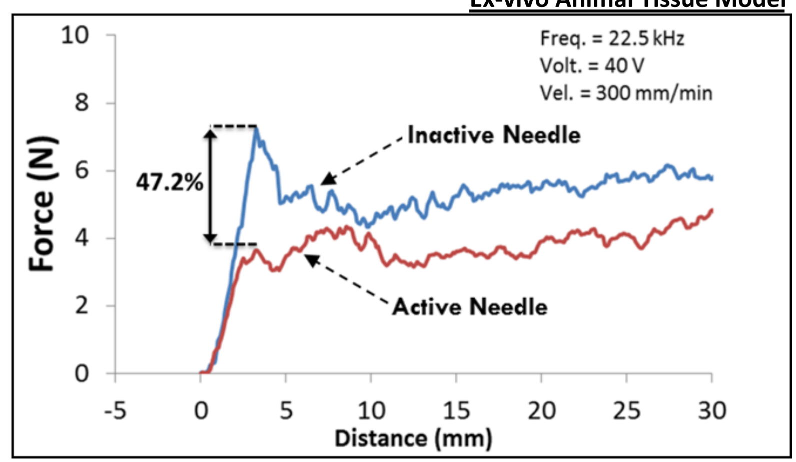
ActiveNeedle makes the standard needle visible in colour under Doppler ultrasound – (a) Inactive and (b) Active Needle

Tissue Mimicking Phantom Model



ActiveNeedle reduces penetration force consequently reducing tip deflection – (a) Inactive and (b) Active Needle

Ex-vivo Animal Tissue Model



Effect of Activation on Needle Penetration Force

OBJECTIVES

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Objectives

- Fabricate and characterize **PZT4** and **Mn:PIN-PMN-PT** devices
- Observe the **effect of pre-stress** on transducer performance
- Observe the **effect of piezoelectric materials** on device performance

PIEZOELECTRIC MATERIALS	k_{33} -	d_{33} pC/N	s_{33} m^2/N	Q_M -	T_C °C	E_C kV/cm
PZT 4	0.68	328	19.6	500	320	14.2
PZT8	0.67	275	18.3	1000	300	19
PMN-PT	0.95	1540	67.7	100	135	2.3
PIN-PMN-PT	0.92	1320	57.3	180	197	5.0
Mn:PIN-PMN-PT	0.90	1341	62.4	810	193	6.0

Comparison between various piezoelectric materials based on key parameters

PZT4 Vs Mn:PIN-PMN-PT DEVICES

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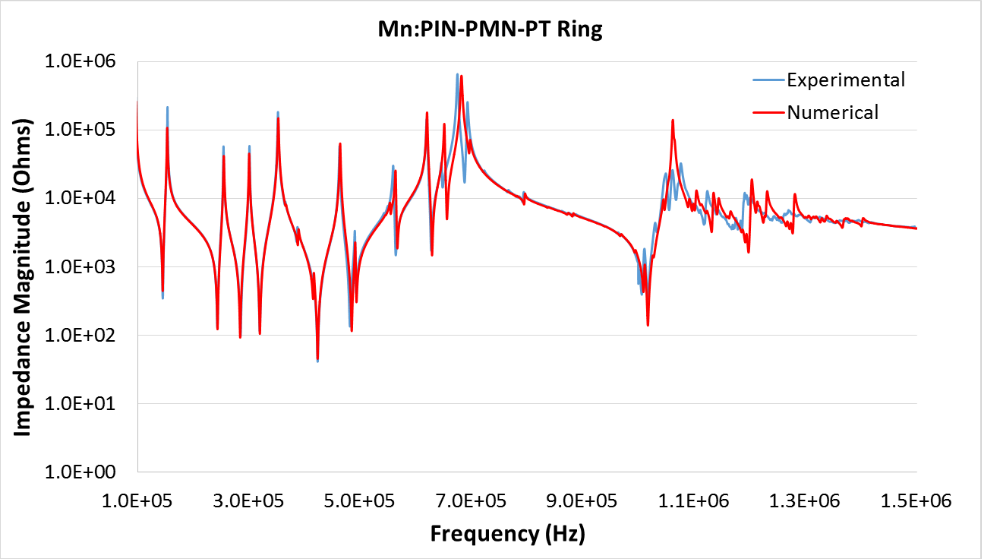
Ring Analysis

