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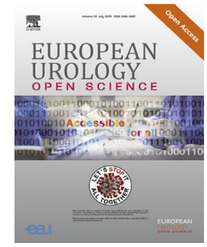

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Determination of Face and Content Validity of Cadaveric Model for Holmium Anatomic Endoscopic Enucleation of the Prostate Training: An ESUT AEEP Group Study

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Abstract

Background: Bench and virtual reality nonbiological simulator models for anatomic endoscopic enucleation of the prostate (AEEP) surgery have been reported in the literature. These models are acceptable but have limited practical applications.
Objective: To validate a fresh-frozen human cadaver model for holmium AEEP training and assess its content validity.
Design, setting, and participants: Holmium AEEP operations on fresh-frozen cadavers performed by an experienced surgeon were recorded, and a video, including the main steps of the operation, was produced.
Outcome measurements and statistical analysis: The video and an accompanying questionnaire were subsequently distributed electronically to ESUT AEEP study group experts and associates ($N = 32$) for assessment of the AEEP training model. A ten-point Likert global rating scale was used to measure the content validity.
Results and limitations: A total of 26 answers were returned (81%). The experts agreed on the model's suitability for AEEP training (mean Likert score: 8). According to the responses, "identifying anatomic structures and landmarks" was the most valuable aspect of the model in terms of AEEP training (median Likert score: 9). Conversely, the experts found the model's ability, in terms of demonstrating laser and tissue reactions, to be weak (median Likert score: 6)
Conclusions: Based on the content validity assessment, the fresh-frozen cadaver-training model for laser AEEP seems to be a promising model for demonstrating and learning the correct prostate enucleation technique.

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Patient summary: An increasing number of researchers have proposed that anatomic endoscopic enucleation of the prostate (AEEP) should replace transurethral resection of the prostate surgery and become the gold standard for treatment of bladder outlet obstruction due to benign prostatic hyperplasia. AEEP requires anatomic familiarity for enucleation, technical knowledge, and a solid training program before starting with the first cases. This is the first cadaver study to assess the content validity of a fresh-frozen human cadaver model for AEEP training.

1. Introduction

It has been more than 20 yr since the adoption of AEEP surgery in urological practice [1]. Despite the popularity of AEEP surgery in the urological community, AEEP has not become widespread due to the lack of a standardized surgical technique as well as a training program, limitations in terms of access to equipment, and a steep learning curve [2,3]. The anatomy of the surgical technique in AEEP differs from that in transurethral resection of the prostate (TURP); surgeons may experience difficulties and stress when first using AEEP, and face the morcellation process [2]. Anxieties surrounding learning a new technique, in addition to associated perioperative complications in their first AEEP surgeries, can result in many surgeons abandoning AEEP in favor of TURP surgery or simple prostatectomy [4,5]. To overcome these drawbacks and encourage widespread adoption of AEEP, training and self-confidence building are extremely important, and a standardized training program may be the key.

For AEEP surgery, specifically holmium laser enucleation of the prostate (HoLEP) surgery, bench and virtual reality nonbiological simulator models have been reported. Although these models are acceptable, they could not be proved as optimal models for training [6]. In terms of its advantage as a learning instrument, a cadaveric model represents true human anatomy, unlike other training modalities [7].

To the best of our knowledge, there are no published studies on the use of human cadavers in AEEP training in the English literature.

In this study, we aimed to validate the use of a fresh-frozen human cadaver model for training in laser AEEP and to assess its content validity.

2. Materials and methods

Following the ethical committee approval (NEU Meram School of Medicine, 2021/3004), surgical procedures were performed in the endoscopic and robotic surgical training facility of the Acibadem Mehmet Ali Aydinlar University, Center of Advanced Simulation and Education (CASE), Istanbul, Turkey, in a fully simulated operating room. Cadaveric specimens were provided by United Tissue Network's local dealer. The cadavers used in the study were preserved at $-7\,^{\circ}$C and defrosted at $14\,^{\circ}$C, 12 h prior to surgery. Anonymity was protected throughout. A surgeon (L.T.) who had carried out >1000 HoLEP procedures performed the operations.

The operations ($n = 2$) were video recorded and then edited to include only the main operative steps. The video (training aid) was subsequently evaluated by an expert group.

