The SEP "Robot"™: A Valid Virtual Reality Robotic Simulator for the Da Vinci Surgical System?

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ABSTRACT

The aim of the study was to determine if the concept of face and construct validity may apply to the SurgicalSim Educational Platform (SEP) "robot" simulator. The SEP robot simulator is a virtual reality (VR) simulator aiming to train users on the Da Vinci Surgical System. To determine the SEP's face validity, two questionnaires were constructed. First, a questionnaire was sent to users of the Da Vinci system (reference group) to determine a focused user-group opinion and their recommendations concerning VR-based training applications for robotic surgery. Next, clinical specialists were requested to complete a pre-tested face validity questionnaire after performing a suturing task on the SEP robot simulator. To determine the SEP's construct validity, outcome parameters of the suturing task were compared, for example, relative to participants' endoscopic experience. Correlations between endoscopic experience and outcome parameters of the performed suturing task were tested for significance. On an ordinal five-point, scale the average score for the quality of the simulator software was 3.4; for its hardware, 3.0. Over 80% agreed that it is important to train surgeons and surgical trainees to use the Da Vinci. There was a significant but marginal difference in tool tip trajectory ($p = 0.050$) and a nonsignificant difference in total procedure time ($p = 0.138$) in favor of the experienced group. In conclusion, the results of this study reflect a uniform positive opinion using VR training in robotic surgery. Concepts of face and construct validity of the SEP robotic simulator are present; however, these are not strong and need to be improved before implementation of the SEP robotic simulator in its present state for a validated training curriculum to be successful.

INTRODUCTION

Minimally invasive robot-assisted surgery is a technique that may be preferred over conventional laparoscopic techniques for selected procedures.[1,2] The Da Vinci Surgical System (Intuitive Surgical, Goleta, CA, USA) is currently the most widely implemented commercially available robotic telemanipulation system for endoscopic surgery. As of June 30, 2009, there have been 1242 unit shipments worldwide—916 in the United States, 221 in Europe, and 105 in the rest of the world.[3] These systems are incorporated in daily surgical practice in a wide variety of surgical, urological, gynecological, and cardiothoracic procedures. The success and increasing popularity of this technology, especially so for procedures in the confined and delicate pelvic abdominal workspace, can be explained by several advantages over other conventional methods of (endoscopic) surgery. The first short-term results of randomized pilot studies have been published, and they seem promising.[4–8]

First, there is preservation of the three-dimensional stereoscopic vision known in conventional open surgery but lacking in two-dimensional monitor-based endoscopic surgery. Next, the operators' wrist function is preserved using articulating instrument tips, providing the operator with seven degrees of freedom of motion, compared to five degrees in traditional endoscopic surgery. In addition to these benefits, surgeons have a comfortable and ergonomic seated operating position with restoration of the natural working axis, the computer corrects the human physiologic tremor, the fulcrum effect is eliminated, and there is improved dexterity due to motion scaling.[5–16] However, a drawback of the Da Vinci system is the lack of haptic or force feedback. In traditional endoscopic surgery, force feedback is reduced but not absent.[17,18]

Training in conventional minimally invasive surgery (MIS) is traditionally performed using a variety of teaching materials, such as standard box-trainers, live animal models, and education in the actual operating theatre. Modern surgical-skills training is shifting more toward a non-clinical setting. This is due to a variety of factors, including medico-legal issues, increasing costs of operating time, resident working hours, and ethical considerations.[19,20]

The ideal way to train robot-assisted MIS would be to practice repeatedly with the robot itself in the operating room with the supporting staff. Early experiences with such a curriculum are positive.[21] However, this approach makes surgical robot training logistically challenging, expensive, and time-consuming.

The use of various virtual reality (VR) simulators in teaching conventional MIS is continuously being developed and validated, although still in its implementing phase. Their use for training MIS skills has grown expansively over the last few years, and has indeed already proven to be effective.[22–28] Recently, a new VR surgical simulator was developed to train robot-assisted MIS: the SurgicalSim Educational Platform (SEP) robot simulator (SimSurgery AS, Oslo, Norway).[29]

A VR-robotic simulation is in theory highly applicable to the construction of a specific Da Vinci training curriculum because of the physical separation between user interface and operative field, for example, the "master" and the "slave." The SEP robot simulator aims at training specific Da Vinci console tasks mimicking the use of the articulating instrument tips in a console-type training situation.