- Piezoelectric rings (OD = 10mm, ID = 5mm and t = 2mm):
  - **Navy Type I / PZT4** Piezoceramic (Meggitt Ferroperm, Denmark) and
  - **Gen. III / Mn:PIN-PMN-PT** Piezocrystal (TRS Technologies Inc., USA)

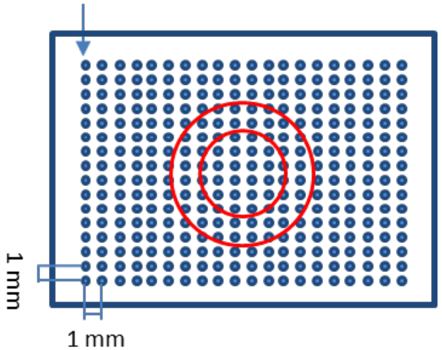
- **Numerical Analysis:** PZFLex (Weidlinger Associates Inc, USA)

- **Experimental Analysis:** Z Analyser (Agilent Tech. 4395A, UK) / Laser vibrometer Scanner (Polytec Ltd, London, UK)

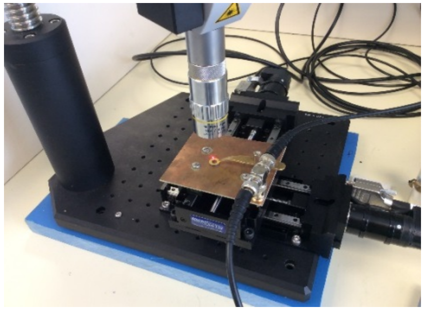
Ring Analysis



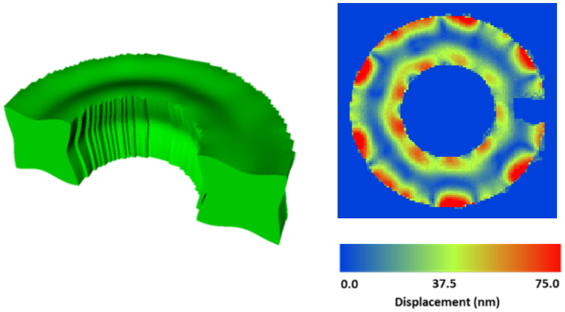
Numerical vs experimental impedance magnitude data of Mn:PIN-PMN-PT ring



Measurement Plan



Experimental Setup for Laser Vibrometer System



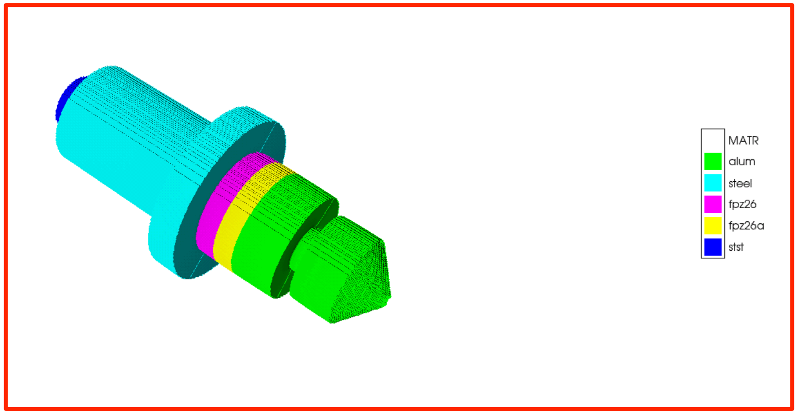
Numerical vs experimental mode shape of PZT4 ring

