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TOPICAL REVIEW

Bladder Monitoring Systems: State of the Art and Future Perspectives

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ABSTRACT The lower urinary tract (LUT) is sensitive to nervous system pathologies, injuries and dysfunctions that may lead to the loss or reduction of bladder fullness sensation. Urination assistive devices aimed at supporting bladder emptying and continence control have been proposed so far. However, patients may not perceive the urge to urinate and activate the device accordingly. In this framework, bladder pressure and volume monitoring is crucial and would lead to optimize the use of assistive devices and reduce side effects for the patient. Despite its centrality in restoring LUT functions, urinary bladder monitoring remains not fully explored, yet. In this review paper, we summarize the efforts performed at the clinical and research level towards efficient bladder monitoring. The analysis of the current state of the art enabled to identify the challenges of the field and to draw potential future directions in LUT dysfunction management by engineering solutions. After the introduction of technologies to support urination, a major focus is placed on three groups of monitoring devices, that is, instruments for a clinical setting, wearable devices for continuous and domestic monitoring, and implantable sensors for chronic monitoring. Finally, the main challenges are identified and discussed, highlighting the most crucial points and the main treatment opportunities.

INDEX TERMS Bladder pressure monitoring, bladder volume monitoring, implantable biorobotic organs, implantable sensors, urinary dysfunctions.

I. INTRODUCTION

The lower urinary tract (LUT) is featured by the urinary bladder, generically identified as the ensemble of detrusor muscle, urethra with sphincter muscles, and prostate (only in men). The bladder is responsible for the collection and excretion of urine [1], [2]. Voiding up to 7 times per day in the waking hours is considered normal in a healthy subject, with a micturition volume of 250–300 ml per void. A healthy adult bladder has a limit of comfortable tolerance of approximately 500 ml, and can accommodate this relatively large volume of urine with little, if any, increase in intravesical pressure, thanks to the viscoelastic compliance of the bladder [3], (TABLE 1).

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The management of this basic physiological function is guaranteed by the coordination between the urinary and the nervous systems. The neural control of the urinary bladder consists of a central circuit in the brain and spinal cord, and of peripheral nerve pathways that connect the end-organ (bladder) to the central circuits (Fig. 1). The afferent pathway - from the bladder to the brain - is responsible for the accumulation and emptying reflexes and for returning the sensation of bladder filling. The efferent pathway - from the brain to the bladder - is responsible for the initiation of the motor signals activating bladder contraction and the reciprocal relaxation of the urethral sphincter to perform the urination [4], [5].

Due to the complexity of the neuro-urological coordination mechanisms, LUT dysfunctions might be ascribed to damages and pathologies of the apparatus itself (non-neurogenic,

TABLE 1. Comparison of urodynamic parameters.

Urodynamic Parameter	Physiological Bladder	Over-active Bladder	Under-active Bladder
Bladder Wall Thickness	1.5 cm (empty status) 0.41 ± 0.16 cm (full status) [257]	/ 0.47 ± 0.19 cm (full status) [91]	<0.54 ± 0.13 cm (empty status) 0.33 ± 0.09 cm (full status) [258]
Compliance	53.0 ± 54.96 ml/cmH_2O [259]	38 ± 29 ml/cmH_2O [260]	63.1 ± 36 ml/cmH_2O [260], [261]
Bladder Contractility Index	100-150 [262]	>150 [262]	<100 [262]
Maximum Volume	400-600 ml [263]	<400 ml [264]	>500 ml [265]
Volume of First Fullness Sensation	250-300 ml [11]	<100 ml [264]	>300 ml [266]
Post-Void Residual Volume	<50 ml [266]	/	>100 ml [266]
Intravesical Pressure	9.4 ± 1.7 cmH_2O (empty status) 20.6 ± 4.0 cmH_2O (50% filling) 25.2 ± 4.7 cmH_2O (75% filling) 43.5 ± 7.3 cmH_2O (full status) [139]	/	/
Detrusor Pressure During Micturition	40-60 cmH_2O [267]	> 60 cmH_2O [267]	<20 cmH_2O [268]
Filling Rate	20-30 ml/min [82]		
Flow Rate	>15 ml/s [269]	<15 ml/s [269]	<10 ml/s [270], [271]
Voiding Frequency	6-8 times/day [272]	>8 times/day [273]	<3 times/day [273]
Mean Voided Volume	331.8 ± 13.28 ml (women) 309.9 ± 13.14 ml (men) [274]	<192 ± 127 ml [269]	/
Voiding Efficiency	94% [275]	87% [275]	31% [275]

Parameters referred to the conditions of physiological, over-active, and under-active bladder.

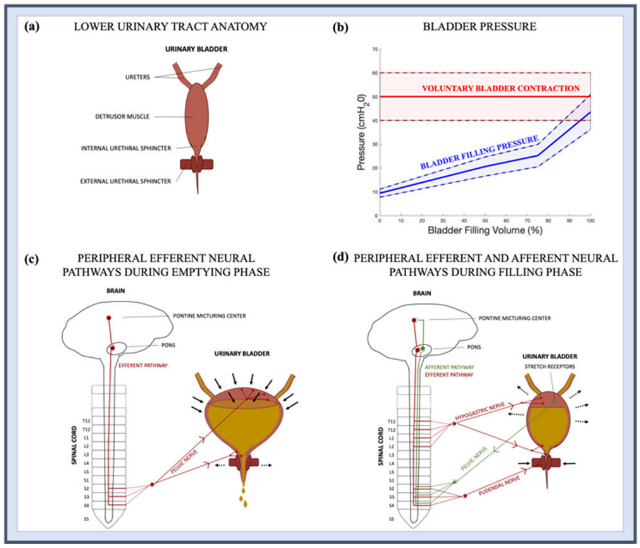

FIGURE 1. Lower urinary tract anatomy and main mechanical/neural features. (a) Representation of the urinary bladder anatomy. (b) Qualitative trend of bladder pressure during the filling phase (blue line) and voluntary bladder contraction pressure (red line). Plot adapted from [139]. (c-d) Lower urinary tract neural connections. Peripheral efferent (in red) and afferent (in green) neural pathways, that innervate the bladder, include the hypogastric nerve (sympathetic system), pelvic nerve (parasympathetic system), and pudendal nerve (somatic system). The bladder fullness status is detected by the stretch receptors in the bladder walls, which send sensory signals through the afferent pathway to the brain in the pons (a broad horseshoe-shaped mass of transverse nerve fibers that connect the medulla with the cerebellum and including neural pathways), and pontine micturing center (region coordinating the bladder and sphincters activity), consequently. During the emptying phase (c) the parasympathetic pathway is activated producing active bladder contraction (straight arrows) and passive urethral sphincters relaxation (dotted arrows). During the filling phase (d) the sympathetic and somatic ways are activated producing passive bladder relaxation/expansion due to urine collection (dotted arrows) and active external urethral sphincter contraction (straight arrows), respectively.

e.g., inflammation and infection of the urinary tract, bladder rupture from external trauma, damages to bladder smooth muscle myocytes, bladder carcinoma) [6], [7], [8], to nervous system pathologies, injuries and dysfunctions (neurogenic, e.g., spinal cord injuries (SCI), stroke, brain cancer) [9], [10], and to degenerative and neurodegenerative pathologies (e.g., Parkinson's disease, multiple sclerosis, diabetes mellitus) [11], [12], [13].

These pathologies might lead to different levels of urinary impairment (TABLE 1) that might be classified in three main groups: i) loss or reduction of bladder detrusor muscle contractility control (a-contractile bladder, under-active bladder (UAB), over-active bladder (OAB), chronic urinary retention), ii) absence of certain LUT anatomical structures (e.g., urinary bladder, sphincter) following cystectomy and sphincterotomy, and iii) loss of bladder fullness sensation [14]. Considering the epidemiology and the lack of effective solutions for the diseases listed above - especially upon bladder cancer [15], [16] and SCI [17], [18] - the study of innovative solutions for the treatment of patients with bladder dysfunctions and for the restoration of urinary functions and sensitivity is of great interest.

Pharmacological [12], [13], [19], surgical [16], [20], [21] and medical devices-based solutions [22], [23], [24], [25] have been proposed to cope with LUT dysfunctions. Implantable medical devices have been suggested to restore both the functionality of the urinary system [22], [25] and missing anatomical segments [24]. The choice of the treatment strategy depends on the cause of the dysfunction (non-neurogenic or neurogenic) and on the level of impairment. Furthermore, urination assistive devices (Fig. 2) such as tools to support bladder emptying (e.g., catheters), control continence (e.g., stimulation systems) or externally collect urine are proposed as an alternative to pharmacological, surgical,

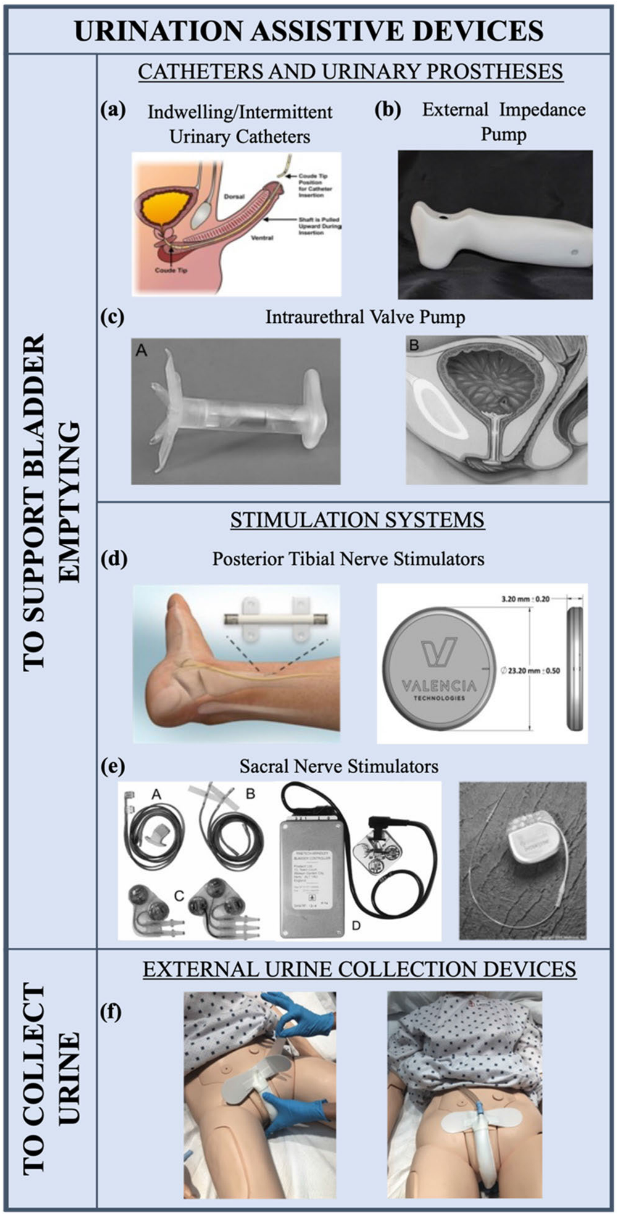

FIGURE 2. Examples of devices to assist the urination classified as devices to support bladder emptying (i.e., catheters and urinary prostheses) (a-e) or to collect urine (f). Catheters and urinary prostheses: (a) Indwelling/Intermittent Urinary catheters [26], Copyright ©2016, Springer Science Business Media Dordrecht, (b) External impedance pump (called URODEA) (provided by the courtesy of URODEA), and (c) Intraurethral valve pump for women (called InFlow) [249], Copyright ©2009, American Congress of Rehabilitation Medicine, Urinary devices for the stimulation of (d) the posterior tibial nerve (commercial devices called BlueWind [250], Copyright ©2017, Springer Science Business Media LLC, and eCoin [41]), and (e) the sacral nerve (commercial devices called Finetech-Brindley Control System [249], Copyright ©2009, American Congress of Rehabilitation Medicine, and Interstim [251], Copyright ©2008, Nature Publishing Group). Example of external collection system (f) for women (commercial device called PrimaFit [252]).

and medical devices-based solutions, in order to facilitate and successfully control the urinary bladder functions.

