Simulation-based prostate enucleation training: Initial experience using 3D-printed organ phantoms

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ABSTRACT

Introduction: Anatomical endoscopic enucleation of the prostate (AEEP) is an effective treatment for benign prostatic hyperplasia (BPH); however, there is controversy regarding the difficulty of learning such a technique. Simulation-based training can mimic real-life surgeries and help surgeons develop skills they can transfer to the operating room, thereby improving patient safety. This study aims to evaluate the validity of a novel organ phantom for use in AEEP simulation training.

Methods: Participants performed AEEP on organ phantom simulators during a masterclass using one of three energy modalities: holmium:YAG laser, thulium fiber laser, or bipolar energy. The organ phantom is composed of hydrogels and uses 3D molds to recreate prostatic tissue.

Participants completed a questionnaire assessing content validity, face validity, feasibility, and acceptability of using the prostate organ phantom.

Results: The novice group consisted of 13 urologists. The median number of AEEP previously performed was 0 (interquartile range [IQR] 0–2). Two experts in AEEP (surgeons having performed over 100 AEEP interventions) also participated. All participants agreed or strongly agreed that there is a role for simulators in AEEP training. Participants positively rated the overall operative experience (7.3/10). Morcellation (4.7/10) and hemostasis (3.1/10) were deemed the least realistic steps. All participants considered it feasible to incorporate this organ phantom in training programs and 92.9% agreed that it teaches skills transferrable to the operating room.

Conclusions: This study has established content and face validity for AEEP with three different energy sources for an organ phantom. Participants considered its use both feasible and appropriate for AEEP training purposes.

INTRODUCTION

Anatomical endoscopic enucleation of the prostate (AEEP) became part of the therapeutic arsenal for benign prostatic hyperplasia (BPH) about 20 years ago.[1,2] AEEP is associated with reduced blood loss and shorter hospital stay than transurethral resection of the prostate (TURP) and open simple prostatectomy (OSP), the current respective gold standards for prostate volumes <80cc and >80cc.[3,4] Although AEEP has been shown to have excellent perioperative and postoperative outcomes with outstanding long-term durability, its acceptance within the urologic community has been slow.[5–7] Some speculate that the reluctance to adopt AEEP may be due to a steep learning curve despite some studies suggesting a similar learning curve to TURP.[8] There is evidence that a surgeon must have completed between 30 and 50 procedures to carry out holmium AEEP safely and efficiently.[9–11] Other considerations affecting individual learning curve include surgeon BPH procedure volumes, endoscopic surgical skill set, and mentorship or fellowship-dedicated training.[12–14]

Simulation-based training has been widely proposed as a method for practicing surgeons to learn AEEP outside of fellowship tutelage.[15–17] Integrating simulators in surgical training allows urologists to safely develop the fine-motor skills required for AEEP without adverse consequences on real patients. Different simulators have been validated for AEEP. These simulators face similar challenges of creating a realistic experience mimicking real-life AEEP and helping surgeons develop skills they can transfer to the operating room.

Among existing AEEP simulators, a prostate bench model by Matsuda and colleagues has acceptable laser-tissue interaction, irrigation and bubbles, yet is limited by lack of bleeding or morcellation.[15,18] Virtual reality simulators can create reproducible surgical experiences without the need for external assessment, but trainees have to search elsewhere to gain

experience using real holmium lasers, irrigation fluid, or experience practicing effective laser safety protocol.[19] Human cadavers are another tool for surgical training in AEEP that can create a highly realistic operative experience, including equipment, set-up and morcellation, however they lack bleeding and their availability is limited.[20,21]

The novel prostate organ phantom engineered by the Max Planck Institute is composed of hydrogels and uses 3D moulds to recreate prostatic tissue and anatomy. While this model has been used successfully to teach TURP to urologists it has not yet been validated for AEEP surgical training.[22] As such, this study sought to validate the 3D prostate organ phantom for AEEP training among urologists with various levels of surgical experience. In the setting of a Masterclass, participants assessed the content validity, face validity, feasibility, and acceptability of incorporating this organ phantom into AEEP training.

