

Programmable prostate palpation simulator using property-changing pneumatic bladder

Aishwari Talhan, Seokhee Jeon^{*}

Department of Computer Science and Engineering, Kyung Hee University, Deogyong-daero, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea

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ABSTRACT

The currently available prostate palpation simulators are based on either a physical mock-up or pure virtual simulation. Both cases have their inherent limitations. The former lacks flexibility in presenting abnormalities and scenarios because of the static nature of the mock-up and has usability issues because the prostate model must be replaced in different scenarios. The latter has realism issues, particularly in haptic feedback, because of the very limited performance of haptic hardware and inaccurate haptic simulation. This paper presents a highly flexible and programmable simulator with high haptic fidelity. Our new approach is based on a pneumatic-driven, property-changing, silicone prostate mock-up that can be embedded in a human torso mannequin. The mock-up has seven pneumatically controlled, multi-layered bladder cells to mimic the stiffness, size, and location changes of nodules in the prostate. The size is controlled by inflating the bladder with positive pressure in the chamber, and a hard nodule can be generated using the particle jamming technique; the fine sand in the bladder becomes stiff when it is vacuumed. The programmable valves and system identification process enable us to precisely control the size and stiffness, which results in a simulator that can realistically generate many different diseases without replacing anything. The three most common abnormalities in a prostate are selected for demonstration, and multiple progressive stages of each abnormality are carefully designed based on medical data. A human perception experiment is performed by actual medical professionals and confirms that our simulator exhibits higher realism and usability than do the conventional simulators.

1. Introduction

Prostate cancer is the second leading cancer and the third leading cause of death in the United States. The American Cancer Society predicted approximately 164,690 new cases and 29,430 deaths in 2018, which is gradual increment from last year by 3330 new cases and 2700 deaths [1]. In addition, in the native Asian population, a gradual increment in prostate cancer has been observed [2–4], and less-critical but equally painful prostate diseases, e.g., benign prostatic hyperplasia (BPH) and prostatitis, are becoming more popular around the world.

Early-stage prostate malignancy can be detected by routine screening [5], which enables the patient to avoid painful living. Two types of screening methods are available for early-stage prostate cancer: testing the prostate-specific antigen (PSA) in the blood of the male patient, which is no longer recommended due to high rates of over-diagnosis [6]. In addition, the study provides evidence that PSA screening is not recommended for age from 55 to 69 [7]. Another way is to directly palpating the prostate gland through the patient rectum using the index finger of

the physician, which is known as digital rectal examination (DRE) [5]. This method is used to discover micro-, meso-, and macroscopic abnormalities on and in the patient's prostate by probing it.

The prostate is a small gland in the male body that is expected to change in size, shape, texture, and stiffness on the occurrence of disease [8]. Different diseases have different haptical symptoms in the prostate; for example, prostate cancer exhibits a stiffer nodule in the gland, whereas BPH shows an enlargement in size at one or multiple places. In addition, these changes are diverse for every individual and the stages of the disease. Haptically distinguishing them is the main goal of the DRE.

It is well known that for a haptic-dominant task such as DRE, a simulation-based training environment significantly helps learn about and objectively evaluate the necessary sensorimotor skills while preserving the patient's safety [9,10]. Also, the realism of medical simulators has physical and virtual extremes on the physical-virtual spectrum [11]. To train for the DRE skills, medical schools use a traditional soft-torso mannequin with an embedded and replaceable static rectal and prostate mock-up. This simple training setup (physical simulator) is very

^{*} Corresponding author.

E-mail addresses: aishtalhan@gmail.com (A. Talhan), jeon@khu.ac.kr (S. Jeon).

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efficient in the initial learning stage. However, the static mock-up has a fixed number of abnormality demonstrations, which prohibits it from being used throughout the training practice [12].

One of the solutions is VR-based DRE simulators, where various types of symptoms can be ideally synthesized. However, in practice, many VR-based simulators lack haptic realism because of the complexity of the haptic feedback during the procedure [12]. In particular, during the DRE procedure, an index finger is inserted into the rectum and palpates a minimum area of the prostate with the fingertip. Inhomogeneous soft tissues surround the entire index finger, and for the diagnosis, the physician should rely on very subtle feedback at the fingertip from the prostate. This incredibly rich haptic feedback is difficult to generate using conventional pure VR-based haptic interfaces. Therefore, many VR simulators have omitted or simplified the fidelity and completeness of the haptic feedback, particularly for the surrounding tissues, and have focused only on the fingertip feedback, which also sacrifices the realism of the simulator.

This paper presents an effective alternative: a haptic augmented/mixed-reality-based palpation simulator, where real and synthetic haptic feedback are adequately mixed to create the desired complex haptic feedback [13]. Our approach is that the surrounding tissues that are not subject to change are supplied by a static tissue-like torso mock-up, whereas the core feedback, which must be carefully configured, adjusted, and even synthesized, i.e., the prostate, is generated by a property-controllable prostate-like-shaped end-effector embedded in the mock-up. For the end-effector, multiple air cells filled with particles are embedded in a silicone prostate-shaped mock-up. By systematically blowing up and vacuuming the cells with an external air source, the size and stiffness of different parts of the prostate mock-up can be controlled, so that various effects of symptoms can be augmented. This end-effector is placed in the torso mock-up, which a practitioner palpates through the mock-up rectal (see Fig. 1). Overall, this approach can provide the real-life-like anatomy with natural kinesthetic and tactile feedback and is reconfigurable for multiple scenarios.

This paper is based on our previous publication on this topic, where the basic idea and prototype were introduced [14]. The present paper first explores the literature overview in physical to virtual DRE simulators. The paper then moves to explaining the detailed hardware design and architecture for controlling stiffness and size of the end-effector (pneumatic bladder). We then establish rendering algorithms that enable the realistic reproduction of multiple symptoms of representative prostate diseases. The proposed simulator is assessed through medical professionals-involved realism and usability tests that compares our

system with four commercial DRE simulators. Finally, the results and comments from the medical experts are discussed.

2. Related work

Many static physical DRE simulators are commercially available and used in medical schools for medical students and professionals. For example, the Prostate Examination Simulator by Life/Form consists of four separate prostate glands with the lower torso, which represent one benign gland and three stages of prostatic carcinoma in varying degrees of development [15]. Similarly, the rectal and prostate examination trainer consists of five interchangeable prostates and two perineum [16]. In addition, there are many products on the market, e.g., [17–19]. However, these simulators only provide unique disease anatomy with a small and fixed number of scenarios, which is insufficient for complete training.

Some researchers focused on the educational aspect of simulators. Balkissoon et al. embedded force sensors into a partial mannequin in order to track the examination performance of trainees [20]. The idea was further extended to a concept of virtual patient, who could be interviewed and diagnosed by a physician (trainee) before and after DRE with a simple conversation [21]. However, the variety of presentable was limited as other static-mock-up-based examples.

The initial design of the VR-based prostate palpation system was reported in Ref. [22] with the use of the PHANTOM haptic interface. In Refs. [23] and [24], a similar VR-based system based on the PHANTOM interface with the SGI workstation was presented. Behind a motion-restricting board, a haptic interface with a finger attachment was placed, where the trainee can insert the index finger for the DRE experience. In this system, only prostate cancer abnormalities verified using four models. More recently, Granados et al. presented a real-time tissue deformation algorithm, thimble-based shear force haptic feedback hardware, and analysis tool. The simulator consisted of a haptic device and a bespoke thimble end-effector for palpation skill training [25,26].

