34th Annual International Conference of the IEEE EMBS
San Diego, California USA, 28 August - 1 September, 2012

Arterial strain measurement by implantable capacitive sensor without vessel constriction

Johannes Ruhhammer[1], Dominic Ruh[1], Katharina Foerster[2], Claudia Heilmann[2], Friedhelm Beyersdorf[2], Alex Barker[3], Bernd Jung[4], Andreas Seifert[1], Frank Goldschmidtboeing[1], and Peter Woias[1]

Abstract— **Cardiovascular disease caused 32.8% of deaths in the United States in 2008 [1]. The most important medical parameter is the arterial blood pressure. The origin of high or low blood pressure can mostly be found in the vessel compliance. With the presented implantable sensor, we are able to directly measure strain of arteries, as an indicator of arteriosclerosis. The sensor is designed as a cuff with integrated capacitive structures and is wrapped around arteries. With a new and innovative locking method, we could show that the system does not affect the arteries. This is demonstrated by theory as well as experimental *in vivo* investigations. Biocompatibility tests, confirmed by histological cuts and MRI measurements, showed that no stenosis, allergic reactions or inflammation occurs. The sensor shows excellent linear behavior with respect to stress and strain.**

I. INTRODUCTION

Blood pressure is one of the most important parameters for evaluating the health status of high risk patients suffering from cardiovascular diseases. However, in most cases, blood pressure itself is only a secondary parameter. The mechanical properties of the cardiovascular system, and in particular of the blood vessels, cause hypertension and related diseases. One essential parameter to be assessed for diagnosis is the elasticity of the vessel in terms of measured strain. We present a novel device for *in situ* monitoring of different key medical parameters and show first results of biocompatibility. A highly elastic strain gauge of low stiffness is designed as an implantable, extravascular mechanical sensor, and is able to continuously measure the arterial strain and shape of the hydraulic blood pulse. Continuous long-term measurements of arterial characteristics can contribute to refined diagnostics and lead to a better understanding of the cardiovascular system. The silicone-based sensor is wrapped around an arterial blood vessel, as seen in Fig. 1, and fixed with an innovative clamping mechanism. MRI measurements and histological cuts show that the device can be attached without constricting the vessel and thus avoiding stenosis. The sensing structure of this capacitive strain gauge is made of highly elastic polydimethylsiloxane (PDMS) loaded with conductive particles. Long-term experiments and histological cuts show that the conductive material can be encapsulated such that no infection or allergic reaction occurs.

[1]are with the Department of Microsystems Engineering (IMTEK), University of Freiburg, Georges-Koehler-Allee 102, 79110 Freiburg, Germany, Email: Johannes.Ruhhammer@imtek.uni-freiburg.de

[2]are with the Cardiovascular Surgery, University Medical Center, Freiburg, Germany

[3]is with the Department of Radiology, Feinberg School of Medicine, Northwestern University, Chicago

[4]is with the Department of Radiology, University Medical Center, Freiburg, Germany

II. DESIGN

A. Sensor Cuff

The capacitive strain gauge is realized by an interdigital electrode structure. The electrically conductive sensing material is sandwiched between two highly elastic PDMS strips. The electric conductivity and high elasticity of the functional layer is obtained by loading different PDMS base materials with a mixture of conductive nano- and micro-sized silver particles. Stiffening of the functional layer is reduced by using a mixture of very soft PDMS base materials and the combination of different filler shapes and sizes. The widths of the individual electrodes and gaps are 50 μm each with a height of 100 μm. The length of the sensing structure can be adjusted to different arterial dimensions. For a length of 20 mm and a width of 5 mm, the base capacitance is around 40 pF, yielding a good signal-to-noise ratio and a small RC time constant. For detecting pulse wave velocities by two consecutive cuffs, a high sampling rate, i.e. a low RC time constant is preferable.

