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External validation of a prostate biopsy simulator

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Abstract

Introduction: Simulation-based training has proven to be a promising option allowing for initial and continuous training while limiting the impact of the learning curve on the patient. The Biopsym simulator was developed as a complete teaching environment for the prostate biopsy procedure. This paper presents the results of an external validation of this simulator, involving urology residents recruited during a regional teaching seminar.

Methods: Residents from 4 academic urology departments of the French Auvergne Rhône-Alpes region, who did not take part in the previous simulator validation studies, were enrolled. After a short presentation and standardized initiation session, residents carried out a simulated systematic 12-core biopsy procedure and were asked to fill in a questionnaire collecting their expectations and evaluation of the Biopsym simulator. The number of biopsies reaching each targeted sector, the total score provided by the simulator and the duration of the procedure were recorded.

Results: Twenty-three residents were recruited. The overall added value (/100) for learning was rated at a median of 100 (interquartile range 83-100), overall realism of the biopsy procedure at 80 (65-89). The median percentage of biopsies reaching the targeted sector was

66.7% (62-75). The median score provided by the simulator was 50% (37-60). For both, the difference between residents with or without prior biopsy experience was not statistically significant. The median duration of the simulated biopsy procedure was 4:58 (minutes:seconds) (3:49 – 6:00). Resident with prior experience required less time to complete the biopsy procedure 3:53 (3:39 – 4:56) vs 5:10 (4:59 – 7:10), $p=0.01$.

Conclusion: This external validation study confirms a high acceptance of the simulator by the target audience. To our knowledge, the Biopsym simulator is the only prostate biopsy simulator that demonstrated such validity as evaluated by clinicians, outside the center involved in its early development.

Résumé

Introduction : La simulation chirurgicale s'impose progressivement comme une option intéressante permettant l'apprentissage initial et l'entraînement à une technique chirurgicale tout en diminuant l'impact de la courbe d'apprentissage sur le patient. Le simulateur Biopsym propose un environnement pédagogique complet pour l'apprentissage du geste de biopsies prostatiques. Nous présentons ici les résultats de la validation externe de ce simulateur, conduite auprès d'internes en urologie recrutés à l'occasion d'une journée de formation régionale.

Méthodes : Des internes de 4 services universitaires d'urologie de la région Auvergne-Rhône-Alpes, n'ayant pas pris part aux précédentes études de validation du simulateur, ont été inclus. Après une courte présentation et une étape d'initiation standardisée, les internes réalisaient une procédure de 12 biopsies systématisées simulée, puis remplissaient un questionnaire recueillant leurs attentes et l'évaluation du simulateur Biopsym. Le nombre de biopsies atteignant chaque secteur prostatique, le score total donné par le simulateur et la durée de la procédure simulée étaient recueillis.

Résultats : Vingt-trois internes ont été inclus. L'apport global pour la formation (/100) était évalué à une médiane de 100 (écart interquartile 83-100), le réalisme global de la procédure à 80 (69-89). Le pourcentage médian de biopsies atteignant la zone visée était de 66,7% (62-75). Le score médian attribué par le simulateur était de 50% (37-60). La différence pour ces deux scores selon l'existence ou non d'une expérience préalable des biopsies prostatiques

n'était pas statistiquement significative. La durée médiane d'une procédure était de 4 :58 (minutes:secondes) (3 :49 – 6:00). Les internes plus expérimentés étaient plus rapides que les internes non ou peu expérimentés 3 :53s (3 :39 – 4 :56) vs 5 :10 (4 :59 – 7 :10), p=0,01.

Conclusions : Cette étude de validation externe confirme une forte acceptation du simulateur par ses utilisateurs cibles. À notre connaissance, le simulateur Biopsym est le seul simulateur de biopsies prostatiques ayant fait la preuve de sa validité en dehors du centre à l'origine de son développement.

Introduction

Systematic prostate biopsy is a key modality in the prostate cancer diagnostics pathway (1). This is supported by present evidence, which confirms improved detection of significant prostate cancer by a combination of both systematic and MRI-targeted biopsies if indicated (2). Thus, there is a persistent need for high-quality systematic biopsy and improved training programs.