METHODS

Study setting

An AEEP Masterclass was hosted by the Canadian Urological Association on November 23-24, 2021. Canadian urologists interested in learning AEEP were invited to participate in this accredited Masterclass. They participated in a series of lectures regarding AEEP including equipment, technique, pre- and post-operative care, outcomes and advanced technique. They then practiced directly on the organ phantom simulators under the supervision of AEEP experts that have performed at least 100 AEEP cases. Each trainee was given a 30-minute timeframe to operate and was mentored by one of the experts. The technique used was the en-bloc enucleation as described by Scoffone et al.[23] A video of the Masterclass with examples of technique can be found at https://player.vimeo.com/video/653401942.

Prostate organ phantom

To simulate the AEEP procedure, the "Endo Urology Trainer" was used, which is an organ phantom of the full urinary tract provided by the Max Planck Institute for Intelligent Systems and the University of Stuttgart. The 3D-printed organ phantoms are patented (EP 3251811 and WO 2017/207361) and recreate the internal anatomy of a bilobar prostate, including the verumontanum, and uses two different materials to clearly distinguish the central from peripheral zones of the prostate. Images of the organ phantom before and after complete enucleation are depicted in Figure 1. The prostate phantom is designed to simulate endourological resections with the 2μm lasers and bipolar electrocautery instruments.[22]

For the purposes of this study, surgeons were assigned one of three energy modalities – holmium:YAG laser, thulium fiber laser, or bipolar energy– and performed the enucleation with genuine instruments and irrigation on the organ phantoms. For AEEP performed using the holmium and thulium fiber lasers, the Shark® continuous irrigation resectoscope with 30° telescope, 26 Fr. outer sheath and 24 Fr. inner sheath with 600μm straight distal end and 24 Fr. obturator (Richard Wolf GmbH, Knittlingen, Germany) were used. The Shark® resectoscope for

bipolar enucleation had a 30° telescope, 26 Fr. outer sheath, 24 Fr. obturator and viewing obturator with a 24 Fr. bipolar enucleation electrode. The Piranha® morcellation system (Richard Wolf GmbH, Knittlingen, Germany) was used for all stations. Figure 2 shows the set-up of the simulator.

Questionnaire

Consent was obtained from each participant according to ethics board authorization (study number: 2022-10107). At the end of the second day of the Masterclass, participants completed a quantitative questionnaire evaluating the validity of the organ phantoms for use in AEEP training. The questionnaire used was a modified version of a validated questionnaire by Antunes et al.[15] Demographic variables and prior experience of participants were also collected.

Content validity was measured by rating the level of agreement with the following four statements: 1) There is a role for a validated AEEP simulator in training; 2) There is a role for simulators in surgical training in general; 3) Simulation-based training and assessment for AEEP is essential to patient safety; and 4) AEEP is an effective method of treatment. Face validity was assessed by both the experts and novice group rating the realism of each component of the operative experience and each step of enucleation on a 10-point Likert scale (1 being "poorly reproduced" and 10 being "realistically reproduced").

Feasibility was assessed posing two questions: 1) Is it feasible to incorporate this organ phantom simulator in a training program? 2) Is it feasible to adopt the prostatic organ phantom to train and assess urologists in: a) anatomy identification, b) power settings, c) fiber positioning, d) effective technique, e) preventing injury, f) avoiding instrument damage, g) avoiding blood loss. We assessed acceptability with the following questions: 1) Should simulation be integrated into training programs? 2) Should simulation be part of certification and recertification? 3) Does this 3D model system teach transferrable skills applicable in the operating room?

Participants were asked to rate the difficulty of each step of AEEP using a 5-point Likert scale.

Operative outcomes

Specimens were examined post-operatively to determine any differences between results applying the three different energy modalities. Rates of capsule perforation as well as each specimen's approximate enucleated percentage were documented.

Statistical analysis

Statistical analysis was performed using SPSS version 27 software (SPSS, IBM Corp, Armonk, NY). Results were summarized descriptively. Previous experience of the novice group was compared to the expert group using the Fisher's exact test. The Mann-Whitney U test was used to compare median values. The difference between mean difficulty scores was calculated with the Student's t-test. The Kruskal-Wallis test was used to determine the effect of prior experience on simulation difficulty. Statistical significance was set at a two-sided $p<0.05$.