Finite Element Analysis

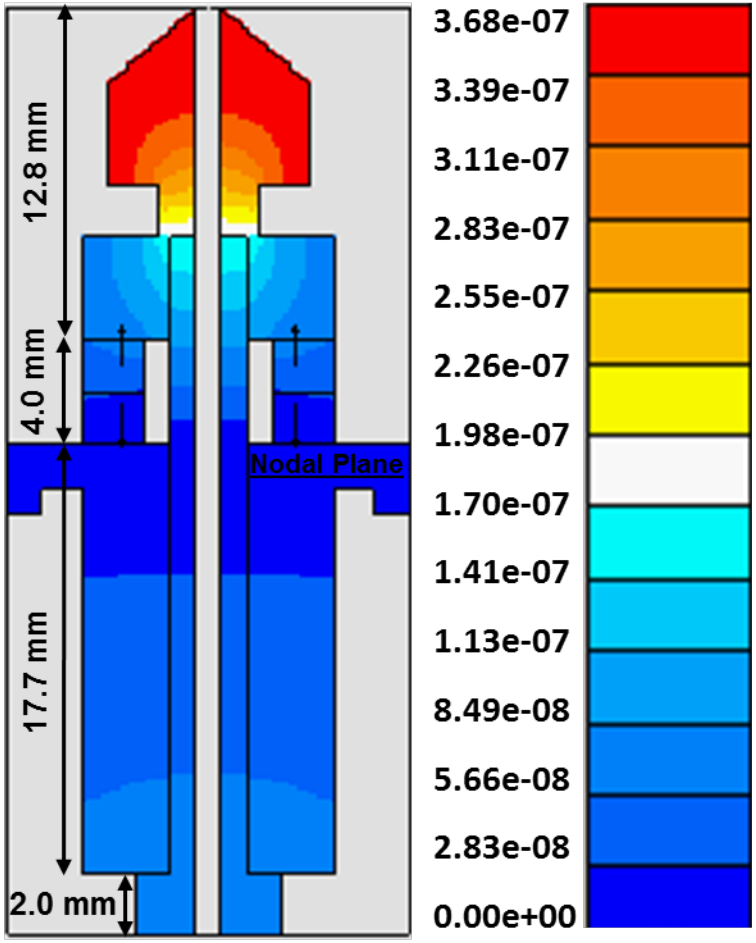
Numerical analysis prior to fabrication:

Requirements:

- Longitudinal mode vibration
- Max. displacement at the collet
- Nodal plan at the back mass



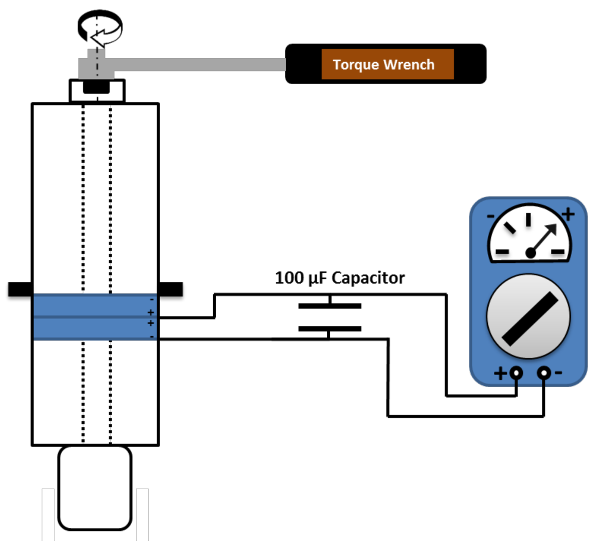
Mode Shape of PZT transducer at f = 69.85 kHz