The even distribution of systematic prostate biopsies is key to avoid missing or under sampling significant prostate cancer (3). So far, training offered to urology residents consist in the performance of several biopsy procedures under the supervision of a mentor. No feedback is provided on the actual distribution of the biopsies, and the pathology report only documents the presence or absence of cancer. A previous study aiming at defining the learning curve of the systematic biopsy procedure has suggested that 12 procedures were needed to reach a plateau, but this number should probably be interpreted with caution as the criterion used to define proficiency (total biopsy core length on pathological examination) does not necessarily imply improved biopsy distribution, as supported by a stable cancer detection rate throughout the study period (4).

Simulation-based training has proven to be a promising option allowing for initial and continuous training while limiting the impact of this learning curve on the patient. However,

many commercialized simulation tools are lacking proper validation, and their added value both as a training and as an evaluation tool are yet to be demonstrated (5).

The Biopsym simulator was developed as a complete teaching environment for the prostate biopsy gesture, including several exercises designed to cover training needs (6), and the possibility to virtually replicate the performance of a systematic, 12-core transrectal prostate biopsy procedure. Previous validation studies have shown that the simulator was capable of discriminating between experts and novices, and that skills acquired on the simulator could be reproduced in a real-life situation (7). Simulation-based training also proved to be superior to conventional training in this randomized study. However, all previous validation studies have been performed in the urology department involved in the simulator design.

We present here the results of an external validation of the Biopsym simulator, involving urology residents recruited during a regional teaching seminar and not involved in the previous simulator validation studies.

Methods

Participants

Participants were urology residents from the French Auvergne-Rhône-Alpes region, originating from 4 urology academic departments (Lyon, Saint Etienne, Clermont Ferrand, and Grenoble), recruited during a regional teaching seminar in October 2019. Residents from Grenoble could only be included if they had not already completed their rotation in the urology department involved in the previous simulator validation studies. Residents were prospectively enrolled, and stratified in two groups according to their prior biopsy experience based on their number of years of training: no or little experience (Post Graduate Year PGY 1-2) and significant prior experience (PGY 3-4-5).

Simulator

The current version of the Biopsym simulator is presented in **Figure 1**. Trainees can manipulate a mock transrectal ultrasound probe to navigate real prostate ultrasound volumes

acquired during 14 transrectal biopsy procedures, representing a range of shapes, gland sizes and difficulties such as artefacts and calcifications. A dedicated software enables the user to simulate a complete biopsy procedure, using the keypad to retrieve samples, and obtain visual feedback and a score evaluating their performance.

Prostate biopsy procedure simulation

Residents were offered a short presentation and standardized initiation session, with the same supervisor, allowing them to familiarize themselves with the simulator features. Once at ease with the use of the simulator, they were asked to autonomously perform a simulated 12-core systematic prostate biopsy procedure. The entire session for each resident lasted about 20 minutes.

Evaluation questionnaire

After completing the simulated systematic biopsy procedure, but before any performance feedback was given, residents were asked to complete an evaluation questionnaire divided into 3 parts (**Appendix**, in English and French).

The first part asked for information about the resident: name, age, dominant hand, sex, experience in prostate biopsy, targeted biopsy experience, video games proficiency.

The second part collected their opinions about the simulator in terms of added value for learning, simulator realism, interface realism, amplitude realism and force feedback realism.

The third part gathered the expectations of the residents regarding the usefulness of such simulation-based training for prostate biopsies in terms of initial teaching of the procedure, continuous training, performance feedback, performance improvement and graduation. For the second and the third parts of the questionnaire, visual scales were used and translated into 0 to 100 scores.

Training outcomes

At the end of the simulated procedure, but after filling in the evaluation questionnaire, residents were provided with feedback on their performance. This included visual feedback with a 3D representation of the prostate contour with their biopsy trajectories, and numerical feedback. The duration of the simulated procedure was also recorded.