Through the use of VR simulation for robotic training objective performance data may be generated to determine the learning curve of a potential endoscopic surgeon. Next, the apparatus can be used to train that same surgeon through repetitive, deliberate practice based on his or her individual performance reports. Once validated, the robotic training tool can be embedded in the high-end of the surgical curriculum of centers using the Da Vinci to train potential users. Furthermore, it may be implemented to maintain, develop, and warrant a high standard of quality of care, training, and testing of surgeons operating with the aid of the Da Vinci Surgical System.

As with any new high-end teaching technology, a full validation process of the SEP-robot simulator is mandatory. To achieve successful implementation into a new training curriculum, validated and objective community-based scoring and proficiency criteria must be obtained.[30] The first steps in this process are the determination of the apparatus's face and construct validity.

Face Validity

Face validity is a form of content-oriented validity in which consensus is obtained among a group of experts. The question is, to what extent does a novel instrument (SEP robot) simulate what it is supposed to simulate (Da Vinci)? Although not a formal validity concept, it refers to a subjective opinion about an instrument, for example, about its appropriateness for intended use of purpose within the target population. Face validity must be considered of utmost importance for the instrument's practical utility, and thus its success of implementation in a training curriculum.

Construct Validity

The concept of construct validity refers to the degree to which a novel instrument actually mimics what it intends to mimic, by direct or indirect standards. It is satisfied when test performance is logical and consistent with outcome parameters of interest.[31] An instrument that is construct valid should thus be able to differentiate between different levels of expertise, for example, novices performing less than experts should be reflected in the outcome parameters of the instrument. The purpose of this study was to determine the face and construct validity of the beta version of the SEP-robot surgical simulator.

SEP ROBOT SIMULATOR

The SEP-robot is the robotic version of the SurgicalSim Education Platform (SEP™).[29] The user interface is a generic surgical robotic interface with 6+1 degrees of freedom, analogous to existing surgical robots: three degrees of freedom for positioning the tool in three-dimensional space (the *x*, *y*, and *z* Cartesian coordinates), three degrees of freedom for orienting the tool in three-dimensional space (the azimuth, elevation, and roll angles), and one degree of freedom for measuring the opening of the grasper holder. The two manipulators are connected onto the basic SEP hardware platform, which

includes a real-time motion tracking system (PATRIOT™; Polhemus, Colchester, VT, USA) providing dynamic, real-time measurements of position and orientation. This information is used to describe the position of each part of the robotic arm using reverse kinematics techniques. A picture of the hardware of the simulator is shown in Figure 1.

The robotic simulator includes training modules for tissue manipulation, dissection, suturing, and knot tying. Modules for training for specific procedures are under development. The SEP-robot simulative system can run parallel with other SEP simulations on the same SEP hardware platform. The application framework is the same as for other SEP products and contains a database for user settings, training session configuration, proficiency levels, simulation results and progression, and so on. All simulation exercises and procedures follow a consistent learning model with clear learning objectives, multimedia tutorials, instructions, simulation, and after-action review. Simulation results are stored and presented numerically and graphically, and can be exported to standard formats for further analyses.

MATERIAL AND METHODS

Two separate questionnaires were prepared to determine face validity, and the responses were analyzed. The questionnaires were derived from previously validated structured questionnaires, as developed by Schijven et al.[32] For construct validity assessment, outcome parameters resulting from a hands-on simulation of the SEP-robot simulator were analyzed.

Face Validity Assessment

The first questionnaire was sent to the 16 users of the Da Vinci Surgical System in The Netherlands. They formed the reference group, and were consulted to determine a focused user-group opinion. Their questionnaire consisted of 19 statements that had to be evaluated with a simple "agree" or "disagree." The questions referred to user demographics, experience with the Da Vinci system, and opinions regarding use of VR in robotic surgical training. The survey was sent by e-mail, and non-responders were sent a reminder after 3 weeks and contacted by telephone after 5 weeks.

The second questionnaire consisted of two parts. Again, the first part contained the 19 statements that had to be evaluated with a simple "agree" or "disagree." This part was to be completed before taking part in an actual hands-on simulation. After the hands-on simulation, the second part of the questionnaire was to be completed by scoring eight statements on a five-point Likert answering scale to validate the current status of the simulator's software and hardware.

Participants in the hands-on experience were physicians with varying levels of MIS experience, none of which had any previous experience with the SEP-robot simulator. For result analyses, a distinction between participants was made based on their MIS experience. Physicians with more than 50 performed MIS procedures were considered experienced, and physicians with less than 50 performed MIS procedures were considered novices.

