

# **Validating the transfer of skills acquired on a prostate biopsy simulator: a prospective, randomized, controlled study**

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## **Abstract**

*Objectives:* To evaluate the ability of students to reproduce the skills acquired on a prostate biopsy simulator in a real-life situation.

*Design:* A prospective randomized controlled study was conducted. Medical students with no experience of prostate biopsy were randomized between arm A « conventional training » and arm B « simulator-enhanced training. » The training was performed for both groups on the simulator. The students in arm B were provided with visual and numerical feedback. The transfer of skills was assessed by recording the position of the 12 biopsies performed by each student on an unembalmed human cadaver using a 3D ultrasound mapping device.

*Setting:* The study was conducted in an academic urology department and the cadaver experiments in the adjoining anatomy laboratory.

**Results:** Twenty-four students were included, and 22 completed the study. The median score obtained on the simulator at the end of the training was 57% (53-61) for arm A and 66% (59-71) for arm B. The median score obtained on the cadaver by students trained with the simulator was 75% (60-80), statistically superior to the score obtained by students trained conventionally of 45% (30-60),  $p < 0,0001$ . The median score obtained by all students when performing biopsies in a real-life situation was 63% (50-80) versus 60% (56-70) for their last training on the simulator.

**Conclusion:** These results support the transfer of skills acquired on the simulator, and the superiority of a training curriculum integrating simulation and performance feedback.

### **Keywords**

simulation; prostate biopsy; prostate cancer; computer-assisted training; surgical education

### **Introduction**

The diagnosis of prostate cancer still mostly relies on the performance of ultrasound-guided systematic prostate biopsies. The even distribution and correct placement of the biopsies require an accurate mental representation of the gland in which to navigate while exploring the prostate volume with the ultrasound probe. This mental representation is acquired after several biopsy procedures under the guidance of a mentor who transfers his own representation, with the risk of transferring his own inaccuracies. Areas of the prostate may then be systematically undersampled, even for experienced operators <sup>1</sup>.

Nowadays, practice is evolving from systematic prostate biopsies towards image-guided, targeted biopsies. The development of MRI-ultrasound fusion devices allows for the visualization of the position of the biopsies, but such devices remain costly, and their use for training can be time-consuming <sup>2</sup>. Targeted biopsies, *a fortiori* when using cognitive fusion, are less likely to be entrusted to a urologist-in-training. A reduced number of biopsies and the increased complexity of the procedure will certainly further contribute to a decrease in training opportunities.

The Biopsym simulator, simulator for prostate biopsies, was first developed in 2008 to allow for the training of the prostate biopsy procedure before practicing on a patient. Through the performance of simulated systematic biopsy procedures, using prostate

ultrasound volumes acquired during real biopsy procedures, the trainee can build his mental representation of the prostate and obtain visual and numerical feedback on his performance. Successive versions of the simulator have allowed its evolution to its current state, and its preliminary evaluation, including the validation of the face, content, and construct of the simulator <sup>3,4</sup>.

The objectives of the present study were to validate the transfer of skills acquired on the simulator to a real-life situation, through a prospective, randomized, controlled study.

## **Methods**

### *Participants*

This study was performed in an academic urology department between February and July 2018. Medical students between the 3rd and 6th year of medical school (pregraduate) and residents with no experience of prostate biopsy (postgraduate year 1) were enrolled prospectively. All students had given oral consent and were informed that they could withdraw from the study at any time.

### *Randomization*

Students were randomized between Arm A « conventional training » and Arm B « simulation-enhanced training. » A 1/1 randomization was performed using the application Randomizer for Clinical Trial (Medsharing).