RESULTS

Demographics
Thirteen participants with little or no AEEP experience (novice group) and two AEEP experts were recruited. The average age of participants was 43 years, and 100% of participants were male. Most participants were urologists with an average 11.7 years of practice, and only one participant was a 5th year resident in urology. The median number of AEEP performed by the novice group was 0 (IQR 0-2) but 12 out of 13 had performed at least 20 TURP annually, and four had performed at least 20 transurethral vaporizations annually. The vast majority (92.3%) of AEEP-novice surgeons and all experts had already used a simulator for training purposes in surgery, but this was the first experience for all participants using an AEEP-specific simulator. See Table 1 for additional details on participants' prior surgical experience.

Operative outcomes
Twenty-two prostates were enucleated: six with a holmium laser, 14 with a thulium fiber laser and two with bipolar energy (Table 2). Organ phantoms enucleated with a holmium laser revealed the fewest capsule perforations, with only 16.7% of specimens being perforated, compared to 57.1% of thulium fiber laser enucleations and all bipolar enucleations.

Content validity
Regarding content validity, 100% of participants agreed or strongly agreed that AEEP was an effective treatment for BPH (Figure 3). All participants also agreed or strongly agreed that simulators have a role to play in surgical training, and specifically in AEEP training. Most agreed that simulation-based training is essential to patient safety, but 13.3% disagreed with this statement.

Face validity
Face validity was acceptable for the overall operative experience which was rated 7.3 on a 10-point scale (Figure 4a). Instrumentation was the most realistic component (9.6/10) while laser-tissue interaction obtained the lowest score (6.1/10). The realism of each individual enucleation step was also rated: creating the 5, 6 or 7 o'clock groove and the anterior groove were judged the most realistic (7.9/10) (Figure 4b). Most steps scored at least 6/10, however hemostasis (3.1/10) and morcellation (4.7/10) were found to be poorly reproduced.

Acceptability and feasibility
It was considered acceptable by 100% of our participants that simulation be integrated into training programs (Figure 5). Only a minority of subjects found it appropriate to make simulation mandatory for certification and recertification (33.3%). All subjects agreed that it is feasible to incorporate this organ phantom simulator within a training program and 86.7% of participants believed it was feasible to use the simulator to train and assess urologists in identifying anatomy and effective technique. Most disagreed that the simulator was a feasible method for training

blood-loss prevention (66.7%). Over 90% of participants claimed that the simulator teaches transferable skills useful in the operating room.

Difficulty

The en-bloc technique appears to be one of the most challenging enucleation steps: about three quarters of subjects found it at least "difficult", and it received a mean score of 3.4 on a 5-point scale (Range 2-5). Morcellation was also considered "extremely difficult" by 26.7% of subjects, however many comments emphasized that the "morcellator was not working well" or "was blocked". Three participants marked hemostasis as non-applicable. Number of TURP or vaporizations performed, years of practice or type of teaching institution revealed no impact on difficulty. Overall difficulty scores for each step of enucleation are summarized in Table 3.

DISCUSSION

Bioengineered 3D organ phantoms are useful tools for various applications in urology surgical education.[24] Notably, they can serve as patient education models, patient-specific models for rehearsing complex surgeries, and general simulation-based training for novice urologists.[25,26] The latter is becoming especially important, as emerging surgical techniques for BPH, such as prostate enucleation, demand great expertise before they can be performed safely and effectively. Trainees can use hands-on models to learn tactile sensation and bimanual instrument handling, which are among the pitfalls of virtual reality technology. Despite the growing need for training tools in advanced BPH surgeries, most 3D organ phantoms in urology seem to have been developed for renal diseases or prostate cancer; they are lacking for BPH surgical training.[24,27]

The novel organ phantom in the present study represents important progress in training AEEP-novice urologists in an era of rapidly growing and increasingly difficult surgical techniques. In the present study, we validated the use of a novel 3D organ phantom for simulation-based AEEP training and found its use both feasible and acceptable.