Similar to our approach, there are many attempts to apply the concept of mixed or augmented simulation in DRE training. Rigsbee et al. initially suggested the ideas of including design characteristics such as a free-standing torso structure and reconfigurable scenarios with performance evaluation feedback to a trainee [27]. This idea was realized in the Virginia prostate examination simulator, where the system used computer control over the flow of water pressure to inflate the balloon, which provided the effect of various diseases in Refs. [28,29]. The system could provide multiple and reconfigurable scenarios by replacing the pre-made

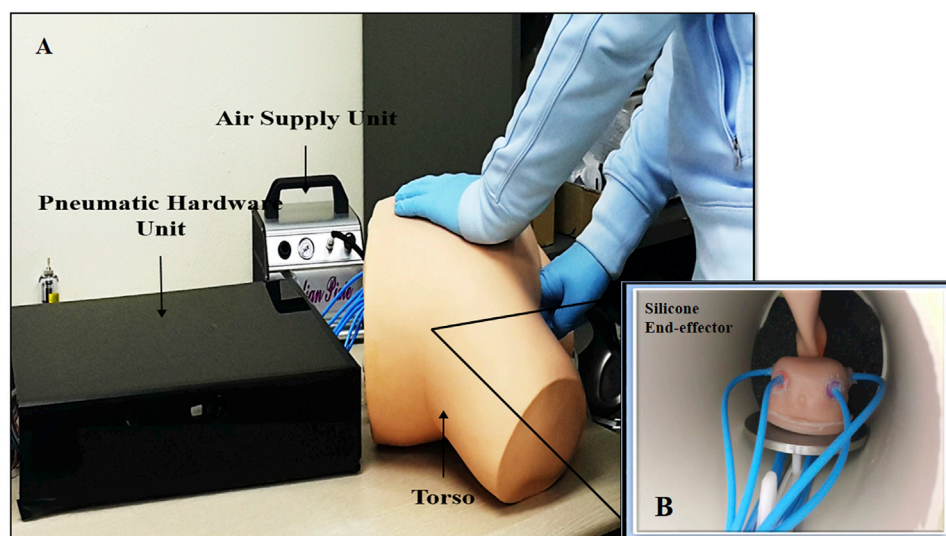


Fig. 1. Overall system components: (A) the system components during palpation, (B) silicone end-effector inside the torso.

programmable prostate model. The system could provide multiple and reconfigurable scenarios by replacing the pre-made programmable prostate model. However, due to limited flexibility of a single instrumented prostate model, the prostate model should frequently be changed for practicing different abnormalities, which may lead to reducing the usability and increment of system bulkiness.

In addition to the human body, there have been attempts to apply the mixed/augmented simulation concept in veterinary medicine. Baillie et al. developed a bovine rectal palpation simulator based on a fiberglass cow model as a life-like anatomy and a PHANToM haptic interface for the feedback [30]. Rissanen et al. reported a study on VR annotation for evaluation in DRE techniques [31].

All of the aforementioned DRE simulators demonstrate a particular illness of the prostate gland with fixed numbers of scenarios. Therefore, in this paper, we suggest a DRE simulator that can generate a reconfigurable, large number of different scenarios for various prostate illnesses (including BPH, prostatitis, and cancer) in a single prostate-shaped end-effector. In addition, the proposed simulator provides realism and high fidelity in scenarios.

3. End-effector design and controlling

Fig. 1 shows the complete system components. A human torso mock-up with a hollow inside embeds a property-changing end-effector. The end-effector is specially manufactured to have multiple air chambers connected to external valves and air sources, which can be blown up for size control and vacuumed with particles for stiffness control (particle jamming effect). The next two sections present the design and control of this pneumatic bladder (silicone prostate).

3.1. End-effector design

A prostate-shaped end-effector was fabricated with Eco-flex (00–30) silicone rubber (Smooth-on, Inc.) and a prostate mold. The Eco-flex silicone has 100% modulus of 10 psi and a 900% elongation at break, which makes it an extremely flexible and robust tissue-like surface [32]. These characteristics of Eco-Flex 00–30 make it perfect to use with pneumatic. A layered structure is constructed inside the end-effector, as shown in Fig. 2a.

The actual prostate gland consists of a median lobe and two lateral lobes. These lobes are touchable during palpation, so mimicking these portions is important. Therefore, layer 1 (uppermost) is fabricated with

Jeltrate Alginate impression material to mimic the surface of the prostate and a mold of a life-form healthy prostate gland frame. The first layer of the end-effector is made of approximately 15 g of silicone composite. Layer 2 consists of four air cells, two for each side of the left and right lobes. The sizes of the cell are approximate 11 mm in height and 18 mm in width. This size is determined based on the actual lobe size and required space for the pneumatic actuation. Particles are filled in these cells to demonstrate the particle jamming effect. In this layer, the air outlets are designed on the sides. Fig. 2b illustrates the location of the cells from the top-view with naming conventions.

Layer 3 is a six-mm-thick silicone layer that covers layers 2 and 4. The fourth layer has three cylindrical air cells with 5 mm thickness, and the silicone layer wall is present between the cells. The cells also contain particles. The air outlets are designed towards the bottom. This layer enables us to control the tenderness in the middle height of the prostate and the overall volume of the gland. The fifth layer covers the cells in layer 4. During the fabrication of the fifth layer, the cotton fabric layer is embedded in the silicone composition to restrict the inflation towards the bottom. In addition, the cotton fabric filter is placed at the air outlet to avoid the leaking of the particles.

To decide the silicone material for the main prostate, we tested two silicone end-effectors with various response characteristics: one was manufactured with Eco-Flex 00–30, and the other was made with Eco-Flex 00–20 with a softer response. Both end-effectors were shown to two medical professionals to ensure the haptic response in comparison with the real prostate. Both medical professionals (Dr. S. Parve (M.D.), personal interview, Jun 1, 2016, and Dr. P. Chide (M.D.), personal interview, Jun 7, 2016) confirmed that the end-effector made of Eco-Flex 00–30 had a more accurate haptic response than that of a real prostate gland. Thus, the Eco-Flex 00–30 end-effector was confirmed to be a potential prostate end-effector for the proposed simulator. Further, we conducted an exploratory study on the end-effector manufactured with the Eco-Flex 00–30 composition.

3.2. Pneumatic controlling

Fig. 3 demonstrates the block diagram of our pneumatic control system. The air supply to the cells of the end-effector is controlled through an array of proportional air control valves (ET-PM-05-25-AO; Clippard Instrument Lab. Inc., USA). This valve provides a positive air pressure to expand the cells. By controlling the duration of the blowing, we can produce seven stages of lumpy tissue from extremely small to very