Displacement plot of PZT transducer at f = 69.85 kHz

Fabrication – Application of Pre-stress

- **Stress-Charge method** was used to apply and control pre-stress



Experimental setup for stress-charge method

$$V = \frac{T * (g_{33} * \varepsilon_{33}^{T} * n * A)}{C}$$

V = Generated voltage (V)

T = Applied stress ($N.m^{-2}$)

g_{33} = Charge constant ($Vm.N^{-1}$)

ε^{T}_{33} = Permittivity at const. stress (F/m)

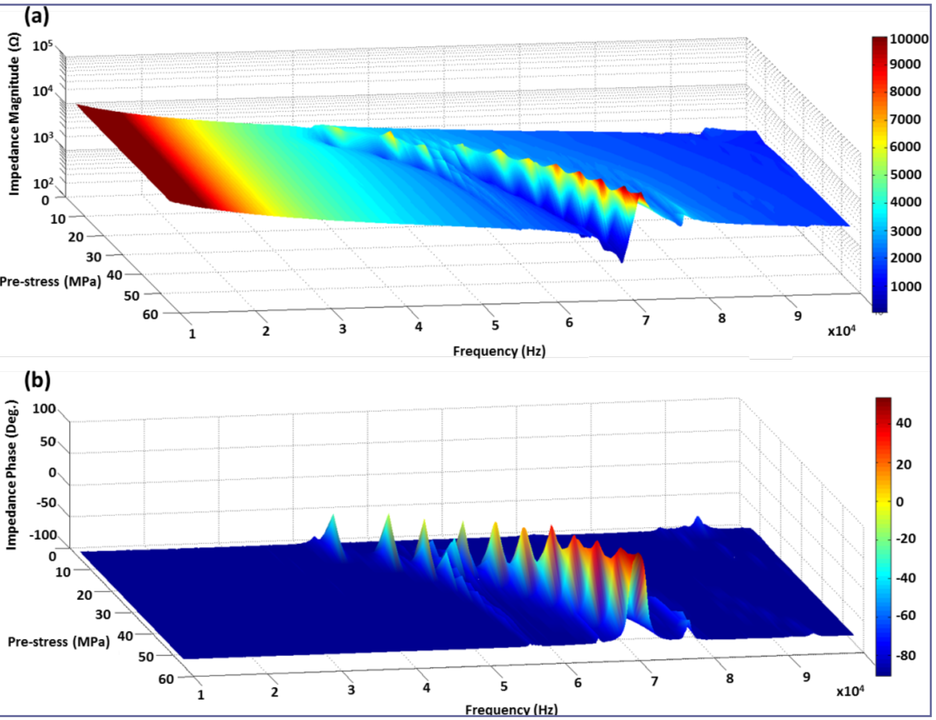
n = No. of rings   A = Area of ring (m^2)

C = Capacitance (F)