### *Student training modalities*

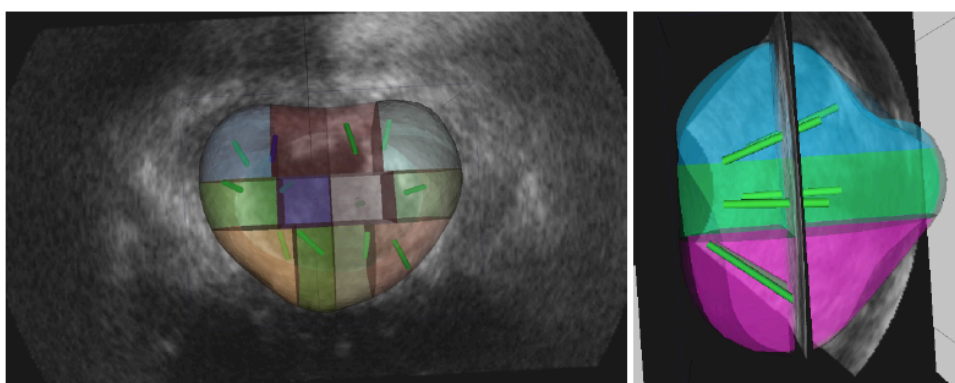
All students were trained on the simulator (**Figure 1**). Students from both arms performed a total of 5 systematic, 12-core, ultrasound-guided prostate biopsies under the guidance of a urologist. The number of procedures was chosen because it corresponded to the median number of biopsy procedures performed by a resident during a 6-month training period based on the analysis of the case logs of 13 residents during two consecutive semesters.



**Figure 1:** Simulator design

Two training sessions were offered per student, with an introduction, an initiation explaining the manipulation of the simulator, and a debriefing at the end of the session. The progression of the students was monitored using visual and numerical (score) feedback. The score and visual output were registered but not provided to students in Arm A « conventional training. » Similarly, no access was granted to the simulator between two biopsy sessions.

The students in Arm B « simulation-enhanced training » were provided with visual and numerical feedback on the distribution of the biopsies (**Figure 2**). They were also allowed to practice on their own using all the exercises available in the simulator, except for the performance of supplementary biopsy procedures. The exercises allow for the training of various aspects of the prostate biopsy gesture, from ultrasound image interpretation to the performance of targeted biopsies on a predefined sector or target <sup>5</sup>.



**Figure 2:** Visual feedback on the distribution of the biopsies

### *Faculty training modalities*

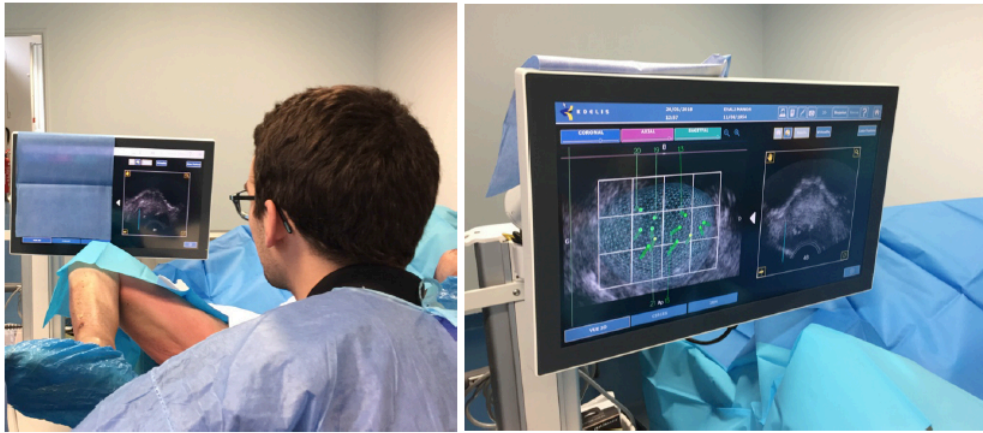
All trainers involved in the validation study received training to deliver a standardized introduction, initiation, and debriefing. All had previous knowledge of the simulator. Faculty training included the amount and type of feedback to offer students during the initial training on the simulator, to replicate the feedback offered during a real biopsy session on a patient. It included help with the probe manipulation and navigation inside the prostate ultrasound images.

### *Validation of the transfer of skills*

The unembalmed human cadaver model was chosen for the validation of the transfer of skills, after a preliminary study allowing to validate the quality of the ultrasound images obtained. The cadaver was installed in the lithotomy position at least 4 hours prior to the biopsy sessions to allow for tissue heating, and the bladder was filled with 50cc of water. Provided that sufficient tissue heating was allowed, the rectal characteristics of the cadaver had no impact on the ultrasound images obtained.