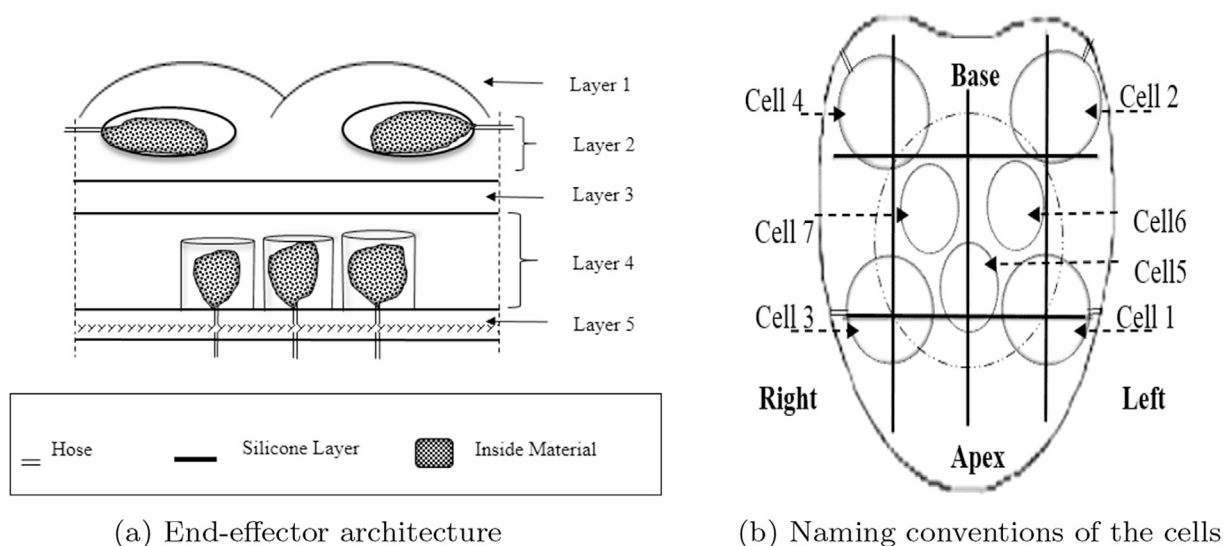


Fig. 2. Illustrations of the layered structure of the silicone end-effector. (a) Design of the layered architecture of the silicone end-effector; (b) overall hollow cell structure from the top-view with the cell's naming conventions.

large, as shown in Fig. 4. In our implementation, each stage of cell size differs in air open duration by 100 and 200 ms for the upper and lower cells, respectively.

The vacuum unit releases air from the cells and creates the particle-jamming effect. Two-way vacuum valves (V2A05-AW1-T1; MEAD Fluid Dynamics Inc., Chicago, IL, USA) are arranged in an array of air vacuum pumps and create negative air pressure. The negative pressure (−6 kpa) generates a strong binding among the particles, which stiffens the overall matter, as shown in Fig. 4 c). This particle jamming effect was used in haptics in several studies [33,34]. For the particle material, we use fine sand. Each cell has approximately 2 g of particles, which is sufficiently small that it cannot be perceived in normal conditions. These particles are embedded in a balloon in each cell.

The positive and negative air pressures are controlled by a software unit designed in Visual C++, and the valves communicate with the software using a data acquisition card (NI PCI- 6220; National Instruments Corporation, USA) with a multiple-relay board using SONGLE SRD relays.

4. Rendering symptoms

To render different diseases, we follow systematic steps to control the system. First, the relating functions from the valves' command parameters, e.g., the duration of opening, to the physical parameters, e.g., the size and stiffness of each cell, are empirically measured and modeled. Then, physical parameters for various symptoms are gathered from the literature and collected from medical mock-ups. Finally, the command parameters for a specific symptom are found from the modeled function. Some physical parameters from the literature cannot be directly applicable, so we manually tuned the command parameters based on the feedback of the mock-ups.

In section 5, the overall fidelity of the control is evaluated in a realism test with actual physicians.

4.1. Characterizing volume changes

In the first test, we characterize the relationship between the duration of positive pressure valves and the size change. For each cell, we measured the height change with respect to the change in the duration of positive air pressure.

The measurement was performed using a Vernier caliper, which was attached downward to a custom-made stand at a fixed height to avoid errors. The caliper's depth tool-tip was manually adjusted to measure the changes in the height of the cell at different air valve opening durations (100 ms step for the upper cells and 200 ms step for the lower cells). The seven cells are measured in Fig. 5. The idle level (L0) indicates the no-air actuation, and the other eight air levels (L1–L8) show the different durations of opening. Three measurements were averaged for each final measurement.

For cells 1 and 4, the height is 15 mm and 17 mm, respectively. Similarly, the approximate height ranges from 0 to 11 mm for cells 2 and 4. The lower layer cells (cells 5, 6, and 7) exhibit a change in height up to 11 mm, where there is less variation in height than observed in the upper layer cells. Additionally, the vacuuming control for the particle jamming effect shows negligible changes in height, which indicates that the size or height of the cell can be independently controlled from the stiffness.

4.2. Characterizing stiffness changes

The second characterization was performed to control the stiffness using the particle jamming effect. To measure the stiffness, i.e., the force relative to displacement changes, we used a force sensor for the force measurements and a haptic device for the displacement measurements. A force sensor (Nano 17; ATI Automation, INC., NC., USA) was attached to the PHANToM haptic interface (Geomagic, model premium 1.5) with a hemispherical metallic tooltip as a contactor. The tooltip manually pushed on each cell from directly above each cell while vacuuming and positive pressuring (ten levels: idle, eight positive pressures, and one

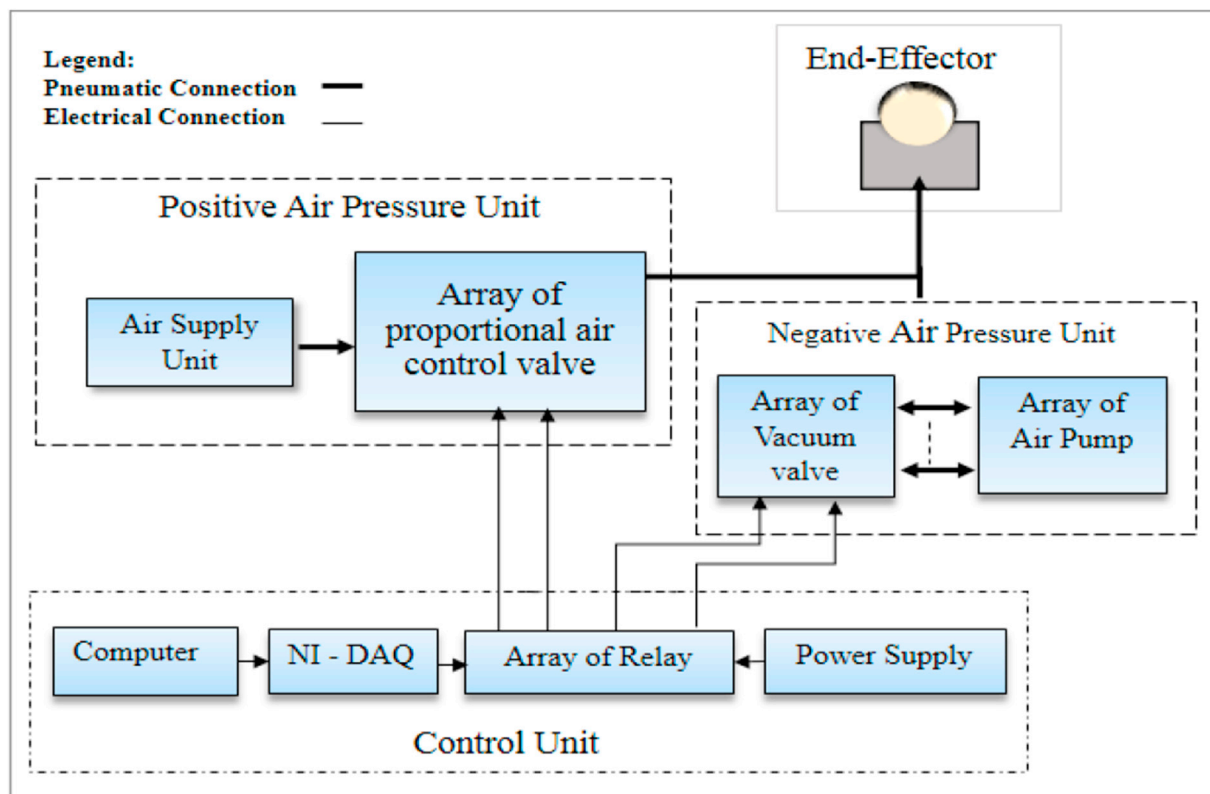


Fig. 3. Block diagram of working model of pneumatic system architecture.