2.1. Surgical technique

The AEEP surgery was performed on two male fresh frozen human cadavers. One cadaver had a history of TURP surgery. The operations were performed using the "omega sign" AEEP technique [8]. The name of the technique is devised from the omega sign–shaped mucosal flap at the level of the apex at the 10 to 2 o'clock position. The pelvis of the cadaver was placed in a supine position (Fig. 1). A 26 Ch. resectoscope (Karl Storz Endoscopy, Tuttlingen, Germany) was introduced, and the anatomic structures and landmarks were exposed. A 100 W holmium laser (Quanta System; Solbiate Olona, Varese, Italy), and a 550 μm end-fire laser fiber were used. The operation started with mucosal incisions made proximally from the bladder neck of the 5 and 7 o'clock positions, targeting the ureteral orifices (Fig. 2A). Subsequently, lateral lobe mucosal incisions were made at the level of the apex (Fig. 2B). At this point, to identify the surgical capsule, the lateral lobes were enucleated minimally. The next step of the procedure involved early mucosal release of the rhabdosphincter at the 10 to 2 o'clock position at the level of the apex. Enucleation started with the median lobe and continued with the lateral lobes (Fig. 2C). Upon completion of enucleation, an omega-shaped mucosal flap was formed by the preserved mucosa (Fig. 2D). The "omega sign" and sphincter coaptation confirmed the successful application of endoscopic enucleation of the prostate.

During the procedure, possible complications, such as capsular perforations (Fig. 2E) and bladder neck undermining (Fig. 2F), were purposely simulated. The enucleated prostate lobes were removed using a 26 Fr nephroscope (Karl Storz Endoscopy, CA, USA) and tissue morcellator (Hawk; Minitech Co., China).

2.2. Content validity

To assess the content validity of the recorded videos, which included the main operative steps of the AEEP procedure,

Fig. 1 – The HoLEP operation room setup of the cadaver positioned in supine position. HoLEP = holmium laser enucleation of the prostate.