A 3D ultrasound volume of the prostate was acquired, and the prostate contours were drawn at the beginning of each validation session. Every student then performed a series of 12 systematic virtual prostate biopsies using a 3D ultrasound mapping device (Trinity, Koelis, France). Virtual biopsies were obtained by performing a 3D-ultrasound scanning of the prostate with the biopsy gun in place ready for firing. Knowing the position of the needle guide solidarized with the probe, the software was able to generate a virtual biopsy position with a precision  $<1\text{mm}$ <sup>6</sup>. Virtual biopsies were chosen to prevent previously performed biopsies from leaving a trace in the ultrasound image that could help or confuse the students. The distribution of the biopsies was hidden to the student during the procedure, and the guidance of the biopsies was performed using only 2D ultrasound images. The location of each biopsy was registered by a 3D scanning of the prostate after placement of the needle guide in position, and the result was provided to the student only after completing the entire procedure (**Figure 3**).

For each student, the location of the 12 biopsies performed inside the prostate contour was registered.



**Figure 3:** Registration of each biopsy location (not shown to the student during the procedure-left picture) and final result

### *Performance scoring*

In order to quantify the performance of the students on the cadaver model, the results of the distribution of their 12 biopsies were anonymously analyzed and attributed a score by three experts (including one from an external institution), blinded to the student's arm. Each expert was asked to give a score in % representing the quality of the distribution of the biopsies. No specific training or indication was provided to the raters so as not to influence the factors taken into account by each expert when attributing a score.

### *Sample size and statistical analyses*

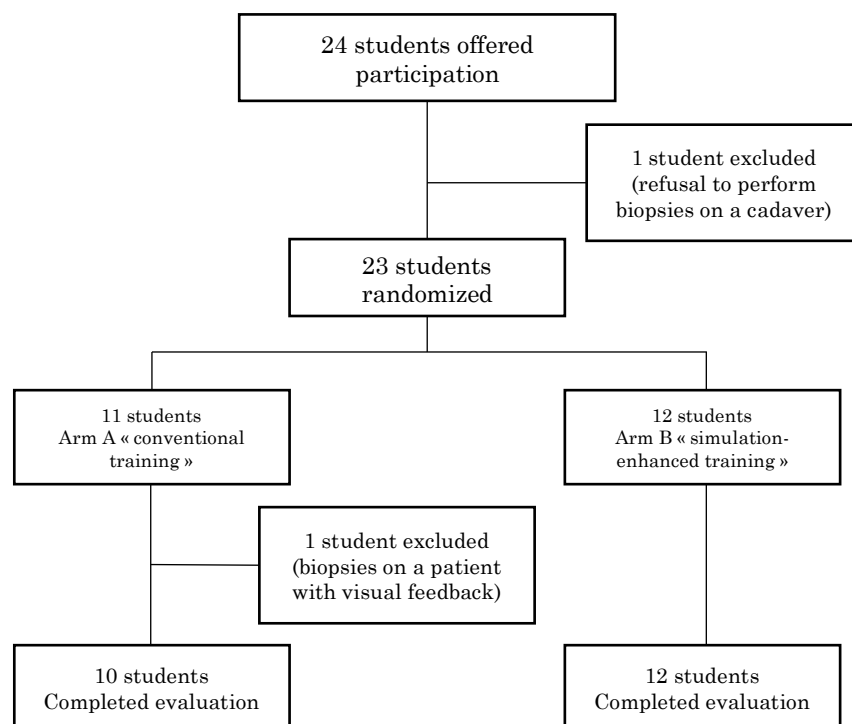
A sample size of 24 students was calculated to show a 17% superiority of score in favor of Arm B « simulation-enhanced training » (corresponding to a difference of 2 correctly placed biopsies), with a power of 90% and alpha-risk set at 5%.

Results are presented as medians (Q1-Q3). The inter-rater reliability of the scores given by the three experts was determined by calculating the intraclass correlation coefficient. A non-parametrical test (Wilcoxon-Mann-Whitney) was used to compare the scores obtained by the students from both arms, combining the three scores given by the three experts. Statistical analysis was performed using R (version 3.2.1; The R Foundation for Statistical Computing, <http://www.R-project.org>), with statistical significance set at  $p < 0.05$ .

