

RESEARCH

A Haptic laparoscopic trainer based on Affine Velocity Analysis: Engineering and preliminary Results

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Abstract

Background: General agreement exists upon the importance of acquiring laparoscopic skills outside the operation room through simulation-based training. Nevertheless such a learning is hindered by several flaws. High-fidelity simulators are cost-prohibitive (which limits training opportunities), and elicit a high cognitive load. Low-fidelity simulators lack in haptic, direct, and summative feedback. This paper introduces a new low-fidelity simulator integrating effective learning features and a new assessment variable while limiting the associated costs. We also detail primary validation results.

Methods: We engineered a low fidelity laparoscopic simulator taking into account psycho-motor skills, direct and summative feedback, and engineering key features (haptic feedback and complementary assessment variables). 77 participants with 4 different surgical skill levels (17 experts; 12 intermediates; 28 inexperienced interns and 20 novices) tested the simulator. We checked the content validity using a 10-point Likert scale and the discriminative power by comparing the 4 groups' performance over two sessions, using 3 variables: time, number of collisions, and affine velocity.

Results: The mean value score of the content validation was 7.57/10. The statistical analysis yielded performance discrepancies on the selected variables among the groups ($p < 0.001$).

Conclusion: We developed an affordable and validated simulator for testing and learning basic laparoscopic skills. The results exhibit three levels of performance. Results show that the embedded evaluation variables are complementary and provide realistic results. The inclusion of a new variable and, meanwhile, haptic, direct, and summative feedback is innovative regarding low-fidelity simulators. Limitations and implementation conditions of the simulator in the surgical curricula are discussed.

Keywords: Minimal Invasive Surgery; Motor Skills; Assessment metrics; Affine Velocity; Simulator validation

1 Introduction

- Minimally Invasive Surgery (MIS) has brought more comfort for the patients in
- comparison to open surgery [1, 2, 3]. However, MIS also challenged surgeons with

4 an increased need for manual dexterity, depth perception, and movement coordi-
5 nation through a 2D screen displaying the surgical field. Therefore, a different skill
6 set, e.g. involving spatial abilities [4], bi-manual coordination [5], and hand-eye co-
7 ordination [6], is essential in MIS practice. At the early stages of MIS learning,
8 the relevance of these skills is increased [7]. How these skills are learned is one of
9 the major concerns of young surgeons training [8]. Although simple observation of
10 laparoscopic skills may help to learn, direct practice on the virtual reality trainer
11 ensures more effective training [9]. During the past two decades, simulation-based
12 training and simulators have been more extensively used in surgeons' training [10],
13 without the risk of harming patients [11, 12], and with health care cost reductions
14 [11]. Two kinds of simulators coexist: low and high fidelity simulators. Low fidelity
15 ones recreate laparoscopic working conditions with simple instruments. They are
16 better suited to novice learners [12] as they are efficient for basic skills acquisi-
17 tion [13] such as clipping, grasping, or cutting. Indeed, a simple simulation training
18 without the pressure of result and enabling to progress at self-pace is less likely
19 to overwhelm novice learners [14]. However, low-fidelity simulators have obvious
20 limitations. First, they do not recreate the human body, making the illusion of real-
21 ity impossible [15]. Second, they fail to provide immediate feedback when an error
22 occurs, or summative feedback on completion of a trial [15, 16], path length or econ-
23 omy of movements either [15, 16, 17]. Inadequate or insufficient feedback seriously
24 hinders learning as their provision is fundamental for effective learning [12, 18, 19].
25 Finally, the use of low fidelity simulators requires the direct observation of an expert
26 for full assessment [15, 20]. Usually few available, these experts do not operate pa-
27 tients while they monitor such hands-on training sessions, and do extra hours that
28 are costly for the Society. Furthermore, their assessment is inherently subjective.
29 This reduces effective training opportunities for novice surgical students [21]. Once
30 one's proficiency is developed, high fidelity simulators are relatively more effective.

