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1 **Equipment failures in laparoscopic surgery: causes and consequences**

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22 **Abstract**

23 **Objective:** The aim of this study was to assess incidence, causes and consequences  
24 of equipment failures in a high volume, advanced endoscopic surgery department.

25 **Methods:** This is a prospectical observational single centre study between April and  
26 July of 2019 in the Gynecological surgery department of the Estaing University  
27 Hospital of Clermont-Ferrand, France. During the study period, 171 laparoscopies  
28 were observed. Data were collected real time by three supernumerary observers.

29 **Results** 66 (38.6%) laparoscopies were complicated by equipment failures. The  
30 bipolar cable and forceps accounted for 31% of the total amount of malfunctions in  
31 laparoscopy. Causes of malfunctions were in 45% due to the instrument per se and in  
32 43% due to the incorrect combination of elements. Less commonly, the equipment  
33 was not available or a mismatched was reported. The total length of the surgery  
34 increased by 1.35% due to the malfunctions. Human error was identified in 50% of  
35 cases. No morbidity, neither mortality was reported in this series; however we  
36 observed 34 malfunctions that could have led to serious consequences for the  
37 patients and 3 incidents induced a real consequence on the operation workflow.

38 **Conclusions** Equipment failure is a common event in endoscopy. On the opposite,  
39 time wasted for the malfunctions is low in laparoscopy, as it only accounts for 1.35%  
40 of the overall surgical time. Human decisions contributed to malfunctions in almost  
41 half of cases. This alarming finding may advise for intensification in training and  
42 upgrading of the surgical team.

43

44 **Key words**

45 endoscopic instruments, equipment failure, human error, improvement

46

47

48 **Introduction**

49 The laparoscopic approach relies on advanced technology with the use of more and  
50 more sophisticated instruments and the need for more training of the surgical team,  
51 as equipment malfunctions accounts for approximately one-fourth of surgical errors in  
52 the operating room (1-2).

53 A good knowledge of the equipment by the surgical team is required, as well as  
54 adequate maintenance of the instruments and a prompt intervention in case of failure.

55 In fact, several authors have already demonstrated the impact of distractions and  
56 malfunctions, which affect surgical workflow and patient's safety. Several studies  
57 have highlighted the negative effects of distractions (such as noise, irrelevant  
58 communications, mobile phones and equipment failures) in surgical theaters (3,4).

59 According to S. Forman et al., equipment failures contribute in half of the cases,  
60 followed by irrelevant communications (26%), and auditory distractions (9%)(5).

61 However, endoscopic tools have significantly improved in the last decade, in  
62 particular in surgical reference centers.

63 The aim of this study is to assess the current incidence of equipment failure in a  
64 high-volume surgical academic department.

65

66 **Material and methods**

67 This is a prospective observational single-center study performed in the gynecological  
68 surgery department of the Estaing University Hospital of Clermont-Ferrand, France.

69 All laparoscopic gynecological procedures performed between April and July 2019  
70 were included, with the exclusion of emergency and trial procedures. Written consent  
71 was ruled out by the institutional review board for the observational study.

72 Data were collected real time by three supernumerary observers. One observer was  
73 the leader, receiving direct training from the senior author, and was the one  
74 responsible for discussing unclear cases and intermediate data with the senior author.  
75 The other two observers were trained by the leader both with the support of the  
76 available literature for the methodology and demonstrative live sessions in the  
77 operative room. Then, they collected pilot data for one week under the supervision of  
78 the leader, and finally started collecting independently. Data were always  
79 cross-checked between the three observers after the surgeries to avoid inter-observer  
80 bias. In case of doubt on objective issues, for example the type of instrument involved  
81 in the malfunction or the cause of the malfunction, the observer had to ask the  
82 scrubbed nurse and/or the first surgeon in order to clarify the doubt. On contrary, to  
83 assess more subjective issues, such as human involvement and responsibilities,  
84 some cases were discussed with the senior author, who was not directly involved in  
85 the surgery. In this way, we tried at best to enhance data accuracy, reducing bias  
86 linked to impartiality and distortion of the information.

87 The amount of procedures and failures was calculated in relation to the operator and  
88 the difficulty of the surgery, by dividing laparoscopies in 3 groups: (a) low difficulty,  
89 such as salpingectomy, annexectomy, ovarian cystectomy, explorative and fertility  
90 procedures; (b) medium difficulty, as hysterectomy and myomectomy; (c) high  
91 difficulty, including laparoscopic prolapsus surgeries, endometriosis and oncologic  
92 surgeries.