Catheterization from the bladder or a stoma (suprapubic catheterization) is typically the elective choice to support patients in bladder emptying [26], [27]. Catheters might be indwelling/permanent (often Foley catheters) or placed intermittently (Fig. 2a). In the first case, the catheter is inserted, hold in place by a water-filled balloon and attached to a bag to collect the urine. In the second case, the catheter is temporarily inserted several times a day at regular intervals to drain the bladder or bladder substitutes. Although permanent catheterization is the most practical solution, especially for bedridden patients and in hospital setting, complications are more severe compared with intermittent catheterization [26]. However, self- intermittent catheterization implies manual and cognitive abilities and dedicated patients training. Despite training and experience, patients might still have difficulties in identifying the right moment to perform the catheterization.

Overall, catheterization should be considered as a short term solution due to the increased risk of urethral trauma, bacterial infections, chronic irritation or bladder stones formation [28], [29]. In addition, a prolonged catheter use can cause bladder volume reduction and even malignant bladder tumors [30], [31]. The FDA-approved inFlow intraurethral valve pump (Fig. 2c) represents a valid alternative to catheterization for women. It is a non-surgical urinary prosthesis devised to be inserted in the urethra and hold in place (for about one month) by flexible fins anchored at the bladder neck. The intraurethral pump can be remotely activated by an external magnet to allow bladder drainage. The device proved efficient in reducing the infection rate and side effects compared to standard catheters [32], [33]. At research level, Clavica et al. proposed a non-invasive and portable device to support the emptying of the bladder without direct contact with the urine and without catheterization. It consists of an impedance pump [34], [35] which generates urine flow by applying an external and intermittent compression of the urethra [36], [37], (Fig. 2b).

In case of loss of emptying control, stimulation systems can act as an alternative to surgery and pharmacological treatment. These devices allow the restoration of bladder continence and of patient control on urination by delivering electrical stimulus through implanted electrodes [38]. Stimulations systems (Fig. 2d-e), often referred as bladder pacemakers, are primarily indicated for patients with non-neurogenic dysfunctions and only for a limited group of neurogenic dysfunctions (especially OAB and UAB caused by SCI) [39].

Although stimulators have been studied for the modulation and stimulation of different nerves or tissues (e.g., posterior tibial nerve [40], [41], pudendal nerve [42], saphenous nerve [43], transcutaneous nerve [44], and intravesical [45]), sacral nerve stimulation (S2-S4 level) is the most widely investigated [46]. Indeed, it allows the recruitment of 1000-times more axons and offers more flexibility in stimulation parameters [47], [48]. Few bladder pacemakers [49], [50], [51], (Fig. 2e), have already received FDA approval and CE Mark and reached the market. Typically, the sacral root stimulator technique is combined with neuromodulation of the posterior sacral roots, to avoid sacral deafferentation (a dorsal rhizotomy at S2-S5 spinal level) and to suppress detrusor hyperreflexia [38]. Side effects, such as pain, increased spasms and collateral neuromuscular reactions, growth of fibrotic tissue, migration of the stimulator, and high rate of long-term ineffectiveness (as consequence of the exhaustion of the nervous response to continuous stimulation) are among the main adverse effects [52], [53], [54], [55]. However, the benefits noted by stimulator users are reduction in urinary tract infections, improvement in social life and improved continence.

Patients suffering from urinary incontinence (UI) might also benefit from external urine collection devices. Collection systems (Fig. 2f) allow urine to be drained through tubes connecting a wearable unit (which design varies with sex) to an external container [56], [57], [58]. Being these devices external, they are less invasive than catheters and allow for independent continence management. However, requiring a urine collection container, their impact on patient's quality of life and discomfort are significant.

Recently, artificial systems have been proposed both for bladder replacement and active voiding, thus coping with highly severe conditions related to loss of control or cystectomy [59]. In this sense, artificial detrusor systems based on smart thermoresponsive polymers [60] or on shape memory alloys [61], [62] possibly coupled with volume sensors [63] have been proposed and tested on small animals. Fully implantable artificial bladders provided with active voiding mechanisms [64], [65] have been proposed as well. Although promising, this approach is still at its infancy and deeper investigation would be needed to reach the efficiency of the biological counterpart.

Despite their variety, all the approaches proposed to cope with urination dysfunctions have in common the lack of feedback to the patient and the need for the user to define the activation/use timing. However, in the wide plethora of LUT pathologies, some patients may not perceive the urge to urinate and activate the assistive device accordingly. In these cases, the patient should rely on self-assessment (based on palpation and percussion of the lower abdomen) or on pre-programmed toilet assistance programs. In both cases, there is a high risk of inaccurate evaluation of the bladder fullness status, need of rescheduling the daily habits for urination at constant intervals of time, and absence of feedback on the success of the emptying [66], [67], [68], [69]. Pavlin et al. demonstrated that abdominal palpation performed either by patients or nurses to estimate the bladder filling status fails in 54% and 46% of the cases, respectively [70].

The incorrect evaluation of the bladder fullness leads to an increased risk of infections and chronic adverse effects due to excessive recourse to catheterizations and neural stimulation, or bladder overdistension due to failure to empty for excessive periods of time.

In this framework, defining strategies and tools to actively monitor bladder health and fullness status would lead to an optimization in the use of assistive devices and in a reduction of side effects for the patient. Furthermore, the design and development of novel chronic monitoring strategies would boost the development of implantable devices.

Given the centrality of bladder monitoring to support the development of novel assistive urinary devices and prostheses, in this paper the authors analyzed the recent progresses in the research and clinical state of the art for this field. In this review paper, monitoring devices have been organized in three groups based on the devices dimension and level of integration and interaction with the body. We will start by analyzing clinical instruments, i.e., external medical devices used in hospital setting for short-term monitoring and imaging. We will therefore critically review the state of the art of wearable devices, i.e., devices designed to be worn by the patient to allow continuous monitoring also in a domestic setting. Then, we will present implantable sensors, i.e., miniaturized systems deeply implanted in the body to allow chronic and long-term monitoring. Finally, we will discuss the potential and future challenges, highlighting the crucial points and open avenues.

II. CLINICAL INSTRUMENTS

In this section we systematically analyzed the instruments used in the clinical setting for bladder monitoring and examination in some cases. Bladder status is typically monitored through urodynamic tests, neurophysiologic analysis (intended mainly for the evaluation of the detrusor functionality [71], [72], [73]), and imaging techniques [74], [75], [76], [77], [78]. Among the anatomical and physiological bladder parameters to be evaluated, pressure and volume appear particularly interesting as they provide information on the physiological e pathological status of the organ, as well as on LUT synergy with the nervous system [79], [80]. Furthermore, their monitoring can be used to define and program micturition timing.

A. URODYNAMIC TESTS

Urodynamics refers to a set of clinical tests, such as uroflowmetry, post-void residual measurement, cystometry, leak point pressure measurement, pressure flow study, electromyography, and video urodynamics [81], [82]. This set of clinical exams allows to analyze pre- and post- micturition urine volume, bladder walls elasticity, bladder capacity, detrusor operation [83] and to correlate these information with LUT health status [84]. Among the various urodynamic tests, cystometry (also known as cystomanometry) is considered the gold standard [85]. This exam provides the pressure-volume relation during the bladder filling and emptying processes. The pressure produced by the smooth detrusor muscle is derived from the intra-vesical pressure and the intra-abdominal pressure, directly measured through dedicated catheters equipped with pressure sensors (placed in the bladder and in the rectum, respectively). In addition to being uncomfortable, invasive and potentially cause of infections, the measurements appear to be affected by motion artifacts caused by bending and twisting of the sensorized catheters. In addition, the filling of the bladder occurs in a non-physiological way and the urethra is obstructed by the catheter itself, thus furtherly reducing the reliability of the test.

Given the invasiveness of the exam, the integration of Micro-ElectroMechanical Systems (MEMS) sensors was proposed at the research level to make the instrumentation less cumbersome. A new system based on suprapubic wearable sensors has been tested for outpatient use [79], [86]. Such a system proved promising in improving the quality of pressure measurements by allowing to discriminate the signals from noise or artifacts.

B. MEDICAL IMAGING FOR BLADDER MONITORING

Medical imaging techniques allow to investigate and analyze bladder anatomy and conformation (e.g., bladder wall thickness, bladder capacity). They can act as a valid tool for diagnosis and for supporting the use of assistive devices, such as catheters. Given this latter potentiality and the suitability of medical imaging techniques in bladder volume estimation, this set of clinical instruments will be here analyzed more in depth with a focus on ultrasound (US) imaging, bioimpedance tomography, near-infrared spectroscopy (NIRS), and magnetic resonance imaging (MRI).

1) ULTRASOUND IMAGING

US scanners are among the most used devices for cystovolumetry, i.e., the measurement of the bladder volume. US imaging exploits pulses of pressure waves emitted by a piezoelectric transducer and their reflection/scattering back to the source upon acoustic impedance discontinuities [87]. Pulses at 3-5 MHz are typically employed for abdominal examinations. Several US beams can be independently shot and registered back by the US probe to reconstruct a 2D tomographic image. The images obtained with this technology have a high temporal resolution and can be observed in real-time. The technique is considered extremely safe thanks to the use of non-ionizing radiations that do not cause acute or chronic side effects.

US imaging requires manual skills and experience with the technique, thus resulting in an operator-dependant method. Consequently, its employment is restricted to the clinical settings where it is mainly employed for assisting catheter insertion [88] and for diagnosis [89], [90], [91], [92]. US have also been proposed for bladder filling state monitoring with the aim to define catheterization timing.