B. Mechanical Clamping

Generally, titanium ligature clips are used for fixation of implants of this kind. Long-term experiments with surro-

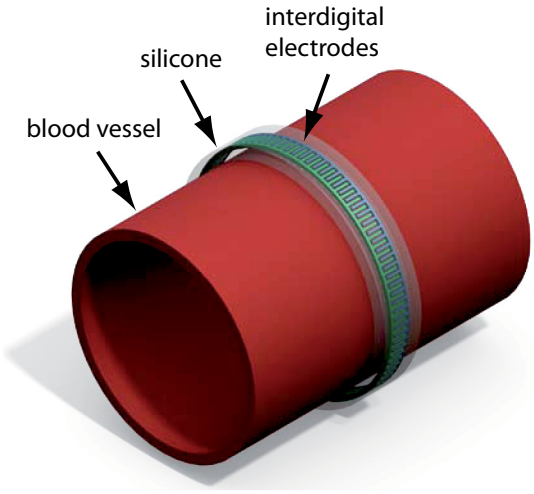

Fig. 1. Schematic of a capacitive sensor cuff wrapped around an arterial blood vessel.

gate cuffs, where the functional layer is omitted, wrapped around different arteries of a domestic pig, revealed that this method does not work properly. All implanted cuffs were cracked after 5 weeks, where breaking points were induced by the titanium ligature clips. A new innovative mechanical clamping method has been designed to overcome this problem. The silicone cuffs are structured such that they work similar to the locking system of a cable tie. The length of the silicone cuffs can be adjusted stepwise by adjusting the number of teeth passing through a fixture made of biocompatible polyimide. A repeated long-term experiment with the new mechanical design demonstrated the excellent biocompatibility and mechanical stability of the new fixation method. This mechanical clamping concept is well suited for fixing cuffs directly at vessels, and moreover, has the potential for solving many other biomedical fixation problems.

III. THEORY

Arterial strain is directly correlated to arterial pressure. If the artery is considered as a pressurized tube, the force equilibrium condition can be obtained from Fig. 2 as

$$-\sigma_r r\mathrm{d}\psi + (\sigma_r + \mathrm{d}\sigma_r)(r+\mathrm{dr})\mathrm{d}\psi - 2\sigma_\psi \frac{1}{2}\mathrm{d}\psi\mathrm{dr} = 0, \quad (1)$$

where σ_r and σ_ψ are the tangential and radial stresses respectively. By neglecting the second order term $\mathrm{d}\sigma_r\mathrm{dr}$, (1) in first order reduces to

$$\frac{\mathrm{d}\sigma_r}{\mathrm{dr}} + \frac{1}{r}(\sigma_r - \sigma_\psi) = 0. \quad (2)$$

The length of a vessel remains constant *in situ*, i.e. the longitudinal displacement is zero, $u = 0$. Additionally, we assume that no twisting occurs, hence the displacement in the circumferential direction is also zero, $v = 0$. The remaining radial displacement $w = w(r)$ is a function of the radius and can be obtained by taking into account the kinematic relationship between displacement and extension

$$\varepsilon_z = \frac{\partial u}{\partial z} = 0,\ \varepsilon_\psi = \frac{1}{r}\frac{\partial v}{\partial \psi} + \frac{w}{r} = \frac{w}{r},\ \varepsilon_r = \frac{\partial w}{\partial r}. \quad (3)$$

If the strains are small and the vessel wall material is considered to be isotropic, Hooke's law is the suitable description for the stress-strain relation. The general form of Hooke's law is

$$\varepsilon_z = \frac{1}{E}[\sigma_z - \nu(\sigma_\psi + \sigma_r)], \quad (4)$$

$$\varepsilon_\psi = \frac{1}{E}[\sigma_\psi - \nu(\sigma_r + \sigma_z)], \quad (5)$$

$$\varepsilon_r = \frac{1}{E}[\sigma_r - \nu(\sigma_z + \sigma_\psi)], \quad (6)$$

where E is the Young's modulus. For $\varepsilon_z = 0$, (4) can be rearranged and inserted into (5) and (6). With (2) and (3), the differential equation becomes

$$\frac{\partial^2 w(r)}{r^2} + \frac{1}{r}\frac{\partial w(r)}{r} - \frac{1}{r^2}w(r) = 0. \quad (7)$$

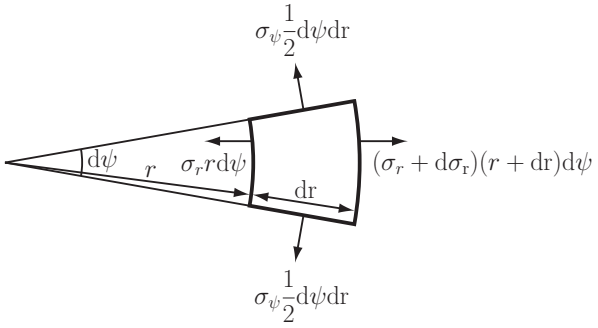

Fig. 2. Stress acting on a pressurized tube segment.