Face validity involved evaluating how realistic the simulation was in terms of the operative experience and specifically in each step of enucleation. Our results are in line with findings from another biosynthetic bench model patented by Matsuda et al., which was validated by two distinct studies.[28] Antunes et al. studied 40 urologists taking a course for holmium laser enucleation of the prostate (HoLEP), which was carried out on a trilobar prostate model.[15] Content and face validity were confirmed, but the overall operative experience was scored slightly higher (8.4 on a 10-point scale) than in our study. Instrumentation was the most realistic component, given that real equipment was used, a finding corroborated by our study. Laser-tissue interaction came in second (8.6/10), whereas laser-tissue interaction was our study's least realistic operative element (6.1/10). Note that our study featured three different energy modalities rather than just one, which may be a confounding factor. Aydin et al. conducted a prospective study of 36 urologists and residents practicing HoLEP on the same prostate model.[18] Their overall operative experience was rated 7.4 on 10, which closely resembles our study finding (7.3/10). The vast majority of their participants agreed on the feasibility of applying the

simulator for anatomy identification, power settings, positioning the fiber, effective technique, avoiding injury, avoiding instrument damage, and avoiding blood loss. Those findings contrast with our results, which show that two-thirds of participants failed to agree that avoiding blood loss was feasible. However, all other components were considered feasible.

Our participants confirmed the content validity of the organ phantom, although they expressed reservations about the need for simulation-based training for patient safety. Few can argue about the general utility of simulators in surgical training, but their precise role remains uncertain. This may be attributed to the fact that simulators are considered to be one adjunct among a variety of AEEP training methods.[29] When urologists were surveyed in the Aydin et al. study about what they thought was the ideal training method, only 13% stated simulation alone and 87% believed it was supervised simulation together with operative room training.[18] Other impactful resources for learning AEEP are mentorship and proctorship, which are known to significantly lower the learning curve and reveal a positive safety profile.[9,12,30] One study by Netsch et al. found that a mentor-based approach could help urologists adopt thulium vapoenucleation and overcome possible complications at the beginning of the learning curve.[14] Structured training programs can use both mentorship and simulation training along with strategic selection of beginner cases to lower the learning curve. One example of a structured training program for AEEP is the Holmium User Group developed in the United Kingdom.[31] Their approach uses modular progression to learn each step of HoLEP. Future studies should focus on longitudinal outcomes in practice when integrating both a simulator and a mentorship-based model.

Participants found the en-bloc technique to be the most challenging part of AEEP. In a training program teaching the en-bloc technique, it would thus be important to allocate enough time to learn this technique or to begin with teaching a 2-lobe or 3-lobe technique, as the least difficult steps are the anterior commissure and bladder neck incisions at 5, 6 or 7 o'clock.[15,31]

Three different energy sources were accessed in this study. While AEEP-novice urologists carried out the procedures – making a higher rate of capsule perforation likely – specimens enucleated with the thulium fiber laser and bipolar energy were disproportionately perforated. On the other hand, only one of six specimens enucleated by novice urologists with the holmium laser showed a capsule perforation. The thulium fiber laser is appreciated for its continuous laser which enables easier plane correction and excellent hemostasis, and has a learning curve that may be shorter than or equivalent to HoLEP, as described by Enikeev et al.[11] In their randomized trial assessing the learning curve of three different energy sources with 30 patients in each group, the complication rates and specifically capsule perforation rates were very similar between the holmium:YAG and thulium fiber laser groups. Our findings may reflect the organ phantom's possible compatibility with the holmium:YAG laser since the model was developed for use with the holmium:YAG laser.

One strength of the organ phantom model in the current study was its acceptability and feasibility. The model was created via 3D-printing and is easily reproducible. All participants considered it feasible to incorporate the organ phantom model in AEEP training. The organ phantom was appreciated for being particularly useful in assessments regarding: positioning the fiber, identifying anatomy and in avoiding instrument damage. The vast majority (92.9%) acknowledged that it teaches transferrable skills needed in the operating room.

The present study is not without limitations. First, the small sample size must be considered. The Masterclass had a total of 15 participants, only two of which were AEEP experts. Because of the few AEEP experts present, accuracy of face validity may be limited, and we were unable to assess construct validity, which should be evaluated in future research with an appropriate sample size. Second, this prostate model was designed for HoLEP, but ultimately there were three energy modalities used in the Masterclass to allow AEEP-novice urologists to practice on different modalities. While it may have been interesting for participants to try different energy sources during the Masterclass, it is difficult to detect trends within each group due to the small sample sizes and the limited number of sessions practicing with each modality. Future studies may benefit from limiting their scope to one energy source and allowing participants more sessions to practice. Third, while the 3D prostate organ phantom realistically reproduced prostatic anatomy, it lacks hemodynamic factors. The surgeon must rely on another resource to learn coagulation techniques. Finally, the morcellator was not entirely functional and consequently not highly ranked for face validity. Similar criticisms regarding hemostasis and morcellation have been noted in conjunction with other synthetic models.[15]

Nevertheless, the present study offers insight on the first-time use of a 3D-printed organ phantom in AEEP training. This information can be relied upon when adopting these models in training programs or longitudinal training studies.