Numerical feedback was given using two scores. A score in % was provided by the simulator software. This score takes into account the length of each simulated biopsy core correctly placed inside the considered sector (for example, the left lateral base sector). A score of 100% thus implies that all biopsies are entirely located within their targeted sector. Given the globally low level of experience of the trainees involved and their high likelihood of obtaining low scores, we added another score simply considering the rate of biopsies correctly reaching the targeted sector (i.e., the proportion of biopsies where at least the needle tip reached inside the targeted sector), in order to better analyze the differences between residents according to their previous biopsy experience and avoid the negative educational impact of receiving a low score. The way scores were calculated was not revealed to the residents during their session and did not bias the evaluation as the scores were communicated after the questionnaire was completed.

Statistical analyses

Results are presented as medians and interquartile ranges (IQR). A non-parametrical test (Wilcoxon-Mann-Whitney) was used to compare the scores obtained by residents according to their prior biopsy experience, and the Kruskal-Wallis test for the comparison of results between centers. Statistical analyses were conducted using R (version 4.0.3; The R Foundation for Statistical Computing, <http://www.R-project.org>), with statistical significance defined at $p < 0.05$.

Results

Participants

Twenty-three residents were recruited, 11 having no or little prior biopsy experience and 12 with previous biopsy experience. The median age was 28 (28-30), and 6 participants

were women (26%). Three residents (13%) were left-handed. A detailed description of the participants is provided in **Table 1**. Of interest, 52% of the residents had previously performed targeted biopsies using an MRI/ultrasound fusion device also providing feedback on the location of the biopsies during a biopsy procedure on a patient.

External validation of the Biopsym simulator

The results of the evaluation of the simulator by the 23 residents are provided in **Figure 2**. The usefulness of the simulator for initial training was rated at a median of 100 for an interquartile range (83-100), overall biopsy procedure realism at 80 (65-89), quality of the graphical user interface at 95 (87-100), realism of the ultrasound images at 87 (69-98), realism of the ultrasound probe range of motion at 87 (72-97) and force feedback realism at 72 (47-88). These scores did not statistically differ between residents with no/little experience and residents with significant prior experience (all p-values>0.05).

The expectations of the residents regarding the use of simulation for the initial teaching of the biopsy procedure are summarized in **Figure 3**.

The usefulness of such a tool for initial procedure teaching and performance improvement was rated at a median of 97 (87-100) and 96 (71-100), respectively. Use of the simulator for continuous training was also supported, with a median score of 88 (73-100) as well as performance feedback 90 (71-100), and potential use as an evaluation tool for graduation purposes, with a median score of 77 (51-87). The expectations did not statistically differ between the two groups « no or little experience » and « significant prior experience » (all p-values>0.05).

Training outcomes and scores

An example of the visual feedback obtained by 2 residents is provided in **Figure 4**.

The median duration of the simulated biopsy procedure was (minutes:seconds) 4:58 (3:49-6:0). The residents with prior experience required 3:53 (3:39-4:56), significantly less

than the residents with no or little experience who required 5:10 (4:59-7:10), $p=0.01$ (**Figure 5A**).

The rate of biopsies reaching the targeted sector was 66.7% (62-75). The 12 residents with prior experience obtained a median score of 71% (66-77), and the 11 residents with no or little experience obtained 66.7% (50-75). This difference was not statistically significant ($p=0.34$) (**Figure 5B**).

The median score provided by the simulator software (taking into account the entire simulated core placement according to the sector targeted) was 50% (37-60). The 12 residents with prior experience had a median score of 55% (48-62), and the 11 residents with no or little experience was 52% (37-57), the difference was also not statistically significant ($p=0.28$) (**Figure 5C**).

The detail of scores obtained by residents from each center is provided in **Table 2**. No statistically significant difference between centers was noted for the 3 outcomes studied, procedure duration, rate of biopsies reaching the aimed sector and simulator score.

Discussion

This study allows for the external validation of the Biopsym prostate biopsy simulator, confirming a high acceptance among participants not involved in the previous simulator development steps.

