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Introduction of a measurement set-up to monitor the pressure applied during hand-held ultrasound elastography

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Abstract

Shear wave elastography may produce misleadingly high values if too much pressure is applied during the imaging process. However, in clinical routine there is presently no way to monitor the pressure applied during the measurements. In this work we introduce a novel measurement set-up which can directly be attached to an ultrasonic imaging transducer and allows to observe the applied pressure in real time. The introduced set-up supports free-hand imaging according to the clinical standard. We tested the set-up by carrying out SWE under varying pressures on *ex vivo* animal tissue. The SWE values increased with pressure as was expected. Thus, the introduced set-up is a possible solution to measure the applied pressure in real-time.

Keywords: Ultrasound, Pressure, Elastography, Shear Wave Elastography, Cancer, Breast Cancer, Phantoms

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1 **Introduction**

2 Supersonic shear wave elastography (SWE) is an ultrasound (US) imaging
3 technique used to visualise and measure the elasticity of tissue. Already the
4 first clinical SWE study showed that applied pressure influences the SWE
5 measurements and recommended avoiding the application of pressure during
6 the procedure (Berg et al., 2012). However, SWE imaging is carried out
7 manually and it is thus, difficult to completely avoid pressure applied by the
8 clinician. Even if the clinician deliberately relieves her or his pressure, the
9 weight of the probe may still cause some pressure to be applied. Hence, it is
10 reasonable to state that application of a constant and reproducible pressure
11 is impossible to achieve in clinical practice.

12 Some previous studies showed the influence of applied pressure on mea-
13 surement of SWE values for breast tissue (Barr and Zhang, 2012; Wojcinski
14 et al., 2013; Bernal et al., 2016; Sayed et al., 2014). Their set-up is not appli-
15 cable in clinically routine SWE imaging, where the patient is in the supine
16 position. In response to the needs, capabilities and limitations of previous
17 work, here we introduce a novel measurement device, which can be attached
18 around an US SWE transducer to monitor the applied pressure in real time
19 with as little impact as possible onto the clinical protocol.

20 **Materials and Methods**

21 The novel measurement device has two requirements to aid clinical rou-
22 tine. First, it should be easily attached around the imaging probe to allow
23 SWE measurements to be made in its presence and absence to avoid bias in

24 clinical practice. Second, the attachment and removal processes should take
25 a maximum of a few minutes to allow application in routine clinical practice.

26 Three observers (2 radiologists, 1 radiographer, all with at least 5 years'
27 experience in breast sonography and 3 years' experience in SWE imaging)
28 were asked to apply pressure with the SWE probe on a commercial phantom
29 (CIRS, Model 059, Norfolk, VI, USA) similar to what they would apply
30 in clinical routine. The phantom was placed on a calibrated scale and the
31 increase in weight was monitored. The applied pressure p was calculated
32 over the transducer's surface (61 mm x 8 mm, $A = 488 \text{ mm}^2$). The applied
33 p differed by at least 0.2 N / 0.4 kPa for the three evaluated observers.
34 Therefore, the sensor should enable an accuracy of 0.1 N / 0.2 kPa. The
35 upper limit of the measurement range was estimated after discussion with an
36 expert radiologist with more than 20 years' experience in US breast imaging
37 and was, accordingly, set to 10 N or 20 kPa.

38 The measurement device is realised as a double shell around the SWE
39 probe **to avoid any damage of the probe. The pressure is** measured
40 **between these shells. The inner shell (Fig. 1a) is attached directly**
41 **to the SWE probe, while the outer shell (Fig. 1b) is moveable**
42 **relative to the inner shell via a sliding system. A spring pushes the**
43 **outer shell upwards onto the pressure sensors, which are attached**
44 **to the inner shell. Thus, the device introduced here measures a**
45 **reduction rather than an increase in applied pressure to allow the**
46 **measurement of unladen pressure.**

47 The shells were created by 3D printing using acrylonitrile butadiene
48 styrene (ABS) plastic. This allowed freedom in the design while keeping

49 production costs low. Four springs press the outer shell upwards with a force
50 of 10 N, i.e. the maximum of the measurement range defined. Two strain-
51 gauge sensors (FSR402, Interlink Electronics, Los Angeles, CA, USA) are
52 positioned on each side of a step leading around the inner shell and convert
53 the applied force into a decrease in electrical resistance and thus, a decrease
54 in voltage drop. The sensors are positioned out of alignment with the centre
55 to allow the measurement of any drift if the pressure is not applied exactly
56 vertically. Careful handling of the sensors was required as they broke easily.
57 The outer shell presses against the pressure sensors. When the SWE probe
58 touches the tissue the pressure on the sensors decreases and a lower signal is
59 produced.