A solution for this homogeneous equation with the basis $w(r) = cr^\lambda$, with λ as eigenvalue, is

$$w(r) = c_1 r + \frac{c_2}{r}. \quad (8)$$

For a vessel with inner radius r_i and outer radius r_o, and by applying the boundary conditions $\sigma_r = -p_i$ at $r = r_i$ and $\sigma_r = -p_o$ at $r = r_o$, we obtain the radial displacement without a cuff at the outer wall ($r = r_o$)

$$w_{\mathrm{nocuff}}(r_o) = \frac{2\Delta p r_i^2 r_o(1-\nu^2)}{E(r_o^2 - r_i^2)}, \quad (9)$$

where $p_o = 0$, $p_i = \Delta p$ and E is used as the incremental elastic modulus E_{inc} in practice [2]. This solution is in accordance with the equation derived by [2].

By applying a silicone cuff around the vessel, the boundary conditions have to be modified as follows.

- Stress at the inner wall of the vessel equals the inner pressure: $\sigma_{r,v} = -p_i$ for $r = r_i$
- Stresses at the interface between the vessel and the cuff materials at vessel radius r_v have to be equal: $\sigma_{r,v} - \sigma_{r,c} = 0$
- Stress at the outer wall of the cuff ($r = r_o$) matches with the outer pressure: $\sigma_{r,c} = -p_o$
- The two materials have a fixed connection, i.e. the radial displacements at the interface have to be the same, with $w_v = w_c$ for $r = r_v$, and the longitudinal displacements of the cuff and the vessel are zero.

In a first approximation, a Poisson's ratio of 0.5 is a reasonable assumption for blood vessels [2] as well as PDMS [3], and $p_o = 0$, $p_i = \Delta p$, as assumed for (9), and $r = r_v$ (i.e. taking the displacement at the vessel wall), the radial displacement becomes

$$w(r_v) = \frac{\frac{3}{2}r_o^2 r_i^2 r_v \Delta p}{r_o^2\left(r_v^2 - r_i^2\right)E_1 + r_i^2\left(r_o^2 - r_v^2\right)E_2}, \quad (10)$$

where E_1 and E_2 are the Young's modulus of the vessel and PDMS, respectively. This equation allows a good approximation of the vessel radial distension with the applied cuff.

Vessel constriction must be avoided in order to prevent stenosis. The difference of radial displacements between the unconstrained and constrained artery, when a silicone cuff is wrapped around, can be calculated by subtracting

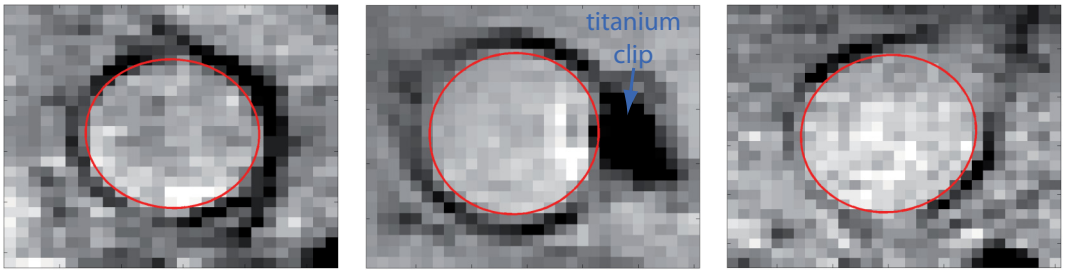

Fig. 3. From left to right: MRI images distal, at the cuff and proximal, voxel size $0.8 \times 0.8 \times 5\,\mathrm{mm}^3$.