CONCLUSIONS

The 3D-bioprinted prostate organ phantom is an accessible and reproducible model that allows AEEP-novice urologists to practice this surgical technique safely. This study has established content and face validity for AEEP using the holmium:YAG laser, thulium fiber laser, and bipolar energy on a novel organ phantom. Participants considered its use both feasible and acceptable for AEEP training purposes.

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FIGURES AND TABLES

Figure 1. Organ phantom before resection **(A)** anterior view; **(B)** base view; and after complete enucleation with a holmium laser; **(C)** anterior view; **(D)** base view.
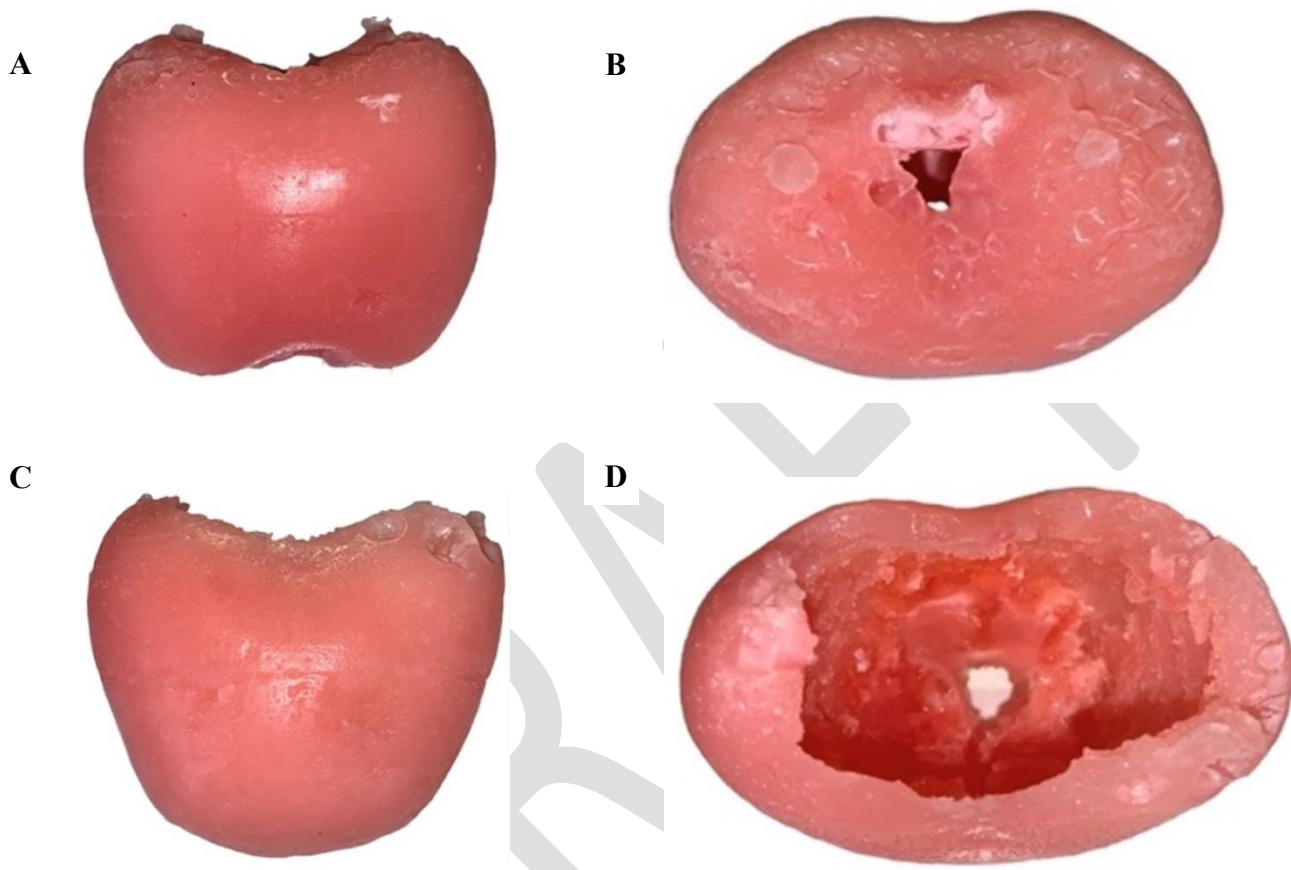
Figure 2. Set-up of the simulator during the masterclass.

