A Strain Gauge-Based Implantable Bladder Volume Monitoring Sensor

Maxime Verstraeten
Bio-Electro- and Mechanical Systems
Université Libre de Bruxelles
Brussels, Belgium
maxime.verstraeten@ulb.be

George Bou Kheir
Department of Urology
Ghent University Hospital
ERN accredited network
Ghent, Belgium
george.boukheir@uzgent.be

Charlotte Sandersen
Faculty of Veterinary Medicine
University of Liege
Liège, Belgium
charlotte.sandersen@uliege.be

Louis Vande Perre
Bio-Electro- and Mechanical Systems
Université Libre de Bruxelles
Brussels, Belgium
louis.vande.perre@ulb.be

Romain Raffoul
Bio-Electro- and Mechanical Systems
Université Libre de Bruxelles
Brussels, Belgium
romain.raffoul@ulb.be

Javier Chávez Cerda
Bio-Electro- and Mechanical Systems
Université Libre de Bruxelles
Brussels, Belgium
javier.chavez.cerda@ulb.be

Thierry Roumeguere
Department of Urology
Hôpital Universitaire de Bruxelles,
Université Libre de Bruxelles
Brussels, Belgium
thierry.roumeguere@ulb.be

Anne Vanhoestenberghe
School of Biomedical Engineering
King's College London
London, United Kingdom
a.vanhoest@kcl.ac.uk

Antoine Nonclercq
Bio-Electro- and Mechanical Systems
Université Libre de Bruxelles
Brussels, Belgium
antoine.nonclercq@ulb.be

***Abstract*— Sensory awareness of bladder fullness can be compromised after spinal cord injuries or due to certain medical conditions, significantly impacting the quality of life for affected individuals. Implantable medical devices that can monitor bladder activity and fullness are being developed to address this issue. In this study, we present a novel strain gauge-based sensor encapsulated in silicone designed to monitor urine volume in the bladder. The sensor is anchored on the bladder wall using hooks, limiting the need for glue or sutures, and enabling minimally invasive implantation. The sensor was validated on both a synthetic bladder phantom and on a pig's bladder during an *in-vivo* study. The results demonstrate the capability of the sensor to provide a linear indication of the infill volume using the bladder wall's strain. This measurement technique was found to be a superior indicator of urine accumulation compared to intravesical pressure, making it a promising choice for restoring sensory awareness through chronic bladder monitoring. Further optimization of the anchoring technique could enhance the accuracy and usability of this approach. This research contributes to the advancement of implantable bladder sensors, with potential applications in improving the management of bladder-related conditions and enhancing the quality of life of people suffering from bladder dysfunction.**

***Keywords*— Bladder monitoring, strain, pressure, bladder volume, urine accumulation, sensor anchoring.**

I. Introduction

The urinary bladder is a highly compliant organ that ensures low-pressure urine storage to prevent urinary reflux, incontinence, or damage to the bladder wall, even for large volumes. Lower urinary tract symptoms affect nearly half of the global population, and various conditions can result in bladder dysfunctions [1]. Some pathologies can cause a decrease in bladder compliance, leading to impaired low-pressure storage and potential upper urinary tract complications. A 2020 survey revealed that 26% of people living with a spinal cord injury require assistance with bladder emptying and lack awareness of bladder fullness [2]. A long-term solution for people with absent bladder-filling sensations could involve a wireless bladder volume and pressure monitoring device to alert when emptying is needed, thus restoring sensory awareness and improving quality of life by enhancing participation in daily activities [3].

A cystometrogram (CMG) is a pressure-volume curve obtained during experimental bladder filling and is commonly used to assess bladder function. A steep rise in intravesical pressure is an indication that cystometric capacity has been reached and that the person needs to void. However, during the filling phase, the pressure is quasi-constant due to bladder relaxation, as shown in Fig. 1. Therefore, intravesical pressure monitoring is inadequate to provide a convenient and early warning of the need to void. It is also not a suitable indicator for chronic monitoring of bladder volume, fullness, or urine accumulation [4]. Studies on animal models confirmed that pressure is indeed an unreliable surrogate of urine volume during the filling phase, especially when considering movement artefacts, and is only useful to monitor the end of the filling phase, where the pressure increases sharply as urine accumulation reaches maximum bladder capacity [5], [6]. Therefore, a volume estimation system based only on pressure monitoring can result in inaccurate volume estimation and false alarms. Moreover, the invasiveness of catheter-based pressure measurements restricts their use to data collection in a clinical environment and makes them unsuitable for long-term ambulatory bladder monitoring [7].