These new users rated the added value and usefulness of the simulator for the simulator as very high, with a median score of 100 (83-100) and 97 (87-100), respectively. Both scores were high irrespective of the participant's previous biopsy experience.

These results are of particular importance for 2 reasons. Firstly, it is the first evaluation of the simulator performed outside the urology department involved in its development, mitigating a potential evaluation bias. Secondly, unlike previously conducted studies, all participants used the simulator for the considered procedure (12-core systematic prostate biopsy). In previous validation studies the participants were expert urologists and medical students (7,8). Their opinions, although of interest, did not necessarily reflect the needs of urologists-in-training. As the present study involved participants coming from 4 different

academic centers, that were therefore exposed to a range of teaching methods, biopsy techniques and patient positioning, their feedback further confirms the place that such a simulator may have in the initial training of urology residents.

The validation of surgical simulation tools has been reported to be lacking for up to 93% of commercially available devices (9). When initiated, advanced validation steps such as transfer validity demonstration (the ability of trainees to reproduce the skills acquired in real-life situations) and external validity were often overlooked.

In this external validation study, residents rated the overall realism of the biopsy procedure at 80, which compares favorably with the results obtained during previous validation studies conducted within the urology department involved in the simulator development, as detailed in **Table 3**. Interestingly, since improving the simulator's physical realism from the initial version of the simulator, median scores provided by the software have proven to be reasonably consistent to the training level of the involved participants.

Although it was not the primary objective of the study and this particular outcome has to be considered as exploratory, we did find some differences between residents with no or little prior experience in prostate biopsy and their more experienced counterparts. The difference was statistically significant for the duration of the procedure, but not for the rate of correctly placed simulated biopsies or global performance score attributed by the simulator software. This can probably be explained more by a lack of power of the study and the small sample size rather than by an absolute absence of difference. These results will have to be further explored and confirmed in a study with a higher number of participants, but this can be considered as an encouraging first step toward the use of the simulator as an evaluation tool.

Interestingly, and unlike previous survey results on the motivation of urology trainees to use simulation tools, residents taking part in this study displayed a high level of engagement and all wished they had had access to such a simulator before performing their first biopsy session (10). Previous experience (unpublished data) has shown that it was possible to fully train a resident with the simulator and have them perform their first biopsy on a patient with an excellent comprehension and mental representation of the prostate. Therefore, we believe

that a virtual-reality simulator-based training should be introduced for every urology resident at the start of their residency.

Some limitations of the study have to be acknowledged. The sample size was limited due to the duration of a simulation session for each resident and the short time frame, as well as the limited number of residents currently in training in the Auvergne-Rhône-Alpes region. Although we only included residents with no prior training within the urology department involved in the simulator development, another limitation was that the urologist in charge of the study set up, supervision and simulator presentation was actively involved in previous validation studies. Additionally, it has not been demonstrated so far that the improvement in the initial training provided by the Biopsym simulator translated into increased prostate cancer detection. A multicentric, prospective randomized trial would be needed to compare cancer detection rates between residents trained using the simulator versus conventional training, in order to further support the clinical relevance of simulation-based training of prostate biopsies.

Conclusion

This external validation study confirms a high acceptance of the simulator among residents recruited from 4 different academic urology departments and not involved in the previous development or validation steps. High scores obtained in terms of overall procedure realism and usefulness of the simulator as an initial training tool also further support the validity of the Biopsym simulator and the place it could take in the training of urology residents. Although limited by the sample size, differences between the results obtained by residents with no or little prior experience and their more advanced colleagues suggest a potential usefulness of the simulator to be used as an evaluation tool.