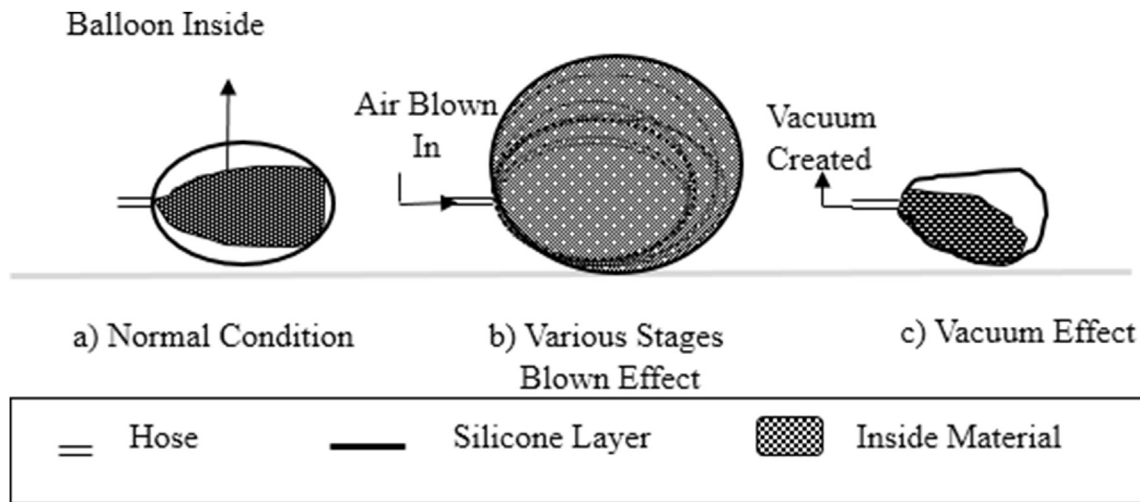


Fig. 4. Inside-air effect in a single silicone cell.

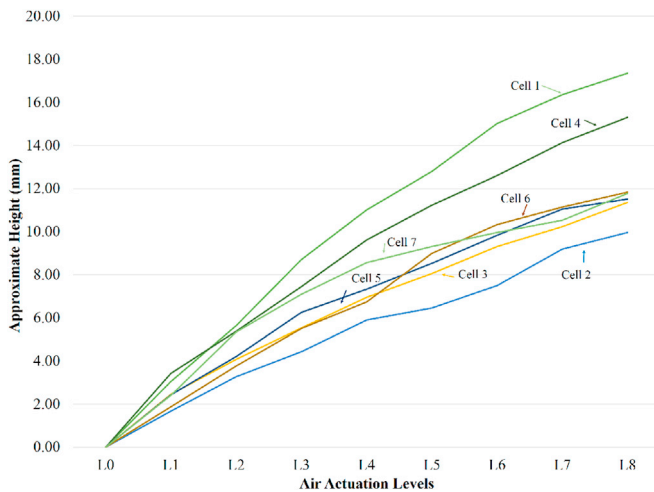


Fig. 5. Positive pressure duration vs. height change for each cell.

vacuuming). The force and position samplings were performed at 1 kHz.

As an example, the force-displacement curves for cells 1 and 6 are plotted in Fig. 6; the representative stiffness value of each cell and the control level are shown in Fig. 7. The representative stiffness values are calculated by averaging the stiffness along the entire measurement in a condition.

The approximated stiffness values are driven from the force-displacement curves of each cell and air pressure condition. The results show that for the upper layer, averaged approximated stiffness ranges from 0.8017 N/mm to 1.532 N/mm, and that for lower layer are 1.58 N/mm to 1.89 N/mm. Therefore, this confirms that our proposed layers architecture is effective to increase in the stiffness range.

As expected, the particle jamming effect is visible for the upper cells (see the increased stiffness values for the vacuuming condition for cells 1, 2, 3, and 4 in Fig. 7 (a)). However, this effect is notably weak for the lower layer cells. This is because the thick silicone layer above the cells compensates for the effect of the actuation. Thus, in our rendering algorithm, we apply only the particle jamming control to the upper cells.

Another notable characteristic from the results is that for the upper cells, although the stiffness decreases slightly during the positive pressure compared with the stiffness of the idle condition (see Fig. 7 (a)), the amount of this decrease is constant for different positive pressures. This result indicates that the positive pressure does not affect the stiffness of the cells once it is pressurized; the stiffness of the cells can be controlled almost independently of the cell size, and vice versa.

4.3. Size and stiffness control

From the stiffness and size characterization data, we introduce a rendering algorithm for our simulator. After the sizes, locations, and stiffness values of multiple abnormalities are provided from medical data (refer to Section 4.4 for these medical data), the expansion duration for the target size is selected from the inverse of Fig. 5 for each cell. If a target abnormality requires stiffening the cells, e.g., a stiffened tumor, the corresponding cells are vacuumed.

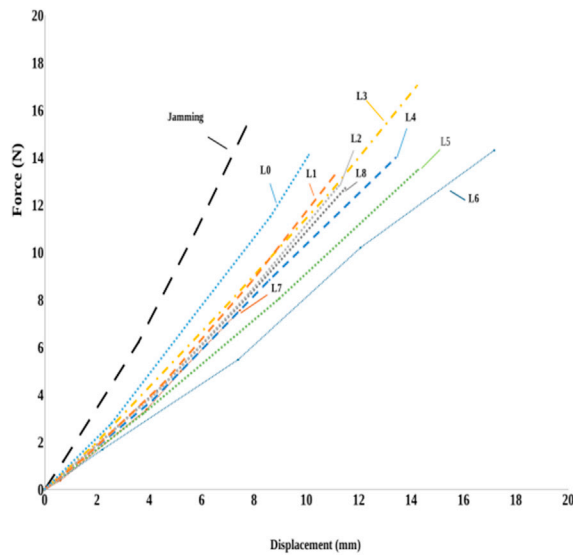
One limitation of the current implementation is that the inflation and vacuuming cannot be simultaneously performed in a cell, so an abnormality that requires both inflation and stiffening of a cell cannot be rendered. However, an alternative is to use the multiple-layered design of the current system; both inflation and stiffening effect can be generated by inflating the lower layer cells while vacuuming the upper layer cells. The feasibility of this approach is confirmed in Section 5. Another alternative is to stiffen one cell and inflate the surrounding cells to render the condition.