US signals have been employed both for 2D and 3D bladder reconstruction. When relying on 2D images, bladder height (H), width (W), and depth (D) are measured on abdominal scans acquired along the transverse and longitudinal planes (Fig. 3a) allowing volume (V) estimation. A geometric correction coefficient (F) should be applied based on the target bladder shape approximation:

$$V = H \times W \times D \times F \tag{1}$$

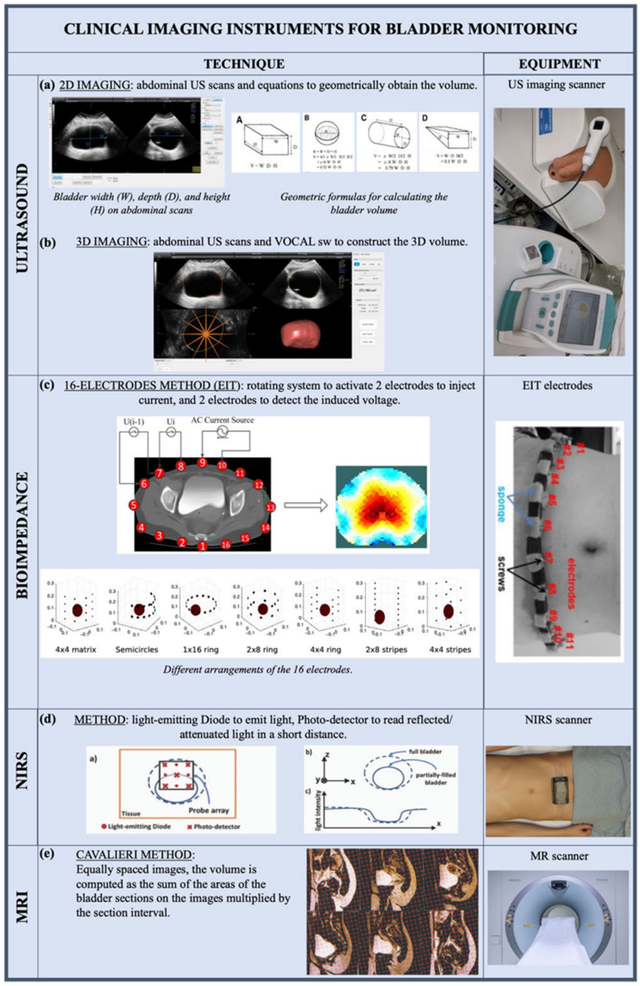

FIGURE 3. Examples of clinical imaging instruments to monitor the urinary bladder. Ultrasound-based volume reconstruction systems (Bladder Scan BVI 9400 [253]) through (a) 2D and (b) 3D methods [102], Copyright ©1998, Published by Elsevier Inc., [105]. Bioimpedance tomography device employed for EIT [132], Copyright ©2016, Taiwanese Society of Biomedical Engineering, with 16 electrodes arranged along different configurations for bladder volume reconstruction and imaging [128], ((c) EIT electrodes [254], Copyright ©2020, IEEE). NIRS method exploiting water or oxyhemoglobin as chromophores and detecting light absorption variations during the filling-voiding cycles (d) [142], Copyright ©2018, IEEE, and NIRS device [255]. MRI (picture of Michal Jarmoluk from Pixabay): Cavalieri method to compute the volume (e) [153], and representation of a commercial scanner.

Different correction coefficients can be used to define the bladder volume as a cuboid (F=0.89), sphere (F=0.52), ellipsoid cylinder (F=0.79), triangular prism (F=0.50) [93], [94], [95], [96], [97], [98], [99], [100], [101]. Bih et al. proposed an optimal correction coefficient of 0.72 as a result of linear regression analysis, leading to a mean volume estimation error of 17.4%±11.6% [102]. The error should be ascribed to imaging artifacts and to bladder shape dependency on age, gender, health status, and filling status that reduce shape regularity [103].

Alternatively, scanning spatially interlocked US images at different angles allows to obtain a 3D reconstruction of bladder volume (Fig. 3b). 3D integration, Virtual Organ

TABLE 2. Commercial US scanners.

Bladder Scanner		Volume Range	Accuracy	Scan Time	Dimensions
BVI 6100 [109]	Verathon Inc.	0-999 ml	±15%	<5 s	/
BVI 9400 [110]	Verathon Inc.	0-999 ml	±15%	/	/
Prime Plus [111]	Verathon Inc.	0-999 ml	±7.5%	/	/
Biocon 700 [112]	de smith medical	0-999 ml	±15 ml (0-99 ml)	2 s	13x26x6.6 cm
			±15% (100-999 ml)		
Cardiotech GT-5500 [113]	Cardiac Direct	0-999 ml	±15%	<3 s	/
Palm Bladder Scan [114]	MEDICA S.p.a	0-999 ml	±25 ml (<150 ml) ±15% (>150 ml)	/	26x31x5 cm

List of US scanners designed to evaluate the bladder volume already on the market. Specifications are reported in terms of volume range (range of volumes that can be detected by the scanner), accuracy, scan time (necessary time the scanner takes to detect the bladder volume) and equipment dimensions.

Computed-aided AnaLysis (VOCAL software), rendering techniques, and other volume reconstruction techniques have been proposed to this purpose [104], [105], [106], [107], [108]. 3D reconstruction of bladder volume has shown promising results in the diagnosis of voiding dysfunctions [105]. Marks et al. have evaluated the use of the technique for defining when to catheterize the patient, comparing the volume estimated with the 3D reconstruction technique and the volume of urine excreted by catheterization (defined as the real volume). The reported results have shown the tendency of the 3D technique to underestimate the bladder volume with an average error of 15.2±44 ml [104]. However, 3D US imaging-based volume reconstruction proved more accurate than 2D imaging-based one, with a mean absolute error of 4.3%±3.7% (transverse scan orientation) and 27.5%±17.8% (using correction coefficient of 0.79 in (1)), respectively [106].

TABLE 2 summarizes the features of commercial US scanners already available on the market and used in a medical setting for bladder monitoring. All US scanners cover a volume range up to 999 ml, and scanning time less than 5 s [109], [110], [111], [112], [113], [114]. Some scanners present different estimation errors for different volume ranges, in particular around ±15% for volumes larger than 100-150 ml, and ±15 ml for lower volumes [112], [114]. In other cases, estimation errors of ±15% (with an offset of 15 ml) or ±7.5% have been reported over the entire volume range [109], [110], [111], [113]. Considering the patient clinical situation, the choice of the US-monitor may be based on the tendency to underestimate or overestimate the volume, preferrable to avoid early and unnecessary urinary catheterization or to prevent bladder overdistension.

Recently, leveraging on the reduction of equipment size and increased portability, US-based volume monitoring has been tested also for domestic use.

Brouwer et al. compared two commercial CE marked US systems (BladderScan BVI 9400 and the Prime - Verathon Medical, Bothell, WA, USA [111]) in an extended study involving 348 patients. The first device tended to overestimate the current bladder volume (+17.5%) and to have low sensitivity to small filling volumes (below 30 ml), whereas the second one (which was used in two working modalities, namely with and without a pre-planning phase intended to define the correct position of the probe) proved an underestimation of the urine level (−4.1% without pre-planning and −6.3% with pre-planning) [115].

A domestic trial involving a patient affected by multiple sclerosis allowed to evaluate the impact of a portable monitoring device used for bladder monitoring and micturition management on patient's autonomy [116]. A substantial reduction in the number of incontinence episodes (from 69 to 39 during 48 h) and of the number of performed catheterizations thanks to an improved voiding efficiency (from 260.8±154 ml to 297.5±138 ml) were obsedved when using a US-based monitoring.

In general, although traditional US devices are widely used in hospital setting and sufficiently accurate for measuring bladder volume, they may not be suitable for domestic use because the instrumentation, even if portable, is cumbersome and expensive [117], [118]. In addition, self-examination is not straightforward, especially for the target patients considered, due to the complexity of the scanning phase and would rise large errors in the estimation of the volume.

2) BIOIMPEDANCE TOMOGRAPHY

A second strategy explored in recent years concerns the analysis of the bioimpedance (i.e., body tissues impedence) measurements to derive bladder volume in bedridden patients or in those with lost bladder sensitivity [119]. In general, the passage of a small alternating current (in the order of μA - mA [120]) across tissues is opposed by body tissues impedance. The bioimpedence includes two components: a resistive one (inversely proportional to the amount of body fluids in the tissue) and a reactive one (directly proportional to the density of cells in the tissue) [121].

In general, a higher mismatch between the target organ and surrounding tissues impedences favors volume estimation. This explains why the technique is widely employed to assess the presence of air in the lungs. On the other hand, using it for bladder volume estimation is more challenging due to the higher omogeneity in tissues conductivity [122], [123].

Nevertheless, experimental evidences showed that the measured impedance features a strong linear correlation with bladder volume (correlation coefficient R=0.916±0.059) for a given urine composition which is related to the conductivity [124]. This method seems promising, in light of its non-invasiveness, easiness of use, and real-time operation.

In addition, the employed electrodes are portable, lightweight, inexpensive, and easy to apply.

The data gathered from bioimpedance electrodes positioned around the patient's abdomen have been used to reconstruct the abdominal tissues anatomy with tomographic techniques (electrical impedance tomography - EIT) [125], (Fig. 3c). EIT is a non-invasive technique based on the conductivity differences of organs/tissues. It derives the spatial distribution of resistivity in a specific body volume by mapping the information on a two dimensional image [126], [127]. The EIT image is obtained as a differential measurement between a reference EIT image of the homogeneous medium (the abdomen with an empty bladder), and an image of the inhomogeneous medium (the abdomen with a bladder in an unknown filling status).

The EIT acquisition apparatus is normally equipped with 16 electrodes positioned in a ring arrangement around the pelvis. Schlebusch et al. conducted a study in which seven different electrode arrangements were simulated and tested, revealing the role of electrodes arrangement [128]. According to the study, the 2 × 8 ring and 4 × 4 ring arrangements (Fig. 3c) appeared to be more sensitive to the bladder volume changes. The EIT image is reconstructed by solving the inverse problem, generally using neural networks [129], [130], [131]. Measuring the average conductivity index (ACI) in each image allows to estimate bladder volume content. ACI can be defined as:

$$ACI = \sum_{i=1}^{N} \frac{\sigma_i}{N} \tag{2}$$

where σ_i is the i-th pixel conductivity, and N is the number of pixels.

Li et al. found a strong linear correlation between ACI and the bladder volume (R=0.98±0.01) [132].

EIT is considered a safe technique since it requires a small alternating current, it can be used as a long-term, continuous imaging method, and the equipment can be constructed at low cost and in portable size [133]. However, as it requires a large number of electrodes, it can be seen also as cumbersome, unconfortable and not easy in terms of electrodes positioning in some patient's conditions (e.g., bedridden patients). In terms of accuracy, EIT cystvolumetry (performed through a commercial system - Goe MF II system) proved comparable with US imaging [134]. Given the characteristics of the EIT technique, it could be used also for the virtual biopsies of bladder tissue and for the recognition of early cancer and flat lesion patients [135], [136], [137].

3) NEAR-INFRARED SPECTROSCOPY

An alternative strategy for bladder volume monitoring relies on NIRS. Similarly to EIT, NIRS relies on tissue properties to estimate bladder volume.

The NIR region of the spectrum (wavelengths between 1100 nm and 2500 nm) is exploited to maximize deep tissue penetration in the cm range [138]. The technique involves the measurement of the tissues absorption, using the modified Lamber-Beer formula: emitting the light towards the tissue, and reading the diffused and reflected light in a short distance (Fig. 3d).

Two different NIRS methods have been explored in urology to monitor the bladder, based on oxy-hemoglobin (HbO_2) and water content variations with bladder volume, respectively. In the first case, the HbO_2 concentration variations occurring in the bladder wall during voiding and filling have been investigated. Such analysis enables at the same time to track the filling level and to identify potential pathological states. Macnab et al. exploited a commercial NIRS setup (Hamamatsu NIRO-300, Hamamatsu Photonics KK, Hamamatsu City, Japan) to study baldder filling. A decrease and increase in blood perfusion (amount of HbO_2) in the bladder wall has been observed, respectively during the filling and voiding phases, as a response to the stretching and the activation of the detrusor muscle [139]. This variation was detected by placing the emission and detection probes on opposite sides of the abdomen and allowed to succesfully discriminate three bladder filling levels (i.e., the volume that leads to the first sensation of filling, the volume that leads to the sense of urgency to void, and the volume that leads to the sensation of being filled to capacity) [140]. Data were collected at 6 Hz with 40 mm inter-optode spacing.

The second NIRS-based method implies assessing bladder volume by monitoring water content variations, being urine composed of 91-96% of water [141]. Selecting the wavelengths at which water features an absorption peak, an increase in bladder volume will result in a decrease in the detected-light intensity [142] enabling volume estimation by detected light analysis.