60 Measurements with and without the SWE probe included within the
61 shells were calibrated to validate the correlation between the applied pres-
62 sure and the signal outputs. The calibration was performed with the device
63 placed directly onto a calibrated scale. The measurements on the *ex vivo*
64 samples were performed according to routine clinical practice but with a cal-
65 ibrated scale underneath. The scale used for the measurements was identical
66 with the one used in the calibration process. The preloaded pressure was
67 increased from 0 g / 0 N / 0 kPa to 1 kg / 10 N / 20 kPa with increments of
68 100 g / 1 N / 2 kPa. For each preload, five measurements were recorded and
69 averaged for evaluation.

70 *Ex vivo* samples including chicken breast, porcine belly, boiling beef and
71 bovine udder were investigated. The *ex vivo* tissues were obtained through
72 a local slaughterhouse and no additional harm was applied to any animal.
73 All images were obtained using the Aixplorer US system (SuperSonic Imag-

74 ine, France), frequency range 4 - 15 MHz, axial resolution 0.3 - 0.5 mm,
75 lateral resolution 0.3 - 0.6 mm, elasticity range 0 - 300 kPa. The SWE mea-
76 surements were performed using a circular region of interest (ROI) with a
77 diameter of 3 mm. The ROI was positioned at the stiffest part of the image
78 excluding artefacts. This procedure is equivalent to the standard imaging
79 process of breast imaging, i.e. our aimed application, in clinical practice.
80 All images were obtained by three observers (two radiologists with at least 5
81 years' experience in breast US imaging and a trained engineer). Each mea-
82 surement started with minimal preload pressure, which was then increased
83 until either the test object was damaged, the image quality was insufficient
84 or the maximum measurement range was reached. Although the aim was to
85 start with 0 N / 0 Pa, this was impossible in practical terms as contact was
86 required to enable transmission of the US into the test object. Thus, the
87 minimum pressure applied was 0.2 N / 0.4 kPa. For each setting three mea-
88 surements were obtained. These measurements were averaged and evaluated
89 using spread-sheet functions (Microsoft Excel 2013).

90 **Results**

91 The measurement set-up was calibrated with and without the SWE probe.
92 Both sensors achieved good reproducibility if the device was used alone with-
93 out the probe (**mean deviation from the average for sensors 1 and**
94 **2: 0.14 V and 0.40 V**). However, if the probe was attached to the pres-
95 sure measurement device, the reproducibility was reduced (**mean deviation**
96 **from the average for sensors 1 and 2: 0.76 V and 0.73 V**). The po-
97 sition of the imaging probe cable was observed to have an influence on the

98 reproducibility. The measurement set-up worked well on the *ex vivo* tissues
99 and handling was similar as in the clinical imaging protocol. Figure 2 shows
100 the correlation of the elasticity parameter mean elasticity E_{mean} for all *ex*
101 *vivo* samples. The E_{mean} and E_{max} values increased approximately linearly
102 with an increasing pre-load, whereas no clear correlation could be observed
103 in the SD values. Figure 3 shows the SWE image in the bovine udder for
104 the minimum (0.2 N) and an intermediate (3 N) pre-load.

105 Discussion

106 Ultrasonic SWE imaging is a hand-held imaging modality and a complete
107 avoidance of applied pressure is impossible. Hence, the pressure applied by
108 the ultrasound probe during clinical assessment should be considered to fur-
109 ther standardize the diagnostic image evaluation. The demonstrated device
110 enables monitoring of the external pressure applied in real time by an ob-
111 server or clinician during SWE imaging. The **measurements are** sensitive
112 to the weight of the probe and the cable, which was not considered when
113 designing the device. The design could be improved in future by taking this
114 into account. The present device was made of plastic by 3D printing. Our
115 approach provided relatively poor physical accuracy and the material is rel-
116 atively soft. **We did not observe any influence from handling the**
117 **outer shell, e.g. squeezing it, on the measurements.** Better results
118 might be achieved if a 3D printing set-up of higher quality was used or if the
119 mechanical components of the device were made of aluminium. However,
120 this would have increased its cost very significantly.