In this study, we propose a novel technique for estimating urine volume using bladder wall strain. While strain monitoring is often performed on low-strain materials, few publications demonstrated its use on deformable organs such as the bladder [8], [9]. Assuming a spherical bladder shape during the filling phase and a known residual volume at the start of filling, the strain of the bladder's outer wall is directly related to its volume and urine accumulation. Monitoring bladder wall strain could provide a less invasive, more accurate and linear indication of urine accumulation during the filling phase, as illustrated in the theoretical wall strain in Fig. 1. Additionally, a strain measurement system could measure local wall distension during bladder contractions.

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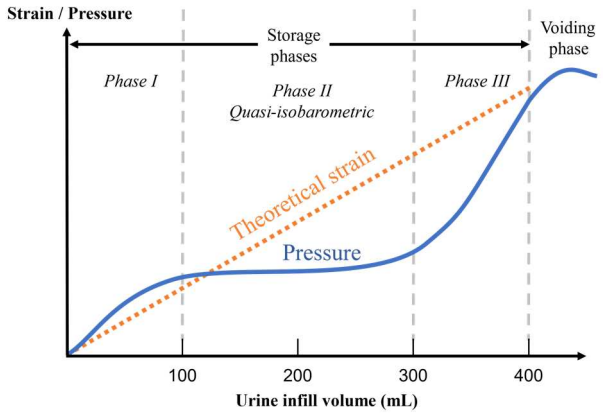

Fig. 1: A cystometry study measures the pressure during bladder filling (typical, idealized curve represented by the solid blue line). During the quasi-isobarometric storage phase II, the pressure remains quasi-constant due to bladder relaxation. Wall strain monitoring is hypothesized to provide a linear estimation of urine volume, as represented by the idealized and theoretical wall strain (dashed line).

This paper presents an anchorable and implantable strain sensor using commercially available resistive strain gauges to monitor bladder volume, urine accumulation and contractions.

II. Materials and Methods

The sensor consists of a strain gauge encapsulated in silicone, along with four stainless-steel hooks that ensure robust anchoring on the bladder wall, allowing for accurate monitoring of its deformation. The resistance readout of the strain gauge is conducted through an external conventional Wheatstone bridge and a conditioning circuit. Experiments were performed on a silicone bladder phantom that replicates the mechanical behaviour of the bladder during filling [10] to validate the sensor's functionality as well as on a pig's bladder to assess its capabilities to monitor bladder volume *in-vivo*.

A. Strain gauge

Strain gauges are sensors that exhibit changes in electrical resistance in response to mechanical deformation. This resistance change can be accurately measured with a conventional Wheatstone bridge or alternative designs [11]. For this application, the resistance variation of a commercially available 120 Ω 13 mm x 4 mm foil strain gauge (RS PRO, United Kingdom) was measured with a conventional Wheatstone bridge, as shown in Fig. 2. This resistance variation (ΔR) is linked to the gauge factor (k), the strain (ε), and the unstretched gauge resistance (R_0), as shown in (1).

$$\Delta R = \varepsilon k R_0 \qquad (1)$$

The output voltage (V) of a balanced Wheatstone bridge also depends on the excitation voltage (E), as shown in (2)

$$V = E\left(\frac{\Delta R}{4R_0 + 2\Delta R}\right) \qquad (2)$$

The bridge excitation voltage was set to a relatively low and balanced level of ± 2.5 V to minimize power dissipation in the resistors and the common-mode voltage. The Wheatstone bridge differential voltage was amplified with a gain of 2,200 V/V by an instrumentation amplifier (AD8221, Analog Devices, USA) and filtered with a second-order Sallen-Key low-pass filter having a cut-off frequency of 100 Hz. The signal was sampled at 1 kHz using a 14-bit analog-to-digital converter (NI USB-6009, National Instruments Corp., USA).