93 For each observed procedure the following data were collected: - name and date of  
94 the procedure; - name of the first surgeon and first assistant; - duration of the  
95 procedure, from the incision to skin closure; - presence of one or more equipment  
96 failure, where the equipment failure was defined as a problem of the endoscopic  
97 equipment resulting in a waste of time and a consequent measure of correction; -  
98 duration of each equipment failure, from the moment it has appeared to its resolution;

99 - causes and consequences for each failure; - possible human error related to the  
100 failure.

101 To achieve it, an equipment catalogue was created, inspired by the one published by  
102 Wattiez et al, 2008 (6), and a specific data collection form was printed and delivered  
103 to the observers.

104 Within the catalogue, equipment was divided into 4 categories: (a) fluid and gas circuit,  
105 including connections and fittings which could interfere with the fluid flow; (b)  
106 endoscopic instruments, such as forceps, scissors and even the small fittings that are  
107 not properly endoscopic but are however functional for the endoscopy, such as  
108 suspension/exposition devices and fascia closure devices; (c) electrical circuit,  
109 including bipolar forceps failing to conduct the electricity or cables and pedals; (d)  
110 video system devices, such as the optic and the camera which could be responsible  
111 of a dirty image or even a missed one.

112 Causes for failure were assessed and divided in 5 groups to improve the uniformity of  
113 language: failure of the equipment itself, lack of availability, incorrect assembly,  
114 mismatch and other causes, such as the humidity for the camera resulting in image  
115 failure.

116 Whenever the equipment failure rises from an omission or a direct action of the  
117 primary surgeon or the operative nurses, this was designated as human error (p.e. the  
118 electrical failure caused by the inadequate or missing connection of the cable is a  
119 direct responsibility of the operator who set up the operating field).

120 Consequences of each failure were recorded as follows: none, if the equipment failure  
121 does not generate any consequence but the waste of time; potential or "near-miss",  
122 whenever the equipment failure induce an effect that is minimal in the specific case  
123 but could have been more severe if it has occurred at a different time (p.e. bipolar  
124 failure in the beginning of the adhesiolysis vs. facing a bleeding); real and serious,

125 when the event induce any consequences related to the patient or the surgical  
126 procedure (p.e. interruption of the procedure, deviation of the surgical strategy).

127 Patients were followed-up during the post-operative days till discharge to identify any  
128 deviation from the normal postoperative course. In the department, patients were  
129 monitored as usual; no further investigation was required for the study. Readmission  
130 or reintervention were monitored for 3 months after discharge.

131

## 132 **Results**

133 During the study period, a total of 171 laparoscopies were observed.

134 At least one equipment failure was reported for 66 (38%) procedures. The total  
135 number of equipment failure recorded was 91; however, some surgeries were  
136 complicated by more than one equipment failure, as listed in **table 1**.

137 Procedures were carried out by 8 senior surgeons, 3 junior surgeons and residents in  
138 rotation, and were divided according to its difficulty, as explained in the methods  
139 section. The incidence of equipment failure increased with the length and the difficulty  
140 of the procedure (**table 2**).

141 As shown in **table 3**, the most common equipment failure was observed in the  
142 category of instruments (n 44, 48%); followed by the electric circuit with 22 cases  
143 (24%) and video system with 13 malfunctions (14%); the category of fluid and gas  
144 circuit was affected by 12 cases (13%).

145 Notably, the most frequent malfunction was related to the electric circuit with both  
146 bipolar forceps and cables dysfunctions (14 cases each), corresponding to the 30.7%  
147 of the total amount of malfunctions (**table 3**).

148 Most often, the failure was due to the instrument per se (n 41, 45%).

149 In 39 cases the malfunction resulted from the incorrect combination of elements  
150 (42.8%). Less commonly, in 8 cases (8.7%), the equipment was not available,  
151 because not sterilized or kept in storage. Mismatched was reported in only 1 case  
152 during one procedure in which two pieces belonging to different boxes were  
153 incorrectly assembled together.

154 Human error was identified in the 50.5% of the times. Nurses, because they are in  
155 charge most of the times of the setting up of the operative field, were involved in the  
156 majority of equipment failure (32.9%).

