Non-invasive Continuous Measurement of Intra-abdominal Pressure

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Intra-abdominal hypertension (IAH) can lead to the failure of multiple organs. Currently, in patients susceptible to IAH, the intra-abdominal pressure (IAP) is assessed only sporadically with an urinary catheter. In a Swiss-Slovenian collaboration, a novel method was developed to monitor the IAP continuously and non-invasively by measuring the bioimpedance and the stiffness of the lower abdominal wall.

CSEM and the Slovenian company TMG-BMC Ltd. studied how the IAP can be monitored by measuring the bioimpedance (BioZ) and the mechanical stiffness of the lower abdominal wall. The partners developed and produced a demonstrator device, referred to as IAP-CMM, and tested it in a pilot clinical research project.

Figure 1 shows a 3D drawing of the IAP-CMM device. Its dimensions are 72×42×23 mm^3. BioZ is measured through four dry, glue-free stainless-steel electrodes which are integrated in the housing. These electrodes serve also to measure abdominal muscular activity (electromyography, EMG). Optionally, two more electrodes (e.g., gel electrodes with glue) can be connected to the device through two plugs on the side of the housing, to allow for longer inter-electrode distances for BioZ measurements. The tension of the abdominal wall is measured through a force sensor whose tip is in direct contact with the skin of the abdomen. The force sensor is conceptually a cantilever beam with a piezoresistive strain gauge at the fixed end. Importantly, the IAP-CMM device allows to synchronously record BioZ and tension of the abdominal wall non-invasively and continuously. A USB plug serves to recharge the internal battery of the device. The device is fixed on the lower abdomen with double-sided medical adhesive that is pre-cut to allow the electrodes and the tip of the force sensor to touch the skin, while covering the USB plug. The device streams the BioZ, EMG and force sensor data to a tablet through Bluetooth Low Energy (BLE). Additionally, at the end of a measurement all data can be downloaded *via* BLE.

To ensure safety, the development of the device was embedded in a risk management process according to ISO 14971, the relevant paragraphs of the IEC 60601 series were taken into account (*e.g.,* limitation of leakage currents), and the device was rigorously tested against the requirements, partially by an external laboratory.

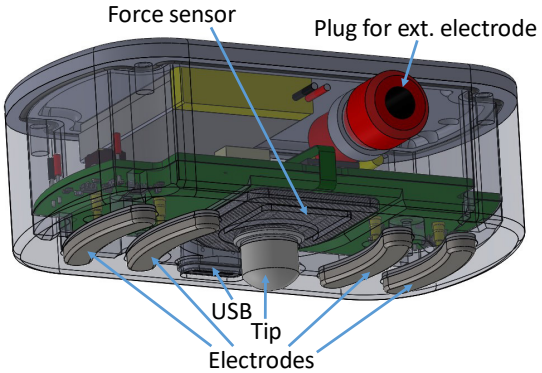

Figure 1: Drawing of the IAP-CMM demonstrator device.

The principle of monitoring IAP changes through BioZ and force measurements was studied with the demonstrator device on 4 subjects who underwent medically indicated laparoscopic surgery at the University Medical Centre of Ljubljana. The study was reviewed by the Slovenian Ministry of Health (study number 0120-190/2021/6). The IAP of the patients was artificially modified during the intervention from 5 mmHg to 25 mmHg. Figure 2 shows how the BioZ and the tension of the abdominal wall increased with IAP. Confirming a previous study [1], we found a linear relationship between IAP and abdominal wall tension. We additionally found that the BioZ increases logarithmically with increases in IAP. At lower IAP, BioZ may therefore be more sensitive to pressure changes. Such behavior could be exploited to detect early onset of IAH, which is defined as IAP>12 mmHg. Note that the absolute, *i.e.*, not normalized values of BioZ and tension are strongly different between subjects, *e.g.*, due to the individual anatomy of the abdominal wall. Therefore, at the current stage, the approach seems mostly suitable for long-term intra-individual monitoring of the IAP.

In conclusion, the present study has shown in a small clinical research study with an experimental demonstrator that changes in the IAP can be monitored non-invasively and continuously by measuring the BioZ and the mechanical tension of the abdominal wall. These results shall be corroborated in already planned studies including more subjects, *e.g.*, to reliably quantify the error with which the presented method estimates the IAP and to evaluate possible calibration procedures.

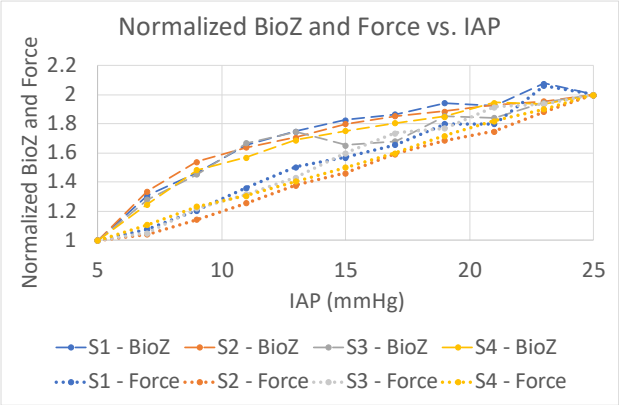

Figure 2: BioZ and force increase with IAP, as recorded on four subjects (S) during laparoscopic intervention.

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[1] M. Kušar, *et al.*, "Preliminary study of reliability of transcutaneous sensors in measuring intra-abdominal pressure.", Sci Rep 12 (2022) 8268.