Construct Validity Assessment

To determine the construct validity outcome, parameters of the hands-on simulation were analyzed. The hands-on simulation consisted of a suturing task. In our study, the task that had to be performed on the simulator consisted of pulling a virtual needle through virtual gastric tissue and placing it in a safe end position in space. No knot had to be applied.

During this task, the following outcome parameters were scored for analysis:

Total procedure time needed to complete the task (seconds)

Tool tip trajectory, an indicator for path length of the instrument tips (cm)

A maximum ("run-out") performance time of 5 minutes was allocated to the particular suturing task. No data were collected in the case of an unfinished task. Correlations between these outcome parameters and the number of performed endoscopic procedures were assessed.

Demographic parameters, gender, age, experience with computer games and, finally, the average number of

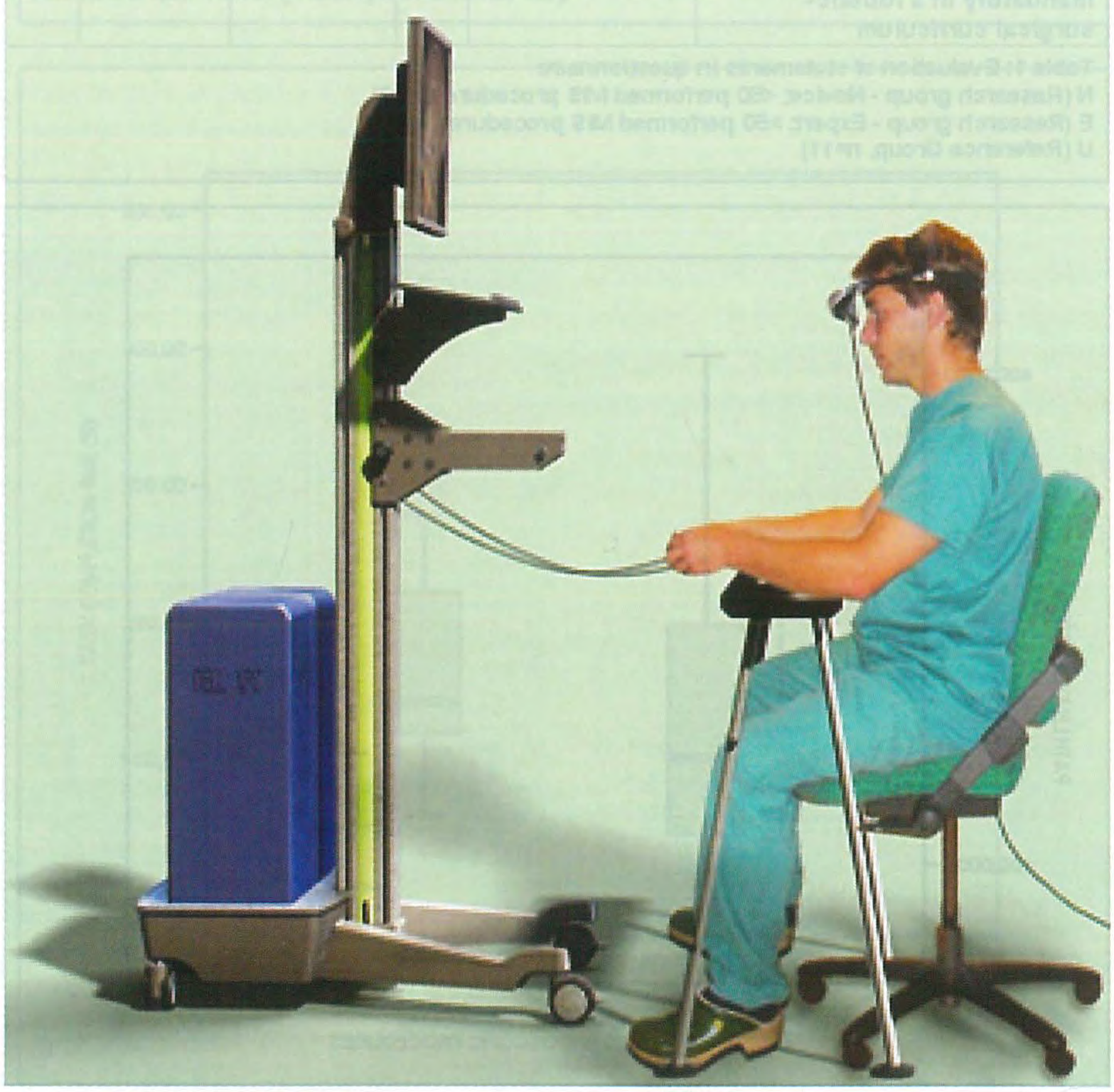

Figure 1. SEP robot's hardware platform.