31 As they can replicate a whole procedure [10] (hysterectomy [22], cholecystectomy
32 [23], or salpingectomy [24], for instance), they are more suited to improve specific
33 procedural skills. As an example, training with the LAP MentorTM (Symbionix Cor-
34 poration, Cleveland, Ohio, USA) or the LAPSIM[®] (Surgical Science, Gothenburg,
35 Sweden) improves the performance of complete and complex laparoscopic proce-
36 dures [10, 22, 23]. Nevertheless, high fidelity simulators are very cost-prohibitive
37 and may not be accessible for regular and personal use [20, 25]. Besides, this lack of
38 availability limits ongoing training and hinders thereby skill retention [26]. Finally,
39 as shown in aviation training, the knowledge required to perform the task, added to
40 the complexity of the instrumentation and the pressure to perform may overwhelm
41 novice users [27]. The latter arguments show that high-fidelity simulators are bet-
42 ter suited for almost graduated interns than for novices. Globally, training skills on
43 both types of simulators are transferable to actual surgery conditions [28, 29]. Nev-
44 ertheless, a recent study showed that a 5-day training course using a box-trainer has
45 better outcomes than the same training using a high-fidelity simulator [30]. Even
46 if low-fidelity and high-fidelity simulators may be considered as a continuum in the
47 learning process [13, 18], a gap remains between them: on the one hand, high-fidelity
48 simulators provide accurate summative and haptic feedback but are expensive, over-
49 loaded and barely available. On the other hand, low-fidelity simulators cost less and
50 are broadly used by surgical students [17], but require supervision and do not pro-
51 vide enough feedback for effective learning at a stage where it is essential to acquire
52 the appropriate skills. To illustrate this gap, Yiasemidou *et. al.* [29] showed that the
53 students who autonomously trained on a “take-home” box trainer (\approx \$500) at home
54 during 6 weeks performed better than the ones who practiced on the High-Fidelity
55 Virtual-Reality-based simulator (\approx \$70,000). Therefore, a solution mixing low-cost,
56 broad availability, autonomous use, and objective automatic assessment should ef-
57 ficiently fill this gap. Concerning the assessment metrics used in surgical training

58 simulators: completion time, instrument path length, number of collisions (between
59 the laparoscopic tools and their environment) or count of dropped objects, are in-
60 direct indicators of laparoscopic proficiency that need to be associated with other
61 objective measures i.e. motion characteristics [14, 16]. A review of existing metrics
62 is provided in [31], which concludes that available metrics do not allow an objective
63 determination of the detailed expertise of subjects. Moreover, users do not consider
64 these metrics consistent with their performance [32]. To illustrate this situation, ex-
65 periments described in [33] revealed that experts performed more smooth, accurate
66 and fine movements compared to novices. Usual metrics do not directly evaluate the
67 curvature of instrument motions, which helps reveal the level of expertise of users,
68 as experimentally shown in this study. To address the above-mentioned flaws, this
69 study aims to develop and validate a new low-cost (\approx \$2500) low-fidelity simulator
70 providing: i) training on basic laparoscopic psycho-motor tasks (requiring spatial
71 and visual-motor capabilities to acquire universal gesture-based skills versus specific
72 surgical ones such as in [34]), ii) both haptic and summative feedback, and iii) a
73 new assessment variable (in a similar approach as Poursartip *et al.* [31]) permitting
74 the evaluation of the delicateness of motions. Thus, this training simulator could
75 be intensively used by students in full autonomy. As shown by Shout *et al.* [35],
76 before testing the training efficiency of a simulator, scientific validation needs to be
77 processed. According to current standards for educational and psychological test-
78 ing [36, 37], we present the preliminary validation results (reliability, content, and
79 relation with experimental designs).