The system was allowed to stabilize thermally for 15 minutes before recording any data to mitigate heat-induced resistance drift. A variable resistor was carefully adjusted to balance the Wheatstone bridge at the start of the experiment.

B. Anchoring

We aim to position the strain sensor on the anterior part of the bladder wall, slightly above the pubic symphysis, for ease of access. The sensor is to be placed between the skin and the adventitia and securely anchored to the detrusor muscle layer, as shown in Fig. 3 (a). In that regard, we have developed a minimally invasive implantation technique using a trocar and a specific delivery system, as illustrated in Fig. 3 (b). The proposed anchoring method is adapted from a patented technique and minimally invasive surgical procedure previously developed by our group for gastric stimulation in

the treatment of obesity, which allowed for prolonged anchoring of implantable devices on the stomach wall of six dogs [12], [13], [14]. Since the bladder is a similarly hollow organ, the anchoring method proposed here is expected, based on our previous experience, to enable long-term anchoring on the bladder wall with minimal erosion.

The strain sensor is anchored using four straight and barbed stainless-steel hooks, 10 mm long, encapsulated in a flexible silicone substrate, and positioned to face outwards from the central plane to ensure secure placement. As the mean thickness of the healthy human detrusor post-micturition is 2.95 ± 1.3 mm [15], the length of the part of the hooks protruding from the silicone is chosen to be less than this mean in order to penetrate the bladder wall while avoiding perforation. This prevents urine leakage and reduces the risk of local tissue inflammation and bladder stones formation.

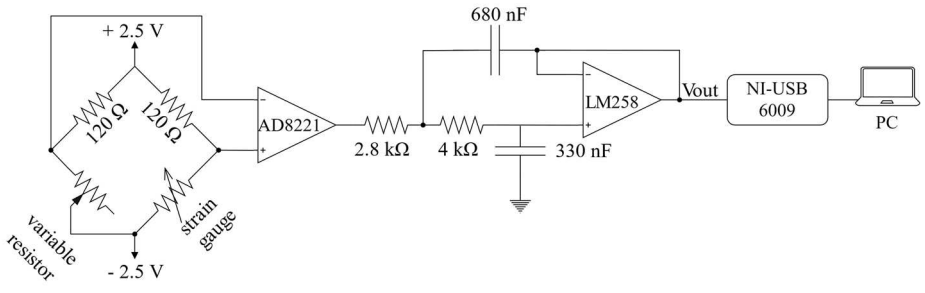

Fig. 2: The acquisition chain is composed of a Wheatstone bridge, a low-pass Sallen-Key filter, and a NI-USB acquisition device.