4) MAGNETIC RESONANCE IMAGING

Imaging techniques such as MRI [143], [144] and computed tomography (CT) [145], [146], [147] allow to reproduce a complete image of the urinary bladder and to overcome the lack of lateral borders often witnessed with US imaging [148]. MRI has been mainly employed for bladder cancer diagnosis [77], [149], [150], [151], while few studies faced bladder volume monitoring. In these studies, bladder volume was estimated by using the Cavalieri method. The method requires imaging of a series of equally spaced, parallel sections of the bladder and computes the volume as the sum of the bladder area identified in each section multiplied by the section interval [143], (Fig. 3e). Heverhagen et al. employed a 1.0-Tesla MR scanner (Magnetom Expert, Siemens, Erlangen, Germany), with a quadrature body coil and a single-shot turbo spin-echo sequence, to collect T2-weighted sequences with an acquisition time of 7 seconds in healthy subjects [152]. Images were analyzed through a dedicated histogram algorithm (IMAGELAB, MeVis, Bremen, Germany) and the bladder volume was calculated as the difference between the pre- and post-void image sets. The voided bladder volume (measured in a graduated cylinder) was 400±33 ml, whereas magnetic resonance yielded 390±31 ml. Walton et al. compared MRI

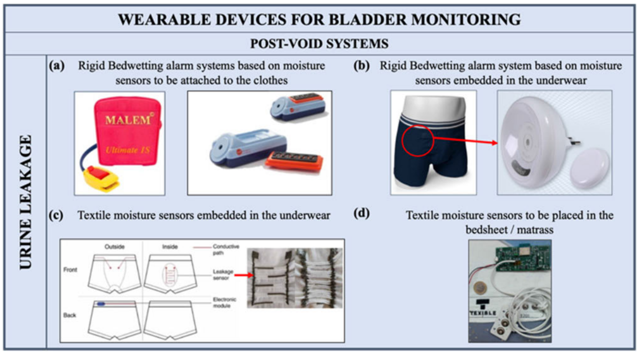

FIGURE 4. **Examples of post-void wearable devices based on moisture sensors to detect the nocturnal urine leakage. Rigid bedwetting alarm systems to be attached to the clothes ((a) commercial devices called Malem, provided by the courtesy of Malem Medical, and DRI Sleeper Eclipse, provided by the courtesy of Anzacare Limited). Rigid bedwetting alarm system embedded in the underwear ((b) commercial device called Rodger bedwetting alarm system, provided by the courtesy of Rodger). Textile sensors embedded in the underwear ((c) sensors placed in boxer underwear [170]). Smart bed insert for detection of urine leakage ((d) sensors placed in bedsheet/matrass [163]).**

and US-based volume estimation and reported an absolute mean discrepancy between the true voided volume and the estimated volumes of 7.7 ml and 67.7 ml for US and MRI (using the Cavalieri method) estimates, respectively [153]. Indeed, despite the higher resolution of MRI compared to US imaging, the use of the Cavalieri method introduces a high estimation error compared to the aforementioned reconstruction strategies. Furthermore, the high cost and complexity of MRI make its use for this purpose questionable and overdimensioned. However, it might be useful as a comparison method to assess the performances of new volume monitoring techniques.

III. WEARABLE DEVICES

Moving from bedside to wearable or portable device enables to increase monitoring time and frequency and to better support patients' continence management during the daily activities. Wearable systems got growing importance in the last decades and assistive devices for patients affected by cardiac diseases or dysfunctions [154], [155], [156], [157], [158] already reached the market. However, the development of wearable systems for LUT monitoring is less mature and mostly at the research level. The systems which will be analyzed in the following often exploit similar physics and working principles as the clinical instruments for volume monitoring presented in the previous Section. However, passing from bedside to portable systems poses great miniaturization and powering challenges which are not straightforward to face. Wearable systems have been grouped in two main categories depending on their capability to perform detection and monitoring after or before the voiding episode. This second class is the most investigated one due to the impact on daily life management and assistance, and includes pressure and volume-based monitoring strategies.

A. POST-VOID SYSTEMS

The market of wearable and portable medical devices for LUT monitoring is dominated by post-void detection devices intended for patients suffering from nocturnal enuresis [159], [160], [161]. These devices typically consist of moisture sensors, placed either in the underwear [162] or in the bedsheet / matrass [163], (Fig. 4d) combined with an alarm system. Underwear rigid bedwetting alarm systems (e.g., Rodger Bedwetting alarm system, Malem Ultimate Bedwetting Alarm, DRI Sleeper Eclipse Wireless Bedwetting Alarm [162], [164], [165], Fig. 4a-b) have proven to be effective in achieving dryness by detecting the first urine drops and making the patient wake up and take back control of the bladder. However, these systems are typically cumbersome and people could be reluctant to use them [166]. Textile sensors could bring a significant paradigm shift in this class of monitoring tools, allowing to replace the rigid sensors and enhancing wearability [167], [168], [169]. Silver or stainless steel yarn textile sensors were fully integrated into the underwear and connected to a sound-emitting device activated as soon as the sensor detects urine drops [170], (Fig. 4c). The sensor relies on the set up of an electrical connection between two electrodes by liquids. Urine can be recognized faster than sweat or air humidity in light of its higher electrical conductivity. To define the optimal pattern of the two electrodes, 12 different sensor designs were tested when changing sensors distribution and size to vary reactivity, detection speed, and electrical conductivity. Despite the benefits produced by this kind of devices on continence management, their use is exclusively nocturnal. Furthermore, in many cases of neurogenic and non-neurogenic UI, patients do not have control of their bladder and sphincter and the use of post-void (first urine drops) detection system would not be useful in blocking the event. Considering the epidemiology of UI and the consequences of the episodes on the patient's social life, pre-void monitoring systems have a much higher social impact allowing to cope with micturition control [171], [172], [173], [174].

B. PRE-VOID SYSTEMS

Only few devices able to foresee voiding by bladder volume or pressure monitoring have reached the market. Pre-void systems have attracted a large interest in the research community with a wider focus on volume monitoring strategies studies. In the following pre-void systems will be analyzed in detail by distinguishing those based on pressure monitoring from those evaluating volume. These latter will be furtherly classified depending on the physical principle (e.g., US) exploited for volume measurement.

1) BLADDER PRESSURE MONITORING

In analogy with cystometry, wearable holters were proposed to diagnose detrusor instability in women [175]. The system (Fig. 5a) includes an intravesical and an intravaginal 3 mm pressure catheters (Gaeltec, HT30, Scotland) connected to

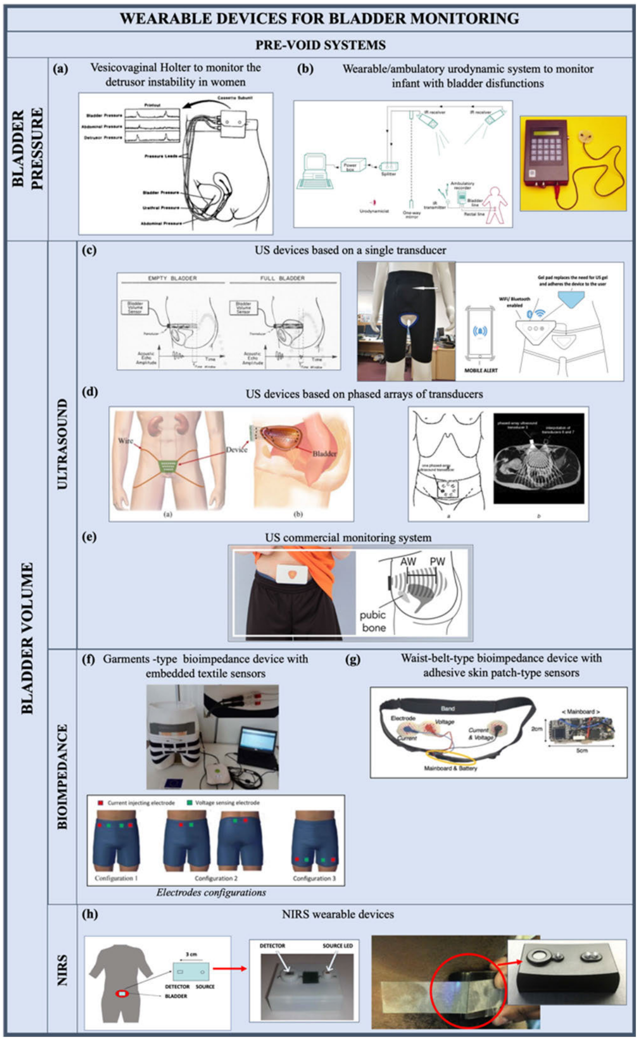

FIGURE 5. **Examples of pre-void wearable devices to continuously monitor the urinary bladder. They are classified as: pressure monitoring systems ((a) vesicovaginal Holter to detect detrusor instability in women [175], Copyright ©1969, The International Urogynecology Journal, (b) urodynamic system to monitor infant with bladder disfunctions [177]); volume monitoring systems. These latter can be based on US ((c) devices with a single transducer [178], Copyright ©1979, IEEE, [187], (d) devices with phased arrays of transducers [182], [183], Copyright ©2004, IFMBE, and (e) commercial device called SENS-U Kids [256], Copyright ©2018, Journal of Pediatric Urology Company); bioimpedance ((f) smart garments with embedded textile sensors [197], Copyright ©2020 IOP Publishing Ltd, (g) sensorized waist-belt with adhesive skin patch sensors [196], Copyright ©2017, IEEE); and NIRS ((h) wearable devices based on NIRS technique [202], Copyright ©2014, IEEE, [203]).**

a wearable customized unit to record data. The intravaginal catheter replaces the rectal one typically employed in cystometry to evaluate abdominal pressure and derive the detrusor pressure [176]. Preliminary tests showed that the urgency events (urge without contraction) perceived by the patients are closely correlated with the number of unstable contractions (contraction is defined unstable if detrusor pressure is higher than 15 cmH_20 without any voiding) detected by the system. Yeung et al. proposed an urodynamic system for ambulatory continuous and real-time monitoring of infants and young children with bladder dysfunctions [177], (Fig. 5b). A double-lumen catheter (Braun, West Germany) was inserted suprapubically to detect intravesical pressure whereas a vented-balloon tipped catheter was placed in the rectum to detect the abdominal pressure. The system consists of a urodynamic recorder (UPS2020, Medical Measurement System, Netherlands) with a specially designed built-in extension board to convert the catheter outputs from digital pressure signals to a modulated infrared wave (wavelength 935 nm, by means of dedicated LEDs) to be transmitted. A receiver mounted on the ceiling of the room receives the signals emitted from the recorder within a 10 m range. The infrared conversion facilitates data transmission from the wearable system, thus eliminating the need for a cable connection to the computer or the need of an on-board data storage system. In addition, the wearability of the device allows patients monitoring under more natural conditions and with minimal stress. However, difficulties for a concrete transfer from ambulatory use to domestic monitoring are very relevant due to the need of a structured environment for light signal detection and due to the required chronic catheters placement.

2) BLADDER VOLUME MONITORING

a: ULTRASOUND SENSORS

As already reviewed in Section II, US is the most explored method for bladder volume monitoring. Wearable US-based devices exploit the same working principle as clinical systems but use different data processing methods which do not imply providing images as output. Indeed, the distance between bladder walls or the size of the bladder itself are not computed from the obtained b-mode images, but by relying on pulses echoes attenuation and time of flight. This shift enables at the same time a significant size shrinkage and a reduction of the computational time. Consequently, the core element in wearable US-based volume monitors is the US transducer which will be connected to suitable control/data processing electronics.

Several devices have been designed, based either on single or multiple transducer arrays.