Table I.

STATEMENT	Disagree %			Agree %			No opinion %		
	N	E	U	N	E	U	N	E	U
I believe it is important to train residents in robotic surgery	0	0	-	100	71.4	-	0	0	-
I believe it is important to train surgeons in using the surgical robot in a simulated environment	0	14.3	9.1	80	85.7	81.8	20	11.8	9.1
I believe it is important to train surgeons in using the surgical robot in a VR simulated environment before operating on patients	0	0	9.1	70	85.7	63.6	30	14.3	27.3
I believe that the SEP 'Robot' is a cost effective way to train the use of the da Vinci SS	0	0	0	20	57.1	54.5	80	42.9	45.5
I believe the SEP 'Robot' is an appropriate method to measure endoscopic proficiency needed for the use of the da Vinci SS	0	0	0	30	42.9	63.6	70	57.1	36.4
I believe the SEP 'Robot'is a effective tool to maintain robot surgical skills	30	28.6	18.2	40	71.4	18.2	30	0	63.6
I believe it is time for a one-day robotic surgery training course in which VR simulation and a general introduction are the basis	10	28.6	36.4	50	42.9	36.4	40	28.6	27.3
I believe that a VR simulator like the SEP 'Robot' is mandatory in a robotic-surgical curriculum	0	0	0	60	28.6	45.5	40	71.4	54.5

Table 1: Evaluation of statements in questionnaire
N (Research group - Novice; <50 performed MIS procedures, n=9)
E (Research group - Expert; >50 performed MIS procedures, n=7)
U (Reference Group, n=11)