80 **Material and Methods**

81 **Engineering and Exercises**

82 This simulator was designed by observing surgeons in operation rooms and isolating
83 key-skills with the help of the Fundamentals of Laparoscopic Surgery [38]. Prono-
84 supination, elbow flexion and extension, wrist rotations, and index finger rotations

85 were the basic anatomical movements that were analyzed. The exercises embedded
86 into this simulator require the user to regularly perform these anatomical move-
87 ments as they consist of navigation tasks using laparoscopic grasping tools while
88 avoiding 3D obstacles displayed on a computer screen. In total, 5 obstacles are dis-
89 played along the trajectory, each one requiring the execution of a specific action
90 (Figure 1). The exercises were submitted to and validated by the Head of Lyon
91 Surgery Department. They combine memory work, skills involving visual-spatial
92 ability [39]. Considering the high cognitive load involved by high-fidelity simula-
93 tors, which may negatively impact the ability to learn medical gestures [40], we
94 followed the recommendations of Mayer and Moreno [41] and kept the exercises
95 and the virtual environment simple, focusing on the gestures (trajectories and tool
96 synchronization).

97 ***Insert figure 1 around here***

98 To avoid high computing costs, we used open-source software and affordable ma-
99 terial [42]. This low fidelity simulator is a computer-based training system. The
100 hardware includes a computer (Microsoft Windows 7® Intel® Core™ i7-6500
101 CPU clocked at 2.50GHz, Nvidia® Geforce GTX940M, 8Go RAM), and a stan-
102 dard monitor displaying virtual 3D environment, associated with two real standard
103 laparoscopic surgical instruments, paired each one with a force-feedback device thus
104 simulating tactile and kinesthetic feedback (Geomagic Touch® haptic device, 3D
105 System Inc.). The latter is a 6 degrees-of-freedom device using three electrical mo-
106 tors as actuators, often used in medical simulators [43]. We developed the soft-
107 ware with Microsoft Visual Studio® 2015^[1] and we used the open-source Haptic
108 Framework CHAI3D 3.1.1^[2] to make the haptic devices, the 3D virtual world, and
109 the Open-GL 4.4^[3] renderer communicating to each other. We designed all vir-

^[1]see <https://www.microsoft.com/france/visual-studio/>

^[2]see <http://www.chai3d.org/>

^[3]see <https://www.opengl.org/>

110 tual objects with the 3DS Max software 2016^[4]. We finally collected and processed
111 performance data (affine velocity, motion duration, numbers of collisions) through
112 Matlab® R2015a (Mathworks)^[5].

113 ***Insert figure 2 around here***

114 Affine velocity is a metric that takes the geometry of the trajectory into account,
115 as well as its dynamics. In 2D drawing, humans tend to decrease the instanta-
116 neous tangential velocity of their hands while the curvature of the trajectory in-
117 creases. Correspondingly, the hand velocity increases when the trajectory becomes
118 straight [44]. Furthermore, this relationship conforms to an empirical two-thirds
119 power law [45]. For a MIS-tool 3D trajectory, this property had to be adapted for
120 spatial motion. Some experimental results suggested that the two-third power law
121 does not fit 3D motions and that a one-sixth power law is needed [46]. The relation
122 between the Euclidean velocity v , the curvature κ , and the torsion τ is defined as:

$$123 \quad v = v_a \cdot \kappa \cdot \alpha \cdot |\tau| \cdot \beta \quad (1)$$

124 where v_a is the affine velocity, α and β are two parameters to be determined
125 according to the skill to be studied. For example, in [47], the motion of an ob-
126 stetrical gesture (typically the installation of forceps during childbirth) was very
127 different from those in MIS. As a result, the parameters used in these previous
128 works could not be used for MIS. Therefore, we had to determine those for MIS,
129 which should fit every motion involved in this hands-on training. This is explained
130 in the next subsection. Affine velocity was utilized to provide a quantitative mea-
131 sure reflecting the quality of the kinematics of users' trajectories. Affine velocity was
132 used instead of the velocity itself because it provides valuable information about
133 the quality and smoothness of the trajectory. Data from each training session (tra-

^[4]see <http://www.autodesk.fr/products/3ds-max/overview>

^[5]see <https://fr.mathworks.com>

134 jectories, moments, and numbers of collisions, right/left-hand distributions) were
135 collected through CHAI3D into a file and post-processed using Matlab to evaluate
136 the trainees' performance. In future versions, these assessment algorithms will be
137 integrated into the simulator software.