The first wearable US monitor attempts employed a single US transducer combined with control electronics to be worn at the belt level [178], [179], (Fig. 5c). Such devices were able to discriminate only between empty and full bladder by detecting when the superior dome of the bladder rose above the symphysis pubis. If the echo was received with a certain delay (associated with the target depth) the volume of the bladder was defined over the volume threshold and the alarm was activated. Preliminary results showed an accuracy of more than 70%. However, fecal content in the colon, excessive abdominal fat, and belt position inaccuracies might produce false positive events.

In a different configuration, the US transducer was placed in the central line of the abdomen to detect the anterior and posterior bladder walls [180]. Bladder volume (V) was computed using the following equation:

$$V = 7.1 \times D \times H - 23 \tag{3}$$

where D is the depth, H the height of the bladder (both measured in the sagittal plane). 7.1 and 23 are optimal fitting values obtained in a previous regression study (based on 24 bladders) [181]. Volume data can be transmitted by a Zigbee wireless communication module to the alarm unit that is triggered if a selected volume threshold is reached. This method has been validated *in vitro* on phantoms and it is declared to be accurate for bladder volumes above 100 ml.

Jo et al. employed a 2-D array of piezoelectric elements (5×5) integrated on thin substrates, with a resonant frequency of 2.2 MH (selected by taking into account the bladder wall thickness and the attenuation of the soft tissue around 0.54 dB/cm) [182]. The system is devised to be placed 2 cm above the pubic bone in line with the navel and to be secured to the body through wires or belts, Fig. 5d). Anterior and posterior bladder walls reflected echoes are employed to derive bladder volume through ellipsoidal fitting. *Ex viv*o experiments on a pig bladder were conducted to validate the proposed system. With the injection volume ranging from 50 ml to 450 ml, the proposed system featured an average error of 24 ml (about 5% if considering the maximum bladder capacity). This error appeared comparable with that experienced by using a commercial equipment (BioCon-700 [112]).

Seven phased-array transducers arranged in a circular pattern (51.4°, and tilted 10° towards the center of the circle, Fig. 5d) were mounted on the front of an ergonomic belt for perpendicular readings of the lower abdomen [183], [184]. The sensor unit composed of phased arrays allows to detect bladder anterior and posterior walls position from echoes with different directions and to reconstruct a 3D convex shell for bladder volume estimation [185]. Over a 24 h testing time, no significant time-drift was witnessed. During *in vivo* tests, the US system proved quite precise in volume estimation with a 4.8% error compared with MRI-based estimation, considered as the gold standard in this study.

Recently, Kuru et al. have proposed an intelligent autonomous decision making system relying on the combination of MEMS US sensors, dedicated electronics and a machine learning (ML) algorithm implemented on a smartphone [186], [187]. Self-adhesive gel pads are employed to keep the sensors in contact with the lower abdomen region. In the first version of the device a single US transducer (central frequency 2.2 MHz) placed on the abdomen with a 15° misalignment with respect to the horizontal axis was employed [186]. Volume processing and voiding alarm triggering are performed by comparing the volume computed from echoed pulses with a pre-trained model. One of the advantages of this approach lies in the possibility to customize the ML trained model accounting for age, sex, and bladder morphology, thus to improve volume reconstruction accuracy. Compared with bladder volumes assessed with traditional US imaging apparatus (in which the bladder volume is approximated to a sphere), the system developed by Kuru et al. proved coherent results. The sensitivity and specificity were 0.89 and 0.93, respectively. A second generation of the system included one pulse generator, a MEMS piezoelectric crystal printed on flexible thin films and four receivers to acquire the echoed pulses [187]. Higher frequencies are used in this case (5–10 MHz) to increase the resolution, but causing an increased attenuation by body tissues (the attenuation coefficient is directly related to frequency [188]). The second version of the device is still under testing.

The presented systems developed at the research level between 1998 and 2011 laid the base for the development of commercial US-based wearable monitoring systems (DFree and SENS-U Kids, (Fig. 5e), [189], [190]). The sensing unit (including both the US transducer and the electronics) is devised to be placed above the pubis. The system sends a notification on the tablet to notify the gradual filling volume and suggests the emptying timing. By analyzing a large amount of data related to the patient physiology and to the use of the device, the system refines and customizes the urination warning alarms.

Despite the good results obtained with US-based systems for continuous monitoring, several limitations associated with such devices must be taken into account. Among them user-dependent placement of the wearable device, possible interference produced by the pubic bone depending on positioning accuracy, and bladder shape approximation might reduce system accuracy. Furthermore, the need to use gel for sensor-skin coupling might block the transpiration of the skin and causes skin irritation on the long run [191].

b: BIOIMPEDANCE SENSORS

In order to estimate bladder volume from electric impedence measurements, four electrodes are typically attached to the lower abdomen surface. One electrode couple injects an alternating current whereas the second one detects simultaneously the induced voltage. The corresponding impedance is derived by the Ohm's law [192]. In analogy with EIT, the measured impedence is correlated with bladder volume. However, in this case, no tomographic reconstruction is performed but the electrodes signal is processed to provide fullness indications. In this direction, the first devices consisted of a data acquisition module connected to the wearable bioimpedance sensors (a pair of excitation electrodes and a pair of measuring electrodes placed on the lower part of the abdomen) and a human-machine interface for real-time patient feedback [193]. The injected sinusoidal current has an amplitude of 1 mA and a frequency of 50 kHz. This system was tested in a clinical setting, but it might be exploited in the future as wearable device.

Palla et al. investigated the possibility of using a bioimpedance commercial system (BodyGateWay, STMicroelectronics), composed of a medical electronic patch designed to be attached on the patient's chest for the monitoring of cardiac and respiratory functions, for real-time monitoring of the bladder volume [194]. Some tests were performed placing the adhesive skin patch on the lower abdomen of a healthy subject in the sitting position (minimal or no movement). 100 μA of injected sinusoidal current and a frequency of 50 kHz were used. The results show clearly a decrease of the impedance values about 1 Ω during the filling phase, and an increase of 1.5 Ω during the emptying phase. The difference of 0.5 Ω from filling to emptying phases can be explained by the fact that in the emptying phase the bladder is compressed by muscles and the volume reached is lower than the initial one (empty bladder).

A similar system was tested also *in vivo* on human subjects confirming bioimpedance decreasing trend during bladder filling [195].

In order to increase the wearability of the sensing unit towards chronic monitoring and to enhance volume estimation precision, innovative designs based on sensorized belts and smart garments have been proposed.

Shin et al. designed a waist-belt-type device with integrated bioimpedance sensors [196], (Fig. 5g). The sensing unit is composed of a pair of electrodes (Ag/AgCl): the first electrode injects a 100 μA sinusoidal current, and the second electrode reads the current/voltage upon tissue crossing. The proposed work includes two main contributions: the development of a single-channel body impedance analysis device wirelessly connected to a smartphone, and the development and validation of a motion artifact reduction algorithm. In order to discriminate motion artifacts, the system exploits multi-frequency sampling and the rapid changes occurring in the impedance trend due to abrupt patient position changes. Differential readings at 10 kHz (the frequency used to see the abrupt changes in the signal that occur during motion) and 50 kHz (the frequency generally used to measure the human body characteristics) are performed to monitor the bladder volume without motion artifacts. The system proved efficient in monitoring three human subjects for 7 days both in the standing posture (no movement) and upon posture variations.

Passing from Ag/AgCl electrodes to textile ones (*textrodes*) allows integration in clothes and underwear [197], [198], (Fig. 5f). Different configurations of tetrapolar silver plating nylon electrodes, varying in the relative positioning of injecting and reading electrodes, were tested *in silico*. *Ex vivo* tests were carried out at 5 kHz on porcine bladders over 350 ml volume (50 ml steps) ranges and by considering urine-like solutions presenting different electrical conductivities (0-0.2-2-4-10 S/m). *Ex vivo* tests enabled to define the electrodes configuration providing the highest amplitude variation between the empty and full status, thus maximizing the reading range and potentially enhancing the volume estimation accuracy. At this stage, only the trend of the data was considered: the qualitative analysis reported promising results, although the experimental conditions were still far from being realistic.

Considering continuous monitoring with a wearable device, the bioimpedance technique appears promising. However, some factors influencing the measurements need to be considered. In fact, both the influence of the body posture during the measurements and the unknown conductivity of the urine prevent a wider diffusion of the technique. Schlebusch et al. investigated the inter-variability and intra-variability of urinary conductivity and presented a method for its compensation [199]. Nine SCI patients with comparable daily-routine were monitored during regular urodynamic examination for several days. Results showed an inter-individual impedance variability in the range 5.9-32.2 mS/cm, and an intra-individual variability in the range 4.8-17.1 mS/cm. The results confirmed the negative correlation between impedance and volume and proved that the slope of the impedance-volume trend depends on solution conductivity, i.e., the higher the conductivity the steeper the negative slope [200]. Schlebusch et al. proposed a method to compensate such a dependence by defining the Impedance Ratio (IR) Method based on three tetrapolar measurements

$$IR = \frac{Z_s - Z_f}{Z_b - Z_f} \tag{4}$$

where Z_f is the impedance measured by an electrode located ventrally in front of the bladder and sensitive to changes in bladder impedance; Z_b is the impedance measured by an electrode located dorsally, used as reference with low sensitivity in the bladder regio; Z_s is the impedance measured by an electrode located on the side, sensitive to bladder size and volume. *In vitro* validation on a phantom proved the robustness to urine composition variations, but higher volume estimation inaccuracies for low filling volume and sensitivity to external disturbances.

c: NEAR-INFRARED SPECTROSCOPY

NIRS technology has also been studied for the design of novel wearable devices to transcutaneously monitor the urinary bladder, exploiting the hemodynamic variations in the microcirculation of the organ and the supply of oxygen during bladder filling and emptying phases [201], [202], [203], (Fig. 5h). The hardware consists of a NIRS device worn by the subject at the abdomen site (above the symphysis pubis across the midline) including small low weight LED light source (emitter probe, 950 nm) placed a few centimeters from the printed circuit detector (receiver probe). The system is connected to a LabVIEW/Matlab interface to analyze the collected data. The proposed system demonstrated the feasibility of such approach. Reading voltage variations could be detected upon voiding: the signal decreases at the beginning of voiding, thus reaching a plateau after 15 s. Despite compact, this device proved able only to detect the voiding (not to make pre-void measurements), thus limiting the potential impact on patients' quality of life.

IV. IMPLANTABLE SENSORS

Implantable sensing solutions represent the optimal way to continuously and chronically monitor the bladder status, thus offering the possibility of restoring the physiological urination process without any impact on the lifestyle of the patient. Indeed, despite wearable sensors might also be eligible for chronic monitoring, the need to carry on the associated control electronics together with the artifacts produced by clothes and daily activities limit their accuracy and increase the burden on lifestyle. Compared to clinical instruments and wearable devices, implantable sensors for bladder monitoring lag behind in the development process with no solution reaching the market, yet. The greatest effort in this direction lies in the design and development of implantable sensing units, mainly obtained by microfabrication technologies. Sensing strategies and adopted designs will be described in this section. In most of the reported cases, data transmission and processing, as well as powering, are still placed outside the body but sensors design is conceived to enable future implantation of the overall apparatus. Among the anatomical and physiological bladder parameters, pressure and volume appear the most investigated ones with implantable sensors to obtain information on the physiological/pathological and filling status of the organ.

A. BLADDER PRESSURE MONITORING

Almost all the bladder diseases and dysfunctions can be prevented or predicted by observing the abnormal bladder pressures (TABLE 1). Implantable pressure sensors can be divided into two categories, namely intraluminal and suburothelial sensors, depending on their working site.