## Results

### Participants

Twenty-four students were offered to take part in the study. One student refused to perform biopsies on a cadaver and was not included in the study. One resident in Arm A « conventional training » was excluded after performing biopsies with visual feedback on a patient during the study. The study flow diagram is detailed in **Figure 4**. The detailed characteristics of the students in both arms are presented in **Table 1**.



**Figure 4:** Study flow diagram

	Arm A « conventional training » (n=10)	Arm B « simulation-enhanced training » (n=12)
<b>Age</b>	21 (21-22)	22 (22-24)
<b>Gender – n (%)</b>		
- Female	5 (50)	4 (33)
- Male	5 (50)	8 (67)
<b>Dominant hand – n (%)</b>		
- Right	8 (80)	10 (83)
- Left	2 (20)	2 (17)
<b>Year of study – n (%)</b>		
- 3 <sup>rd</sup>	3 (30)	2 (17)
- 4 <sup>th</sup>	5 (50)	7 (58)
- 5 <sup>th</sup>	1 (10)	1 (8)
- Resident	1 (10)	2 (17)
<b>Video games player – n (%)</b>		
- Yes	6 (60)	5 (42)
- No	4 (40)	7 (58)
<b>Musician – n (%)</b>		
- Yes	3 (30)	5 (42)
- No	7 (70)	7 (58)

**Table 1:** Participants characteristics

### *Learning curve*

The median scores obtained by all participants during their first and last biopsy sessions on the simulator were 47% (38-58) and 60% (56-70), respectively. The detailed progression of each group is presented in **Table 2**.

	Arm A « conventional training » n=10	Arm B « simulation-enhanced training » n=12	All students n=22
<b>Biopsy 1</b>	40 (13-56)	55 (44-57)	47 (36-58)
<b>Biopsy 2</b>	61 (43-69)	51 (41-65)	56 (41-68)
<b>Biopsy 3</b>	57 (57-58)	64 (54-68)	57 (54-67)
<b>Biopsy 4</b>	58 (57-61)	60 (48-68)	58 (53-63)
<b>Biopsy 5</b>	57 (53-61)	66 (59-71)	60 (56-70)

**Table 2:** Learning curve of the students in both arms (scores in % given by the simulator for each biopsy session)



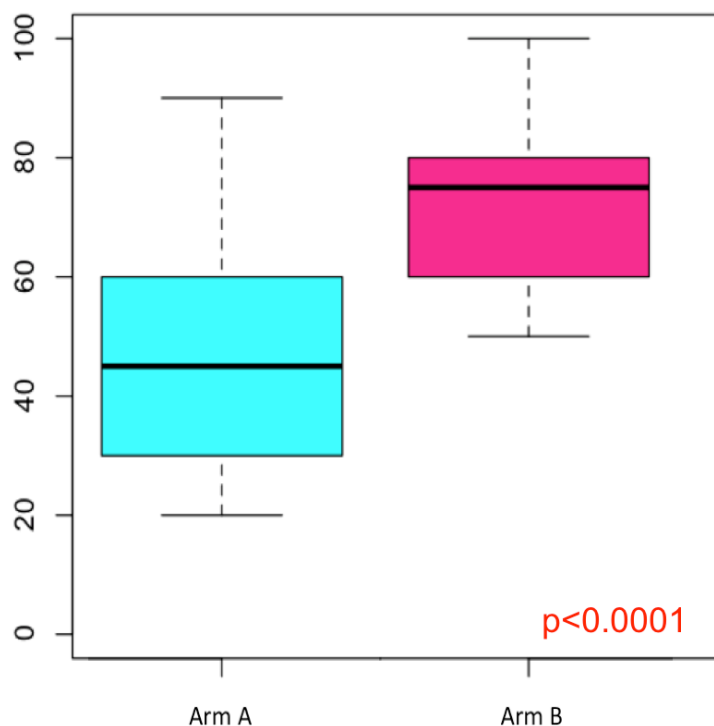
### *Transfer of skills*

The evaluation of the transfer of skills was performed during six sessions on two unembalmed male human cadavers. The median duration of a 12-core biopsy procedure was 13 minutes (11-16).

