Smart Wearable Device for Nocturnal Enuresis

Kaya Kuru¹, Benjamin Jon Watkinson¹, Darren Ansell¹, Dave Hughes², Martin Jones¹, Noreen Caswell¹, Peter Leather¹, Kina Bennett³, Paula Sugden³, Carl Davies¹ and Christian DeGoede³

Abstract—This research was designed to evaluate if it is viable to awaken children with urinary incontinence at the pre-void phase using a smart wearable device and enable them to control incontinence with fine-tuned individual parameters determined by the device intelligently. To address this research question, a miniaturised wearable smart device was built in this multidisciplinary research to monitor the non-linear behaviours of the bladder during its expansion with urine intake. The device, with its customisable abilities, sets an individual alarm point to awaken the child with incontinence before voiding. Safety parameters, aesthetics and ergonomic use of the device were investigated through hospital trials with children and the device was improved based on the obtained feedback from these trials. *Clinical Relevance*—The device will help children learn how to control their incontinence over time.

I. INTRODUCTION

This study was designed to assess if it is feasible to: i) awaken children with Nocturnal Enuresis (NE) at the prevoid phase using a smart wearable device and ii) enable them to control incontinence with fine-tuned individual parameters determined by the device intelligently using ultrasound (US) technologies. A miniaturised smart medical instrument – the so-called MyPAD – was built to treat NE by involving the public and patients. Readers are referred to our earlier published patents and papers [1], [2], [3], [4], [5], [6], [7] to discover the elaborated phases of this multidisciplinary research. In this particular study, efficiency, safety parameters, aesthetics and ergonomic use of the device were investigated through hospital trials with children under the observations of physicians and nurses.



Fig. 1: First miniaturised device

*This research was funded by NIHR (II-LA-1116-20007). All experimental procedures involving human subjects described in this paper were approved by Manchester Central Research Ethics Committee (247101).

¹K. Kuru, B. J. Watkinson, D. Ansell, M. Jones, N. Caswell, P. Leather and C. Davies are with the School of Engineering and Computing, University of Central Lancashire, Preston, PR1 2HE, UK kkuru@uclan.ac.uk

²D. Hughes is the CEO of Novosound, Newhouse, Scotland, ML1 5UH ³P. Sugden, K. Bennett and C. DeGoede are with Lancashire Teaching Hospitals NHS Foundation Trust, Sharoe Green Ln, Preston PR2 9HT

II. METHODOLOGY

The first miniaturised device built in this research is shown in Fig. 1. The primary components of the Artificial Intelligence (AI) interface instilled into the device are delineated in Fig. 2 with the employed AI techniques. A merge of Bidirectional Long Short-Term Memory Recurrent Neural Networks (Bi-LSTM-RNN) and Reinforcement Learning (RL) is utilised. The main elements of the device are i) one US transducer for emitting single element US signals, ii) four US transducers for receiving A-mode echoed pulses within a depth up to 15 cm, iii) a US electronics unit for tuning signals, iv) a printed circuit board (PCB) for processing the acquired echoed pulses and establishing a bridge between the US electronics, and v) an AI unit for determining and setting individual alarm points.

A. Trials, Observations and Advancement

The validation of the system was conducted both on the tissue-mimicking phantom developed in this research and on volunteers. 8,876 data samples (both from the phantom and volunteers) were used to establish the trained model and 980 reserved data samples were used to test the model, resulting in a sensitivity (Se) (i.e., "Alarm" signals correctly classified as "Alarm") value of 97.1% and a specificity (Sp) (i.e., "No-Alarm" signals correctly classified as "No-Alarm") value of 99.2% with an overall accuracy rate of 98.2%. Physicians and nurses from the Royal Preston Hospital evaluated the performance, efficiency, safety parameters, aesthetics and usability of the prototype MyPAD instrument (Fig. 1) on children at the Lancashire Research Facility. During these trials, data samples were recorded from different stages of the bladder while the bladder was filling up with urine to power the decision-making capabilities of the AI interface. The observations perceived by the physicians and nurses and their recommendations to empower the device are provided in Tables I and II. The advancements on the device considering these observations and recommendations are presented in Table III.

The advanced device, as displayed in Fig. 3, was reexamined by the hospital staff with comprehensive tests on children. Further feedback and data samples were collected from the facility to further improve the device.

III. CONCLUSION AND FUTURE WORK

The device, developed in this research to treat urinary incontinence, was improved based on the obtained feedback from parents, children, physicians, and nurses during hospital trials. The outcome of the clinical trials provides robust

979-8-3503-8338-6/23/\$31.00 ©2023 IEEE

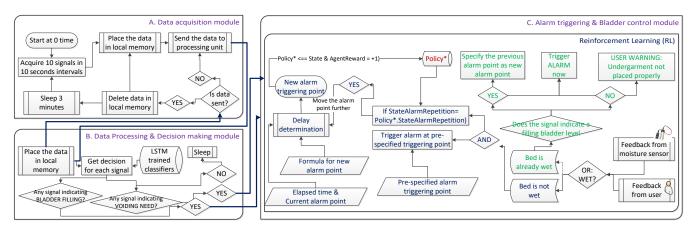


Fig. 2: The primary components of the AI interface instilled into the device.

