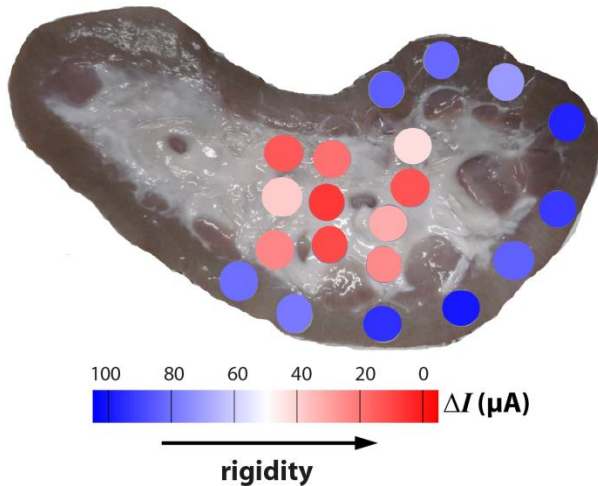




Surgical Device for Real-Time Elastography

Technology Description



Comparative measurements of elasticity in different parts of a sectioned pig's kidney using our new device. The difference in electric current ΔI , measured when the water jet of the device is on or off, depends on the sample's elasticity. As can be seen, the inner parts of the organ are much more rigid than the margins.

Mechanical elasticity is a central parameter of living cells and tissues. Cancerous and healthy tissues, for example, have a different elasticity. Therefore, tools are under development to make tissue elasticity a new diagnostic marker in medicine¹. Nevertheless, these efforts have been hampered by poor spatial resolution (i.e. ultrasound elastography) or by their usability being restricted to an *in vitro* environment (i.e. scanning ion conductance microscopy^{2,3,4} (SICM)).

Here, we present a novel instrument which transfers principles of SICM into the macro-environment of endoscopy or laparoscopy. This opens the door for a real-time measurement of tissue elasticity, e. g., during minimally invasive surgery.

Our handheld device uses the pressure of a water jet for inducing a deformation of the outer surface of any given tissue. The resulting change in a simultaneously recorded ion current between two electrodes on the "water nozzle" renders characteristic parameters for the elasticity of the tissue.

Innovation

Up to now: Scanning ion conductance microscopy suitable only for *in vitro* measurements of cells and tissues in the lab.

Now: Our new device permits direct determination of tissue elasticity *in vivo*, for example during minimally invasive surgery or diagnostics.

Market Potential

Minimally invasive surgery is on the rise. The global market for endoscopy is forecasted to 33.7 billion US-Dollars in 2016. In Germany, nearly half of all surgeries are minimally invasive. The German market for endoscopy and surgical instruments amounted to 630 million € in 2012⁵. Our new tool adds new diagnostic possibilities to this growing market.

Applications

- **In vivo diagnosis** during endoscopy: A direct differentiation of tissues becomes possible. During colonoscopy, for example, a surgeon will be provided with another clue for the decision whether a tissue is cancerous or not.
- **Tactile feedback** during robotic surgery. Minimally invasive surgery is still hampered by a lack of haptic information. With our method a surgeon could localize nerves and vessels, which have to be treated with special care.

Proof of Concept

Established, please refer to the next page.

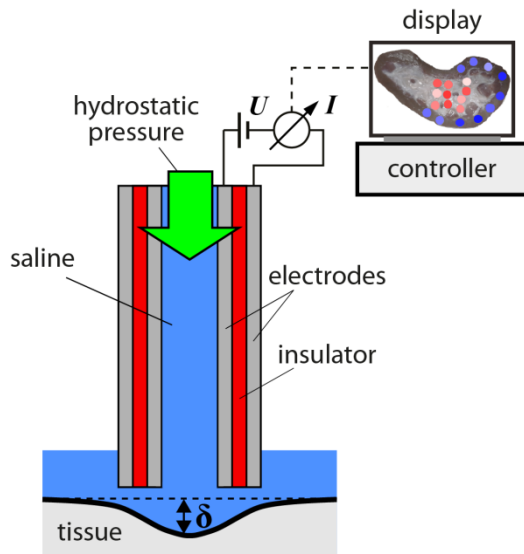
Requested Cooperation/IP Status

Licensing - implementation in an endoscopic system.