157 The total duration of the 66 surgeries complicated by equipment failure was 135 hours  
158 and 03 minutes. The global estimated delay due to malfunctions was 1 hour, 49  
159 minutes and 35 seconds. This results in a total length of the surgery increased by  
160 1.35% due to malfunctions.

161 As regards consequences of equipment failure, no morbidity neither mortality was  
162 reported in this series; however we observed 34 (37.3%) “near-misses” cases, that  
163 could have led to serious consequences for the patients, such as uncontrolled  
164 bleeding in case of bipolar failure.

165 Furthermore, incidents induced a real consequence on the operation workflow or on  
166 patient well-being in 3 cases; in one report the bipolar forceps broke in several small  
167 pieces into the abdomen causing a significant waste of time and modification of the  
168 operative strategy, as well as a consistent risk for the patient in case of inadequate  
169 recovery of all the pieces; in another case, the suspension device broke while  
170 extracting it and a small part of it was lost in the abdominal wall; in one more case, the  
171 malfunction caused a modification of the surgical strategy and a significant delay  
172 leading to a stressful overload for the surgical team and a non optimal development of  
173 the surgery itself.

174



175 **Discussion**

176 This study provides a snapshot on the current state of the endoscopic gynecology,  
177 highlighting the incidence of equipment malfunctions and the role of surgeons and  
178 nurses in their management.

179 In fact, risk management principles; such as avoidance of equipment failures,  
180 communication and teamwork, training and updating are essential to protect patient  
181 safety, as well as to improve surgical performances (7).

182 Data collection has been performed in a university department with a high volume of  
183 laparoscopic surgeries.

184 There are few papers in literature about this subject. Wattiez et al published in 2008 a  
185 paper with a similar methodology to the present study, representing a benchmark for  
186 our data (6). Overall incidence of equipment failures reported by Wattiez et al on 116  
187 operative procedures was 38.8%, a value that is very similar to our overall percentage  
188 of 38%. The time needed to solve the malfunction is significantly reduced in our study,  
189 probably due to a better knowledge of the equipment and improved surgical skills,  
190 especially as regards laparoscopic procedures (increase in the length of the  
191 intervention of the 1.35%, compared to the 7% of the previous series).

192 According to both previous and current series, the principal incidents were related to  
193 the energy sources, in particular bipolar coagulation devices. This finding was already  
194 reported by Borie et al (8) who analyzed 876 adverse events related to health care  
195 (AERHC), reporting a persisting misunderstanding of the energy sources appropriate  
196 usage within the medical and paramedical teams.

197 As regards our findings, most of the low difficulty procedures were performed by junior  
198 surgeons and/or residents, whose surgical skills and knowledge of the equipment are  
199 frequently inferior in comparison to senior surgeons'.

200 Nevertheless, laparoscopic skills and expertise may not be enough to prevent and  
201 treat in a short gap of time the malfunctions; as demonstrated by Marlies P. Schijven  
202 et al (2) through a serious game simulating incidents in the operative room, expert  
203 laparoscopic surgeons were less skilled in solving malfunctions than laparoscopic  
204 equipment specialist (45.0 % vs 68.9,  $p=0.01$ ). Moreover, this study shows that  
205 experienced surgeons were unable to outperform novice and intermediate surgeons  
206 in dealing with laparoscopic equipment failure. These findings are alarming and show  
207 how important is the continuous training throughout the laparoscopic surgeon's  
208 careers.

209 The Federation of Visceral and Digestive Surgery (FCVD) is in charge in France of the  
210 continuing medical education of digestive surgeons and propose an interesting  
211 program to consolidate knowledge and abilities on the fundamental use of the surgical  
212 energy (FUSE). The program was welcomed by the 485 participants and seems to  
213 help in achieving objectives (9).

214 Moreover, the implementation of checklists (10)(11) in the preoperative phase and the  
215 assessment of instruments before the operative act may have a impact in reducing  
216 equipment failures (7), despite they may be not sufficient to prevent intraoperative  
217 malfunctions.

218 Further investigations are required to assess the impact of a preoperative check-list  
219 on the development of equipment failures during the surgery; a clinical audit may be a  
220 useful strategy to implement some corrective measures and obtain an improvement.

221 Another aspect that has to be taken in consideration in future studies is the correlation  
222 between equipment failure and declaration of medical device incidents, in order to  
223 assess the frequency of instrument's replacement and to enhance device's  
224 traceability and safety (12).