Figure 3. Content validity of the simulator.
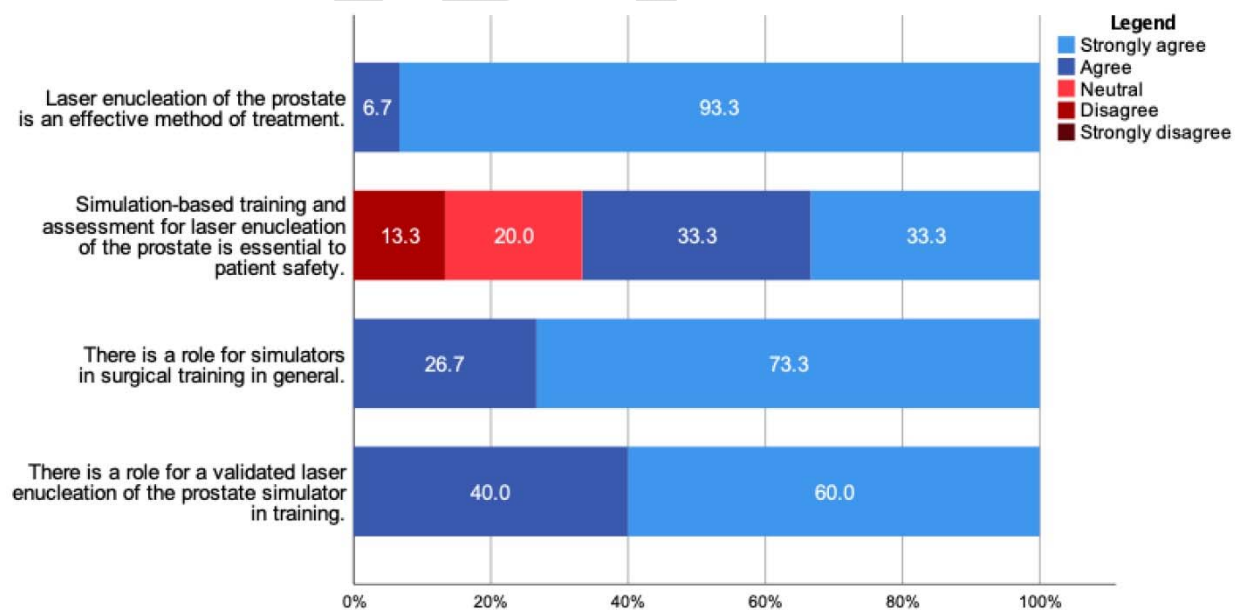
Figure 4. Face validity of **(A)** the operative experience and **(B)** each step of enucleation using the simulator.
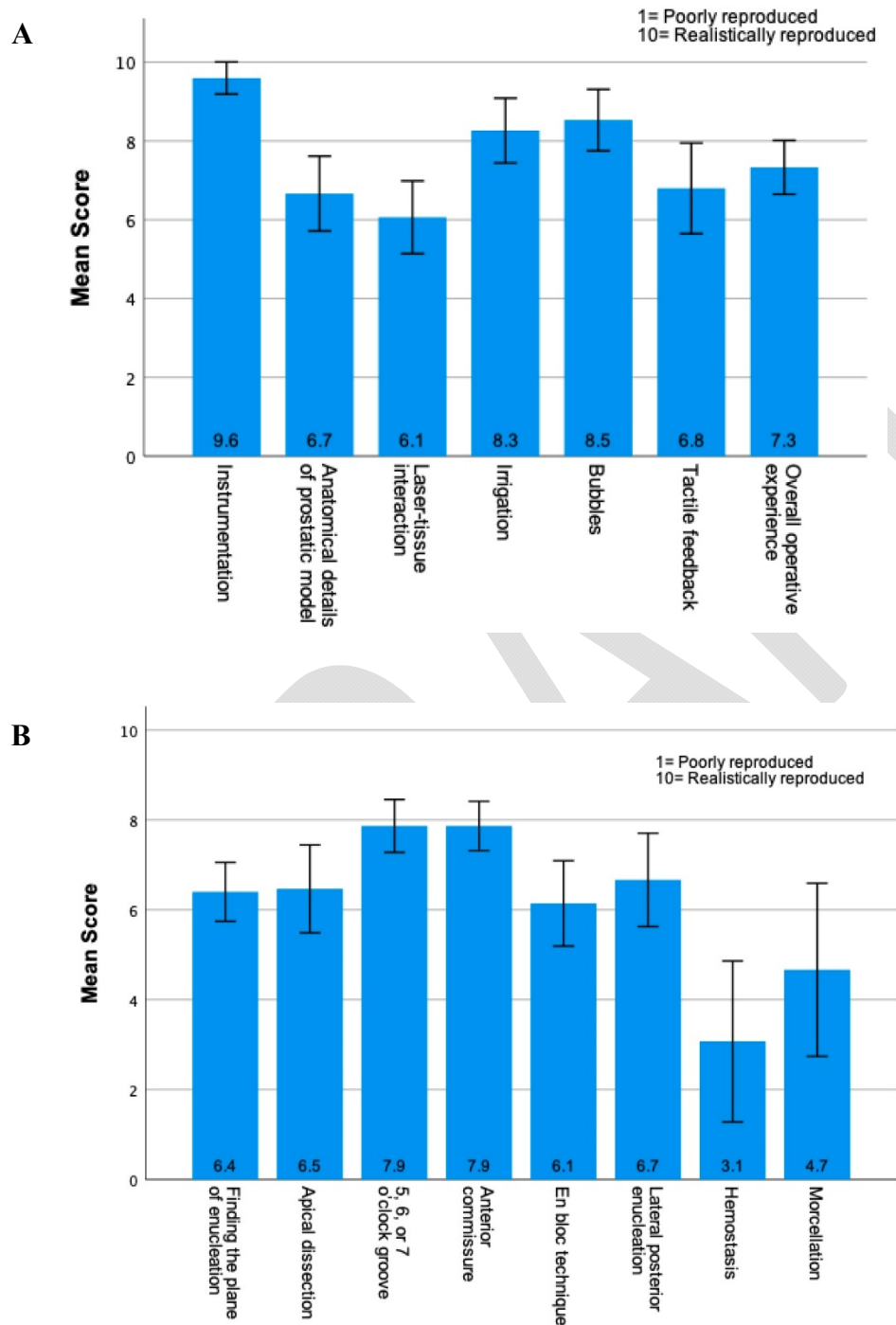
Figure 5. Feasibility and acceptability of the organ phantom in training.
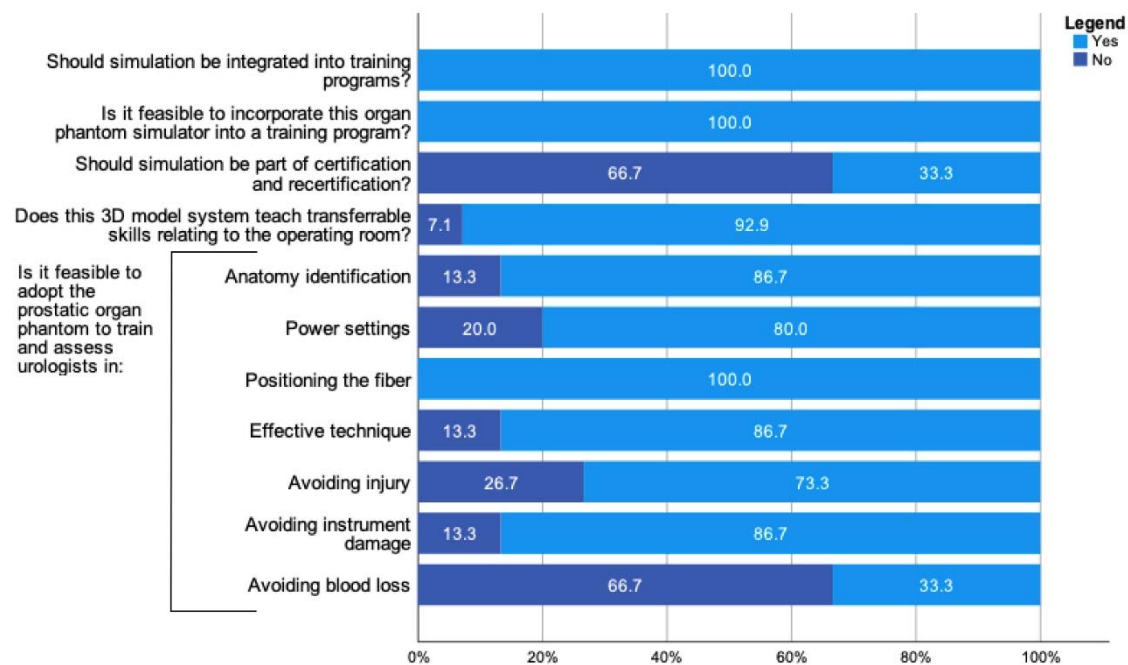
Table 1. Previous experience of participants in the masterclass				
Previous experience		**Expertise**		**p**
		Novice (n=13)	**Experts (n=2)**	
Duration of urological practice, years (SD)		12.9 (11.2)	5.0 (4.2)	0.358
Number of TURP procedures performed annually (%)	Less than 20	1 (7.7)	2 (100)	**0.038**
	20–50	10 (76.9)	0	
	More than 50	2 (15.4)	0	
Number of transurethral vaporisation procedures performed annually (%)	Less than 20	9 (69.2)	2 (100)	1.000
	20–50	4 (30.8)	0	
	More than 50	0	0	
Percentage of practice that consisted of laser enucleation of the prostate procedures in a year (%)	Less than 50%	13 (100)	0	**0.010**
	About 50%	0	1 (50)	
	More than 50%	0	1 (50)	
Median approximate number of laser enucleation of the prostate procedures performed (IQR)		0 (0–2)	560 (NA)	**0.010**
Median number of years of experience practicing laser enucleation of the prostate (IQR)		0 (0–0.5)	5 (NA)	**0.019**

