DOI 10.5162/sensor2013/D9.1

From Head to Toe: Sensors for applications at and within the human body

Thorsten Meiss
Technische Universität Darmstadt, Merckstr. 25, 64283 Darmstadt
t.meiss@emk.tu-darmstadt.de

Abstract
The miniaturization allows for a widespread use of sensors at humans while ensuring least backlash onto the user. Inertial sensors undergo a massive use as externally applied sensor devices for movement tracking in sports, work and as a signal input for assistance devices. Here, questions about packaging are already solved. Higher scientific and engineering questions and safety concerns remain for sensors applied inside the human body. Blood and tissue contact lead to very high demands on packaging stability with the additional requirement of biocompatibility. While for sensors for short time use inside the body diffusion processes have to be regarded, especially for implants a long-term sealing is necessary. For many types of implants expected to be used in the future, the packaging and assembly technologies are part of active research. This overview of state of the art sensors reveals main requirements and application hurdles for different application scenarios and for different locations where sensors are applied at and within the human body – starting from low to high invasivity. It turns out that the main parameters for widespread application are safety issues and the complexity of packaging technologies for the special sensor.

Key words: Medical Sensors, Micro Sensors, Implants, Biomedical Measurement, Physical Quantities

Introduction

Research and development of micro sensors started in the 1960s with the development of integrated silicon pressure sensors [1]. In the 1980s the establishment of area-wide research on micro system technology led to the facilitation of sensor principles and new assembly technologies. Today, companies are able to produce micro sensors with high long term stability and high resolution to relatively low cost. So nowadays, besides a still increasing part in researching new sensor principles like magnetic or nano sensors, the dominant part of research is the development of new applications with available sensors and technologies. This area is a valuable part for companies due to the shorter path to revenue. Nevertheless, since this phase is already achieved for inertial sensors and for pressure sensors applied at the outer body, still technological research has to be done for sensors applied within the body and for sensors demanding for more sophisticated packaging techniques than inertial sensors.

Sensor systems for body motion

A strongly establishing field of medical sensing is 3D-Body-Motion-Tracking with body worn sensors. Therefore, three axis acceleration sensors and three axis gyroscopic sensors are combined to one inertial measurement unit (IMU) [2]. The data from acceleration sensors is used to determine the orientation towards ground. By measuring and integrating the acceleration $a(t)$ twice, the actual position of the device can be estimated from a given starting condition. Since rotation of the device affects the orientation of the accelerometers, gyroscopes are used to orientate the IMU based coordinate system into a ground based coordinate system. Due to the integration of sensor data to calculate the position, a drift in the sensor signal affects the orientation and position data. Magnetometer sensors are used to measure orientation, reducing the offset drift induced by mathematically integrating the angular rate of the gyroscopes. So the orientation can be realigned. Additionally, pressure sensors are used to measure height for correction of the sensor data. To facilitate sensor fusion Extended Kalmann filters are used to weight the different noise contributions of the sensors and to calculate a result with least uncertainty [3]. Due to the availability of inertial sensors many companies offer inertial navigation systems. One main advantage results from the fact that the measuring quantity – acceleration, angular rate and magnetic field – are practically not influenced by the packaging of the sensor. So the widespread of these sensors is fostered by the ability to achieve a hermetic sealing relatively easy with common micro technologies. The silicon sensors are mass manufactured in large batches, whereby the hermetic sealing is provided on wafer level using conventional assembly technologies like anodic bonding of glass or silicon fusion bonding [4]. In many medical devices for example for gait analysis [5, 6] and for broad application like commercial health applications with smartphones [7], only widely available standard device packages are needed.

The application of IMUs includes, but not encompasses body worn systems for:

- gait analysis,
- activity and power measurement for over weighted and sportive individuals, amputees and athletes, etc.,
- posture analysis and control,
- control of assistive devices,

to give an overview.

For measuring human activity the exact orientation and position of the body is not always of importance. Then the signal interpretation may be very simple with only very low requirements on computing power.

Inertial sensors applied at the body or in clothes are already quite common scenarios today. Within the human body IMUs are used to correct the orientation of endoscopic images, when endoscopes are rotated [8].