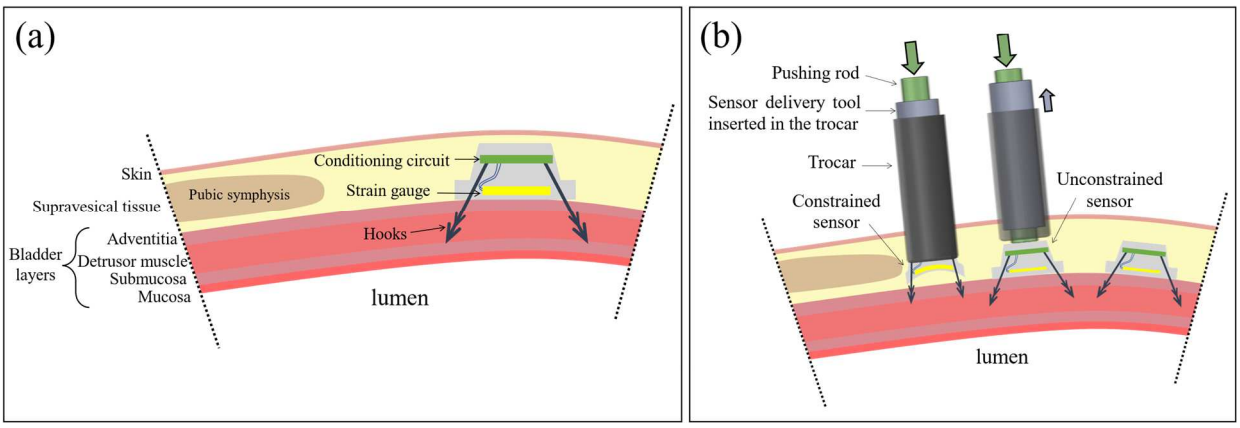

Fig. 3: Illustration of the sensor implantation process on a human bladder. The sensor anchors on the detrusor on the anterior part of the bladder wall detrusor near the pubic symphysis with stainless-steel barbed hooks. (a) Illustration of the sensor position on the bladder wall. (b) Illustration of the delivery system allowing a minimally invasive implantation.

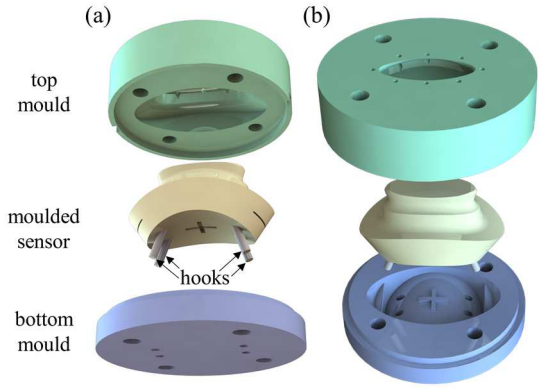

Fig. 4: Mould assembly used to encapsulate the strain gauge and the hooks. (a) Bottom view. (b) Top view.

C. *Encapsulation and molding*

The silicone encapsulation serves multiple purposes, including protecting and isolating the strain gauge and providing a robust embedding of the hooks. A silicone material with higher compliance than the bladder wall was chosen to prevent stressing the bladder wall at the anchoring point. A wide range of bladder tissue elasticity has been reported, varying from 0.25 MPa to 2.3 MPa, depending on factors such as location on the bladder wall, type of test performed, rate of strain, and experimental conditions [16]. DragonSkin 10 MEDIUM (Smooth-On, USA, mix ratio 1A:1B, pot life: 20 minutes, cure time: 5 hours, 100% modulus: 0.151 MPa) was selected for its suitable elasticity and pot life for the casting process. The silicone encapsulation also provides additional benefits, including (1) a biocompatible outer layer that covers sharp edges to protect the host body, (2) protection against corrosion of metallic contacts and exposed metal (if void-free adhesion is achieved), and (3) prevention of cables and connections tearing that could occur due to sensor deformation [17].

A two-part mould was designed in Solidworks CAD software (Dassault Systèmes, France) and 3D-printed in PLA with a Prusa MK3 (Prusa research, Czech Republic), as shown in Fig. 4. Before encapsulation, 32 AWG insulated wires were soldered to the gauge terminal pads. The gauge and the hooks were cleaned with isopropyl alcohol to remove soldering flux. Heat-shrink tubes were placed and heated on a third of the hooks' length to increase the surface of adhesion with the silicone. Additionally, both the strain gauge and the hooks were dipped in MED2-161 silicone primer (Nusil Technology, USA), placed on paper towel, and left to dry for 30 minutes.

Stiffer silicone rubber (MoldStar™ 31T, Smooth-On) was used to coat the terminal contacts of the strain gauge and prevent any cable tear. A thin (< 1 mm) layer of DragonSkin 10 silicone was then mixed and left to cure. After 30 minutes, with the silicone still tacky, the strain gauge was gently dropped onto the thin silicone layer and left to fully cure. This eases the accurate longitudinal placement of the gauge in the encapsulation mould by fixating the position of the silicone layer, and this ensures that the gauge will be fully encapsulated, even underneath it. The strain gauge was then placed in a two-part mould and the hooks were inserted in the mould by piercing the thin silicone layer. A new mix of DragonSkin 10 was prepared, degassed (200 mbar vacuum) to remove air bubbles, and poured inside the mould. The mould was then placed inside the vacuum bell for 15 minutes, degassed, and left to cure at room temperature (23 °C). The sensor was retrieved 5 hours later.