138 The first step to tune the affine velocity computation was to get enough data to
139 determine the best α and β values for this simulator. We collected an adequate
140 sample of 46 trajectories ranging from novices to experts (see the next section).
141 We independently verified their skill level so that they could serve as references.
142 After the process proposed in [47], we first interpolated the trajectories of both
143 tooltips into cubic splines and computed the values of the Euclidean velocity v , the
144 curvature κ and the torsion τ (measuring how much the trajectory twists out of the
145 plane of curvature). Then, we performed a logarithmic linearization of (1):

$$146 \quad \log(v) = \log(v_a) + \alpha \cdot \log(\kappa) + \beta \cdot \log(|\tau|) \quad (2)$$

147 We performed multivariate linear regression using a gradient descent algorithm
148 to determine these parameters. The average values of α and β should fit the best
149 laparoscopic medical gestures to allow a realistic computation of affine velocity. For
150 this medical gesture, we found $\alpha = -0.048$ and $\beta = -0.0026$.

151 Validation processes

152 According to the American Psychological Association guidelines [48] and stan-
153 dards [36], we validated the simulator's content evidence and discriminative power.

154 Content Evidence validation and its internal consistency

155 We examined if the simulators' items completely represent a basic surgical skill-
156 learning tool. For the first exercise (figure 1), participants should replicate the tra-
157 jectory as fast as possible with their dominant hand only, the non-dominant hand
158 staying motionless while holding the second laparoscopic tool. During the second

159 exercise, participants had to perform the same trajectory as fast as possible with
160 their dominant hand while the non-dominant hand should simultaneously complete
161 a small trajectory. After completing the two exercises, the participants were invited
162 to globally assess the simulator using a 25-item questionnaire on a 10-point rating
163 scale. Six questions evaluated the general aspect, 5 the didactic components, 4 the
164 perception of reliability, 7 questions were linked to the training and learning power,
165 and finally, 3 questions were related to the simulators utility. Finally, the internal
166 consistency test ensured the reliability of the responses [49, 50].

167 Discriminative validation (relation with experience) and temporal stability

168 Another approach to validate this simulator was to compare expert and novice
169 performances [51, 52]. Obviously, the simulator should show that experts perform
170 better than novices. This should indicate that successful performance on the simu-
171 lator requires surgical expertise. We thus tested here the simulators' discriminative
172 power by comparing participants' performances on the two exercises through three
173 variables (time, number of collisions, and affine velocity). Finally, we tested the
174 temporal stability i.e. the reliability of measurements by a test-retest session. Five
175 participants among the experts group were randomly selected for this comparison.
176 As recommended, the two testing sessions were separated by at least one month
177 without any practice on the simulator [53].

178 Participants

179 Seventy seven participants (Mean age=30.8; Female=26; Male=51) agreed to par-
180 ticipate in the study. There were 17 experts (Mean Age=41.5; Female=4; Male=13)
181 selected with reference to the number of medical procedures they already performed
182 (more than 100 interventions as the main operator). Twelve surgeons of interme-
183 diate surgery experience (1 female and 11 males, mean age=28) were selected in
184 the second group as they had between 5 and 20 interventions as main operator.
185 Twenty-eight inexperienced interns with basic open surgery experience e.g. knot

186 tying and suturing were included in the third group. They additionally observed
187 laparoscopic interventions without performing any operation. There were 8 females
188 and 20 males in this group (Mean age=25.3). Twenty novices unrelated to medical
189 education or surgical skills were also selected, representing 13 females and 7 males
190 (Mean age=31.5). The latter group did not complete the questionnaire because their
191 opinion was not relevant to the content validation process. Among the expert group,
192 one participant did not complete the questionnaire. This experiment did not require
193 any IRB approval. Verbal consent was provided by every participant. Participants'
194 demographic and surgical specialty information is summarized in table 1.