Sensor systems to measure muscle activity

During rehabilitation after stroke or to measure the extend of muscle usage during training of healthy users electromyography (emg) sensor systems are used. The electrical signal provided by the muscles during action are captured with electrodes, amplified, filtered and recorded.

Systems with integrated electrodes, but also with alternative measurement principles facilitating electromechanical sensors, are under development. Alternative measurement methods using mechanical tension / impedance and the change of shape of the muscles during action are under scientific investigation [9, 10, 11]. These methods have promising advantages like the possibility of wearing the sensors over clothes, so that assistive devices like orthosis and prosthesis can easily be deployed and removed during daytime. Additionally, the attachment of the sensors shall become easier and safer and therefore more appropriate for the elderly [12].

Today, the control of emg facilitating orthoses is possible with glued electrodes. Implanted electrodes are in discussion to be realized in the future.

The packaging of the externally applied sensors features relatively low requirements. Drawbacks result from the low robustness of electrode contact to the skin. Therefore, completely packaged sensors with mechanical interface to the human can be a comfortable alternative to systems with electrode interface.

Sensor systems at the external eye

Increased fluid pressure in the eye can damage the optical nerves leading to glaucoma. The intraocular pressure changes quickly during one day. Current measurement methods are performed under local anesthesia of the eye in a medical practice. Therefore, monitoring the pressure profile continuously is not possible for the majority of patients which are prone to glaucoma.

By measuring the curvature of the eye it is possible to track the changes of intraocular pressure. The company Sensimed, a spin-off from École polytechnique fédérale de Lausanne (EPFL) has developed a disposable contact lens with which the continuous profile of the pressure change can be recorded [13].

The contact lens comprises an integrated silicon chip and an antenna. The antenna receives inductively coupled energy used with a micro chip. With a small strain gage the curvature of the cornea is measured. The measurement values are transmitted to the receiver wirelessly. Even though the energy is supplied from the outside, the allowed period of usage is limited to 24 h due to packaging and legal issues.

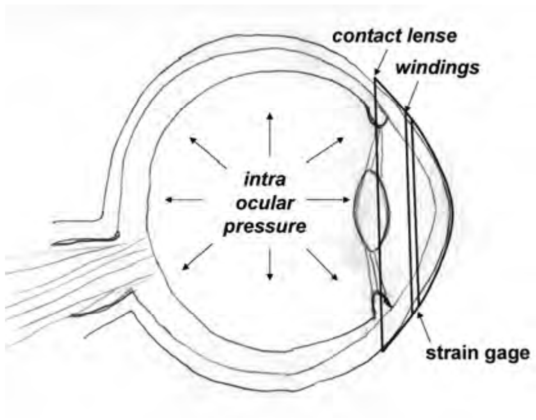

Fig. 1. Working principle of contact lens for continuous monitoring of intraocular pressure.

In this case of application the packaging has to be biocompatible to not affecting the eye. The measuring quantity – the mechanical curvature of the cornea – has to be correctly, reliably and dependably transmitted from the cornea onto the packaged strain gage. The packaging has to provide electrical insulation and chemical stability as well as mechanical stable properties over the time of application, here 24 h.

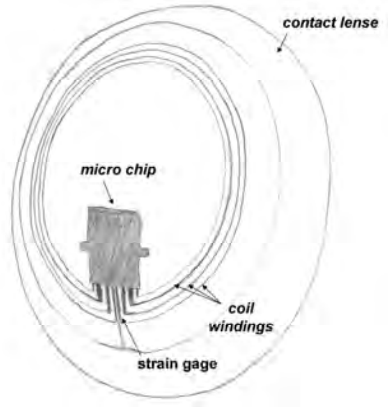

Fig. 2. Contact lens with strain gage, signal electronic and coil for receiving energy and transmission of data. Photographs can be viewed here: [14]

One advantage of the system results from the wireless energy and data transmission along with the mechanical measurement principle. This allows for a complete sealing with silicone, so that no electrodes or electrical feedthroughs are needed. This diminishes packaging challenges, where electrodes have to be sealed at the silicon chip. The declaration as disposable product avoids the need to resterilize the product after use.