D. *Sensor validation on a bladder phantom*

The proposed setup to validate the sensor is shown in Fig. 5. A bladder phantom, accurately mimicking a healthy bladder's mechanical behaviour during filling [10], was used to simulate physiological bladder filling. The phantom was made of a 3.5 mm thick Ecoflex™ 00-30 silicone rubber layer and a wire net, to limit the maximum cystometric capacity, as in humans. The phantom was suspended above the ground with a stand, and a sensor was anchored on the phantom wall by inserting each hook into the wall until the sensor stayed firmly in place. A Luer-lock connection with a T-valve was used to connect a syringe and fill the phantom with water while recording the intravesical pressure with a pressure sensor (ABP series gauge pressure sensor, Honeywell International Inc., USA). The syringe was placed in a KDS100 syringe pump (KD Scientific, USA), and the filling rate was set to 9 mL/minute, following usual recommendations for cystometry studies [18] for a total volume of 400 mL, corresponding to the maximum cystometric capacity of the phantom.

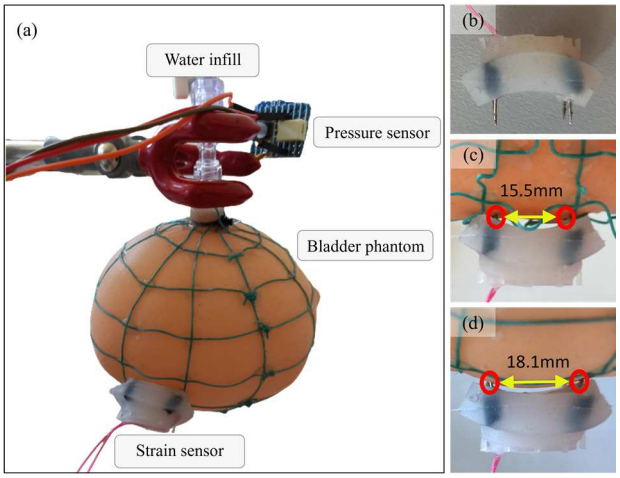

Fig. 5: The sensor is anchored on the bladder phantom while the phantom is filled with water and both pressure and strain are recorded. The distance between the hooks (circled in red) increases and the sensor's curvature decreases with increasing bladder volume. (a) Validation setup (picture taken at an infill volume of 250 mL). (b) Encapsulated sensor. (c) Sensor anchored on an empty bladder phantom. (d) Sensor anchored on a bladder phantom near maximum capacity.

After anchoring, a filling test up to cystometric capacity was performed on the phantom to ensure that the sensors do not detach at any point during filling and to ensure no water leakage. Subsequently, ten additional fillings of 400 mL were performed to assess the sensor's capabilities to monitor the wall deformation. Following the tenth filling, with the phantom near cystometric capacity, it underwent manual compression multiple times to mimic detrusor contractions. Prior to each filling, the Wheatstone bridge was balanced using the variable resistor and strain was recorded with the setup previously described in Fig. 2. The pressure was similarly recorded with the same analog-to-digital converter, and MATLAB R2022a (Mathworks, USA) was used to analyse the results.

After the experiments, the strain sensor was removed, and a new filling was carried out to assess that no hook perforated the phantom wall. This assessment was performed by observing if water leaked at the anchoring points during a filling test after the sensor removal.

E. Sensor validation on a pig bladder in-vivo

The strain sensor was also validated in a pilot *in-vivo* study, which was approved by the local ethics committee for animal experimentation (ethical application 23-2554) and was fully compliant with EU guidelines. A young female Piétrain x Landrace pig (78 kg) was chosen because, unlike in males where the urethra is highly convoluted, transurethral catheterization is possible in the supine position using standard urodynamic equipment.

The animal was premedicated using ketamine (10 mg/kg IM) and midazolam (0.5 mg/kg IM). Anaesthesia was induced with propofol (3 mg/kg IV) and was maintained with isoflurane (in oxygen/air, aiming for an end-tidal isoflurane concentration of 0.8%) and propofol (at a rate of 20 mg/kg/h). Fentanyl (at a rate of 10 µg/kg/h) was administered for analgesia.