The inter-rater reliability between the three experts was good (Intraclass correlation coefficient ICC=0,755; IC95% [0.58-0.88],  $p<0,0001$ ).

The median score given by the 3 experts to the entire cohort was 63% (50-80). The median score in arm A was 45% (30-60). The median score in Arm B was 75% (60-80). The scores obtained by the students in Arm B « simulation-enhanced training » were significantly superior to the scores obtained by the students in Arm B « conventional training » ( $p<0.0001$ , **Figure 5**).

The distributions of prostate biopsies of the 22 students are provided in the **Appendix**.



**Figure 5:** Scores obtained by students from both groups (experts rating)

## Discussion

This study shows validity evidence of the transfer of skills acquired on the Biopsym simulator used for the initial training of the prostate biopsy procedure.

In the field of surgical simulator validation, transfer validation studies are often missing. In most cases, simulated procedures were laparoscopic or robotic procedures, probably because of an easier recording and *a posteriori* visualization of the surgical performances of the trainees <sup>7,8</sup>. The human cadaver model has already been described for the transfer validation of the skills acquired on a ureteroscopy virtual-reality simulator <sup>9</sup>, and this is to our knowledge the first study attempting at evaluating the transfer of skills in the specific domain of ultrasound-guided prostate interventions.

Noureldin et al. recently called for a shift in theory and terminology for validation studies in urological education <sup>10</sup>. This plea for a change is based on a profound modification in the concept of validity from several standards for educational and psychological testing since 2014. Still, the vast majority of urological validation studies rely on the former definitions of face, content, construct, and transfer validity.

The « conceptual framework » of the Biopsym simulator was defined and described through previous validation studies, whose results gathered initial evidence (content evidence, internal structure evidence, response processes evidence) towards the validity of the simulator. The results from the present study further contribute to this validation process by showing validity evidence of the transfer of skills for the initial training of the prostate biopsy procedure. Although no direct comparison can be made between the two scores, the median score given by the experts during the final evaluation (63%) also supports the clinical relevance of the scoring system used on the simulator (median score during the last biopsy 60%), and the possibility to use the simulator as an evaluation tool.

Several points of discussion have to be taken into consideration when analyzing these results. Although the simulator was designed to be used without supervision, the initial training of prostate biopsies still required the guidance of a trained urologist. The scores at the end of the training were on the high side of the scores obtained during previous validation studies <sup>3</sup>. This underlines the importance of the human factor in simulation training and the need for external validation to validate the reproducibility of these results obtained by trainers involved in the simulator development.

The unembalmed human cadaver model was chosen for obvious ethical reasons, but also because it allowed for the direct comparison of the performances of all students in the exact same conditions. However, the absence of reaction to pain or discomfort, as well as the absence of movement of the “patient,” have to be taken into account as they reduce the realism of the model used. Still, other features such as the deformation and movements of the prostate when applying excessive pressure on the ultrasound probe were well reproduced.

Finally, in order to prevent model deterioration, students performed virtual biopsies. This was necessary to avoid leaving a trace from previous biopsies but could be considered as bias, as biopsies were not actually performed. Nevertheless, each virtual biopsy was registered while the student was holding the biopsy gun needle ready for firing, and it is only the gesture of firing the needle that was not performed.

## **Conclusion**

These results support the transfer of skills acquired on the simulator and show the superiority of a training curriculum integrating simulation and performance feedback. Although no direct comparison can be made between the two scores, the median score obtained by the students during the final evaluation also supports the clinical relevance of the scoring system used on the simulator and the possibility to use the simulator as an evaluation tool.