4.4. Rendering diseases

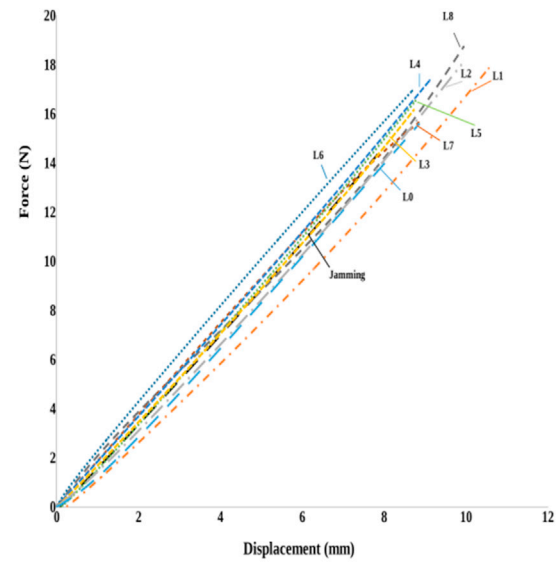
In this section, the physical characteristics of various prostate diseases are gathered from the literature and actual measurement experiments to render realistic symptoms in our simulator. The three most common diseases for a prostate gland are prostate cancer, BPH, and prostatitis. These diseases also have different stages with different physical characteristics [39].

Prostate cancer is associated with an irregularly firm or hard prostate nodule during a rectal examination. To describe different stages of prostate cancer, doctors use the tumor (T), node (N), and metastasis (M) staging system (TNM system). The first four columns of Table 1 provide a systematic categorization of the healthy prostate and cancer diseases using this TNM system. The stages of the cancer development are described by the system based on the size, position, and quantity of the tumor (T), tumor in lymph node (N), and metastasis cancer (M). T, N, or M with a letter (X) or a number (0–4) represents the severity. An alphabet letter (a, b, and c) describes a substage of cancer severity [35–38]. The last three columns represent the control parameter to actuate the specific abnormality in the pneumatic bladder. Accordingly, the control parameters are set to actuate various effects in the upper and lower cells with different combinations of the position and size of air actuation levels (L1–L8). For example, to render the stage IIA–T2b cancer, one or two upper cells are stiffened, and one or two lower cells are inflated at L2, L3, or L4 level.

BPH is associated with the hyperplastic process of tissues, which

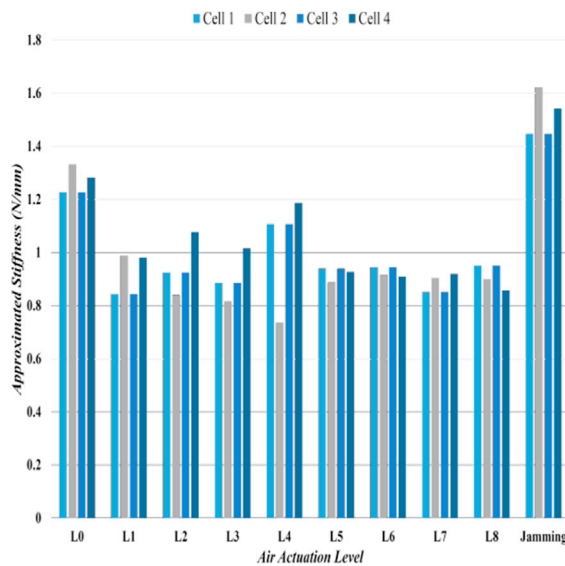


(a) Cell 1

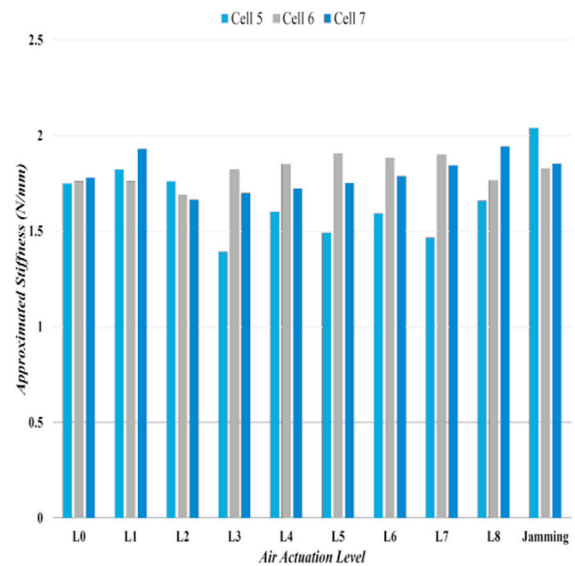


(b) Cell 6

Fig. 6. Representation of the force-displacement graph of upper layer cell 1 and lower layer cell 6.



(a) Upper Cells 1, 2, 3, and 4



(b) Lower Cells 5, 6, and 7

Fig. 7. Approximated stiffness of the end-effector made from Eco-flex 00–30; (a) upper layer; (b) Shows the lower layer cells. In the air actuation stages, 'L0' is the normal level, and L1–L8 are the increasing levels of air. 'Jamming' is the particle jamming effect.

results in the growth of glandular-epithelial and stromal/muscle tissue and eventually produces prostate enlargement. In addition, the distinction between the right and left lobes of the prostate becomes blurred with the severity of disease [41,42,45,46]. The four stages (I–IV) in Table 2 describes the severity of BPH. The last four columns represent the control parameters for each stage. Since it does not come with a stiffened prostate, both the upper and lower cells are inflated. The combinations of different air actuation levels (L1–L8), positions, and numbers represent the severity of disease in each stage.

Prostatitis is an infection of bacteria in the prostate. Because of this infection, the prostate becomes both enlarged and stiffened, so it shows a combined effect from cancer and BPH. Based on [47,48], there are four stages, depending on the degrees of tenderness, swell, and induration of the prostate, as summarized in Table 3. While rendering the prostatitis,

vacuuming (stiff) and inflation effects (L1–L8) were performed in the upper cell, where the samples with only inflation (L1–L8) were applied to the lower cells. Various control combinations of the air actuation stages and numbers of cells provided different severities on the diseases as shown in Table 3.

Our simulator renders the diseases listed in this section based on the control parameter combinations suggested in the tables. The diseases and stages in this section cover almost every abnormality that can be encountered in the field, which our flexible simulator can render without replacing any hardware configuration. This characteristic is one of the strongest points of our approach. In the next section, we assess our approach in terms of this usability aspect and the quality and realism of the rendering results.

Table 1

Prostate cancer severity stages and the control parameters for each stage based on [15–17,35–38].

* T = Tumor, N = Node, M = Metastasis, NA = No Actuation, Solidify = Particle Jamming actuation, Lx = Number of levels of air actuation, where ● represents position of upper and ● lower layer cells.

Diseases	Stages and Grades				Control Parameters for Abnormality Actuation			
	Stages	T*	N*	M*	Position	Upper Cells*	Lower Cells*	
Normal (healthy) Prostate	0	TX or T0	N0	M0	Healthy Prostate		NA	NA
Cancer	I	T1a, T1b, or T1C	N0	M0	One cell at one lobe		Solidify	L1
		T2a						
		Any T1 or T2a						
	IIA	T1a, T1b, or T1C	N0	M0	One cell at one lobe		Solidify	L2, L3, or L4
		T2a			One-half of one lobe			
		T2b			More than one-half of one lobe			
	IIB	T2c Any T1 or T2	N0	M0	Both lobes of prostate		Solidify	L2, L3, or L4
	III	T3a	N0	M0	One side and tissue just outside		Solidify	L2, L3, L4, or L5
		T3b			Tumor may grow beyond the prostate			
	IV	T4 Any T	N0 N1 Any N	M0 M1	Tumors may spread beyond the prostate		Solidify	L3, L4, L5, L6, L7, or L8

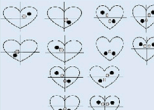
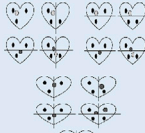
5. Evaluation by medical professionals

The augmented simulation has two merits: better realism than the pure VR simulators and better flexibility than the static mock-up-based

simulators. In this section, we evaluate our system in both aspects in two consecutive user experiments. The first experiment evaluates the fidelity of the haptic feedback of our simulator by showing that it was as realistic as the actual DRE experience or better than commercially

Table 2

BPH stages and the control parameters for each stage based on [16,17,40–44]. *Lx = Number of levels of air actuation, where ● represents position of upper and ● lower layer cells.