195 ***Insert Table 1 around here***

196 Data analysis

197 Data were analyzed using SPSS 21.0 (SPSS Inc.)^[6]. To assess content evidence, we
198 applied a one-factor ANOVA to compare groups with post hoc Tukey correction
199 tests. A level of $p \leq 0.05$ was considered statistically different. Cronbach alpha test
200 measured the internal consistency of the questionnaire with the α -value set at 0.7).
201 We used non-parametric tests to compare groups regarding time, number of colli-
202 sions, and affine velocity (discriminative protocol), as the number of samples is too
203 low for parametric tests. We performed the Kruskal-Wallis test to compare the three
204 groups, and the Kolmogorov Smirnov for two-by-two comparisons. The statistical
205 threshold was set at $p \leq 0.05$. Finally, correlation coefficients evaluated the temporal
206 stability of the simulator's measure.

207 Results

208 Content evidence and its internal consistency

209 All participants positively rated the simulator whatever the group of inclusion,
210 with mean (\pm SD) scores being 7.25 ± 0.8 , 7.74 ± 0.6 , and 7.72 ± 0.7 for the expert,

^[6]See <http://www.ibm.com/software/analytics/spss/products/statistics/index.html>

211 intermediate and inexperienced levels, respectively. ANOVA did not provide any
212 difference among the 3 groups ($p=0.13$, NS). The internal consistency of the content
213 evidence questionnaire revealed a high Cronbach alpha coefficient of 0.87.

214 Discriminative validation (relation with experience) and temporal stability

215 *Exercise 1*

216 *Time:* Experts and intermediates completed this exercise faster than inexperi-
217 enced interns and novices. Mean times were 82.4 s (SD=22.1 s), 81.5 s (SD=23.7 s),
218 122.3 s (SD=50 s), and 156.8 s (SD=53 s) for experts, intermediates, interns, and
219 novices respectively. The Kruskal-Wallis test revealed a significant difference among
220 the groups (chi-square = 32.802, $p<0.001$) with a mean rank of 22,41 in the ex-
221 perts, 20,92 in the intermediates, 43,14 in the inexperienced interns and 58,15 in the
222 novices. Post hoc tests showed significant differences between experts and both in-
223 experienced interns ($p=0.007$) and novices ($p<0.001$). Intermediates outperformed
224 inexperienced interns ($p=0.01$) as well as novices ($p<0.001$). Finally, inexperienced
225 interns tend to be faster than the novices ($p=0.06$).

226 *Collisions:* Experts and intermediates made fewer collisions than inexperienced
227 interns and novices. The mean number of collisions was 9.4 (SD=5.8), 8.8 (SD=4.7),
228 17.3 (SD=8.2), and 24.5 (SD=19.5) for experts, intermediates, interns and novices,
229 respectively. The Kruskal-Wallis test revealed significant differences among groups,
230 (chi-square = 22.48, $p<0.001$) with a mean rank of 24.24 in the experts, 22.83 in
231 the intermediates, 46.30 in the inexperienced interns and 51.03 in the novices. Post
232 hoc tests showed significant differences between experts and inexperienced interns
233 ($p=0.004$); experts and novices ($p<0.001$) and as well as between intermediates and
234 inexperienced interns ($p=0.007$); intermediates and novices ($p=0.001$).