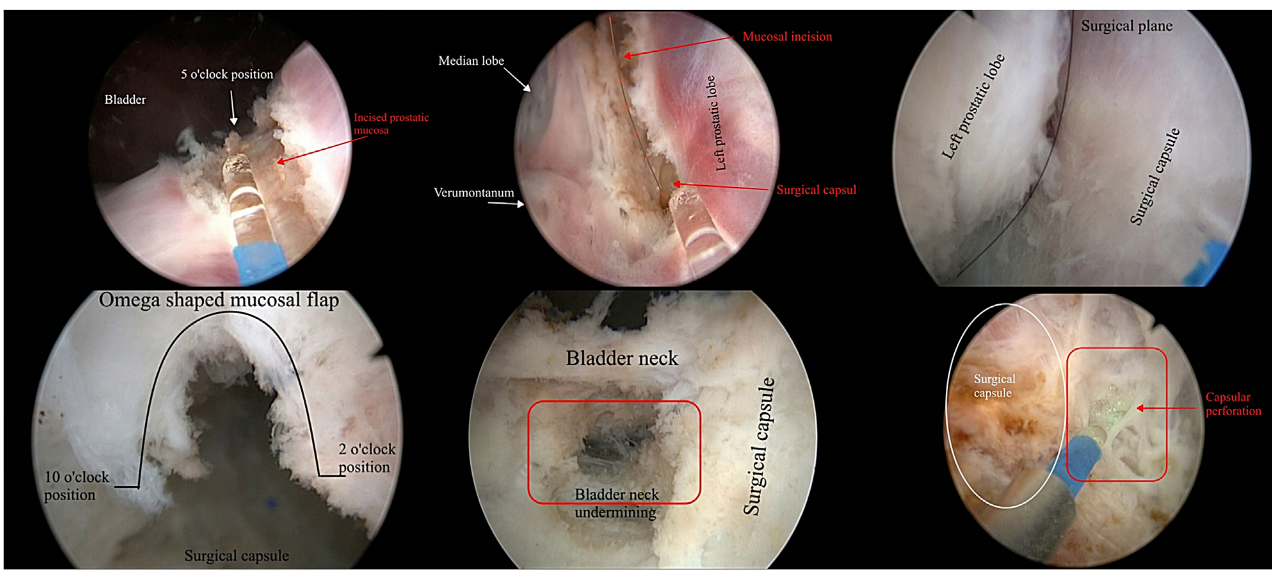

Fig. 2 – Several surgical views from the LEP procedure in the human cadaver: (A) cadaver's 5 o'clock mucosal incisions; (B) lateral lobe mucosal incisions of cadaver, at the level of apex; (C) cadaver's lateral lobe enucleation; (D) omega-shaped mucosal flap formed by the preserved mucosa of the cadaver; (E) surgical capsule perforation; (F) bladder neck undermining. LEP = laser enucleation of the prostate.

the edited video and a ten-step questionnaire (appendix) related to the video content, were distributed electronically to ESUT AEEP study group members and associates. All respondents were practicing AEEP in a high volume and contributed to the literature. The ESUT AEEP study group members have discussed the study method and possible questions for survey in Zoom meetings. The group members (L.T., T.H., C.S., S.A., G.B., and A.P.) have published before about the AEEP techniques, equipment, tissue interactions, and the anatomic landmarks. The literature has been reviewed and the questions were determined accordingly. Content validity was checked with a ten-point Likert global rating scale ranging from "very bad" (score: 1–2) to "bad" (score: 3–4), "good" (score: 5–6), "very good" (score: 7–8), and "excellent" (score 9–10).

2.3. *Statistical analysis*

The Statistical Package for Social Sciences, version 23.0 software (SPSS, Chicago, IL, USA) was used. Kolmogorov-Smirnov, kurtosis, and skewness tests were used to assess the normality of the data. Descriptive statistics of scale

Table 1 – Descriptive statistics of the responses to all questions

Questions	Median	IQR	Mean	SD	25th percentile	75th percentile
1	8	2	7.23	2.04	6	8
2 [a]	8	3	7.5	1.55	6	9
3	9	2	8.81	1.09	8	10
4 [a]	7	4	7.19	2.82	6	10
5	8	4	7.54	2.14	6	9
6	6	4	6.88	2.47	6	9
7 [a]	7	4	7	2.51	6	9
8 [a]	8	3	7.23	2.19	6	9
9 [a]	8	3	7.58	2.31	6	9
10	8	2	7.96	1.45	7	9

IQR = interquartile range; SD = standard deviation.
[a] Parameters are suitable for normal distribution; others are non-normal.

samples were expressed as mean ± standard deviation and median ± interquartile range (IQR). The results were presented graphically using divergent bar graphs.

3. Results

AEEP was performed successfully in two fresh-frozen human cadavers. The cadaver ages were 62 and 65 yr. Prostate volumes of the cadavers were 40 and 60 ml, respectively. Operative times of the two procedures, including morcellation, were 25 and 30 min, respectively. Of 32 questionnaires distributed, 26 fully completed questionnaires were returned. Table 1 provides a summary of the responses, together with descriptive statistics. Of the participants, 53.84% agreed on the model's suitability for AEEP training (median [IQR] Likert score = 8). An inter-rater reliability analysis was performed on the evaluation data of 26 referees. The intraclass correlation coefficient value was calculated as 0.675 ($p = 0.002$). According to the answers to the questions, which evaluated different aspects of the model, "identifying the anatomic structures and landmarks" was the most valuable aspect of the model. The participants (84.61%) agreed strongly (median [IQR] Likert score = 9 [2]). The model's adequacy in terms of demonstrating laser-tissue reaction (38.46%, Q. 4) was relatively weak (median [IQR] Likert score = 6 [4]). All other aspects of the model, including "developing the layer between the adenoma and prostate capsule" (53.84%, Q. 4; median [IQR] Likert score = 8 [4]) and "recognition of complications during the procedure" (61.53%, Q. 2; median [IQR] Likert score = 8 [3]), were considered realistic. A bar graph shows the responses to all the questions with the median values (Fig. 3).