1) INTRALUMINAL SENSORS

Intraluminal pressure sensors typically include a pressure sensing unit properly encapsulated to enable floating/anchoring in/to the bladder structure and to protect the active components (sensor and electronics) from the harsh working environment which tend to produce fluid infiltrations and corrosion. Wang et al. designed a minimally invasive system for long-term intraluminal pressure monitoring covering the range of abnormal and critical bladder pressures (1033.51-1385.05 cmH_2O) [204]. The proposed system includes an absolute pressure sensor (ATP015, Asia Pacific Microsystem, Inc.) sealed in a floating and anticorrosive balloon (diameter of 25 mm and volume 8.2 cm^3), (Fig. 6a). The sensor is composed of bridging resistors, and the pressure values are estimated based on output voltage measures. A similar design was proposed by soebadi et al. [205]. The active system, defined as bladder pill, is designed to be inserted through the urethra [206]. It features a soft, low-profile encapsulation (16 Fr catheter) and presents a polyurethane tail to be anchored to the tissue, with a total dimension of 30-40 cm length, and 4.6 mm DIAMETER (Fig. 6b). The sensing unit consists of a MS5637 pressure sensor microchip (measurement specialties, New Jersey, USA) able to detect pressure in the range of 305.92-1223.66 cmH_2O, thus enabling pathological conditions diagnosis. *In vitro* pressure measurement error was 0.263±0.154 cmH_2O, while *in vivo* tests performed on mini pigs revealed that the pressure values recorded with the target device were in line with those measured through an air-charged urodynamic catheter used as control.

Recently, Li et al. designed an intraluminal fully implantable biomicrosystem for filling state monitoring [207], (Fig. 6). The sensing unit consists of a miniaturized pressure sensor (MS5540CM, Intersema) able to detect pressure in the range of 1-100 cmH_2O (resolution 0.1 cmH_2O). Polydimethylsiloxane (PDMS) was employed as encapsulation material to provide biocompatibility and watertight protection (overall size 1.9 cm x 1.2 cm x 1.8 cm). The system was tested *in vivo* on rabbits, resulting in satisfactory performance and safety. The bladder pressures were simultaneously detected by the biomicrosystem and conventional cystometry (Biopac MP 36, BIOPAC Systems, Santa Barbara, CA, USA), showing similar signal during the voiding phase and a correlation coefficient of 0.885. The measurement error of the sensor was around ±1% over the 7 days of implantation when compared with standard cystometry.

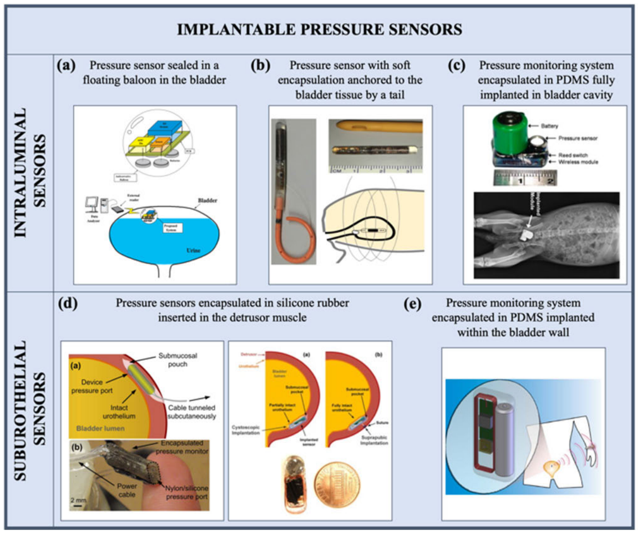

FIGURE 6. Examples of implantable sensors to chronically monitor the urinary bladder pressure. Intraluminal pressure sensor positioned in the bladder lumen ((a) sensing unit sealed in a floating and anticorrosive balloon [204], Copyright ©2008, IEEE, (b) sensing unit composed of the Bladder Pill anchored to the tissue by a polyurethane tail [205], (c) fully implantable biomicrosystem in the bladder cavity of a rabbit [207]). Suburothelial pressure sensors for detrusor contractions monitoring ((d) sensing unit encapsulated in silicone rubber [209], [211], Copyright ©2018, ©SAGE Publications (e) fully implantable biomicrosystem encapsulated in PDMS [210], Copyright ©2009, IEEE).

TABLE 3 summarizes the characteristics of the analyzed intraluminal pressure sensors.

2) SUBUROTHELIAL SENSORS

Detrusor contraction monitoring using a suburothelial pressure sensor was suggested in several works mainly by the same research group (Majerus et al.). The first sensor design consisted in a piezoelectric pressure sensor encapsulated in silicone rubber (sensing range of 0-2200 cmH_2O, pressure sensitivity of 0.8 cmH_2O, sensing accuracy of ±1.6 cmH_2O, overall dimensions 7.0 mm × 3.5 mm × 15 mm) [208], [209], (Fig. 6d). The prototype was implanted in 2 animals (feline and canine) for acute tests and 1 animal (canine) for chronic testing (13 days). The detected suburothelial

TABLE 3. Intraluminal pressure sensors.

Intraluminal Pressure Sensors			
Prototype	'A Mini-Invasive Long-Term Bladder Urine Pressure Measurement ASIC and System' Wang et al. [204]	'Wireless intravesical device for real-time bladder pressure measurement: Study of consecutive voiding in awake minipigs' Soebadi et al. [205]	'Designing and Implementing an Implantable Wireless Micromanometer System for Real-Time Bladder Pressure Monitoring: A Preliminary Study' Li et al. [207]
Dimensions	Diameter: 25 mm Volume: 8.2 ml	Diameter: 4.6 mm Length: 30-40 mm	Length: 19 mm Width: 12 mm Height: 18 mm
Weight	~4.1 g	1 g	~5 g
Sensing Range	1033.51-1385.05 cmH_2O	305.92-1223.66 cmH_2O	1~100 cmH_2O

List of implantable intraluminal pressure sensors. The prototype specifications are reported in terms of dimensions, weight, and sensing range (typical bladder pressures below 100 cmH_2O).

TABLE 4. Suburothelial pressure sensors.

Suburothelial Pressure Sensors			
Prototype	'Suburothelial Bladder Contraction Detection with Implanted Pressure Sensor' Majerus et al. [209]	'Wireless micromanometer system for chronic bladder pressure monitoring' Fletter et al. [210]	'Is submucosal bladder pressure monitoring feasible?' Basu et al. [211]
Dimensions	Length: 15 mm Width: 7 mm Height: 3.5 mm	Length: 15 mm Width: 7 mm Height: 3 mm	Length: 15 mm Width: 6.8 mm Height: 3 mm
Sensing Range	0-2200 cmH_2O	0-250 cmH_2O	0-2200 cmH_2O

List of implantable suburothelial pressure sensors. The prototype specifications are reported in terms of dimensions and sensing range (typical bladder pressures below 100 cmH_2O).

pressures were compared with intraluminal pressures measured by a commercial urethral catheter (SPR-524 Mikro-Tip Pressure Catheter, Millar Instruments, Houston, Texas). During acute testing, an average 0.93±0.03 and 0.89±0.03 correlation coefficient between the proposed suburothelial device and the reference urethral catheter in electrically stimulated bladder contractions and manual compressions was witnessed, respectively. Subsequently, the authors implanted the same sensor inside the bladder lumen to verify how the implant site plays an important role and achieved higher correlation when inserting the device inside the bladder lumen (0.98±0.02) rather than in suburothelial position. Given the long-term testing of the proposed system, the effects of the working environment were evaluated by recording device progressive deterioration.

Device implantation within the bladder walls was proposed to protect the sensing unit from contact with urine and avoid mineral encrustation and stone formation [210]. Piezoresistive mems pressure sensor (SM5102, SiMicro) were proposed to this purpose. Basu et al. proposed a device (6.8 mm × 3.0 mm × 15 mm) implanted by a cystoscope and tested on calves [211], (Fig. 6d). The absolute pressure sensor worked in the range 0–2200 cmH_2O, with a 0.5 cmH_2O precision. Simultaneous pressure recordings from the sensor and an intravesical water-filled catheter showed good agreement in pressure values for bladder volumes below 100 ml (root-mean-square error of 3.00 cmH_2O between device and reference). However, for bladder volumes larger than 100 ml, readings from the submucosal device diverged significantly from the reference catheter.

TABLE 4 summarizes the characteristics of the analyzed suburothelial pressure sensors.

B. BLADDER VOLUME MONITORING

Volume estimations are usually performed as indirect measurements, as seen in the previous Sections. The same principle applies to implantable solutions. Based on the measured quantity/parameter to be correlated with bladder volume, implantable sensors will be grouped in three classes, namely sensors detecting bladder dimension change, bladder walls deformation, and electrical properties variation. In the following, each class will be analyzed in detail by focusing on the employed sensing principle.

1) BLADDER DIMENSION CHANGE MONITORING

In the case of the bladder dimension variations, different strategies have been proposed based on the estimation of the distance between pairs of sensors anchored to the external bladder walls, usually in diametrically opposed positions. Both capacitive and magnetic sensors have been proposed to this purpose. The measurements (in capacitance and magnetic field) are converted into distance values to enable volume estimation assuming a certain geometric shape of the bladder (e.g., sphere).

Lee et al. proposed MEMS pyrex-gold-PDMS microelectrodes to be used as capacitive sensors [212]. THE sensor is designed as a honeycomb in a rectangular shape (2,3 μm × 3,2 μm × 500 μm), (Fig. 7a). During the tests, performed on bladder of rats (about 100 times smaller than human's bladder), two sensors were sutured on the external

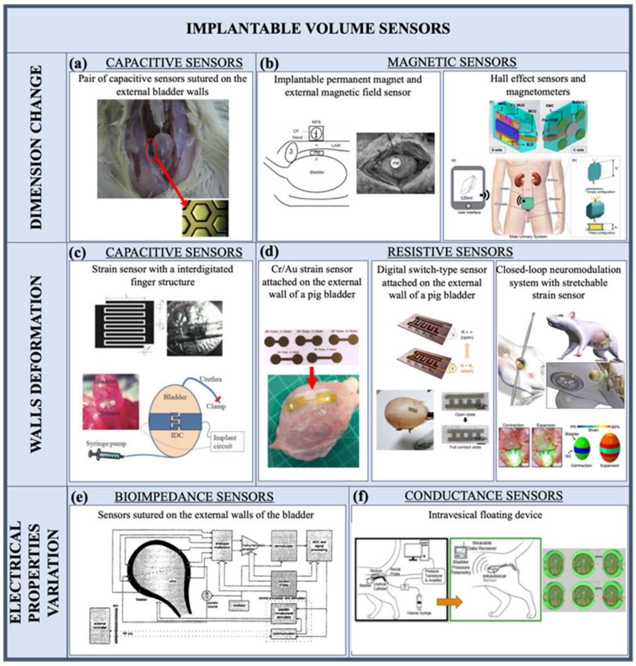

FIGURE 7. **Examples of implantable sensors to chronically monitor the urinary bladder volume. Bladder dimension changes ((a) based on capacitive [212], and (b) magnetic sensors sutured/attached on the external walls of the bladder [24], Copyright ©2021, IEEE, [213], Copyright ©2009, American Congress of Rehabilitation Medicine), bladder walls deformations ((c) based on capacitive [219], Copyright ©2013, IEEE, and (d) resistive sensors attached on/ placed around the bladder [216], [217], [218], Copyright ©2019, Springer Nature Limited), electrical properties variations (e) based on bioimpedance sensors attached to the bladder [222], Copyright ©1997, IFMBE, and (f) conductance sensors attached into the bladder [223], Copyright ©2018, IEEE) monitoring.**

bladder walls and capacitance measurements were recorded during infusion of saline solution in the bladder (filling range 0.2–2.4 ml). The capacitance was measured by the electrodes every 2 minutes and converted into distance values to enable volume estimation by assuming a spherical bladder. The volume of saline infused into the urinary bladder was compared with the estimated volume. *In vivo* testing on rats proved the tendency of the method to overestimate bladder volumes below 0.6 ml (about a quarter of the capacity) due to the inaccurate geometric approximation when the bladder is still partially collapsed. For volumes higher than 0.6 ml, the estimates were statistically correlated with the injected volume ($p < 0.01$) and not significant differences were observed.