235 *Affine velocity:* Experts and intermediates outperformed inexperienced interns
236 and novices in the affine velocity variable. Mean affine velocities were 0.023 m/s

237 (SD=0.0024 m/s), 0.022 m/s (SD=0.0030 m/s), 0.026 m/s (SD=0.0055 m/s) and
238 0.030 m/s (SD=0.0038 m/s) for experts, intermediates, interns and novices re-
239 spectively. Kruskal-Wallis test revealed significant differences among groups, (chi-
240 square=30.65, $p < 0.001$) with a mean rank of 25.76 for the experts, 19.08 for the
241 intermediates, 41.86 for the inexperienced interns and 58.20 for the novices. Post
242 hoc tests showed significant differences between experts and novices ($p < 0.001$) and
243 between experts and unexperienced interns ($p = 0.05$). Post hoc tests showed also
244 significant differences between intermediates and inexperienced interns ($p = 0.009$)
245 as well as between intermediates and novices ($p < 0.001$). There was also a significant
246 difference between inexperienced interns and novices ($p = 0.003$).

247 ***Insert figure 3 around here***

248 *Exercise 2*

249 *Time:* Experts and intermediates completed the second exercise faster than inex-
250 perperienced interns and novices. The mean movement time was 109.5 s (SD=30 s),
251 107.1 s (SD=34.1 s), 147.3 s (SD=41 s), and 188.1 s (SD=46.6 s) for experts, in-
252 termediates, interns and novices respectively. The Kruskal-Wallis test revealed a
253 significant difference among the groups, (chi-square=34.09, $p < 0.001$) with a mean
254 rank of 21.97 in the experts, 21.88 in the intermediates, 42.09 in the inexperienced
255 interns and 59.43 in the novices. Post hoc tests showed significant differences be-
256 tween experts and inexperienced interns ($p = 0.01$); experts and novices ($p < 0.001$)
257 but also between intermediates and inexperienced interns ($p = 0.02$) as well as be-
258 tween intermediates and novices ($p < 0.001$). Movement time was also different be-
259 tween inexperienced interns and novices ($p = 0.02$).

260 *Collisions:* Experts and intermediates made fewer collisions than inexperienced
261 interns and novices. The mean number of collisions was 17.7 (SD=10.3), 19.6

262 (SD=5.9), 23.3 (SD=13), and 37.5 (SD=20.1) in experts, intermediates, interns,
263 and novices respectively. The Kruskal-Wallis test revealed significant differences
264 among groups, (chi-square=14.703, $p=0.002$) with a mean rank of 27.21 in the
265 experts, 33.88 in the intermediates, 37.52 in the inexperienced interns and 54.18
266 in the novices. Post hoc tests showed significant differences between experts and
267 novices ($p=0.002$) and between intermediates and novices ($p=0.03$). There was also
268 a significant difference between inexperienced interns and novices ($p=0.03$)

269 *Affine velocity:* Experts and intermediates outperformed inexperienced interns
270 and novices. Mean affine velocity were 0.028 m/s (SD=0.0042 m/s), 0.029 m/s
271 (SD=0.0055 m/s), 0.032 m/s (SD=0.0056 m/s) and 0.033 m/s (SD=0.0051 m/s)
272 in experts, intermediates, interns and novices respectively. The Kruskal-Wallis test
273 revealed significant differences among groups, (chi-squared=10.41, $p=0.015$) with a
274 mean rank of 26.88 in the experts, 31.83 in the intermediates, 42.89 in the inexperi-
275 enced interns and 48.15 in the novices. Post hoc tests showed significant differences
276 between experts and novices ($p=0.04$) and tend to be different between experts and
277 inexperienced interns ($p=0.06$).

278 ***Insert figure 4 around here***

279 Finally, regarding the temporal stability of the simulator's measure, we found a
280 correlation for the number of collisions and for the time variables between the two
281 sessions ($r=0.89$; $p=0.04$).