Diseases	Stages		Control Parameters for Abnormality Actuation			
			Position		Upper Cells*	Lower Cells*
BPH	I	The presence of enlarged prostate but does not provokes the bladder triggering a voiding response than a normal individual.	One cell at one lobe		L1	L1
	II	The presence of enlargement provokes the bladder triggering a voiding response than normal individual.	One cell at a lobe		L2 or L3	L2 or L3
	III	The occurrence of enlargement creates the common obstruction symptoms. Predominance of irritative should suggest voiding dysfunction.	More than one-half of a lobe		I3, I4, or L5	I3, I4, or L5
	IV	Due to extreme enlargement patients will have complications such as retention of urine, bladder stones, and unary track infection (UTI).	More than one-half of a lobe and spread		L4, L5, L6, L7, or L8	L4, L5, L6, L7, or L8

available static simulators, and the second experiment assessed the system in terms of usability and flexibility in comparison with the existing static simulators.

5.1. Realism experiment

To investigate the realism of the proposed simulator, a comparative perceptual experiment has performed with five medical professionals who have sufficient experience with the DRE procedure. In the experiment, the realism was assessed by directly comparing the system with four commercial static DRE simulators.

5.1.1. Experimental setup and method

5.1.1.1. Participants. Five volunteers (ages 25–36, all females), two experienced physicians and three nurses with trained DRE were recruited. All of them had completed at least ten DRE procedures before the study (mean number of procedures = 16.6, SD = 16.91). Three members had never tried any simulator for training themselves. Written informed consent was obtained from the participants. The participants were compensated with 30,000 Korean Won (equivalent to 27 US Dollars) for their time (approximately 1.5 h for both experiments).

5.1.1.2. Setup and procedure. In the study, four different commercial static mock-up-based simulators were used for comparison: BPH100 BPHtrainer (Pharmabotics Ltd.) [44], Anatomical 3000 (GPI anatomical Ltd.) [17] without a rectal wall, prostate examination simulator LF00901U (Life/form Ltd.) [15], and Clinical Prostate/Rectal Examination R10081 (FS Anatomic) [16]. For convenience, the alphabetical order was given as A to D, respectively. The identities of the individual simulators were not disclosed to the participants until they finished the experiment. In addition, the presentation order of the simulators was randomized across participants.

On arriving, the participants filled out the consent form and received an explanation regarding the experiment procedure. Then, the participants were blindfolded to avoid biased judgments and wore gloves with lubricants to perform the procedure. Then, the five simulators (four commercial simulators and one proposed) were sequentially presented to the participants for their investigation.

When one of the simulators was presented, a trial began, and the experimenter dragged the index finger of the participant towards the

prostate gland for the palpation. The participants were asked to freely explore the gland. In the trial, 8 questions were verbally asked and verbally answered by the participants on a 7-point Likert scale. After five trials, written comments were also gathered. The entire procedure took approximately 45 min.

The questions in this study are summarized in Table 4. The first question set (N1–N4) was to access the fidelity of the prostate model, and the second question set (A1–A3) evaluated the realism of the rendered abnormalities. The prostate end-effector was placed in the torso of the mock-up, except for N1, for which the prostate model was directly exposed to the participants. The final question (C1) was used for the overall simulation fidelity.

5.1.1.3. Presented abnormalities. For questions A1 to A3, the abnormalities were presented to the participants. For testing, we selected four representative abnormalities from Tables 1 and 2: prostate cancer at stage I, prostate cancer at stage IV, BPH at stage III, and BPH at stage IV. These abnormalities were selected because most simulators can simulate them. The results of the realism experiment are explored in the section 6.1.

5.2. System design and usability test

We conducted an additional study to evaluate the system in design and usability perspective because one of the benefits of using a mixed simulation design is its relatively higher flexibility and usability. The experimental procedure was extremely similar to that of experiment 1. The same four commercial simulators were compared with our system through predefined questions related to the design factors and usability.

5.2.1. Experimental design

In this experiment, the participants were instructed to freely explore (both visually and haptically) the five systems with no restriction, so they inspected all functionalities and design parameters of each system. This time, they were not blindfolded. After exploring each system, the participants were asked to verbally answer the question related to the system design and usability, as shown in Table 5.

In particular, the first two questions were dedicated to accessing the overall effectiveness of the simulator, i.e., the sense of being situated in the actual DRE room or presence, which were taken and modified from the well-established presence questionnaire [49]. The first question

Table 3

Prostatitis stages and the control parameters for each stage based on [17,47,48]. *Solidify = Particle Jamming actuation, Lx = Number of levels of air actuation, where • represents position of upper and • lower layer cells.

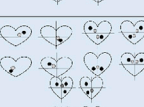
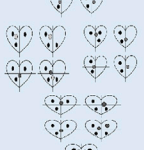
Diseases	Stages	Control Parameters for Abnormality Actuation			
		Position		Upper Cells*	Lower Cells*
Prostatitis	I Acute bacterial prostatitis (ABP): The prostate may feel abscess which includes swelling.	One cell at one lobe		Solidify Or L1	L1
	II Chronic bacterial prostatitis (CBP): prostate may feel normal (rarely), boggy, or very tender fully indurated.	One cell at one lobe		Solidify, L2, or L3	L2 or L3
	III Chronic a bacterial prostatitis: IIIA: Inflammatory IIIB: Non-inflammatory.	More than one-half of one lobe		Solidify, L3, L4, or L5	L3, L4, or L5
	IV Asymptomatic inflammatory prostatitis	More than one-half of and spread		Solidify, L4, L5, L6, L7, or L8	L4, L5, L6, L7, or L8

Table 4

Description of each factor evaluated by the medical professionals in the realism test.

Main Factors	Sub factors	Question
Prostate without abnormality effects	N1: Bare prostate without torso	How natural did your interaction with the prostate seem compared with the real prostate?
	N2: Size of prostate in a torso	How natural did you feel the prostate size during palpation compared with the real prostate?
	N3: Stiffness of the prostate in a torso	How natural did you feel the prostate hardness during palpation compared with the real prostate?
	N4: Overall prostate fidelity	How natural did your interaction with the prostate seem compared with the real prostate?
Prostate with abnormality effects	A1: Size of abnormalities	How natural did you feel the abnormality size during the DRE compared to the real DRE?
	A2: Stiffness of abnormalities	How natural did you feel the abnormality hardness during the DRE compared to the real DRE?
	A3: Overall abnormalities fidelity	How natural did your interaction with the abnormality seem feel compared to the real DRE?
	C1: Overall simulator fidelity	How similar is the simulation output to the real one?
Fidelity of complete environment (prostate + torso)		

measures the effectiveness of the overall diseases rendered by the simulators, and the second asks about the effectiveness of the surrounding rectal wall. The third question is about the flexibility of the system usage, which is one of the important factors for the overall usability. The final question asks about the final user experience after using the system.

The same physician participants performed this experiment. The participants explored the individual simulator in a random order. The study took approximately 25 min. The results of system design and usability test are referred in section 6.2.