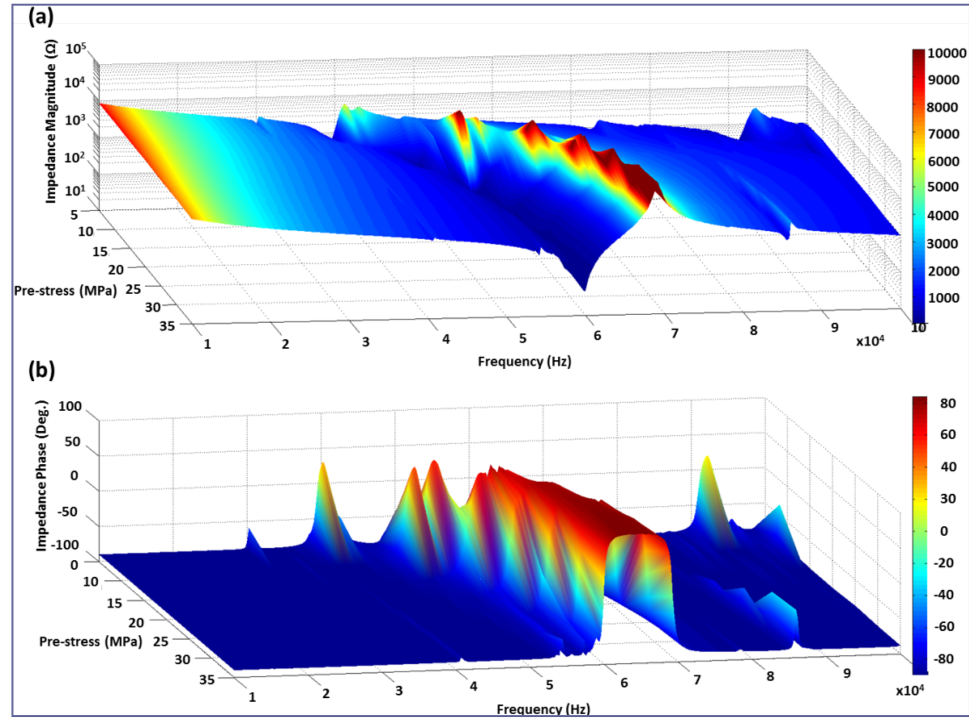
- **55 MPa (PZT)** and **35 MPa (Mn:PIN-PMN-PT)** were applied

- **Variation in key parameters** was observed for every 5 MPa

Fabrication – Pre-stress



Impedance magnitude (a) &phase (b) plots of PZT transducer with pre-stress



Impedance magnitude (a) & phase (b) plots of Mn:PIN-PMN-PT transducer with pre-stress

Parameters	PZT4 based Transducer	Mn:PIN-PMN-PT based Transducer
Frequency, F_e	↑69.61	↑52.74
Impedance, Z_e	↓89.45	↓92.36
Coupling coeff., k_{eff}	↑8.00	↑61.17
Quality factor, Q_M	↑203.24	↑154.69
Capacitance, C_{Lf}	↑5.94	↑20.22

Variation in key properties with applied pre-stress

Characterization - Methods

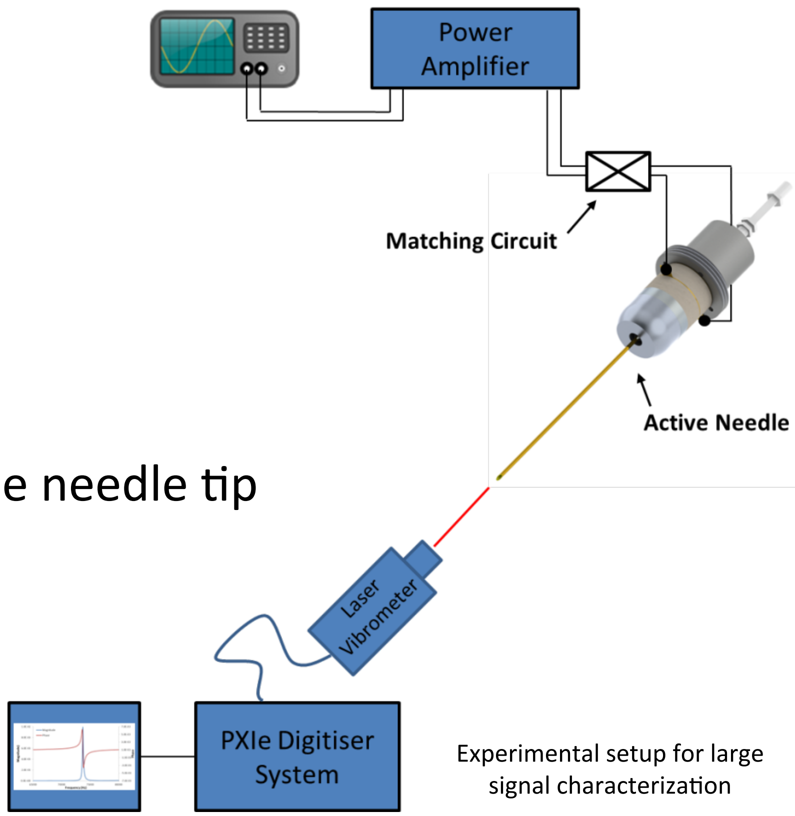
Small Signal Characterization

To determine the **performance measurement parameters**

- Electrical (f_e) and mechanical (f_m) resonant frequencies
- Electrical impedance (Z_e)
- Coupling coefficient (k_{eff})
- Mechanical quality factor (Q_M)
- Low frequency capacitance (C_{LF})