282 Discussion

283 This study demonstrated the reliability and content evidence of this low-fidelity
284 simulator in laparoscopic motor skills learning. The difference we observed among
285 groups' performance also accounts for the discriminative power of the simulator. The
286 users uniformly rated the way the simulator exhibits actual motor abilities required
287 by real surgery. Surgeons' global agreement about the usefulness of the simulator for
288 surgical curricula is attested through a large number of participants, where 3 levels

289 of practice were represented (from inexperienced interns to expert surgeons, with
290 an intermediate level). The outcome scores are in line with the outcomes from other
291 studies dealing with the validation of computer-based systems [54]. The MIST VR
292 (MenticeMedical Simulation, Gothenburg, Sweden), was for instance rated by an
293 average score of 7 in a comparable study [54]. Since this validation process, several
294 studies used the MIST VR to train basic laparoscopic skills, thereby demonstrating
295 the relevance of the simulator in laparoscopic training [52, 55]. Taken together, this
296 indicates that the surgeons validated positively the way in which laparoscopic skills
297 are simulated. Regarding the discriminative power of the simulator, both exercises
298 exhibited a slightly different pattern of results. In general, we can observe that for
299 both exercises, experts and intermediates outperformed inexperienced interns and
300 novices according to the three dependent variables we selected i.e. movement time
301 duration, number of collisions, and affine velocity (figures 1 and 2). This confirmed
302 that the simulator discriminated among 4 expertise levels. In other words, surgical
303 skills are required to perform well on the simulator. The simulator thus highlighted
304 the main abilities needed by MIS. When looking closer to the results of exercise
305 1, experts and intermediates perform similarly. This outcome is consistent as these
306 groups have real experience and this first exercise did not require advanced la-
307 paroscopic skills. The same argument can explain the discrepancy between experts,
308 intermediates, and the other groups, which do not master laparoscopic motor skills,
309 even basic ones. This is a positive outcome as our purpose was to engineer a low
310 fidelity simulator for the training of basic surgical skills, thereby more fitted for
311 beginners [13]. In the second exercise, the pattern of results is quite similar to that
312 of the first exercise. However, when looking closer at data (figure 3), only the novice
313 group is systematically outperformed by the other groups (with the exception of
314 affine velocity where only the experts outperformed the novices). To better analyze
315 and understand these results, we should consider that this was a bi-manual task,

316 while the first exercise only involved one hand. Surgery skills required the coor-
317 dination of the two hands [56] and the ability of using both hands is essential in
318 laparoscopic surgery [7, 57] and in open surgery [5]. Thus, prior open surgical expe-
319 rience helped the experts, intermediates and inexperienced interns to overcome the
320 difficulty of the bimanual task, while the novices did not benefit from previous ex-
321 perience. A laparoscopic simulator should obviously include bi-manual tasks. While
322 analyzing the main outcomes, we can underline some limitations. The discrimina-
323 tive validation protocol may also be seen as a limitation when considering that one
324 single trial was performed. Results would have been reinforced with several trials in
325 each experimental condition. However, running several trials means taking the risk
326 of starting a fast learning stage [58], which can also affect the outcomes. Indeed,
327 Dayan and Cohen observed that a fast learning stage can improve motor execu-
328 tion after one repetition [58]. However, taken together, the results of the validation
329 protocols suggest that the three variables we selected to evaluate the laparoscopic
330 proficiency on this simulator are relevant. Indeed, for an objective overview of the
331 trainee's skills, the three variables should be analyzed in a complementary way.
332 This last point meets the existing literature, stating that time and collisions are
333 indirect indicators of laparoscopic proficiency and that they need to be associated
334 with objective measures i.e. motion characteristics, provided by the affine velocity
335 [14, 16].