121 Our study showed that even amongst observers who apply the same imag-

122 ing protocol a bias in the SWE measurements may occur. Thus, real-time
123 feedback to the observer would be helpful to standardise the imaging proce-
124 dure. Definition of a pressure, which should be applied for the best clinical
125 performance, or adjusted cut-off thresholds for benign / malignant differenti-
126 ation would be of interest in the future. Additionally, monitoring the applied
127 pressure and consequential changes in elasticity during clinical examination
128 might also improve the benign / malignant differentiation, based on the cor-
129 relation with malignancy noted in previous studies (Krouskop et al., 1998;
130 Barr and Zhang, 2012; Syversveen et al., 2012; Sayed et al., 2014; Bernal
131 et al., 2016). Hence, real-time measurements of the applied pressure might
132 give clinicians a novel SWE biomarker.

133 Previous studies introduced different pressure application or measure-
134 ment arrangements such as (Barr and Zhang, 2012; Syversveen et al., 2012;
135 Sayed et al., 2014; Bernal et al., 2016; Bell et al., 2016, 2014; Gilbertson and
136 Anthony, 2015). However, to the best of the authors' knowledge only the set-
137 up introduced by Gilbertson and Anthony (2015) permits **a quantitative**
138 **analysis of the applied pressure** for hand-held US imaging and could
139 thus, be applicable to breast cancer imaging. This set-up requires a special
140 handling and is relatively heavy (about 700 g, mass of an US probe < 100 g),
141 **whereas the introduced set-up is much lighter (about 220 g). Al-**
142 **though this nearly triples the weight of the transducer during the**
143 **measurement, the** device introduced in this work has amongst the intro-
144 duced solutions the lowest impact onto the clinical imaging protocol and has
145 thus, the highest potential for transition into clinical routine.

146 A clinical trial was not possible with the device that has been described as

147 **the attachment and removal process of the set-up is still too time**
148 **consuming.** Measurements were performed only using *ex vivo* samples.
149 **Inaccurate SWE values might be derived from *ex vivo* tissues due**
150 **to the lack of perfusion. Nevertheless, this study shows that a**
151 **clinical study using the introduced measurement set-up would be**
152 **feasible.** This has potential to improve not only the benign / malignant
153 differentiation of solid breast lesions but also to improve prediction of lesion
154 behaviour and the use of personalised therapy.

155 **Conclusions**

156 SWE increases with applied pressure and inter-observer variations in the
157 clinical application of SWE may thus, bias the diagnostic performance of
158 SWE. Hence, real time monitoring of the applied pressure would be clinically
159 useful. The measurement device introduced here is the first step towards
160 introducing a method for examining the pressure applied during clinical
161 examinations. The results from a preliminary *ex vivo* study showing an
162 approximate linear increase in elasticity are promising. However the device
163 design should be improved to enhance its clinical applicability.

164 **Acknowledgements**

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166 and the Engineering and Physical Science and Research Council (EPSRC,
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208 **Figure Captions**

209 **Figure 1:** Two shells are attached around the ultrasound probe: a) an inner
210 and b) an outer shell. Two pressure sensors are attached to the inner
211 shell. The observer presses the outer shell onto the sensors.

212 **Figure 2:** The mean elasticity E_{mean} increases with pressure in the *ex vivo*
213 samples (**correlation of 0.997, 0.981, 0.135 and 0.935 for the**
214 **chicken breast, porcine belly, boiling beef and the bovine ut-**
215 **ter**).

216 **Figure 3:** SWE image of a bovine udder with a) minimal, i.e. 0.2 N, and
217 b) intermediate, i.e. 3 N, pre-load. **The E_{mean} values were 77 kPa**
218 **and 230 kPa.**