Alternatively, magnetic field-based sensors were combined with magnetic field sources to perform distance measures to be correlated with bladder filling state. Different sensor–field source combinations (varying in source type and number, relative sensor – source position and sensors type) were proposed to cope with volume monitoring, both in natural and artificial bladders.

Wang et al. proposed the combined use of an implantable permanent magnet (coin-shaped, axial magnetization, coated with a silicon membrane, 44 mm × 44 mm × 44 mm in size) placed on the anterior wall of the bladder, and of an external magnetic field sensor attached to the lower abdomen, (Fig. 7b). In this case, the aim is not to directly estimate the effective intra-bladder volume, but to detect when bladder volume overcomes a certain threshold [213]. The external sensor includes a rotating magnetic bar and operates as a compass by detecting magnet axis rotation with respect to the fulcrum during voiding and filling. Bar rotation is produced by the approaching or departure of the implantable magnet during filling and voiding, respectively. The system was tested on canine models while filling the bladder from 25 ml to 200 ml volume (25 ml steps) by a transurethral catheter. The rotating magnetic bar of the external sensor was positioned at 70° for empty bladder. With the gradual increase of the bladder volume, the bar rotated from 70° (0 ml volume) to the range of 117°-127° (200 ml volume). The external sensor was connected to an alarm system, to be activated upon threshold volume reaching (about 150 ml in this case). It is worth underlying that combining implantable (passive) and external (active) components allows to solve powering-related issues, which often represent a significant bottleneck in implantable devices development.

Magnetic sensor-based distance measures were proposed also to monitor the volume of a fully implantable artificial bladder, (Fig. 7b). Hall effect sensor (high sensitivity) and magnetometer (low sensitivity) were employed jointly to detect low and high bladder filling volumes, respectively [24], [214]. With volumetric and geometric considerations on the artificial bladder shape, the measured distances were correlated to filling volumes. Bench tests were performed to evaluate the performance of the prototype, resulting in estimation errors lower than 15% for volumes larger than 100 ml. in this case, all the elements of the sensing units are implanted on the artificial bladder walls. The authors considered the integration of a battery to provide power supply to the electronic components and further investigations to evaluate a power transfer strategy for battery recharging to allow extended lifetime.

Recently, Mandal et al. proposed a US system (diameter of 25 mm) composed of an implantable unit (US transmitter and piezoelectric transducer) and an external one (power supplier and data receiver) to monitor the size of the natural bladder [215]. Bladder size was derived from the time-of-flight difference between the front and back walls. The system was tested *in vitro* during filling cycles on bladder phantoms (both spherical and non-spherical shapes) filled with water and immersed in saline solution to simulate surrounding tissues. Although estimation errors lower than 15% for volumes in the range of 50-300 ml were obtained, more tests are needed to validate the system in more realistic conditions (i.e., *ex vivo* or/and *in vivo*).

2) BLADDER WALLS DEFORMATION MONITORING

In analogy with the natural system where stretch receptors determine afferent fullness sensation (Fig. 1), artificial stretching sensors placed on bladder walls were investigated.

Both resistive and capacitive sensors have been proposed to detect bladder stretching during urine accumulation. However, measuring bladder deformations poses several challenges mainly related to the need to find optimal mechanical compliance between the sensor and the tissue without constraining the stretching or compressing the tissue. Furthermore, given the anisotropic contraction and expansion of the bladder during filling and voiding, correlating tissue deformation and volume variation is not straightforward. The most interesting solutions proposed so far come from the field of soft conformable electronics, as a way to reduce the compliance mismatch between the sensor and the tissue and include both resistive and capacitive sensors.

Hannah et al. designed a resistive strain sensor consisting in an ultra-thin Cr/Au sensor fabricated on a polyurethane film (50μm thick substrate) [216], (Fig. 7d). The sensor was designed to be both conformable and biocompatible, so as to allow its implantation.

Considering bladder maximum filling volume 160 ml and a 6 mm long sensor, *ex vivo* tests on pig bladders proved sensitivity values of 0.1 Ω/ml and 0.03 Ω/ml when placing the sensor between the bladder nec and bladder base with vertical or diagonal orientation, respectively. Different adhesive materials were investigated to attach the sensor to the external walls of the bladder (i.e., transparent silicone sealant, a biocompatible hydrogel, tri-laminate silicone/acrylic gel) with the hydrogel providing the best outcome in light of the easier manipulation and higher stretchability than the sensing unit.

A second type of sensor to detect bladder deformation based on resistance measurements has been proposed by Kim et al. In this case, it is not a strain sensor but it acts as a digital switch and includes multiple electrodes pairs connected in parallel on two long rails [217], (Fig. 7d). During the collapse of the bladder, the electrodes are pulled closer causing the formation of a closed circuit. The distance between the first and last pairs of electrodes defines the dynamics of the sensor (detectable volume range), while the resolution depends on the number of electrodes pairs assembled in the structure. By increasing the number of electrodes, it is possible to sequentially and discreetly recognize distinct filling phases. Indeed, by considering the same resistance for each pair of electrodes, the sensor resistance decreases by 1/n, where n is the number of electrodes in contact. The sensor was manufactured using conductive polypyrrole/agarose hydrogel composite encapsulated with PDMS, and the contact sensors are composed of a thin layer of Cr/Au (15/80 nm). Having to follow the variations in elongation of the underlying tissue, different concentrations of the polypyrrole/agarose hydrogel were evaluated to obtain a value of the Young's modulus similar to the bladder one (around 10 kPa). *Ex viv*o testing on pig bladders confirmed the feasibility of this solution, showing that the sensor resistance decreases as the number of contact electrodes increases during bladder emptying. The proposed sensor has the advantage of not being affected by long-term drift due to the digital nature of the measurements. However, to implement a practical implantable sensor, a calibration process to define the optimal position of the sensor, the distance between the electrodes, and the number of electrodes pairs would be necessary.

Recently, Mickle et al. proposed for the first time the use of an implantable resistive stretch sensor for closed loop bladder neuromodulation, (Fig. 7d). A soft stretchable strain gauge to be placed around the bladder was proposed to this purpose. The expansions and contractions of the urinary bladder result in variation of the strain gauge output (resistance values), that is correlated to the bladder volume (assuming a spheroidal shape). The sensor was connected to an optoelectronic stimulator able to perform closed-loop optogenetic peripheral neuromodulation of the bladder [218]. A soft unit inserted subcutaneously in the abdomen of the small animal (rat) is composed of a wireless data communication unit to send the readings to an external unit (smartphone or tablet), and a wireless energy harvesting unit (low-powered radio frequency-embedded microcontroller and wireless power management circuitry) to power the entire system. *In viv*o tests in metabolic cage showed an accurate monitoring of the bladder activity (filling and voiding), with a large decrease in resistance, thus decrease in bladder size, correlated with voiding events. Upon 7 days, the implant showed minimal effect on bladder physiology, and no detectable harm or distress for the animal.

Implantable capacitive strain sensors were proposed as well for bladder monitoring (Fig. 7c). Cao et al. reported the use of a capacitive sensor featured by a metal interdigitated finger structure, printed with al on a polyimide substrate and encapsulated with PDMS. 40-60 fingers (length of 500 μm) separated by a 5 μm of gap were employed [219]. The capacitance of the structure depends on geometrical and physical parameters of the sensor (e.g., finger length, width, and number, separation gap, permittivity of the pdms, thickness of the polyimide) and can change due to bladder deformation. The relationship between stretching and capacitance has been investigated, resulting in a decrease in capacity as the bending angle increases. the sensor was tested on rats, in a miniaturized configuration to be wrapped around the bladder. As the bladder expands or collapses, the sensor would be stretched or bent causing a shift in the output. However, the sensor proved efficient in tracking the volume on a reduced volume variation range and further investigations on this kind of technology would be needed to cover the entire filling-voiding range.

3) BLADDER ELECTRICAL PROPERTIES VARIATION MONITORING

A bladder monitoring technique that is still little explored in implantable systems involves the analysis of the electrical properties of the bladder and their variation with the health, filling, and perfusion status of the organ. Both changes in impedance and conductivity performed with implantable sensors have been investigated for bladder volume estimation.

Performing bioimpedance measurements through implantable electrodes presents several challenges. Some of them, as the dependence on adjacent organs and on urine composition, were already discussed in Section III. However, when passing to implantable solutions, sensors direct contact with the organ and sensor/control electronics implantability should also be taken into consideration. Despite scarcely employed for bladder monitoring, implantable bioimpedance sensors have been interestingly proposed for kidneys, liver and esophageal monitoring. The outcomes obtained for different districts monitoring might represent an important starting point to translate this approach also to bladder monitoring.

Rodriguez et al. proposed and tested *ex vivo* on sheep kidneys and liver an implantable device for bioimpedance monitoring. The study aimed at proving the feasibility of performing bioimpedance monitoring directly on the organ walls. The emphasis is placed on the analysis of technical aspects, such as the appropriate frequency range for implantable monitoring systems (2 kHz - 2 MHz) and the size and geometry of electrodes for the current injection and voltage detection [220]. The system consists in a 4-terminal impedance sensing unit, based on gold sensors (Ni/Au, Electroless nickel immersion gold process). The demand for limited size of the implantable sensing unit (13 mm $\times$ 3 mm) implies the electrodes to be small and placed in close proximity. This result in a spatially confined reading area, thus in the possibility to reject the disturbances produced by adjacent tissues.

Cao et al. proposed *in situ* bioimpedance monitoring for the recognition of esophageal gastro-reflux episodes by relying on the change of impedance produced by fluids with different ion concentrations. The proposed system is composed of an impedance sensing unit to identify the episode combined with a pH sensor to provide information about the reflux acidity [221].

The only study reporting the use of implantable bioimpedance sensors for bladder monitoring dates back to 1997 [222], (Fig. 7e). If a low-intensity sinusoidal current is injected across the bladder, an electric field is produced directly in the urine. By placing the electrodes in diametrically opposite positions, the changes in the output signal can be correlated to the changes in the bladder volume. In addition, with the use of multiple pairs of electrodes, the anisotropic bladder shape variations could be monitored, allowing the volume to be reconstructed more accurately. The system was tested on a latex balloon to validate the idea with 4 impedance electrodes.

Although the problem of signal attenuation due to the presence of skin, organs and fat between the bioimpedance electrodes and the target organ does not persist with implanted electrodes, the authors identified other potential limits of this strategy: the contribution on impedance measures of adjacent organs in direct contact with the electrodes and the bladder, and possible false-reset of the system if a post-urination residual volume remains inside the bladder.