TABLE I: Observations of the medical professionals.

1	Overall it seems alright to wear. When not moving you can't feel it is there unless
	you touch it.
2	It didn't move, but the child was in the bed most of the time. Also, the tight clothes
	helped keep it in place.
3	Even when going to the toilet, it stayed in place.
4	The device can be uncomfortable when moving around.
5	The garment does look weird, but once you wear it, it looks alright.
6	Garment did not have a hole for the probe wires.
7	Waterproof connectors were quite bulky.
8	Battery wires and probe wires were not adequately restrained.
9	The circuit box got noticeably warm after 4 hours of use, which is slightly worrying
	when children will wear it for up to 10 hours in bed under the blankets.
	·

TABLE II: Recommendations from the facility.

- 1 Less breakable (the connection of the battery charger came out. The device looks delicate).
- 2 Fewer parts: a device in one piece, rather than the 3 components connected with
- wires. There was no way to attach the battery case to the probe case. 3 Sealant around the electronics case made the device look too much like a prototype.
- 4 All parts needed labelling to improve ease of use.
- 5 The child felt the size of the US box. It would be better with no wires attached.
- 6 The garment looks alright, but it needs to fit the child.
- 7 Some stickers would make it look more attractive for younger children.



Fig. 3: The advanced MyPAD device: i) US transmitter, ii) US receivers, iii) US electronics, iv) PCB, and v) AI unit.

empirical support for the efficacy of the MyPAD device, both in setting appropriate alarm points at the pre-void phase as delineated in Fig. 4 and in helping the child control his/her incontinence with fine-tuned individual parameters determined by the device with successive uses. The smart machine will be improved and miniaturised further to ensure its efficacy.

REFERENCES

 D. W. Ansell, C. Sanders, P. Leather, K. Kuru, and M. Amina, "Methods and apparatuses for estimating bladder status," Oct. 25 2022, uS Patent

TABLE III: Improvements at the university lab.

- 1 Extra heatshrink was added to the battery and probe wires to prevent tangling.
 - Garments were adjusted to allow for probe wires.
- 3 All components were labelled to improve ease of use.
- 4 Velcro loop was used to attach the battery to the electronics case.
- 5 The electronics case was resealed with clear silicon to improve waterproofing and aesthetics.
- 6 Decision-making ability of AI was improved by incorporating the collected data instances into the training process.

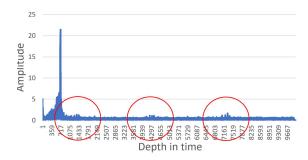


Fig. 4: A-mode pulses acquired from the walls of the bladder.

11,482,327.

- [2] K. Kuru, D. Ansell, M. Jones, C. D. Goede, and P. Leather, "Feasibility study of intelligent autonomous determination of the bladder voiding need to treat bedwetting using ultrasound and smartphone ML techniques," *MBEC*, vol. 57, no. 5, pp. 1079–97, 2018.
- [3] D. Ansell, K. Kuru, and P. Sugden, "Mypad: A pre-void alarm device for the treatment of nocturnal enuresis (ne)." Royal Manchester Children's Hospital, Manchester, UK: North West Bladder Study Day, March 2019.
- [4] K. Kuru and H. Yetgin, "Transformation to advanced mechatronics systems within new industrial revolution: A novel framework in automation of everything (aoe)," *IEEE Access*, vol. 7, pp. 41 395–41 415, 2019.
- [5] K. Kuru, D. Ansell, M. Jones, B. J. Watkinson, N. Caswell, P. Leather, A. Lancaster, P. Sugden, E. Briggs, C. Davies, T. C. Oh, K. Bennett, and C. D. Goede, "Intelligent autonomous treatment of bedwetting using non-invasive wearable advanced mechatronics systems and MEMS sensors," *MBEC*, vol. 58, no. 5, pp. 943–65, 2020.
- [6] N. Caswell, K. Kuru, D. Ansell, M. J. Jones, B. J. Watkinson, P. Leather, A. Lancaster, P. Sugden, E. Briggs, C. Davies, C. Oh, K. Bennett, and C. DeGoede, "Patient engagement in medical device design: Refining the essential attributes of a wearable, pre-void, ultrasound alarm for nocturnal enuresis," *Pharmaceut Med.*, vol. 34, no. 1, pp. 39–48, 2020.
- [7] K. Kuru, D. Ansell, H. Hughes, B. J. Watkinson, F. Gaudenzi, M. J. Jones, D. Lunardi, N. Caswell, A. R. Montiel, P. Leather, D. Irving, K. Bennett, C. McKenzie, P. Sugden, C. Davies, and C. DeGoede, "Treatment of nocturnal enuresis using miniaturised smart mechatronics with artificial intelligence," *IEEE Journal of Translational Engineering in Health and Medicine*, vol. 11, pp. 1–10, 2023.