Tactile Sensors for Minimally Invasive Surgery

A large challenge for the physician in minimally invasive surgery results from the lack of tactile information from the tip of the long and thin instruments. Techniques are evolving to regain haptic information by measuring the contact forces at the tip of instruments like endoscopes, catheters and guide wires.

Force Sensors for surgical instruments and surgical robots

Several approaches have been made to restore the haptic sense which is lost when long instruments are used to operate with inside the body. For instruments force measuring clamps [15] or sensitive tool platforms [16, 17] have been designed.

There are not many systems with force feedback actively used in the market. In robot surgery the "Da Vincí" robot (Intuitive Surgical) is the most common known system. Force measurement is planned to be established at the holder of the instruments. Up to now it was not reported that the instruments itself support force feedback from the direct tip of the instruments.

The force measurement during advancing of catheters during treatment of the heart is of great interest. The system "Sensei X" from (Hansen Medical) [18] allows for guiding catheters inside the heart. It provides haptic feedback of forces, which are measured at the proximal catheter part, which is advanced by the system.

Direct measurement of forces at the tip of catheters is provided by the "TactiCath" system (Endosense) [19]. A fiber optic sensor is integrated into the tip of a 2.33 mm diameter catheter. The force is measured as a vector measure F_x, F_y and F_z. It is displayed at a graphic display, showing contact forces of the catheter tip. The catheter with integrated sensor is built as a disposable product and is commercially available.

To enable haptic feedback of forces from guide wires, we built special force sensors, which are integrated into guide wires for revasculation of closed heart arteries [20, 21]. The feedback shall enable the physician to feel the way of the wire through the occluded vessels and to reduce the contact forces and therefore the risk of complications. To integrate sensors into the thin guide wire, the sensors have a miniaturized size with dimensions of $0.2 \cdot 0.3 \cdot 0.6\ mm^3$. This marks the current state of the art in miniaturization of force sensors.

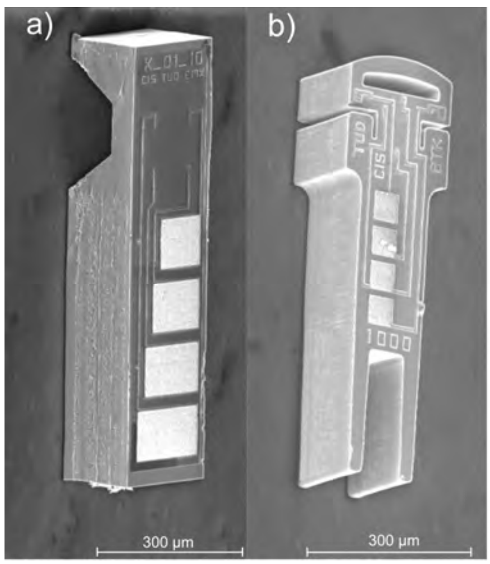

Fig. 3. Two types of miniaturized silicon force sensors to be integrated into the tip of guide wires for heart catheterizations [20]

These guide wires with sensors are designed as disposable product. The project is still part of the research.

Sensors for Implants

A long dream in patient treatment is the compensation of lost organ functions by use of long term medical implants. The most famous implant is the cardiac pacemaker, the first one implanted 1958. Today, worldwide approximately 730.000 pacemakers are implanted each year worldwide [22]. But also cochlea implants – 219.000 are already implanted worldwide in 2010 [23] – and deep brain stimulators for e.g. treating Parkinson's disease and depression are in use.

The electrical stimulation of the heart with pacemakers is an already very good established application. Electrodes are used to measure electrical potential and to simulate the heart cells. The electrodes are connected to the main unit by a standardized connector.

Whereas the connection of small numbers of electrodes at pacemakers is already a good working solution, research question have to be solved for micro systems interacting with tissue and neurons with a larger number of electrodes. Examples are the retina implant, which restores a fraction of lost vision [24, 25], or neural interfaces, which are implanted in the brain to measure neural activity and to stimulate brain function [26]. There is still the need for long term stability of the electrical feedthroughs [26, 27] and hermetic covering of sensors [28] which is part of the research and currently not in clinical use.