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	All Residents (n=23)	Residents with no or little experience (n=11)	Residents with significant prior experience (n=12)	p-value (*statistically significant)
Age median (IQR)	28(28-30)	28 (27-28)	30 (29-31)	0.0008*
Gender n (%)				
- Female	6 (26)	4 (36)	2(16)	0.3
- Male	17 (74)	7 (64)	10 (84)	

Dominant Hand n (%)				0.52
- Left	3 (13)	2 (18)	1 (8)	
- Right	20 (87)	9 (82)	11 (92)	
Use of videogames median/100 (IQR)	23 (6 – 45)	23 (1-30)	32 (12-75)	0.21
Prostate biopsy experience n (%)				0.007*
- 0 to 10	10 (43)	8 (72)	2 (17)	
- 10 to 50	12 (53)	3 (28)	9 (75)	
- 50 to 100	1 (4)	0	1 (8)	
Targeted biopsy experience n (%)	12 (52)	4 (36)	8 (66)	0.16

Table 1: Participants' characteristics

	Center 1	Center 2	Center 3	Center 4	p-value
Duration (min:s) median (IQR)	4:58 (3:46-6:00)	6:13 (5:05-7:29)	4:15 (4:05-4:46)	4:29 (3:45-6:05)	0.47
Rate of biopsies reaching the aimed sector (%) median (IQR)	67 (58-75)	75 (73-77)	75 (71-83)	67 (50-75)	0.37
Simulator score (%) median (IQR)	50 (36-58)	46 (40-55)	53 (49-63)	49 (35-57)	0.78

Table 2: Training outcomes - Detailed scores obtained by residents from each center

Study	Participants	Score median (IQR)	Overall realism median (IQR)	Usefulness for initial training median (IQR)
2013 – Initial validation [7]	Novices (n=14) Experts (n=7)	60 (43-68)	90 (71-97)	82 (79-96)
2019 – Second version validation [9]	Novices (n=10) Confirmed (n=11)	43 (33-55)	77 (57-90)	100 (87-100)
2020 – Transfer of skills validation [5]	Medical students (n=22)	47 (36-58)	NR	NR
2021 – External validation	Residents (n=23)	50 (37-60)	80 (69-98)	97 (87-100)

Table 3: Overall realism and usefulness for initial training of the biopsy procedure and Biopsym score across validation studies (NR – not recorded)



Figure 1: Current version of the BiopSym simulator.