6. Results

6.1. Realism

Fig. 8 shows the averaged ratings of the questions about the realism of the normal prostate (N1–N4). For all questions, our simulator received higher ratings than did the other simulators. The additional statistical analysis (one-way ANOVA test) indicates that only the score for our simulator for question N1 is statistically different from others ($F = 4.926$, $p = 0.0062$). Also, all subjects rated with higher realism ($M = 6/7$, $SD = 0.70$, $P. Var. = 0.39$). For question N2, average perception of proposed simulator E ($M = 5.45/7$, $SD = 1.40$, $P. Var. = 1.02$) which is slightly higher than simulator B ($M = 5.2/7$, $SD = 0.86$, $P. Var. = 0.748$) and D ($M = 5.2/7$, $SD = 1.09$, $P. Var. = 0.98$). Among all simulators, subjects responses to questions N3 ($M = 5.8/7$, $SD = 0.836$, $P. Var. = 0.55$) and N4 ($M = 5.6/7$, $SD = 0.95$, $P. Var. = 0.64$) showed higher realism to the simulator E. The results indicate that the proposed system provides a relatively higher or at least comparable level of realism to the commercialized physical simulators.

The results of the questions for the realism of abnormalities (A1–A3) are shown in Fig. 9. Across the factors, our system has higher or comparable average ratings to the other simulators. Specifically, for question A1, simulator E ($M = 5.6/7$, $SD = 0.49$, $P. Var. = 0.24$) and C ($M = 5.6/7$, $SD = 0.49$, $P. Var. = 1.35$) showed similar realism which is higher than the other commercial simulators. Also, in response to question A2 and A3 all subjects perceived high realism in our simulator E ($M = 5.8/7$,

$SD = 0.83$, $P. Var. = 0.55$). However, among all simulator the realism of abnormality stiffness has scored the approximately 60–80%.

In addition, the absolute value of the scores is considerably high for all questions (approximately 81%). Although the ANOVA test did not give a significance value, these results indicate that the haptic fidelity of the rendered abnormalities using our system is as high as or even higher than commercialized simulators, which have been used in the field.

The final question was about the overall fidelity (C1) of the simulator. Fig. 10 shows the averaged results. Again, our simulator scored higher ($M = 5.8/7$, $SD = 0.44$, $P. Var. = 0.16$) than the others did (no statistical significance), which indicates that the final fidelity of the feedback is as high as that of the other simulators.

One meaningful observation from this result is that the simulator E (proposed) and simulator C ($M = 5.2/7$, $SD = 0.44$, $P. Var. = 0.16$), which share the same torso mock-up, with only the prostate part being changed inside, had different results. Thus, the augmented effects of the proposed architecture of the end-effector are reasonably effective, and the proposed prototypes exhibit enhanced perception compared to other simulators.

6.2. System design and usability

The experimental results are shown in Fig. 11. In every dependent variable, our simulator received the highest score. In particular, for factor U1 subjects rated that the diseases rendered by simulator E and D possess highest fidelity ($M = 5.8/7$, $SD = 0.54$, $P. Var. = 0.24$) among others. The system learnability U3 and overall user experience U4 scores of our system ($M = 6.4/7$, $SD = 0.54$, $P. Var. = 0.24$ and $M = 6.2/7$, $SD = 0.4$, $P. Var. = 0.16$, respectively) are statically significantly different from other values (F -value = 5.709, p -value = 0.0031 for the fidelity scores and F -value = 3.407, p -value = 0.0279 for the user experience scores), which indicates that the overall feeling of the diseases and rectal wall was very effective in our simulator. Moreover the flexibility and final user experience were very convincing.

In terms of flexibility, all participants remarked that the proposed simulator E was fast and easy to use and learn. Although simulator C ($M = 5.8/7$, $SD = 0.74$, $P. Var. = 0.56$) has a very intuitive and simple structure to have the prostate simulate different diseases (the second highest score), it suffers from physical replacement, which may be the reason for the lower score.

7. Discussion

As alluded in the introduction, a medical simulator can be entirely physical, purely virtual, or partially virtual [11]. The two extremes both have disadvantages; fully physical simulators usually provide a fixed number of scenarios and diseases [15,17,18,44], while pure virtual simulations suffer from low fidelity feedback (especially haptic feedback). This paper introduces a mixture of the two extreme, hoping to

Table 5

Description of the system design and usability test.

Factors	Description
U1: Flexibility and faithfulness of providing abnormalities	How faithful was the simulator to the action that you initiated?
U2: Rectal wall effectiveness	How convincing was your experience to sense the moving finger in the rectum compared to the real DRE?
U3: Learnability	How easily did the participants adjust to the DRE simulator environment?
U4: Overall system rating	How proficient in exploring and interacting with the environment did you feel at the end of the experience?

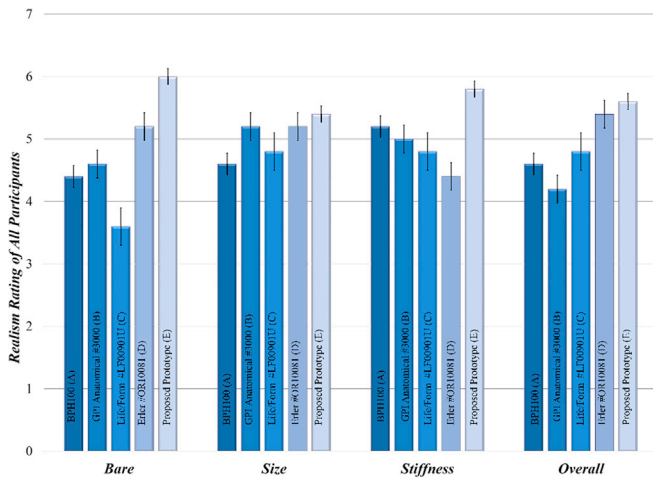


Fig. 8. Averaged realism ratings of the participants for the normal prostates.

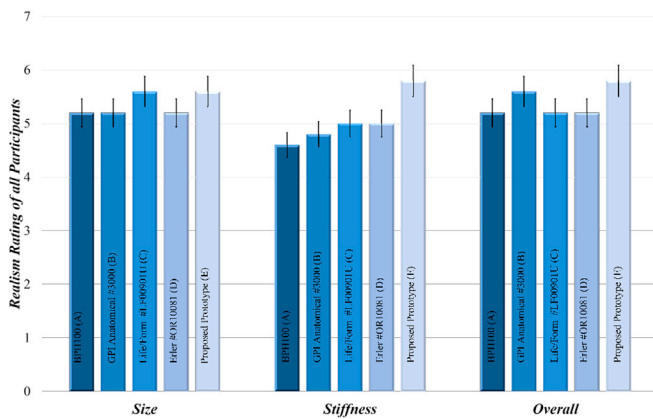


Fig. 9. Averaged realism ratings across the participants for abnormalities.