4. Discussion

Lower urinary tract symptoms secondary to bladder outlet obstruction due to benign prostatic hyperplasia (BPH) are an important and common health issue in aging men [8]. In 1998, Gilling et al [1] introduced the anatomic AEEP technique, which employs holmium laser energy. A major advantage of this technique was that it was based on the same anatomical principles as those applied in open surgery. This anatomic approach led to improved perioper-

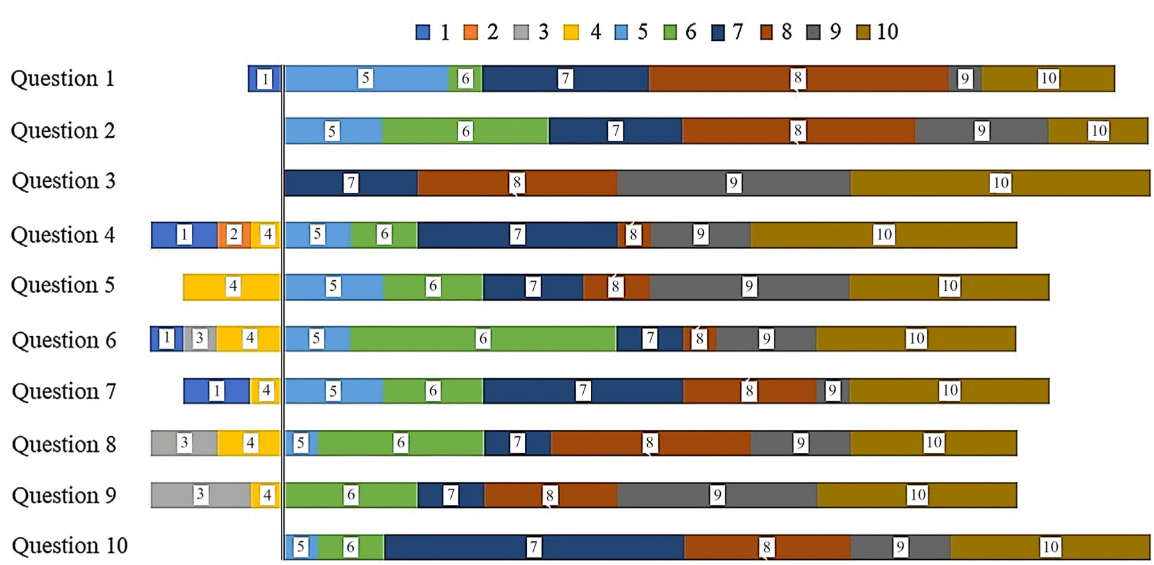

Fig. 3 – Bar graph showing the responses to all questions, including the median number.

ative and functional outcomes, with HoLEP surgery generally associated with enhanced hemostasis and increased intraoperative safety and patient satisfaction as compared with that observed in TURP surgery and open simple prostatectomies [9]. Perioperative parameters, such as reduced length of hospital stay and urethral catheterization time, were reported to be additional advantages of HoLEP surgery. In addition, long-term functional outcomes of HoLEP surgery were comparable with those found in open simple prostatectomies [10,11]. The European Association of Urology recommends laser AEEP using a Ho:YAG laser in men with moderate-to-severe lower urinary tract symptoms as an alternative to TURP or open simple prostatectomy surgery [12]. The American Urological Association recommends that clinicians consider HoLEP surgery or thulium laser AEEP, depending on their expertise [13]. Moreover, some recent studies have advocated that AEEP should replace TURP surgery and became the gold standard for BPH treatment [14,15].

Despite the advantages of AEEP, expert opinion, and guidelines of relevant organizations, some problems associated with AEEP remain to be overcome. These include the steep learning curve, which currently prevents the widespread application of AEEP [16]. The steep learning curve is because AEEP is technically and anatomically different from TURP that represents the standard of care for the majority of surgeons who approach to AEEP. Surgeons require technical knowledge, familiarity with endoscopic anatomy, and to complete a solid training program before starting with AEEP, handling the morcellation subsequent to the procedure. As reported previously, mentorship and proctorship are very effective in shortening surgery-related learning curves [17,18]. Owing to the lack of a globally accepted and applied training program and model for AEEP, surgeons' first experience of HoLEP surgery takes place under the guidance of a mentor. Nevertheless, an optimal and realistic training model and a standard training program are needed for learning laser AEEP outside the operating room before starting with human procedures. In this regard, computer-based simulators have advanced at a rapid pace in accordance with technological developments and become an established and valid method for surgical training [19,20]. Bench and virtual reality nonbiological simulator models are also available for laser AEEP training [21,22]. However, compared with the cadaver model, these models have apparent limitations in nature. Low anatomical fidelity, lack of tactile feedback, limited depth perception, and no full procedural simulation in bench and virtual reality nonbiological simulator models may become more pronounced, especially for anatomic AEEP, which has a steep learning curve with ambiguous surgical landmarks compared with other surgeries [23].