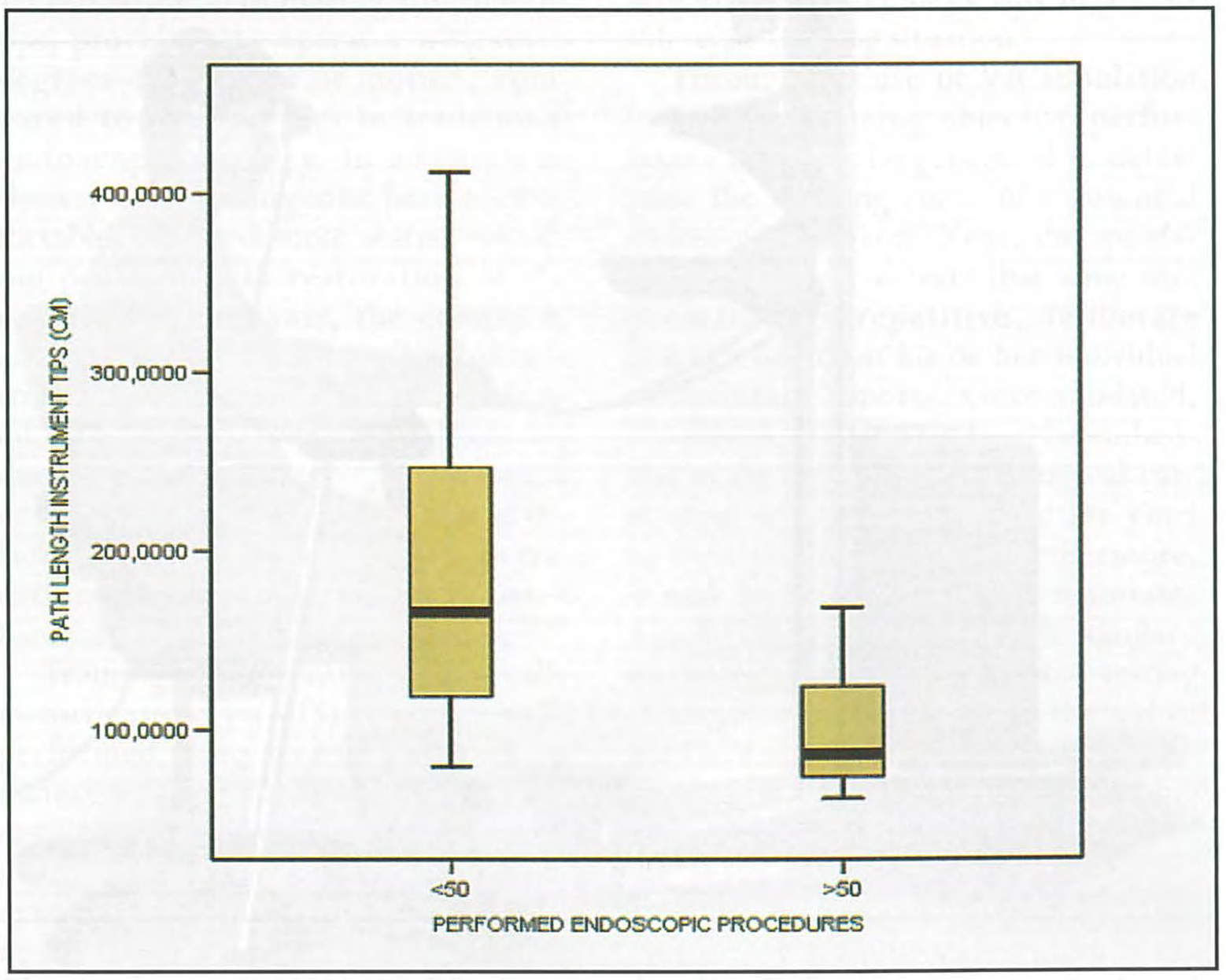

Figure 2. Box plot illustrating path length of instrument tips vs. performed MIS procedures.

endoscopic procedures performed per year were also analyzed for correlation with the outcome parameters.

STATISTICS

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) v. 13.0. Face validity was assessed using descriptive dichotomous variable data analysis for the proposed statements. To validate the current status of the simulator's hardware and software, analysis of the second part consisted of assessment of the results of eight statements with a five-point Likert scale using the Kolmogorov-Smirnov test to assess significance.

For assessment of the outcome parameters for construct validity, a two-tailed Mann-Whitney U test was used. Also, correlations between the mentioned outcome parameters and the degree of endoscopic experience were assessed using a Pearson's two-tailed bivariate correlation analysis.

RESULTS

Face Validity

First, the focused user-group opinion among Da Vinci users regarding a specific VR robotic training simulator was evaluated.

Actual Da Vinci Users: Reference Group

Eleven of the 16 addressed Da Vinci users in the Netherlands responded to the questionnaire (69%). The male:female ratio in this group was 9:2 and it consisted of four gynecologists, four general surgeons, and three urologists. Total experience in the use of the Da Vinci robot ranged from less than 50 performed procedures in nine respondents (82%) to between 50 and 100 performed procedures in one respondent. One respondent (a general surgeon) stated to have performed over 100 robot-assisted laparoscopic procedures.

Of the respondents, 80% agreed that it is important to train interested surgeons in the use of the Da Vinci robot with the use of specific VR techniques. Also, the majority of these respondents (67%) estimate a VR training module like the SEP-robot to be a cost-effective

option of robotic training. These answers show a positive attitude toward implementation of a VR simulator in robotic surgical training in the majority of the aforementioned respondents, being the reference group of actual Da Vinci users.

Potential Da Vinci Users: Research Group

The participants of the hands-on SEP-robotic simulation study were separated into two categories based on individual MIS experience. An experienced group of potential Da Vinci users (more than 50 performed MIS procedures, to be called MIS experts) was identified, and a novice group of potential Da Vinci users (fewer than 50 performed MIS procedures, to be called MIS novices) was identified. Two participants, both novices, were not able to complete the task in the designated time span and, as a consequence, their outcome parameters could not be recorded. The male:female ratio of this group was 11:6, and the mean age was 33 (SD: 5 and 4).

Of the research group, a total of 17 participants completed the questionnaire after taking part in the suturing task, of which 16 participants completed both task and questionnaire. This group was used for further analysis and it consisted of seven MIS experts and nine MIS novices. Among the participants, the following medical specialties were represented: nine general surgeons, four urologists, one orthopaedic surgeon, and two gynecologists.

All respondents of the MIS novice group agreed on the fact that it is necessary for senior residents to train with the skills needed for robot-assisted endoscopic surgery during their residency. In the MIS expert group, 72% agreed with this statement. Concerning the statement of the importance to train on robotics with the aid of VR, 70% of the MIS novice group and 86% of the MIS expert group agreed. These results, combined with those of the reference group of actual Da Vinci users, are shown in Table 1.