Large Signal Characterization

To determine the **displacement amplitude** at the needle tip



Experimental setup for large signal characterization

Characterization - Results

Small Signal Characterization

- Numerical Vs Experimental – **Good agreement**
- **Large variations** in Z_e and Q_M due to pre-stress
- **Mn:PIN-PMN-PT transducer** has lower F_e, higher k_{eff} and comparable Q_M
- **Standard G20 needle** introduced new resonance

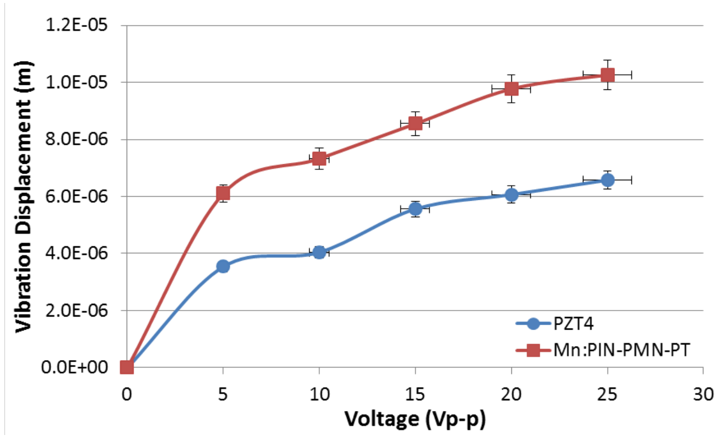
Parameters	PZT4 transducer		Mn:PIN-PMN-PT transducer	
	Num.	Exp.	Num.	Exp.
F_e (kHz)	69.85	69.85	63.70	59.95
Z_e (Ohms)	140	392.76	18.5	44.98
k_{eff} (-)	0.27	0.26	0.48	0.50
Q_M (-)	310.2	69.85	530.8	47.96

Parameters	PZT4 transducer	Mn:PIN-PMN-PT transducer
F_e (kHz)	39.59	35.55
Z_e (Ohms)	1682.23	382.72
k_{eff} (-)	0.16	0.27
Q_M (-)	132.06	93.63

Comparison between PZT and Mn:PIN-PMN-PT Devices

Large Signal Characterization

- Generally, **large tip displacement** recorded
- Mn:PIN-PMN-PT had **approx. 2 times** displacement