Animal models and human cadavers seem to be the best models for surgical training. However, the dissimilarities of animal tissue and anatomy with human tissue and anatomy can be problematic in terms of surgical skill transference to real practice [24]. In addition, there is a potential risk for infections with animal models [25]. As cadaver model represents the actual anatomic environment, they are superior to computer-based simulators, dry laboratory models, and animal models. Fresh-frozen, formalin-embalmed, or Thiel-embalmed cadavers can be used for surgical training, and human cadavers have successfully been used previously in surgical training prior to performing various urological interventions [26]. Human cadavers have been proved to be an ideal model for teaching surgical skills prior to performing surgery in the operating room. A number of studies reported that cadaveric training improved the confidence of surgeons in terms of surgical skills during their training [27] and that it enhanced the transition to real surgical practice [28].

It is logical to assume that surgeons who are confident about the application of a particular surgical procedure will be willing to perform that procedure. However, the use of cadaveric models in surgical training has limitations, including high cost and a need for a facility in order to maintain and store the cadaver. Cadaver models with multiple purposes for use by different disciplines would increase their efficiency and reduce their costs [29].

Different AEEP techniques (eg, three-lobe and enblock) have been reported in the literature [2,30]. We focused on the "omega sign" AEEP technique because it represents our standard of care technique, other than for its favorable perioperative and functional outcomes [31]. In addition to demonstrating laser AEEP surgical technique, an additional aim of our model was to illustrate the main steps of the surgery, including the "omega sign" technique.

The operative steps included instrument handling and tissue flexibility other than colors, identification of anatomic structures, and landmarks; mucosal incision between adenoma and prostate capsule, recognition of laser and tissue reactions, sphincter anatomy, and coaptation, other than complications during the procedure, were also evaluated. These steps were assessed through the edited video by the experts and compared with real patient experience.

Unsurprisingly, the model's adequacy in terms of demonstrating laser and tissue reactions was relatively weak. The reasons can logically be the lack of hemodynamic factors and low compliance of the specimens, as reported in cadaver studies. However, other than in this area, all the participants agreed or strongly agreed on the high fidelity of the fresh-frozen human cadaver model of laser AEEP surgery. As observed in other urological settings with structured training programs [18,32], this model could be included in the future training curriculum for AEEP to improve the learning process and ensure patient safety.

This study is not without limitations; although human cadavers in laser AEEP training are a realistic alternative to actual surgical experience, their limited availability, linked legal aspect in some countries, and high cost are major limitations. In addition, bleeding and respiratory movements cannot be simulated in cadaver models. We have to obtain feedback from the trainees and evaluate the outcomes with further construct and predictive validity studies.

5. Conclusions

This is the first study to demonstrate the content validity of a fresh-frozen human cadaveric model for use in holmium laser AEEP training. The realistic anatomy and tissue similarity of a cadaver model make it suitable for AEEP training, and our cadaver model may facilitate the AEEP learning process. Future research comparing the views of experts and trainees on the AEEP model would help shed light on the validity of the model in AEEP training. After confirming the structural validity of the AEEP model, we believe that it can be included in AEEP surgical training programs.

***Author contributions*:** Ali S. Gozen had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Tunc, Gozen.
Acquisition of data: Guven, Zor.
Analysis and interpretation of data: Tunc, Gozen.
Drafting of the manuscript: Zor, Guven, Tunc.
Critical revision of the manuscript for important intellectual content: Gozen, Bozzini, Scoffone, Misrai, Herrmann, Porreca, Ahyai.
Statistical analysis: Guven.
Obtaining funding: None.
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Supervision: Gozen, Bozzini, Scoffone, Herrmann.
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