To evaluate the quality of the software and hardware of this particular simulation, differences in opinion between MIS experts and MIS novices of the research group on the simulated environment of the SEP-robot were assessed. Both MIS novices and MIS experts were offered a tailored session of full hands-on simulation after an ini-

Table II.

RATINGS *(5-point Likert scale)*	Total	Novice group < 50		Expert group > 50		P-value*
	Mean	Mean	SD	Mean	SD	
Realism of the movement of the virtual instruments in the SEP 'Robot' simulation	2,94	2,90	0,88	3,00	0,82	1,000
Realism of the behaviour of the stitch thread in the SEP 'Robot' simulation	3,12	3,00	0,94	3,29	0,95	1,000
Realism of the behaviour of the stitch needle in the SEP 'Robot' simulation	3,41	3,50	0,52	3,29	0,76	1,000
Realism of the virtual environment of the SEP 'Robot' simulation	3,06	2,90	0,88	3,28	0,95	0,922
Realism of the virtual endoscopic instruments of the SEP 'Robot' simulation	3,71	3,50	0,84	4,00	0,00	0,852
Overall ergonomics	2,88	3,10	0,99	2,57	1,13	0,621
Ergonomics hand-pieces	3,00	3,30	0,82	2,57	1,13	0,621
Design of the simulator	3,23	3,60	0,70	2,71	0,76	0,155

Table 2: Research group MIS Novice (n=9) and Research group MIS Expert (n=7) opinion on hard-and software of SEP 'Robot' (**Kolmogorov-Smirnov test*)