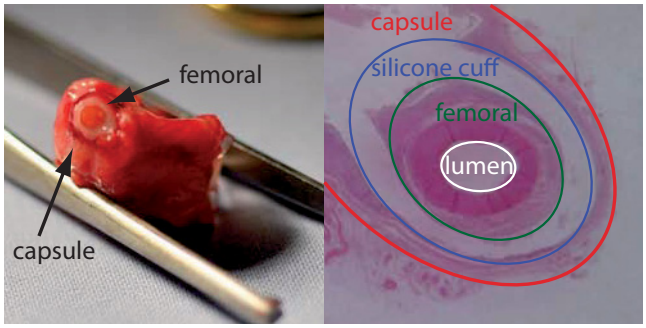

Fig. 4. Femoral artery with silicone cuff and surrounding tissue directly after explantation (left). The artery has a diameter of ∼8 mm. Histological cut through the femoral artery with surrounding silicone cuff (right).

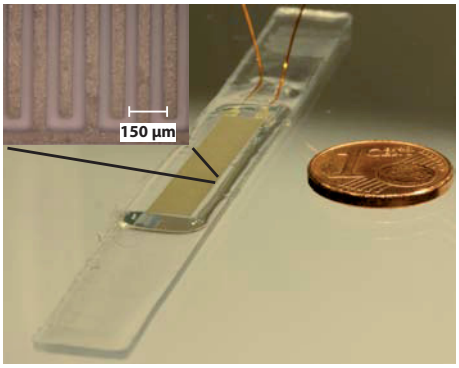

Fig. 5. Capacitive strain gauge. The strip has a width of 10 mm and a thickness of 1.1 mm. The interdigital electrode structure has a length of 32.05 mm and a width of 5.15 mm. The thickness around the active area is slightly increased to 1.4 mm.

(10) from (9). The cuff has a thickness of 1 mm and a Young's modulus of 0.16 MPa. According to [4], a carotid artery, of a male between 45 and 49 years, has a diameter of ∼7.8 mm, a wall thickness of ∼0.6 mm, and a Young's modulus of ∼0.77 MPa. With an assumed pressure change of $\Delta p = 6\,\mathrm{kPa} = 45\,\mathrm{mmHg}$ which is approximately the pressure difference between diastolic and systolic pressure, the radial displacement of the constrained vessel wall is reduced by about 16% at systolic pressure.

IV. EXPERIMENTAL RESULTS

To examine whether significant constriction of the vessel takes place, *in vivo* experiments with surrogate cuffs wrapped around different arteries have been carried out on a domestic pig. Fig. 4 shows the femoral artery directly after explantation (left) and a histologic cut (right) after an implantation time of 5 weeks. There is no indication that the artery was constricted or a blood-clot was formed. Similar results were obtained by three other surrogate cuffs placed at the femoral and carotid artery.

The result was confirmed by MRI measurements performed directly after implantation of a surrogate cuff in an anesthetized domestic pig on the descending abdominal aorta. Here, the cuff was fixed with a standard titanium ligature clip. The MRI instrument was a 3 Tesla Siemens MAGNETOM Trio and the voxel size was set to $0.8 \times 0.8 \times 5\,\mathrm{mm}^3$. Images were taken distal, proximal, and directly at the cuff. The measurements were taken during a breath hold and triggered by pulse oximetry. The images were obtained using a 2-D multislice balanced SSFP gradient echo sequence, perpendicular to the vessel. The area enclosed by the lumen is determined through an ellipse which is fitted to a calculated closed contour of several selected pixels, see Fig. 3. By comparing the lumen of the three positions, no significant difference is visible.

Histological examination (Hematoxilin-Eosin and Elastica-van-Gieson staining) of the surrounding tissue showed a thin fibroblastic encapsulation of the device, but no increased occurrence of inflammatory cells or foreign body giant cells. The artery exhibited normal wall structure and no signs of constriction. Neither by macroscopic nor by histologic inspection further signs of an inflammatory or allergic body reaction could be detected. This result was confirmed by histologic examinations in further experiments where several silicone patches were implanted directly beneath the skin over a period of 5 weeks. The silver loaded PDMS was encapsulated into the same PDMS which was used for the cuffs and was also implanted for a period of 5 weeks into a domestic pig. Again, there were no signs of inflammatory or allergic body reactions and no silver particles were found in the vicinity of the silicone patch.