Although partially solved, challenges remain by combination of mechanical sensors and electrical feedthroughs for long term implants. For pacemakers pressure sensors have been integrated. The basic questions of sealing, sensing and stimulation with the pacemaker seem to be solved. But the pave to market is already not completed. The measurement of pressure for clinical use is still under way [29].

It can be concluded that the electrical stimulation with pacemakers with four electrodes is an already very good established solution. But the stimulation of nerves with several hundreds of electrodes is still not solved for long-term use. If measurement of mechanical quantities like pressure or force is required, even though in principle no electrical feedthroughs are required, additional packaging challenges have to be solved.

From this current survey of different sensors, looking at the ease of usage of inertial sensors in the first section and their ease of use, it can be concluded that hermetic sealed implants can be forecasted a bright future. The less connections to the outside, the easier and the more reliable can be the function.

One can depict this findings based on two examples. One idea is to facilitate energy deployment for long term implants by fuel cells, which directly convert the blood sugar into electric energy. This can lead to a steady supply with energy without recharging. But a blood powered system reveals several major challenges due to direct interaction of blood and implant. Giving one prospective from this survey, for a glucose measuring implant, today it ideally will be constructed with a hermetic sealing and a power supply by batteries or by accumulator with inductive coupling. The measuring principle should be a principle which penetrates the hermetic sealing, for example electric or mechanic waves. Another example is a completely hermetically sealed pressure sensor with inductively coupled energy and signal transmission [30]. No feedthroughs are needed and the surface can be perfectly adapted to achieve high biocompatibility.

Generalization of Findings and Outlook

From the examples of different sensors general findings can be derived. Sensors with only small demands on packaging can achieve a fast breakthrough in mass markets. Good examples are inertial sensors in smartphones and the like.

For sensors used in direct contact with the skin cleaning and disinfection can be required. For the use in natural orifices sterilization has to be made possible. Three options are possible: resterilization, covering with a sterile interface or offering as a disposable product.

Major drawbacks result from electrical connection to the human. Electrodes for external surface-emg degrade over time and the signal is prone to disturbances. For electrodes at implants the contact to the tissue and the long-term hermedicity of the packaging is still a part of research. In several application new micro sensors measuring mechanical quantities may replace principles which use electric coupling due to the possible design without the need for feedthroughs. Nevertheless, for future applications of new implants like adaptive brain stimulators, retina implants or bidirectional neural interfaces and the like, these research questions of long term stable contacts have to be solved.

References

[1] G. Gerlach, R. Werthschützky, 50 Jahre Entdeckung des piezoresistiven Effektes: Geschichte und Entwicklungsstand, *tm, Technisches Messen*, 10 pp. 53-76 (2005)

[2] O. J. Woodman, An introduction to inertial navigation. *Technical Report*. University of Cambridge (2007)

[3] T. Lefebvre, H. Bruyninckx. J. De Schutter, Kalman filters for non-linear systems: a comparison of performance, *International Journal of Control* 77-7, pp. 639-653 (2004)

[4] J. A. Dziuban, Bonding in Microsystem Technology, *Series in Advanced Microelectronics*, Vol. 24 (2006)

[5] A. M. Sabatini, C. Martelloni, S. Scapellato, F. Cavallo, Assessment of Walking Features From Foot Inertial Sensing, *IEEE Transactions on Biomedical Engineering*, VOL. 52, NO. 3, 486-494, (2005)

[6] Xsens, MVn bIoMeCH, Ambulatory Measurement of Human Motion, *Product Description,* Xsens Technologies B.V., Enschede (2012)

[7] R. K. Ganti, Multisensor Fusion in Smartphones for Lifestyle Monitoring, *IEEE Conf. on Body Sensor Networks*, 36 - 43 (2010)

[8] A. Schneider, K. Höller, D. Wilhelm, J. Hornegger, H. Feussner, Nutzen der automatischen Bildrotation bei hybriden NOTES-Eingriffen, *Endoskopie heute*,pp. 23-34 (2010)

[9] J. Hielscher, T. Meiss, J. Block, R. Werthschützky, Estimating Muscular Activity of the Quadriceps Femoris Muscles by Measuring the Change in Shape*, AMA Conf. Sensor + Test* (2013)

[10] T. Hemmerling, Phonomyography - Acoustic myography using condenser microphones. *Anaesthesia and intesive care* (2002)