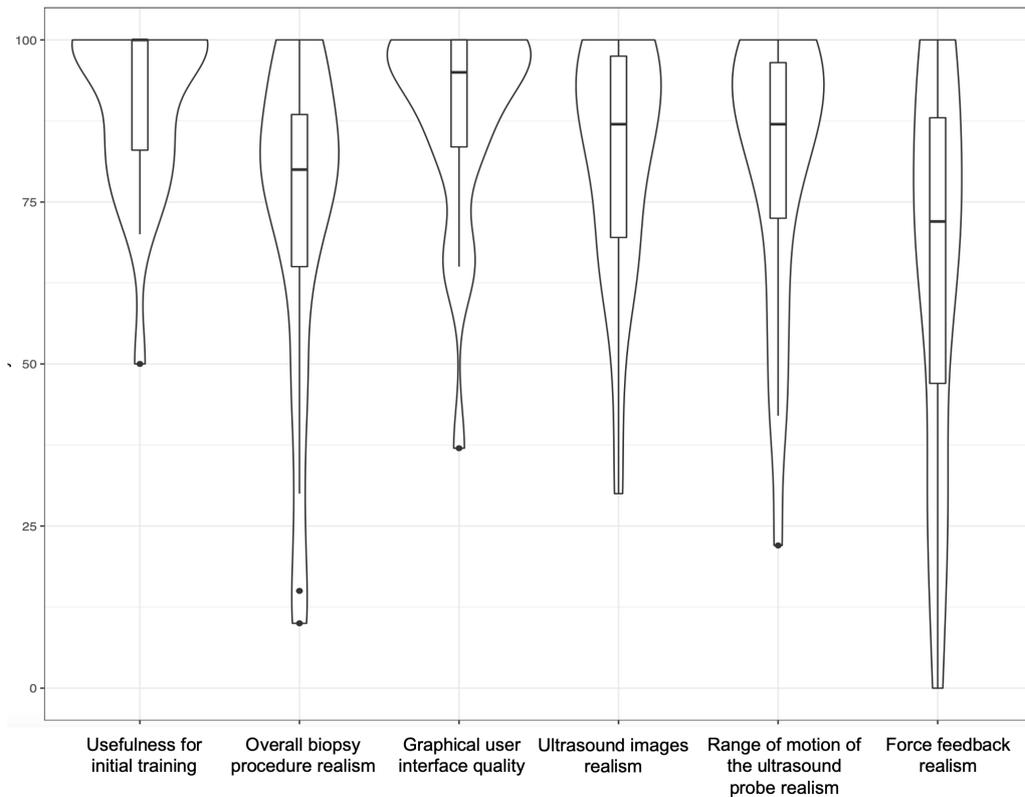


Figure 2: Simulation realism and usefulness for initial training (scores from 0 to 100, 100=highest agreement).

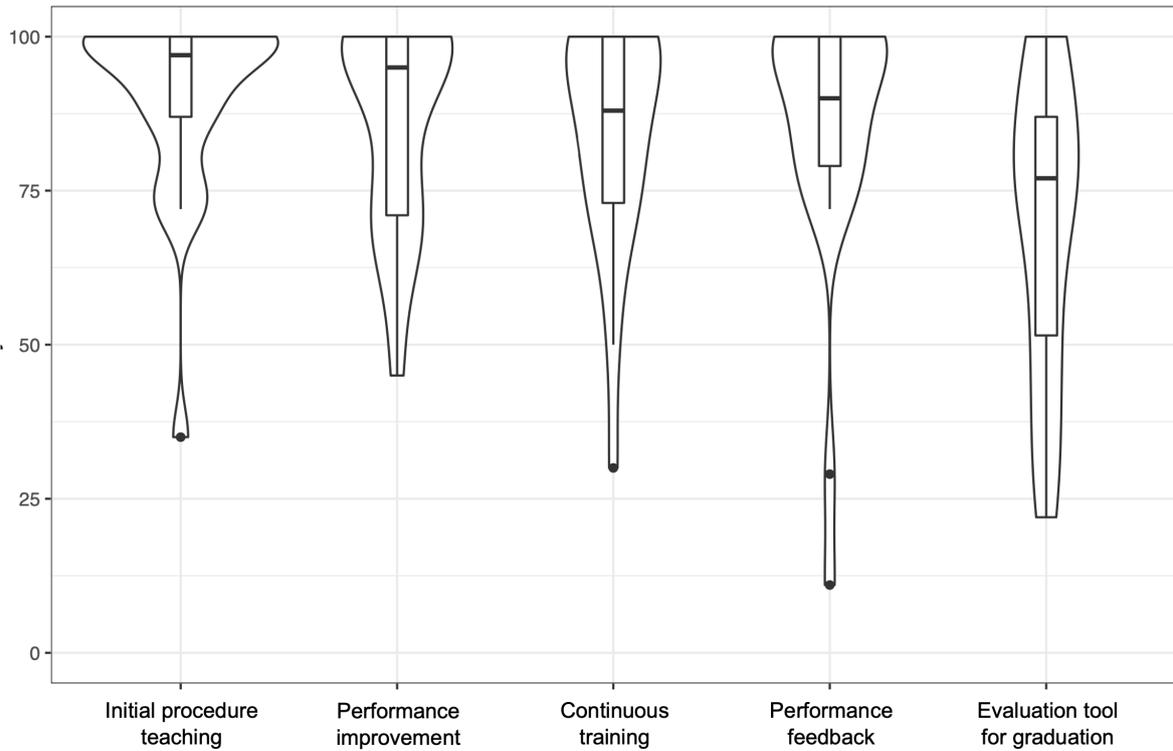


Figure 3: Expectations of the residents with regard to simulation for the use of prostate biopsy teaching and training (scores between 0-100, 100=highest agreement).