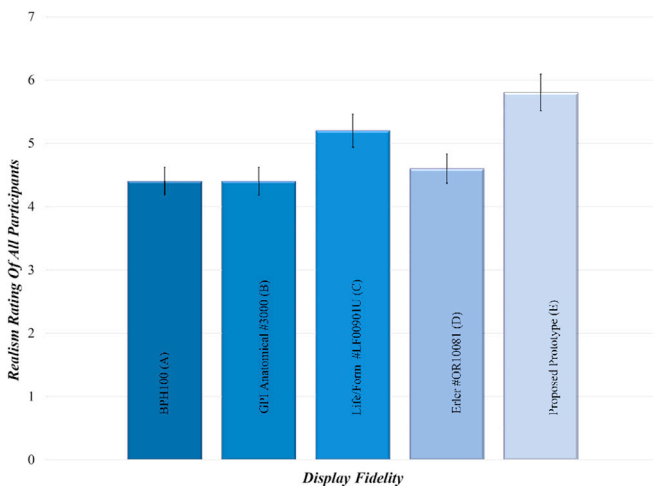


Fig. 10. The average ratings for the display fidelity.

complements each other's weak points, by mixing real and synthetic haptic feedback. Assuming that both flexibility and realism can be obtained through the concept of mixed simulation, we implement and evaluate our prototype simulator.

Through our medical professional-involved experiments, we proved that our new simulator indeed has benefits over commercialized

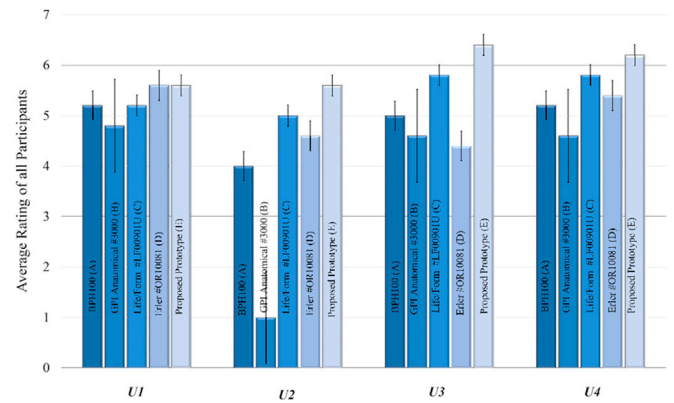


Fig. 11. Average ratings of all participants for the perception of the system design parameters and usability. The error intervals depict the 95% confidence level.

simulators with respect to the flexibility and realism. Our proposed simulator has acquired the highest scores among five commercial simulators in realism and usability. We also note that our new single, programmable, and flexible end-effector enables us not to physically replace anything to provide different symptoms including BPH, Prostatitis, and Cancer maladies on multiple stages. This is another point that contrasts our simulator with other mixed or virtual reality-based simulators. A large number of examples only provide a limited number of illnesses [23, 25] or needs to physically replace a part of mock-up that significantly reduces the usability of a system [15,17,18,28,44].

Finally, we also have fascinating subjective comments from the participants. One participant, who was critical in the assessment, gave a perfect score for our simulator on the stiffness of the prostate (N3). One participant commented that "Among all devices, the most profitable and effective one is definitely this system (proposed). When I put my finger into this simulator, I am capable of feeling some real cases that I experienced before in the hospital." Another considerable comment was "While moving the finger inside, I feel prostate moving inside, and this is just like real practice. Furthermore, while examining the abnormality realism (A3), "another participant mentioned that "I was able to determine, examine properly and differentiate the normal to different stages of prostate cancer, but the simulator E (proposed) was more closely related to the real case." and "The natural conditions are quite similar to the one provided." In addition, subjects mentioned that "The advantage of this system is that it is very similar to the real feeling. The stages of the prostate were quite perfectly detectable.", and "The control over diseases was determined, and it was closely related to natural examination of a human being." Another positive remark on the display fidelity of the proposed system is "A very outstanding system with the real environment." One participant also mentioned that "It was easy to detect different stages." While stating about the created environment, one of the participants commented that "The rectal wall and environment were similar to the examination of a human being; it is just clearer (in the proposed simulator) compared to other simulators."

In the second user experiment, the system design parameters and usability have shown equal and higher proficiency as compared to other commercial simulators. There are some points to be discussed. The disease correctness scores from all simulators are evenly high because the existing simulators focus mostly on recreating diseases. In addition, the same rectal walls were used for simulators C and E, and the scores for C and E on the rectal wall were similar. However, the final user experience score of our simulator is significantly higher (approximate 80% high reliability) than that of C (approximate 70% high reliability), which demonstrates that the system flexibility and usability have a significant role in the final user experience and that our approach, i.e., applying

haptic augmentation on the simulator to preserve the realism and increase flexibility, actually worked.

Also, we received several interesting and positive subjective comments from the participants. One participant stated that "I think students in university and healthcare providers in the hospital can use this simulator very easily." Similarly, other participants mentioned that "This simulator will help the medical students to examine easily and study the anatomy and abnormalities feel while a DRE is performed," and "This system can be added to medical colleges to teach medical students." Furthermore, one participant remarked "For the proposed simulator, it was quite easy to operate, and the environment was perfect; I quickly managed to understand different stages of prostate abnormality."

Additionally, a few suggestions were provided by the participants. One participant recommended including the surrounding structures, e.g., a bladder and other pelvic structures around the prostate, to increase the realism. Another comment was that the overall stiffness of the glands appeared slightly higher than the real case.

8. Conclusion

In this paper, we introduced a new prostate palpation simulator based on augmented haptics that can provide a high degree of realism and flexibility to simulate an DRE environment and result in an effective user experience for the training. The applications of pneumatic actuation, particle jamming, and the layered design of silicone bladders are presented to build a highly effective DRE simulator. Because of the layered structure and particle jamming, the size, stiffness, and location of multiple abnormalities can be systematically and independently controlled. The controllable stiffness and size range are sufficiently large to cover these actual abnormalities. The control parameters for each specific abnormality are listed, and the rendering algorithms are reported. In two different human perception studies with actual medical professionals, we compared our system with four existing commercial simulators and demonstrated the competence of our approach in terms of the realism, usability, and final quality of the user experience.

For future studies, we are now attempting to increase the number of pores to increase the spatial resolution of pores in the end-effector to go beyond the one-pore-for-one-abnormality. One significant direction is to increase resolution, the rendering of in-homogeneous cancer or macroscopic texture on lumps will be possible. We will also examine the effect of our approach on the actual training performance of the students using large-scale user studies with medical students. Despite the promising results, the physical robustness of the current implementation of end-effector is not at the level of practice use due to manual construction of pneumatic parts. We will focus on increasing reliability of our implementation by introducing high quality manufacture techniques.

We will also extend the concept of augmented feedback to other body part, e.g., needle insertion on lumbar puncture (LP) and emergency cardiopulmonary resuscitation (CPR). In order to facilitate the implementation process, we will also introduce an end-effector manufacturing guideline, generalized rendering algorithms, and tissue responses database.

Conflicts of interest

None Declared.

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Aishwari Talhan received a B.E. degree in information technology and an M.E. degree in embedded systems and computing from Nagpur University, MH, India, in 2005 and 2009, respectively. She also worked as a lecturer at Nagpur University and a software developer at Nagravision (formerly EnMedia Technologies), Bangalore, India, in 2012. She is currently pursuing a Ph.D. degree in computer science and engineering at Kyung Hee University, South Korea. Her research focuses on haptics, augmented reality environments and virtual reality environments for medical applications.

Seokhee Jeon received B.S. and Ph.D. degrees in computer science and engineering from Pohang University of Science and Technology (POSTECH) in 2003 and 2010, respectively. He was a postdoctoral research associate in the Computer Vision Laboratory at ETH Zurich. In 2012, he joined the Department of Computer Engineering at Kyung Hee University as an assistant professor. His research focuses on haptic rendering in an augmented reality environment, applications of haptics technology to medical training, and the usability of augmented reality applications.