Once sedated, a double lumen cystometry catheter (9 Fr, Amecath, Egypt) was inserted into the bladder and a Foley catheter (14 Fr) was inserted into the animal's rectum. Both catheters were flushed with saline and connected to a urodynamic system (Newton, Tic Medizintechnik, Germany) for pressure recording. The bladder was exposed via a midline laparotomy, and the resistive strain sensor previously validated on the phantom was anchored to the pig's bladder wall at the bladder dome. Although we did not place the sensor minimally invasively, we chose this position as it would be most accessible for a future suprapubic minimally invasive implantation.

Subsequently, the bladder was emptied and filled with saline to the cystometric capacity of 900 mL at 90 mL/min, for four repetitions. The resistance values were recorded using the acquisition chain previously described in Fig. 2.

III. Results

A. Validation on the phantom

Two sensors were successfully manufactured and anchored on two bladder phantoms. With the sensors in situ, no leakage from any anchoring points was observed during the filling experiment. However, during the subsequent filling test after sensor removal, three out of the eight hooks of the two sensors had inadvertently perforated the phantom wall and reached the lumen, leading to water leakage through these points. This highlights the difficulty of assessing the anchor's depth within the bladder wall when the anchoring is performed manually. The other five hooks were successfully anchored without perforating the phantom wall.

Pressure and strain were recorded during ten experiments. Both measurements were averaged over the ten experiments and normalized to their respective values at cystometric capacity. The resulting average strain and pressure are plotted against the water infill volume in Fig. 6 (a).

Average strain values provide a linear relationship to the infill volume ($R^2 = 0.995$), establishing strain monitoring as a valuable indication of water accumulation inside the phantom. In addition, during manual compression of the phantom to simulate detrusor contractions, not only did the intravesical pressure rise sharply, as would be expected, but a similarly sharp increase in strain was also measured, indicating that an increase in wall tension results in a measurable change in strain, as shown in Fig. 6 (b). Once the manual contractions were stopped, the water still moving inside the phantom induced local wall stress, which is visible as ripples in the baseline part of the strain measurement as it can be seen in the rightmost part of Fig. 6 (b).

B. Validation on the animal model

Although anchoring the sensor without perforating the wall proved to be challenging, no leakage was observed at the anchoring points. The sensor detached from the wall during the first cystometry once the bladder reached approximately 75 % of the cystometric capacity, thus requiring the suturing of the sensor to the wall. Fig. 7 shows the sensor anchored on the bladder wall, and the measured pressure and strain during a cystometry. The strain measurement demonstrated a linear relationship to the infill volume ($R^2 = 0.968$). Minimal bladder relaxation was observed. We attribute this to the high infill rate of 90 mL/min, and the leakage through the external sphincter that occurred as the pressure increased sharply near the cystometric capacity. Strain measurement errors at low infill volumes are attributed to challenges in anchoring, leading to insufficient sensor deformation at low volume.