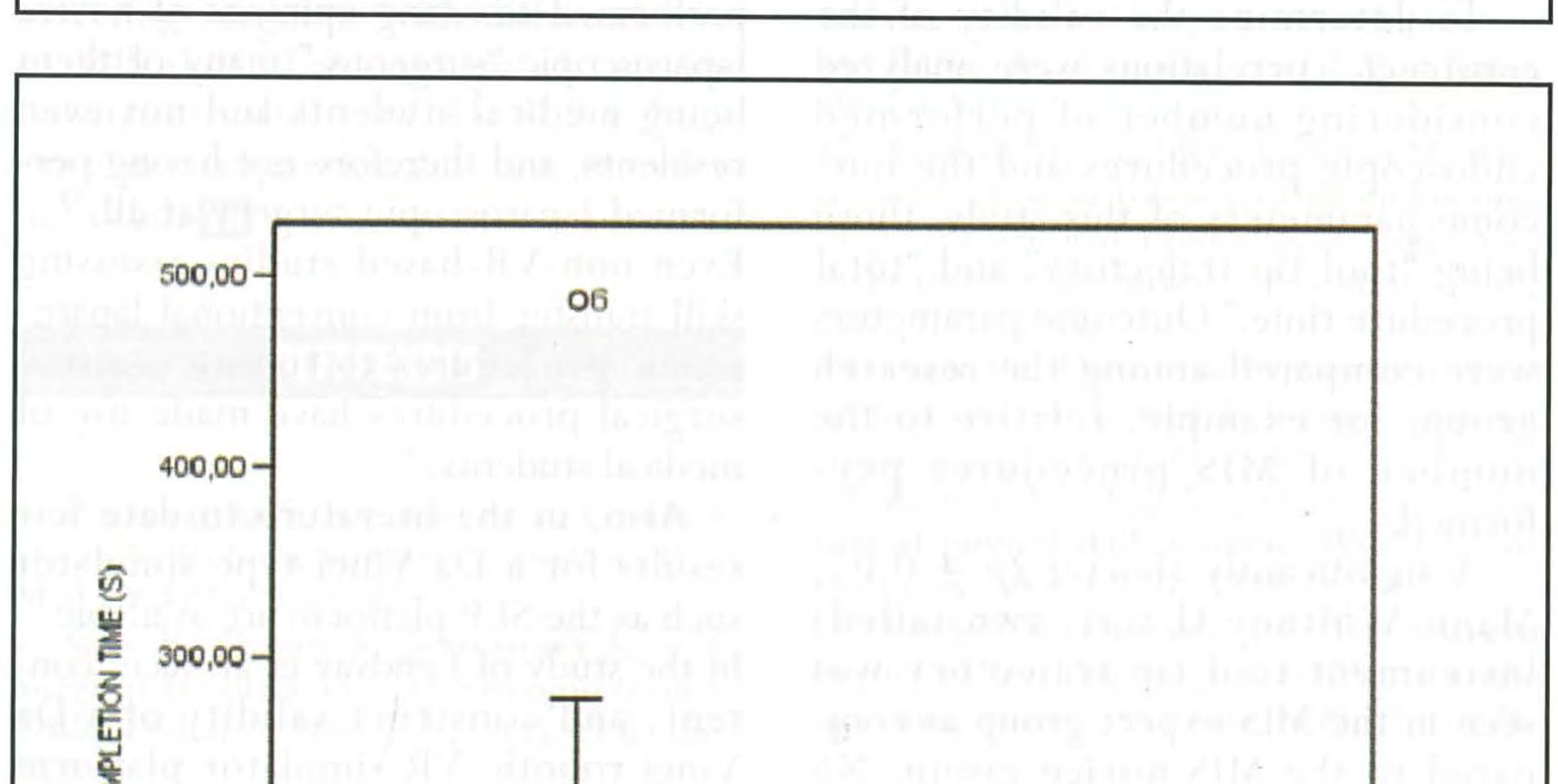

Figure 3. Box plot illustrating task completion time vs. performed MIS procedures.

tial familiarization run on the simulator.

With regard to the overall quality of the software of the apparatus, the MIS expert group had a more favorable opinion than the MIS novice group, with mean outcome scores of 3.4 and 3.16, respectively. This section of the questionnaire studied the opinion regarding the realism of the simulated environment, the realism of the endoscopic instruments and their movements, and the behavior of the thread and the suturing needle. Overall, the opinion of the software in both the MIS novice and the MIS expert group is uniformly positive.

Regarding SEP's hardware, opinions tend to be more conservative and less uniform among the reference group. Considering the design and ergonomics of the presented simulator, the MIS experts appeared to be unconvinced with a mean score on these items of 2.6, compared to a more favorable attitude of 3.3 within the MIS novice group. The results for the evaluation of both the software and hardware are displayed in Table 2.

Construct Validity

To determine the validity of the construct, correlations were analyzed considering number of performed endoscopic procedures and the outcome parameters of this study, those being "tool tip trajectory" and "total procedure time." Outcome parameters were compared among the research group, for example, relative to the number of MIS procedures performed.

A significantly shorter ($p = 0.05$; Mann-Whitney U test, two-tailed) instrument tool tip trajectory was seen in the MIS expert group as compared to the MIS novice group. No difference was found in the end parameter of "total procedure time." These results are illustrated in Figure 2 and Figure 3, respectively.

The remaining correlations analyzed showed no significant differences between tool tip trajectory vs. average number of laparoscopic procedures per year (bivariate correlation coefficient = -0.494, $p = 0.06$; Pearson's two-tailed) and total task time and average number of endoscopic procedures per year (bivariate correlation coefficient = -0.413, $p = 0.126$; Pearson's two-tailed).

DISCUSSION

Our results reflect a positive attitude toward the training of robotic skills in a virtual environment, suggesting a solid base for implementation of a VR simulator in a robotic educational curriculum. This is true for all three of the questioned groups, that is, the reference group of Da Vinci users and the research groups of potential Da Vinci users (the latter group split into expert and novice MIS surgeons). Cost-effectiveness and the possibility to measure proficiency parameters are considered to be important potential benefits of any VR simulator in robotic surgical training.

One might argue that in our study, the group of participants having a "hands-on" experience with the simulator was analyzed in categories based upon their level of MIS experience, not on their level of robotic experience. This is true—in fact, very few of our participants had any experience in robotic surgery at all. Nevertheless, many studies assessing "face validity" of novelties, such as psychomotor surgical VR systems in the recent past, were performed assessing opinions of novice laparoscopic "surgeons," many of them being medical students and not even residents, and therefore not having performed laparoscopic surgery at all.[33–35] Even non-VR-based studies assessing skill transfer from conventional laparoscopic procedures to robotic-assisted surgical procedures have made use of medical students.[36]

Also, in the literature to date few results for a Da Vinci-type simulator such as the SEP platform are available.[37] In the study of Lendvay et al. face, content, and construct validity of a Da Vinci robotic VR simulator platform was assessed. The majority of participants in the mentioned study lacked robotic experience and were still in training for the performance of conventional laparoscopic procedures.[37] One might conclude that the study participants used by Lendvay et al. were therefore comparable to the participants of this particular study, based on endoscopic experience.