Patent pending. Priority date: 2013-08-07
DE10 2013 108512 – WO2015/018900

Experimental Data

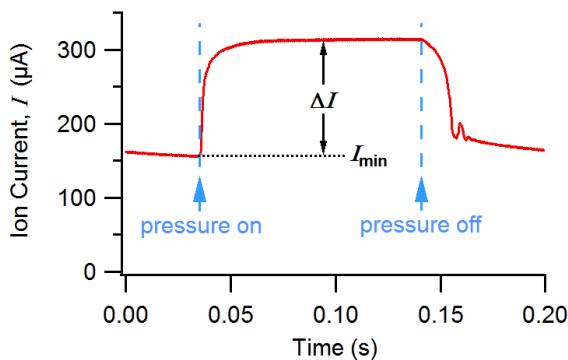
Overall Design of the new Instrument



Our system works by applying a water jet through a central nozzle. The water jet indents the underlying tissue. This indentation (δ) is sensed by an ionic current (I) that flows between electrodes (gray) on the in- and outside of the nozzle: The current passes through the saline solution below the nozzle. The magnitude of this ionic current is a measure of the elasticity of the underlying tissue. For a larger indentation (i.e., a softer tissue), a higher current is measured. Thereby, the tissue elasticity can be calculated using a simple model.

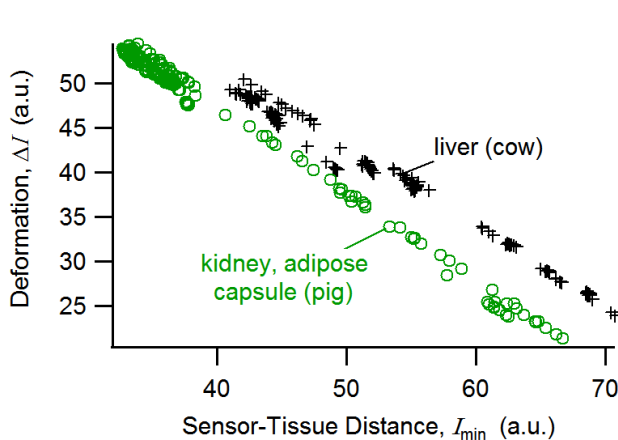
The instrument can be integrated in an endoscope, which the surgeon can manually move across the tissue surface, thereby measuring different parts of an organ. The whole system can easily be sterilized. Please note, that it also permits examination under different settings: The surgeon could apply pharmacological substances or dyes for tissue staining with the water jet.

Schematic Representation of a Single Point Measurement



This figure shows a schematic representation of our measurement principle. When the pressure is switched on, the tissue below the nozzle is deformed and the measured ionic current (I) increases. When the pressure is switched off again, the tissue relaxes and the current decreases. From a combination of the minimum (I_{\min}) and maximum ($I_{\min} + \Delta I$) currents, the elasticity of the sample can be deduced. Typical currents are in the microampere range.

Differentiation of Tissues by their Elasticity



Proof of concept elasticity measurements of different tissues (liver from cow, kidney from pig). As can be seen, a clear differentiation between the two tissue samples is possible, with the liver tissue being more elastic than the kidney tissue.

Even more important: This general relationship can be found independently of the actual distance between the nozzle and the tissue surface. Therefore, the variability in the surgeon's hand movements is compensated.

Thus, our new instrument can differentiate tissues based on their elasticity. This will add a diagnostic parameter to endoscopic inspections or minimally invasive surgeries.

REFERENCES

- 1 Jonietz E., Nature 491 (2012), S56-S57
- 2 Sánchez D. et al., Biophysical Journal 95 (2008), 3017-3027
- 3 Rheinlaender J. and Schäffer T.E., Soft Matter 9 (2013), 3230-3236
- 4 Schäffer T.E., Analytical Chemistry 85 (2013), 6988-6994
- 5 <https://www.medizintechnologie.de/infopool/medizin-technologie/2013/minimal-invasive-chirurgie/> (accessed on 20/07/2015)