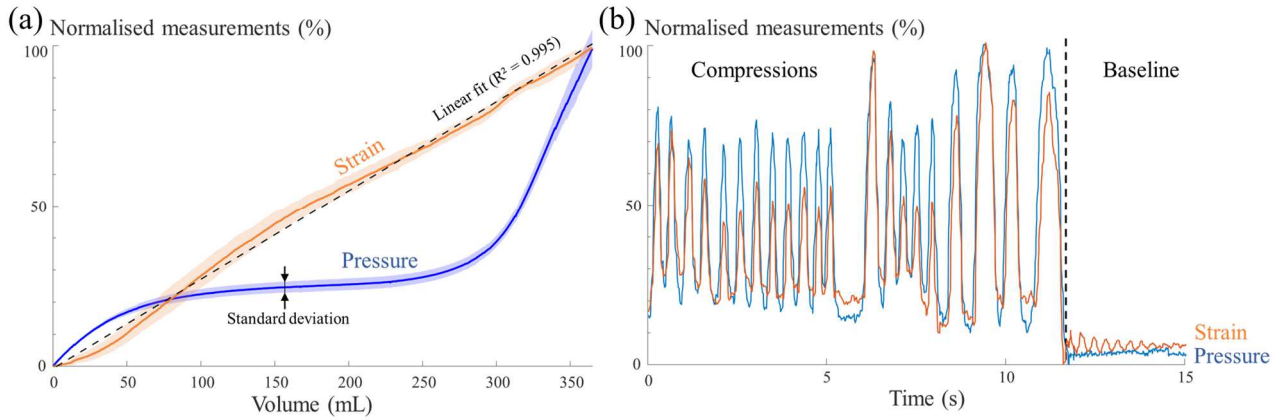

Fig. 6: Experimental pressure and strain measurements. (a) Data recorded during phantom filling, normalised to their values at cystometric capacity and averaged over ten experiments. (b) Data recorded during phantom compressions to simulate contractions, normalised to their maximum amplitude.

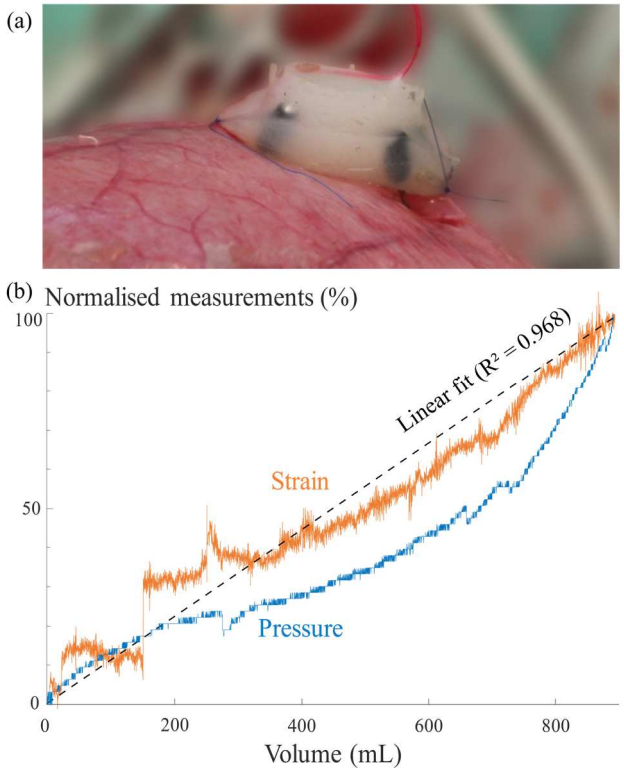

Fig. 7: Sensor validation on an *in-vivo* pig bladder. (a) Sensor anchored on the wall of the exposed pig bladder. (b) Normalized pressure and strain measurements during a cystometry.

IV. Discussion

The proposed strain monitoring technique offers accurate linear monitoring of the infill volume of a bladder, showcasing the potential of anchored strain sensors as an alternative to conventional pressure sensors and transducers that are inadequate for bladder volume and urine accumulation monitoring. Strain sensors could also prove useful to monitor detrusor contractions and thus monitor hyperactive neurogenic bladders, in which contractions can occur even at low infill volume, or to monitor healthy bladders in which an increase in contraction frequency indicates that the bladder reaches maximal capacity.

Accurate strain measurements require the user to be stationary, as urine's motion inside the bladder could locally stretch the bladder and impact the measurement. To address this, incorporating an accelerometer near the strain gauge could provide valuable information to accept or reject measured strain data based on the bladder's and patient's motions during *in-vivo* applications [6].

Although promising results were observed on the phantom and in prior studies, where a similar anchoring technique has demonstrated effectiveness for anchoring implants to the stomach for over a year [13], the sensor detached from the bladder wall near cystometric capacity. Further investigation may be required to ensure adequate anchoring of the sensor to the highly compliant organ that is the bladder. Indeed, the large wall strain, coupled with wall thinning and the need for meticulous care to prevent perforation could lead to insufficient anchoring at high bladder volume. It is important to note that, as the bladder was no longer under abdominal wall pressure once exposed, we observed an almost twofold increase in cystometric capacity (900 mL vs. 500 mL). We estimated the normal capacity before laparotomy by filling the bladder and waiting for leakage, which occurred at 500 mL. As pigs under anaesthesia do not void physiologically by bladder contraction and sphincter relaxation, this leak corresponds to overflow incontinence, which is also higher than the normal voiding threshold. Therefore, the current anchoring method may be sufficient when the sensor is implanted on the bladder, in the abdomen of an awake pig.