First measurement results with a functional cuff, including a capacitive interdigital electrode structure, as shown in Fig. 5, were obtained by recording the change in capacitance as a function of applied strain. The inverted capacitance changes linearly with strain, which can be seen from Fig. 6, where the inverse capacitance is plotted against strain. This correlates well to the theory of a plate capacitance, where capacitance is

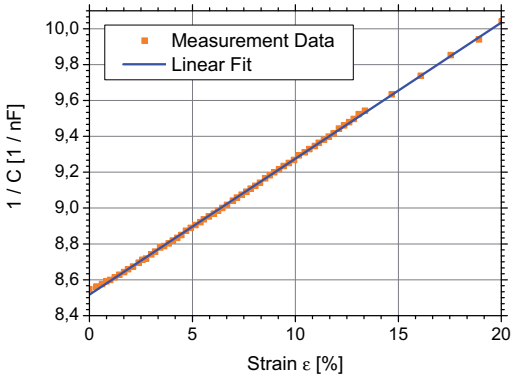

Fig. 6. Inverse capacitance as a function of strain.

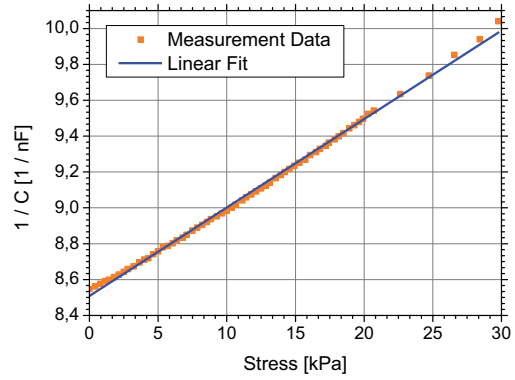

Fig. 7. Inverse capacitance as a function of stress.

reciprocal to distance. The stress-strain relation is linear for the silicone in the considered range, hence the dependence between the capacitance and stress is also linear, see Fig. 7. The resolution of the capacitance meter was 100 fF (Agilent 4263B LCR Meter), which is sufficient to resolve strains of $\sim$0.2%. This can be improved by todays capacitance-to-digital converters providing resolutions of < 1 fF and allowing much more sensitive measurements.

V. CONCLUSION

In vivo experiments have shown that it is possible to wrap silicone cuffs around different arteries without constriction. There was no sign of a stenosis after 5 weeks of implantation. Although we did not employ any certified biocompatible silicone, there was no sign of an incompatibility of the material with the surrounding tissue. First experiments with a capacitive strain gauge show that the strain can be transformed linearly into a capacitance change. The system is able to resolve relatively small strains, suitable to measure small vessel distensions with a good resolution. Currently, different *in vivo* experiments are prepared to directly measure the aterial strain *in situ*, in particular with respect to longterm stabilized calibration.

REFERENCES

[1] V. L. Roger, A. S. Go, D. M. Lloyd-Jones, E. J. Benjamin, J. D. Berry, W. B. Borden, D. M. Bravata, S. Dai, E. S. Ford, C. S. Fox, H. J. Fullerton, C. Gillespie, S. M. Hailpern, J. A. Heit, V. J. Howard, B. M. Kissela, S. J. Kittner, D. T. Lackland, J. H. Lichtman, L. D. Lisabeth, D. M. Makuc, G. M. Marcus, A. Marelli, D. B. Matchar, C. S. Moy, D. Mozaffarian, M. E. Mussolino, G. Nichol, N. P. Paynter, E. Z. Soliman, P. D. Sorlie, N. Sotoodehnia, T. N. Turan, S. S. Virani, N. D. Wong, D. Woo, and M. B. Turner, "Heart disease and stroke statistics - 2012 update - a report from the american heart association," *Circulation*, vol. 125, no. 1, Mar. 2012. [Online]. Available: http://circ.ahajournals.org/content/125/1/e2

[2] W. W. Nichols, M. F. O'Rourke, and C. Vlachopoulos, *McDonald's Blood Flow in Arteries, 6th ed: Theoretical, Experimental and Clinical Principles*, 6th ed. Hodder Arnold Publishers, Sept. 2011.

[3] B. Erman and J. E. Mark, *Structures and Properties of Rubberlike Networks*. Oxford University Press, USA, 1997.

[4] W. A. Riley, R. W. Barnes, G. W. Evans, and G. L. Burke, "Ultrasonic measurement of the elastic modulus of the common carotid artery. The Atherosclerosis Risk in Communities (ARIC) Study," *Stroke; a Journal of Cerebral Circulation*, vol. 23, no. 7, pp. 952–956, 1992. [Online]. Available: http://www.ncbi.nlm.nih.gov/pubmed/1615543