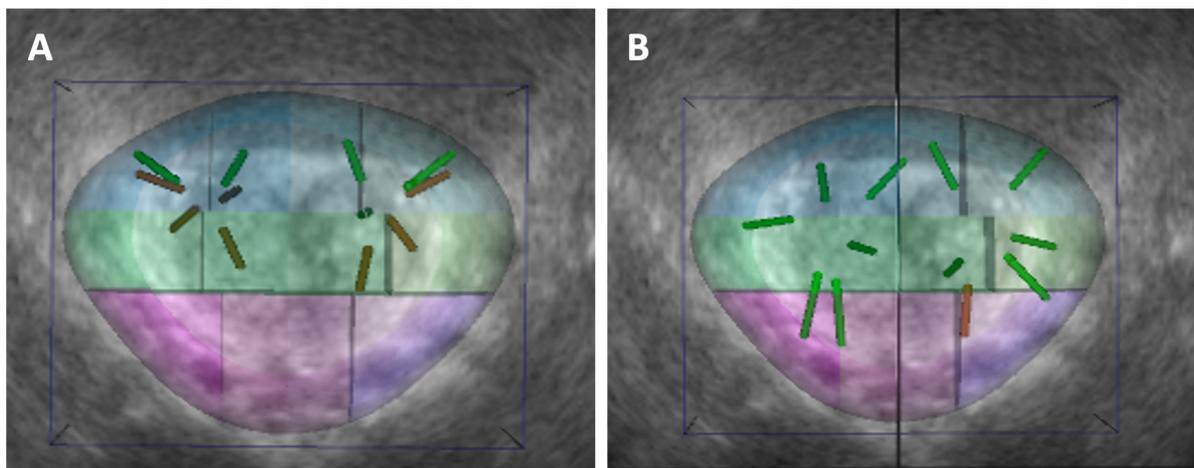


Figure 4: Examples of visual feedback obtained by 2 residents (A-no prior biopsy experience; B-prior biopsy experience) at the end of the simulated procedure, showing the prostate contour, targeted sectors and simulated biopsy trajectories. (prostate sectors: blue = base, green = mid, pink = apex).

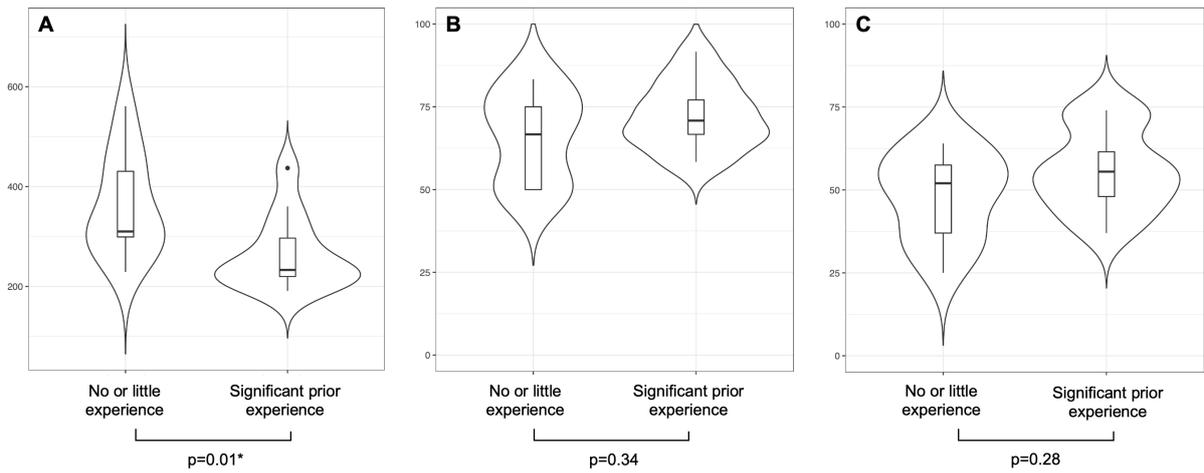


Figure 5: Training outcomes and scores. A-Duration of the simulated 12-core systematic biopsy procedure; B-rate of biopsies reaching the aimed sector (where at least the tip of the simulated core was inside the sector - in %); C-score given by the simulator (taking into account the length of each simulated core inside the sector – in %). *statistically significant