Biopsy needle with local bioimpedance measurement and real-time tissue classification

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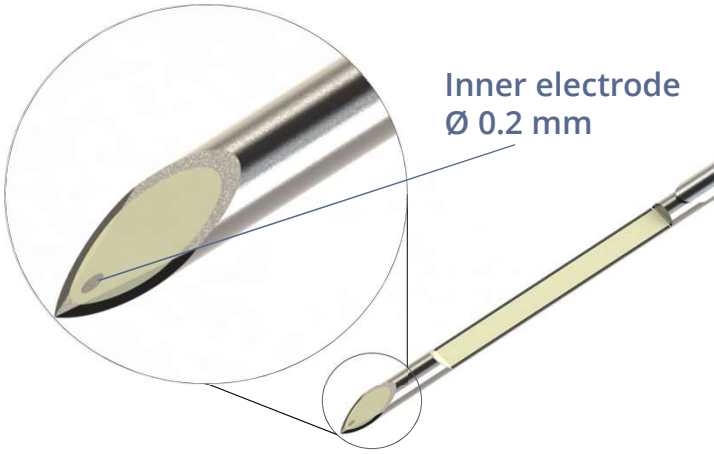


Background

Biopsy procedure is challenging, yet representative tissue sample is critical for accurate diagnosis. Local tissue detection could enhance the procedure and improve biopsy quality. We have developed biopsy needle with local tissue detection ability. Real-time measurement is performed from the very tip of the needle.

Aim

1) Examine measurement properties and resolution to detect small targets
→ Computer simulations

2) Assess feasibility of the method and evaluate tissue classification accuracy
3) Provide initial classifier for clinical studies
→ *In vivo* animal study

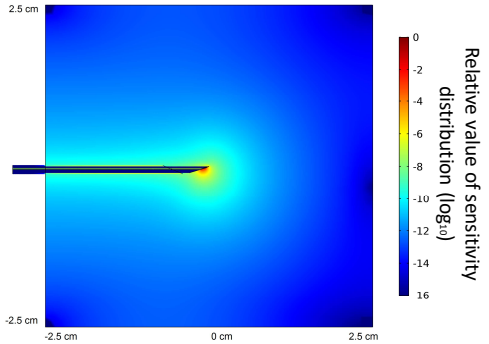
Measurement device

- Bioimpedance spectra over 15 measurement frequencies in kHz range
- Sampling rate 200 Hz
- Maximum likelihood classifier
- Real-time tissue detection

Injeq BZ-300 series analyzer

Simulation results

Sensitivity distribution is local and focused on the needle facet. Penetrations through small target show high resolution: already 1 mm targets are correctly measurable.



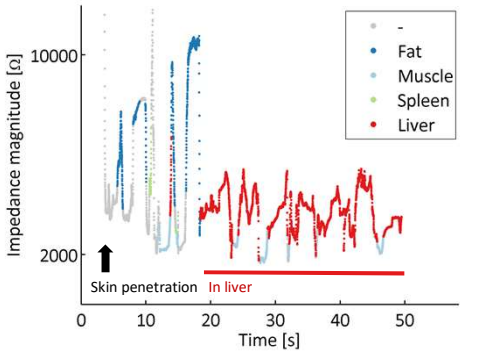
Sensitivity distribution of 18G Injeq IQ-Biopsy™ needle

In vivo results

Signal has high variance due to tissue heterogeneities, yet real-time classification is possible to perform. Crossvalidation of visual control data provided over 90% accuracy to classify tissues from moving needle.

Classification results with 7-fold needle-specific crossvalidation

		Needle location (visual control)				
		Fat	Muscle	Blood	Spleen	Liver
Data amount		4320 22 s	4136 21 s	4045 20 s	4200 21 s	3646 18 s
Classification	Fat	99 %	0 %	0 %	0 %	0 %
	Muscle	0 %	93 %	8 %	2 %	5 %
	Blood	0 %	0 %	92 %	0 %	0 %
	Spleen	0 %	1 %	0 %	94 %	4 %
	Liver	0 %	6 %	0 %	4 %	91 %



Example of ultrasound guided liver puncture. Coloring according to classification

Methods: Simulations

Finite element method simulations were performed with Comsol Multiphysics software. Sensitivity distribution was simulated in homogeneous 3D volume conductor. Measurement signal during penetration of heterogeneities was simulated with multiple 3D geometries and conductivities with small targets or membranes in large block.

Conclusions

The biopsy needle has high resolution in simulations and yet, it is feasible *in vivo* according to animal study. The method has potential to improve biopsy procedure and is ready for clinical studies.

Methods: Animal study

Anesthetized pig was punctured *in vivo* and bioimpedance spectra recorded. First, ultrasonography guided punctures were performed to liver. Then, multiple tissues measured under visual control (21 punctures to each). Data was gathered from moving needle to provide realistic data representing authentic use of the device. Tissue classifier was created and tested using needle-specific 7-fold crossvalidation with the outlier-removed visual control data.

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