McAdams et al. suggested an implantable monitoring of the bladder fullness based on conductance measurements recorded directly inside the bladder lumen by a floating system [223], (Fig. 7f). In this case, the system is composed of three electrodes positioned on the case of the floating device, two cathodes and a common anode for stimulation and detection, respectively. The sensed current is determined by the number of ions (volume of urine), and the density of ions (urine concentration). To avoid the corrosion, the sensors are composed of Pt-Ir (robust corrosion resistance properties). Bench tests were performed by reproducing an environment similar to the bladder lumen, thus by dipping the sensors in a latex balloon filled with saline solution (5% saline). A look-up table is used to obtain the output volume from two parameters, i.e., urine conductivity and detected voltage. The proposed system recognizes full and empty bladder conditions, but it cannot estimate the filling volume in an accurate way. Indeed, the floating system (dimensions of <2 cm^3) proved a volume estimation accuracy of ± 20 ml in a full-scale volume range of 5-50 ml (capacity of feline bladders).

V. DISCUSSION

In the context of bladder dysfunctions, the study of urinary bladder chronic and continuous monitoring is becoming more and more interesting, both at medical and engineering level. Two parameters are typically used for bladder monitoring, namely bladder pressure and filling volume. Since the first is not strongly related to the urine volume due to the elasticity and compliance of the organ walls that allow bladder filling without significant changes in pressure, this parameter is mainly considered for the detrusor contraction monitoring during voiding.

In the clinical setting, several options already exist to monitor the urinary bladder, exploiting different techniques, such as US and bioimpedance. Given the size and cost of the devices, the use of the instrumentation is limited to a clinical setting and to short-term monitoring tasks.

Although urodynamic tests, in particular the cystometry, are defined as gold standard for bladder monitoring by the International Continence Society [85], the invasiveness of the procedures and the presence of motion-induced artifacts led a focus switch over clinical imaging techniques and diagnostic tools in urology.

US imaging is among the most used diagnostic tools in hospital and can be employed also for volume monitoring. Despite the good performance of commercial US equipment in bladder volume monitoring (TABLE 2), their wider adoption outside the clinical setting is prevented by the operator-dependent nature of the exam, the presence of the pubic bone in the lower abdomen, and the need for a coupling medium between the skin and the probe. Furthermore, a significant miniaturization of the existing equipment would be required to extend their use in chronic and continuous monitoring settings [191]. Some attempts have been made in this direction producing promising results with portable systems; however, they also share the same positioning precision-dependent performance drift as clinical equipment.

Bioimpedance -based volume monitoring is less explored, yet promising. It only requires easy-to-apply, inexpensive, light-weighted electrodes connected to a reading/stimulation system. Depending on electrodes configuration and number, as well as on data processing method, both tomographic images and volume estimations can be obtained.

In light of these features, bioimpedance appears to be at the forefront for the development of small systems, towards wearable (sensorized belt and garments) and implantable solutions. Electrodes are crucial for the success of the method and interesting perspective came from the use of textile electrodes allowing to overcome skin irritation and allergic reactions issues faced with Ag/AgCl electrodes and to foresee long-term monitoring. However, as *textrodes* are sensitive to mechanical flexion and stretch, they should be close-fitted like a second skin and not subjected to external pressure.

Additional challenges as the influence of the body posture during measurements and the unknown conductivity of urine are still to be faced and prevent at present a wider diffusion of the technique.

In terms of accuracy, no significant differences are observed between the main clinical techniques discussed. New forms of bladder monitoring have been preliminarily investigated, ranging from NIRS to MRI.

Moving to wearable systems did not produce remarkable decrease in accuracy despite bringing the advantages of domestic monitoring over longer timeframes. This should foster further research in this direction towards not invasive, lightweight, low power wearable solutions to be used daily. Indeed, at present, only rigid post-void systems have reached a suitable development stage to allow commercialization. On the other hand, pre-void monitoring systems still need further investigation to reach the same kind of maturity. The results summarized in this review paper and the impact that safe and efficient bladder volume and pressure monitoring by wearable devices might have on patients' daily life (i.e., increase the quality of life, while reducing adverse effects of non-efficient voiding management) should motivate this research effort.

In the attempt to deliver sensors able to monitor bladder filling status 24/7 and to send data to the patient and eventually to artificial assistive devices (neurostimulators, artificial bladder, artificial sphincter) towards autonomous management of the urinary disfunctions, implantable solutions represent the most interesting perspective. Several strategies and sensor technologies have been reported in this review paper to monitor the pressure and volume of the urinary bladder.

In TABLE 3 and TABLE 4, the characteristics of the analyzed research works are reported for intraluminal and suburothelial pressure sensors. Considering a recommended range of 0-100 cmH_2O for physiological pressure (approximately 50 cmH_20 at the initiating phase of voiding; normal, smooth, arc-shaped trend curve without any rapid changes in amplitude during voiding [83], TABLE 1), the ranges of the proposed sensors appear large enough to detect also abnormal and critical pressures associated with bladder and detrusor dysfunctions. All the presented systems are sufficiently miniaturized and light weighted to be inserted through the urethra in the bladder lumen and to be implanted in the suburothelial position.

In the case of floating and implanted intraluminal sensors, the encapsulation of the sensor to avoid urine encrustation and corrosion is among the first challenges to be faced [224]. On the other hand, in the case of suburothelial sensors, the damage of the detrusor muscle during implantation, and the migration of the electronics should be considered.

Monitoring bladder size variations using capacitive or magnetic solutions has produced promising results. However, estimating bladder volume from walls distance measurements with a single mathematical formula and a reference shape model limits accuracy. Considering magnetic field-based sensing, the presence of other surrounding magnetic fields that can interfere with the system must be considered. Indeed, also compatibility with common imaging tools (e.g., MRI) should be taken into account to avoid limitations on patient's health care.

The deformation of bladder walls, instead, has been monitored by resistive and capacitive strain sensors, and interesting results have been reported for the latter ones. To cope with this kind of measurement, sensors should conform perfectly with the elasticity of the tissue, and extend without opposing resistance or stress to the tissue. In addition, a system of multiple sensors should be considered to follow the anisotropic contraction and expansion of the bladder. The monitoring of bladder fullness exploiting the variations of electrical properties of the tissues is little explored in an implantable setting. No quantitative studies are present in literature, thus not allowing a comparison of accuracy with other techniques. However, as reported in Section IV, the qualitative analysis of the techniques highlighted the limits to be overcome to allow the monitoring of the bladder filling phase, e.g., adopting strategies of subcutaneous implantation of the electrodes [220], [222].

VI. OPEN CHALLENGES

Clinical instruments and wearable devices to monitor the urinary bladder have reached a good level of maturity, at present. However, from a clinical and engineering viewpoint, the main challenges concern implantable units. The main advantage that pushes forward the study of implantable solutions lies in designing a monitoring solution that can guarantee the patient a physiological control of the bladder, thus re-gaining a good quality of life. However, performing reliable and chronic sensing remains an open challenge.

Indeed, biocompatibility, miniaturization, long-term integration of the implantable unit (not only the sensing element, but also the associated electronics), wireless powering, and data transmission are among the crucial issues to allow implantability.

Encapsulating the implantable unit with a biocompatible coating material is considered as a possible solution to limit the activation of immunological responses and the growth of fibrotic tissue (which might lead to implant failure) [225], [226]. Given the complexity of urinary system environment and the tendency of surfaces in contact with urine to undergo corrosion, biofilm and encrustations deposition, biocompatibility is not the only requirement for functional urinary devices. They should resist to the formation of biofilms and encrustations, and they should protect the control electronics and sensing units from deterioration and from contact with the biological fluids.

The appearance of encrustations is influenced by the surface properties of materials in contact with urine, such as surface defects and roughness causing a lowering of the interfacial tension which leads to the nucleation of the crystals [227]. In this framework, both bactericidal and antifouling coatings have been proposed, together with materials featured by a high chemical inertia and antifouling properties [228], [229]. However, the bactericidal coatings present a limited lifetime which prevents their use in chronic implants. Few materials were successfully tested as anti-encrustation coatings [224], [230]. However, longer-lasting testing is required to assess stability and efficiency on the long term. Furthermore, the materials suitability in terms of resistance to encrustations strongly depends on the working site and on the urine dynamics in the target region. Recent studies suggested that in urinary sphincters, where materials interaction with the flow is of shear type, material chemistry plays a minor role compared to urine flow, which might drag away crystallization seeds [231].

Advances in nanoscale materials and organic materials [232] are providing new venues for miniaturized integrated circuits, extensible electronics, and tattoo-like electronics that could be integrated in implantable solutions [233], [234], [235]. The main goal is to develop electronics capable of bending, stretching, compressing, twisting and deforming while maintaining high levels of performance, reliability and integration [236]. New flexible electronics designs and manufacturing strategies, ranging from the class of lithography techniques to novel inkjet printing strategies [238, p. 3], [238], [239], are paving the way to the development of a wide range of implantable devices [240], [241]. In this regard, although research efforts are focused on wearable sensors attached to the skin, several implantable sensors have been proposed and reached promising preliminary results in recent years [242], [243], [244]. Most of these sensors are devised for subcutaneous implantation and sometimes to be sutured/adhered to the organ wall (the heart, in most of the cases). Despite the efforts made and the results achieved, a factor that prevents the good functioning of flexible electronics is the resistance it applies to the elongation of the underlying tissue. In fact, it should conform to the movement and the continuous and cyclical change of shape of the target organ. In addition, further research is needed to reach long-term reliability, mechanical stability and integrity of the interfaces between the circuits and the surrounding material and components (e.g., urinary prostheses or neurostimulation systems) [245].

In addition to the design of flexible electronics intended as the sensitive unit, frontier research is developing also innovative solutions for antennas allowing data transmission. Flexible antennas, textile antennas that incorporate conductive threads, antennas constructed with liquid metals that exploit soft microfluidic networks, structures for skin-like and epidermal electronic devices represent interesting examples in this sense. In this case, the major effort to be made is directed towards the design of high-efficiency antennas to guarantee the communication link even between an implanted unit (in a biological environment surrounded by tissues) and an external one. These would guarantee and improve the connection between the sensing units and a human machine interface, as well as guarantee wireless powering or battery recharging [246], [247].

Lastly, considering the working context of implantable monitoring devices, sleeping and working modes could be alternatively exploited to save the battery power for long-term observations, since bladder parameters (i.e., pressures and volume) do not vary with fast dynamics. Future development of the systems shall consider the integration of commercial batteries or the adoption of charging strategies: a duration of about 10 years for the monitoring device before replacing the battery is considered acceptable. Indeed, the future prospect is directed towards the development of wireless charging and data transfer systems with absence of cables to avoid hindering the patient's movements [248].

VII. CONCLUSION

The monitoring of the urinary bladder is a relevant topic for the management of patients with lut dysfunctions. Some of the reviewed technologies are currently used in the clinical practice to check the state of the bladder on a daily basis. Domestic and chronic bladder monitoring would be highly desirable, yet still remains an open challenge. Good results were obtained in the last decades with wearable monitoring systems. However, their accuracy proved highly patient-related (e.g., US Monitor) and the presented solutions are not mature enough to significantly improve the patient's life quality. On the other hand, implantable bladder monitoring is still at an initial research stage. Although several implantable sensing strategies have been explored and have shown promising results, there are not many quantitative studies allowing to state the superiority of a certain solution. However, implantable sensors are gaining increasing attention, even coupled and connected to other systems, such as artificial bladders [24] and neurostimulators [218]. Overall, despite the several challenges to be faced, the potential revenues that efficient wearable and implantable bladder monitoring systems might produce on patient lifestyle and health is impressive. Furthermore, if reliable bladder monitoring system will be available, bionic solutions for bladder functions replacement and assistance might witness a development boost and become a viable path for patients suffering from lut pathologies and disfunctions.

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