Comparison between PZT and Mn:PIN-PMN-PT Devices

PRE-CLINICAL STUDIES

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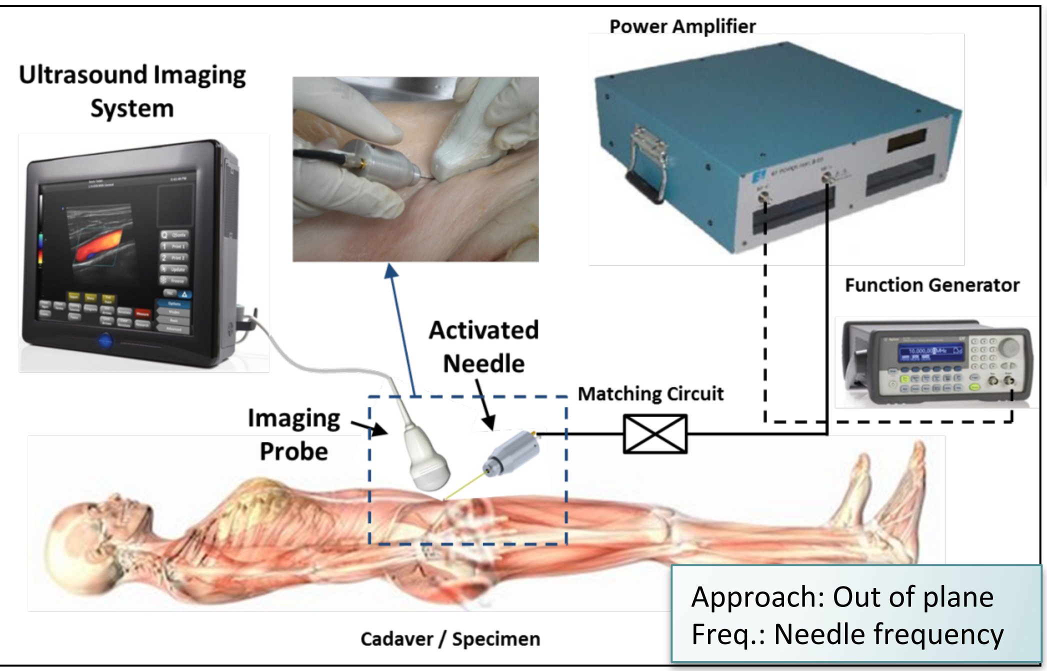
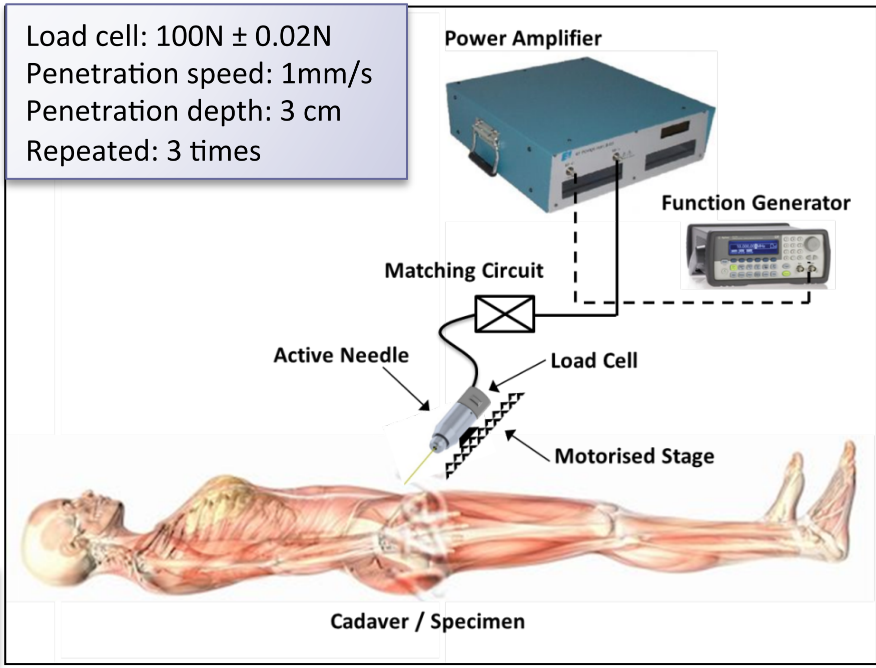
Experimental Setup