336 **Conclusion**

337 The outcomes of the aforementioned validation protocols showed that the simulator
338 we described is a reliable and innovative device reproducing the main laparoscopic
339 basic motor skills. It required bi-manual coordination while providing haptic and
340 summative feedback. The inclusion of haptic feedback and complementary (innova-
341 tive) evaluation variables such as the affine velocity, represents originality regarding
342 low-fidelity simulators [15, 16, 20]. The low associated costs (\approx \$2500) obviously con-

343 trast with high-fidelity simulators [25]. Its virtual operation theater (unlike Islam et
344 al. in [59]) enables the development of new sets of perfectly reproducible exercises
345 featuring objective instantaneous haptic and summative feedback, thus contrasting
346 with usual low-fidelity simulators. As training solutions outside the operation room
347 need to be engineered for the initial training period of surgeons [5, 60], and as this
348 simulator main aim is the learning of basic laparoscopic skills, we could assume that
349 this simulator might be a mean to complement the existing contents of basic sur-
350 gical education. This perspective needs, however, to be confirmed by investigating
351 the implementation of this simulator in an early training stage along with the study
352 of the impact of haptic feedback on learning.

353 **1 Declarations**

354 Ethics approval and consent to participate

355 This experimental design is a behavioral study based on observation. It is a non-interventional experiment as defined
356 and described by the French law Jardé. This means that neither intrusive intervention in the participants' organism,
357 nor ingestion of active molecule present in a drug is carried out. In line with the Helsinki declaration, all participants
358 were instructed about the main aims of the experiment, and the main operations they will have to manage. After
359 that, all participants signed an informed consent describing their rights. With respect to French ethical law and with
360 the Helsinki declaration, we did not submit a file to an ethics committee. All informed consents are available on
361 request.

362 Consent for publication

363 Not applicable.

364 Availability of data and materials

365 The datasets used and/or analysed during the current study are available from the corresponding author on
366 reasonable request.

367 Competing interests

368 The authors declare that they have no competing interests.

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372 Author's contributions

373 BDW and CB actively designed and realized the prototype of this simulator. RM, AL, NH supervised this work. XM
374 and CC oversaw it. All these people contributed equally to the writing of this paper.

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540 Figures

Figure 1 Overview of the simulator. the user manipulates real MIS tools connected to the haptic interface hidden under the cover which mimics the patient's skin. The trainee monitors his gestures in the virtual environment through the monitor.

Figure 2 Screenshot of the trajectory to perform in exercise 1 from the starting position (1) to the ending position (2). The trajectory had to be performed without touching the 3D structures. The 5 obstacle avoidance requested implicitly the following skills: grasping and releasing the green sphere to start, jumping over the central block in A (insertion, withdrawal), taking a curve in B, moving straight between the blocks in C, going round in D, and E, simulating loops necessary for knot tying. Mean values (SD) for time, collisions and standard deviation means for affine velocity in exercise 1 for experts, intermediates (INT), inexperienced interns (I. Interns) and novices.
 *= $p < 0.05$; **= $p < 0.01$; ***= $p < 0.001$

Figure 3 Mean values (SD) for time, collisions and standard deviation means for affine velocity in exercise 1. For experts, intermediates (INT), inexperienced interns (I. Interns) and novices.
 *= $p < 0.05$; **= $p < 0.01$; ***= $p < 0.001$

Figure 4 Mean values (SD) for time, collisions and standard deviation means for affine velocity in exercise 2. For experts, intermediates (INT), inexperienced interns (I. Interns) and novices.
 *= $p < 0.05$; **= $p < 0.01$; ***= $p < 0.001$

541 Tables

Table 1 Participants' demographic and specialty.

Group	Total Number (Male:Female)	Mean age (range)	Paediatric specialty	Gynaecology specialty	Urology specialty	Digestive specialty	Visceral specialty	Orthopaedic specialty	General
Experts	17 (13:4)	41.5 (62-30)	1	1	8	4	2	1	0
Intermediates	12 (11 :1)	28 (32-25)	0	0	10	0	2	0	0
Inexperienced Interns	28 (20 :8)	25.3 (40-23)	0	0	0	0	0	0	28
Novices	20 (7:13)	31.5 (53-18)	0	0	0	0	0	0	0