[11] M.T. Tarata, Mechanomyography versus Electromyography, in monitoring the muscular fatigue, *Biomedical Engineering Online* (2003)

[12] M. Grün, T. Meiss, R. Müller, J. Block, D. Heitzmann, S. van Drongelen, M. Vanoncini, S. Wolf, P. Pott, H.F. Schlaak, R. Werthschützky, R. Konigorski, Active Knee Orthosis for Supporting the Elderly*, Conf. on Biomedical Engineering*, Jena (2012)

[13] Sensimed, Principles and rationale for the SENSIMED Triggerfish Sensor device, *Product Description*, Sensimed AG, Lausanne (2012)

[14] Sensimed AG, SENSIMED Triggerfish - Continuous Monitoring of IOP up to 24 Hours, *Product Description,* Sensimed AG, Lausanne (2012)

[15] S. Sokhanvar, M. Packirisamy and J. Dargahi, A multifunctional PVDF-based tactile sensor for minimally invasive surgery, *Smart Materials and Structures,* 16-4, pp. 989-998 (2007)

[16] U. Seibold, B. Kübler, G. Hirzinger, Prototype of Instrument for Minimally Invasive Surgery with 6-Axis Force Sensing Capability, *IEEE Conf. on Robotics and Automation (ICRA)*, pp. 496-501 (2005)

[17] J. Rausch, R. Werthschützky, A Miniaturised Piezoresistive Multi-Component Force Sensor for Minimally Invasive Surgery. *AMA Conf. Sensor + Test*, Vol. 1, pp. 26-28 (2009)

[18] Hansen, Sensei X Robotic Catheter System. *Product Description,* Hansen Medical Inc, Mountain View (2010)

[19] Endosense, The TactiCath: A new standard in Ablation Catheters. *Product Description,* Ensosense S.A. (2011)

[20] T. Meiss, Silizium-Mikro-Kraftsensoren für haptische Katheterisierungen: Entwurf, Musterbau und Signalverarbeitung sowie erste Validierung des Assistenzsystems HapCath. *Dissertation,* Technische Universität Darmstadt (2012)

[21] T. Meiss, C. Budelmann, T.A. Kern, S. Sindlinger, C. Minamisava, R. Werthschützky, Intravascular palpation and haptic feedback during angioplasty, *IEEE Conf. World Haptics 2009*, 380 - 381 (2009)

[22] H.G. Mond, A. Proclemer, The 11th world survey of cardiac pacing and implantable cardioverter-defibrillators: calendar year 2009 - a World Society of Arrhythmia's project. *Pacing. Clin. Electrophysiol*. 34,8, pp 1013-1040 (2011)

[23] NIDCD Fact Sheet: Cochlear Implants, *NIH Publication* No. 11-4798 (2011)

[24] K. Stingl et al, Artificial vision with wirelessly powered subretinal electronic implant alpha-IMS, *Proc R Soc B 2013,* 280:20130077 (2013)

[25] L. Greenemeier, FDA Approves First Retinal Implant, *Nature News*, Feb 15 (2013)

[26] G.J. Suaning, M. Schuettler, J.S. Ordonez, N.H. Lovell, Fabrication of multi-layer, high-density micro-electrode arrays for neural stimulation and bio-signal recording, *IEEE/EMBS Conference on Neural Engineering*, pp. 5-8 (2007)

[27] A. Schatz, J. S. Ordonez, T. Stieglitz, Ensuring minimal humidity levels in hermetic implant housings*, IEEE Conf. Engineering in Medicine and Biology*, pp. 2296 - 2299 (2011)

[28] W. Betz, Flexible mikroelektromechanische Implantate für den chronischen Einsatz: Verkapselungskonzepte und Testverfahren für die Materialcharakterisierung, *Dissertation*, Universität Duisburg-Essen (2011)

[29] VDI/VDE, Cardiac Output Monitor mit pulmonalarteriellen Sensoren - COMPASS, *VDI/VDE Innovation + Technik GmbH* (2010)

[30] FHG, Druckknopf im Kopf*, Forschung Kompakt 10.2012*, Fraunhofer-Gesellschaft (2012)