This is not necessarily a treat in the search of face validity of a training novelty, as an initial liking to a novelty must be present to acquire interest and early adopters of technology. In fact, the early adopters among surgeons now regularly using the Da Vinci have adopted their robot surgical system without having any surgical robotic experience indeed. Acknowledging the vulnerability of a surgeon's learning curve, the U.S. Food and Drug Administration (FDA) now requires manufacturers to train surgeons on a two-day training course before they can use robotic surgical systems on patients.[38] In fact, in the development of a cost-effective training apparatus for robotic surgery, opinions on face validity aspects from a target group audience (aspiring experienced laparoscopic but novice robotic surgeons) is therefore of utmost importance.

For the SEP-robot Da Vinci simulator of this particular study the overall opinion on the hardware and software is positive, although the reference group commented negatively on the hardware interface of the SEP-robot simulator and MIS experts of the research group were not satisfied with the apparatus' overall ergonomics, in particular the ergonomics of the hand pieces. Face validity is therefore questionable.

Only one of the variables measured assessing the apparatus' construct validity proved to be significant, namely the parameter "tool tip trajectory," assessed in the research group between MIS novices and MIS experts (in favor of the expert group, thus reflecting MIS experience). In contrast, the parameter "average number of MIS procedures per year" (also reflecting MIS experience) did not discriminate, neither did other parameters assessed. One must therefore question the apparatus' construct validity in this setting and context.

Again, one might argue that the research group was not suited for assessing the SEP's construct validity as they are not actual robotic-user surgeons. However, a robust Da Vinci simulator should be able to discriminate between the "level of MIS skill" easily; as the concept of robotic surgery is intuitive in itself, it is believed to require less psychomotor adaption than laparoscopic surgical situations or simulators.

The validation scores regarding SEP's software were uniformly positive between MIS novices and MIS experts. As for SEP hardware, the overall scores between MIS novices and MIS experts was less agreed upon. Especially, MIS experts are unconvinced. Results indi-

cate the ergonomics of the design to be problematic. The rating of the overall ergonomics and ergonomics of the hand pieces scored the lowest of all questioned, as reflected by the participants in the MIS expert group.

This result may be explained by the fact that the hardware of the Da Vinci, among other features, consists of a users' surgical console as part of the interface between surgeon and patient. Sitting comfortably within the console, the surgeon "commands" the robot's arms through telemanipulation. The ideal situation for VR-simulation of the Da Vinci would therefore be to integrate an actual Da Vinci console within the VR simulator or, maybe even more logical, to integrate a VR simulator for training purposes in an actual Da Vinci console. The major advantage of such a principle is that it provides the robotic-surgery trainee with exactly the same circumstances and conditions as when performing real-time robotic-surgery operations. This accounts for the seated operating position, the hand pieces, the three-dimensional vision, and the experience of working from within the console. The results therefore suggest that major adjustments to mainly the robot's hardware are necessary.

RECOMMENDATIONS

For the simulator of study, overall ergonomics and ergonomics of the hand pieces of the SEP-robot need to be improved. Afterward, the simulator needs to be re-assessed for its validity. In contrast to the setup of earlier studies in current literature assessing non-robotic surgery, we feel that actual Da Vinci users should be the first to assess this type of simulator and its validity rather than potential Da Vinci users in future studies.

In this respect, it must be mentioned that other corporations are involved in developing VR-assisted robotic surgery training simulators for the Da Vinci system. A promising novelty is the MIMIC dV-trainer (MIMIC Technologies, Seattle, WA, USA).[38,39] The combination of a haptic hardware platform, mimicking the actual Da Vinci console and handpieces, offering three-dimensional VR-educational programs, and optional haptic feedback as a surplus that is both appealing and promising. Validation studies are currently at the concept of study stages.

CONCLUSION

The results of this study reflect a uniform positive opinion using VR training in robotic surgery and the necessity of implementing VR-tailored robotic training in the curriculum for potential Da Vinci users.

The apparatus of study was the SurgicalSim Education Platform, a simulator for robotic surgery. Our results indicate the simulators' hardware interface and ergonomics to be problematic among (potential) user groups. In terms of face validity, the overall opinion on the hardware and software was positive, although actual Da Vinci users commented negatively on the hardware interface of the SEP-robot simulator and expert potential users were dissatisfied with the apparatus' overall ergonomics. Face validity is therefore questionable.

Construct validity could be established only for the outcome parameter "tool tip trajectory" by the SEP-robot assessing surgeons with different level of MIS skill. The concept of face and construct validity of the SEP-robotic simulator is questionable, and therefore not valid. STI

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