Pre-clinical trials were carried out on soft embalmed **Thiel cadaver models**

Needle Visibility Test



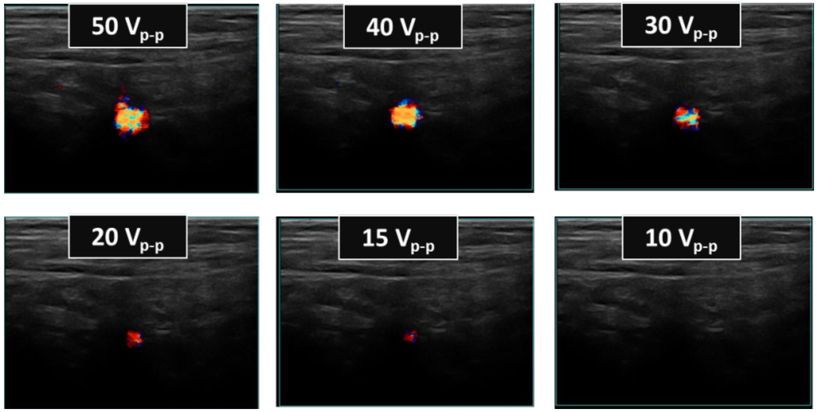
Needle Penetration Force Test



Results

Needle Visibility Test

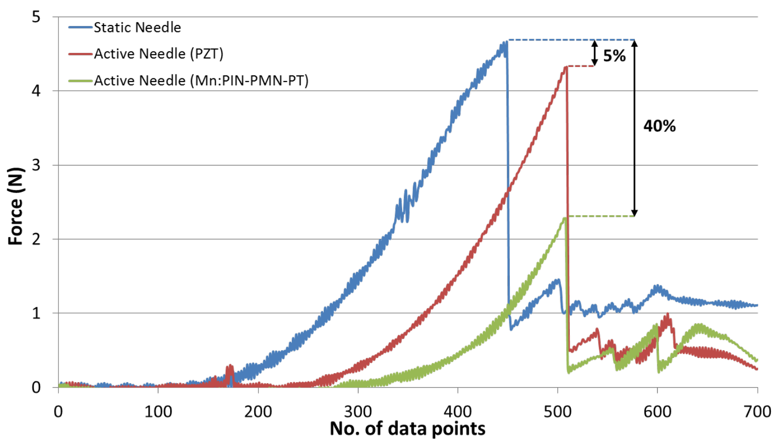
- Needle **tip was visible** in both cases
- Mn:PIN-PMN-PT **more responsive** at $10V_{p\text{-}p}$



Out of plane images of standard needle driven by PZT device

Needle Penetration Force Test

- Both devices **reduced penetration force**
- Mn:PIN-PMN-PT device showed significant reduction compared with PZT (40% : 5%)
- Reduced **force** = reduced **tip deflection**



Reduction in penetration force with PZT and Mn:PIN-PMN-PT devices

SUMMARY & ACKNOWLEDGMENT

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Summary

- **Clinical Need:** To improve needle targeting by reducing needle placement errors
- **Solution:** ActiveNeedle for enhanced visibility and reduced tip deflection
- **Current work:** Mn:PIN-PMN-PT based device has shown **clear performance benefits**:

Parameter	PZT	Mn:PIN-PMN-PT
Frequency, f (kHz)	69.850	59.950
Electrical impedance, Z_e (Ohms)	392.76	44.98
Coupling Coefficient, k_{eff} (-)	0.26	0.50
Quality factor, Q_M (-)	69.85	47.98
Tip displacement, X (μm)	6.57	10.3

- Mn:PIN-PMN-PT device further **improved tip visibility** and **reduced penetration force**
- Mn:PIN-PMN-PT can **supersede** traditional piezoceramics in a range of applications

Acknowledgement

- **Xiaochun Liao**, PhD student
- The **UK EPSRC** for funding under the USNOBS project
- **TRS Technologies** for the supply of Mn:PIN-PMN-PT piezocrystals and
- **Weidlinger Associates** (PZFlex) for the FEA research license

THANK YOU!

AWARDS & RECOGNITIONS

- Converge Challenge – 2nd Prize, 2014
- RSE Enterprise Fellowship Award, 2014
- OBR OneStart EU Competition – 3rd Prize, 2014
- HTC – Best Novel Idea, 2014
- EPSRC Funded Venture Award, 2012

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