Type of affiliated institution	Non-teaching	6 (46.2)	0	0.486
	Teaching	7 (53.8)	2 (100)	
Before this masterclass, have you ever used a simulator for surgical training?	No	1 (7.7)	0	1.000
	Yes	12 (92.3)	2 (100)	
Before this masterclass, have you ever used a simulator for laser enucleation of the prostate training?	No	13 (100)	2 (100)	1.000
	Yes	0	0	

Boldface print indicates p<0.05. IQR: interquartile range.

Table 2. Performance results of masterclass		
Outcomes of masterclass		**Number of specimens (n=22)**
Perforated specimens (% per laser type)	Holmium (n=6)	1 (16.7)
	Thulium fiber (n=14)	8 (57.1)
	Bipolar (n=2)	2 (100)
Amount resected (% of total)	Less than 50%	9 (40.9)
	About 50%	7 (31.8)
	More than 50%	6 (27.3)

Table 3. Difficulty of each step of enucleation using the simulator				
Steps of enucleation	**Mean score* (range)**	**Novice**	**Experts**	**p**
Finding the plane of enucleation	2.9 (2–4)	2.8 (2–4)	3.5 (3–4)	0.207
Apical dissection	2.6 (1–4)	2.6 (1–4)	2.5 (2–3)	0.903
5, 6, or 7 o'clock groove	1.7 (1–3)	1.7 (1–3)	1.5 (1–2)	0.740
Anterior commissure	1.7 (1–4)	1.7 (1–4)	2.0 (1–3)	0.689
En bloc technique	3.4 (2–5)	3.5 (2–5)	3.0 (2–4)	0.569
Lateral posterior enucleation	2.3 (1–4)	2.2 (1–3)	2.5 (1–4)	0.887
Hemostasis	1.8 (1–5)	1.9 (1–5)	1.0 (1–1)	0.418
Morcellation	2.6 (1–5)	2.9 (1–5)	1.0 (1–1)	**0.002**

*On a 5-point scale, where: 1=not difficult, 2=slightly difficult, 3=difficult, 4=very difficult, 5=extremely difficult. Boldface print indicates p<0.05.