## **Acknowledgments**

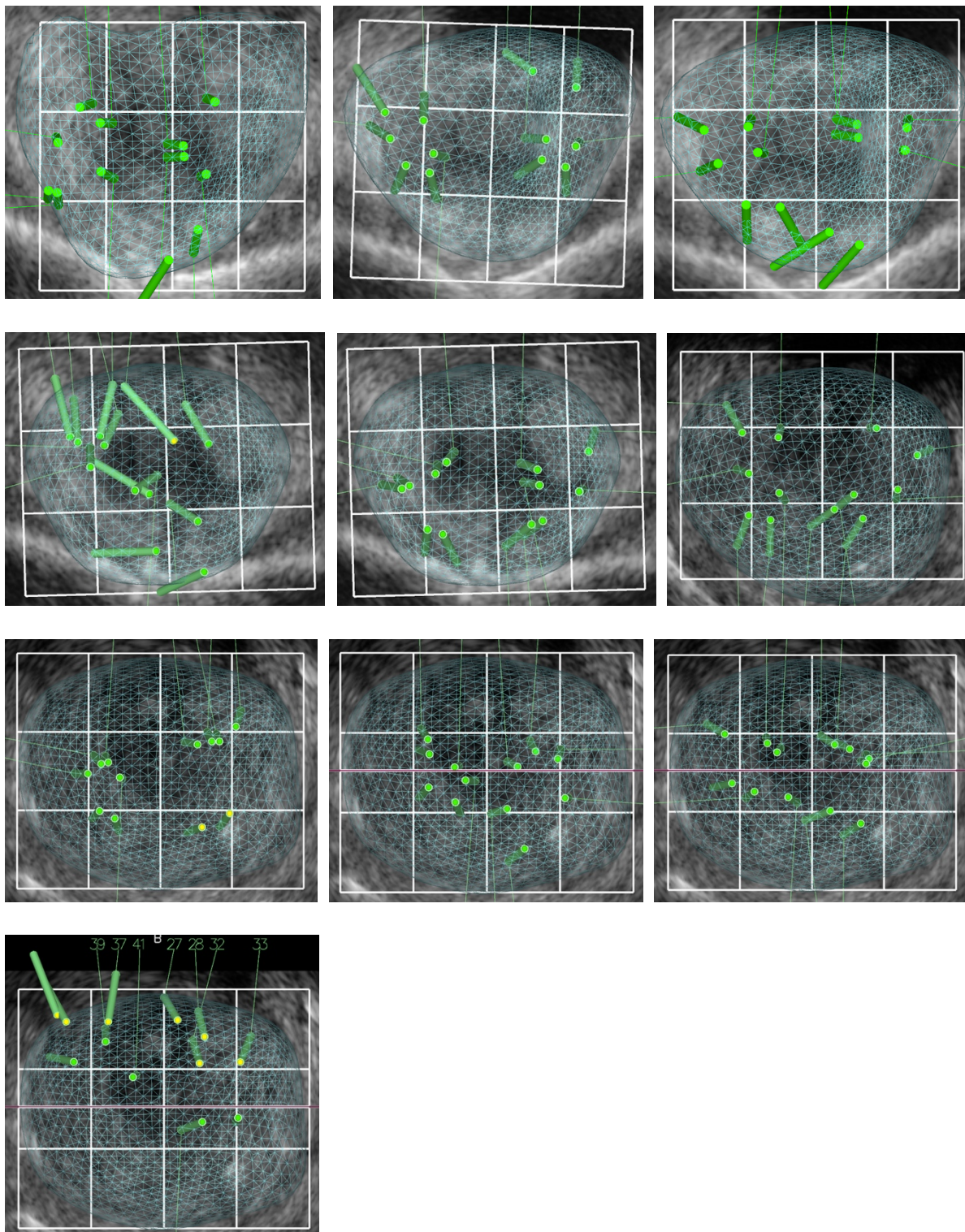
This work was partly supported by Agence Nationale de la Recherche (PROSBOT project ANR-11-TECS-0017, Equipex Robotex ANR-10-EQPX-44-01, Labex CAMI ANR-11-LABX-0004), French Industry Minister (FUI MIRAS project) and by the Association Francaise d’Urologie – AstraZeneca (grant G. Fiard). The authors also wish to thank Mr. Philippe Masson from the LADAF for his invaluable help during the cadaver study.

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## Appendix

### Arm A « conventional training »





## Arm B « simulation-enhanced training »