The anchoring technique lets the sensor be implanted with minimally invasive surgery techniques, as described in Fig. 3. This approach may reduce the risk of erosion encountered in previous studies with pressure sensors implanted in the suburothelial layer [5], [19]. Specific guiding tools may be necessary to ensure reproducibility and accuracy, and to minimise measurement errors at low filling volumes due to suboptimal sensor placement and initial deformation during anchoring. However, in this study, we chose to only evaluate the strain-volume relationship and the anchoring to the bladder wall, which could be compromised by an incorrect minimally invasive implantation.

Perforating the bladder wall is to be avoided and, as demonstrated on both the phantom and during *in-vivo* experimentation, this is difficult to perform while ensuring robust anchoring. However, we expect the implantation to be easier on neurogenic overactive bladders as they are significantly thicker than healthy bladders [20]. Moreover, the length of the hooks could be adapted to the patient's bladder wall thickness to prevent perforation. The ideal anchoring location must still be determined to maximize the linearity

between bladder volume and local wall strain. This optimization may, however, be limited by the surgical constraints when using a minimally invasive implantation, hence the current choice for a suprapubic implantation [13].

While the current sensor design yields satisfactory results, there is potential for further improvement. For instance, replacing the conventional Wheatstone bridge with alternative resistance-measurement configurations would remove the need for calibration, limit the current flow within the implantable device, and decrease heat-induced drift [11]. Although the Wheatstone bridge configuration is sensitive to temperature changes, we do not expect it to be a significant issue in chronic experiments as the typical temperature change of urine in the body is stable, i.e., $36.61 \pm 0.5\,^{\circ}\mathrm{C}$ [21]. Exploring other strain sensors, such as soft capacitive strain sensors, could also be beneficial due to their increased maximum strain, low hysteresis, and high linearity, making them excellent alternative candidates for this application [22]. Miniaturisation and encapsulation of the acquisition chain near the strain sensor could allow for wireless data transmission, eliminating the need for cable feed-throughs and reducing the risk of erosion associated with wires [19].

Finally, while phantom validation enables efficient and rapid testing, further *in-vivo* investigation in additional animal models is needed to fully evaluate the sensor's capabilities and the impact of its anchoring position on volume estimation. Chronic experiments would be of interest to further evaluate the anchoring, the reproducibility of the sensor measurements, and to assess whether voiding prediction is possible with our proposed device. "Skin-safe" silicone was used to prevent adverse effects on the bladder during the acute experimentation, and we foresee the use of medical grade silicone with similar tensile properties, such as MED-4805 (Nusil, USA) for *in-situ* sensor implantation over longer periods (e.g., several days).

V. Conclusion

This work presents an anchorable and implantable strain sensor using commercially available resistive strain gauges to monitor bladder volume and urine accumulation. It is a promising solution to the challenges associated with a lack of bladder sensory awareness and overcomes the limitation of volume monitoring based on pressure measurements. By providing real-time and continuous monitoring of bladder volume, this approach could benefit people with bladder dysfunctions who are at risk of complications such as urinary tract infections, renal damage, and incontinence. Indeed, a reliable bladder monitoring system would help them protect their upper urinary tract, enhancing their quality of life and reducing the burden associated with such conditions.

The proposed approach involves an implantable flexible silicone device that can be anchored on the bladder wall and provides wall strain measurement. The implantable device's flexibility and silicone material offer several advantages, including reduced erosion risk, minimized patient discomfort, and potential for long-term reliability.

Optimization of the device design and anchoring technique, and exploration of different strain sensors could further improve this innovative approach's accuracy, reliability, and usability. Further animal studies will be required to validate the sensor's usability in clinical applications.

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