225 In our center, scrubbed nurses are not always involved in the surgery, especially in  
226 “easy” procedures. This could lead to an inadequate preoperative check of  
227 instruments and to an improper assembling of components. In case of implementation  
228 of new check-lists, their extensive application to all procedures must be ensured, even  
229 in case of lack of dedicated staff.

230 We chose not to not include emergency procedures in the study in order to follow the  
231 methodology. Nevertheless, it could be interesting to investigate the incidence of  
232 equipment failure during emergency in further studies.

233 Patient safety incidents occurring in the gynecology theatre may originate from  
234 apparently innocuous incidents, such as a bipolar forceps failure or sheaficient  
235 knowledge of a new device. Interventions may include investment in continuing  
236 medical education (9), assessment and competency of gynecological surgeons,  
237 especially consultants and residents, team briefing after the appearance of a  
238 incident, implementation of clinical audit, instrument's adequate preoperative check.

239

## 240 **Conclusions**

241 Equipment failure is a common event in laparoscopy. Nevertheless, this study shows  
242 how time wasted for malfunctions is low in laparoscopy, as it only accounts for 1.35%  
243 of the overall surgical time. Human decisions appears to be involved in problems  
244 onset in almost half of cases. This alarming finding may advise for intensification in  
245 training and upgrading of the surgical team, implementation of check lists and clinical  
246 audit.

247

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249 helping in improving quality of the collected data.

250

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252 nothing to disclose.

253

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289 **Tables**

290 Table 1. Number of equipment failures per surgery

291 Table 2. Surgeons, type of surgery and incidence of equipment failure by type of  
292 surgery

293 Table 3. Catalogue of endoscopic equipment and related rate of malfunction

294

|  |           |
|--|-----------|
| <b>Interventions complicated by EF</b> | <b>66</b> |
| interventions with 1 EF                | 49        |
| interventions with 2 EF                | 12        |
| interventions with 3 EF                | 3         |
| interventions with 4 EF                | 1         |
| interventions with 5 EF                | 1         |
| <b>Total of EF</b>                     | <b>91</b> |

Table 1. number of equipment failures per surgery

(EF= equipment failure)

|                       | <b>Laparoscopies (N°)</b> |                    |                    |
|-----------------------|---------------------------|--------------------|--------------------|
|                       | Low difficulty            | Medium difficulty  | High difficulty    |
| <b>Senior surgeon</b> | <b>19 (4 EF)</b>          | <b>27 (16 EF)</b>  | <b>56 (42 EF)</b>  |
| Surg 1                |                           | 7 (7 EF)           | 20 (21 EF)         |
| Surg 2                | 5 (1 EF)                  | 5 (1 EF)           | 15 (6 EF)          |
| Surg 3                | 3 (0 EF)                  | 7 (5 EF)           |                    |
| Surg 4                | 2 (0 EF)                  | 2 (0 EF)           | 11 (8 EF)          |
| Surg 5                | 5 (1 EF)                  | 2 (0 EF)           | 7 (4 EF)           |
| Surg 6                | 1 (0 EF)                  | 3 (2 EF)           |                    |
| Surg 7                | 1 (1 EF)                  |                    | 3 (1 EF)           |
| Surg 8                | 2 (1 EF)                  | 1 (1 EF)           |                    |
| <b>Junior surgeon</b> | <b>28 (9 EF)</b>          | <b>14 (6 EF)</b>   | <b>3 (1 EF)</b>    |
| Surg 9                | 13 (4 EF)                 | 4 (2 EF)           |                    |
| Surg 10               | 10 (3 EF)                 | 5 (3 EF)           |                    |
| Surg 11               | 5 (2 EF)                  | 5 (1 EF)           | 3 (1 EF)           |
| <b>Residents</b>      | <b>16 (7 EF)</b>          | <b>8 (6 EF)</b>    | <b>0</b>           |
|                       | 16 (7 EF)                 | 8 (6 EF)           |                    |
| <b>TOTAL</b>          | <b>63 (20 EF)</b>         | <b>49 (28 EF)</b>  | <b>59 (43 EF)</b>  |
| <b>% EF</b>           | <b>22% (20/91)</b>        | <b>31% (28/91)</b> | <b>47% (43/91)</b> |

Table 2. Surgeons, type of surgery and incidence of equipment failure by type of surgery

(Surg= surgeon; EF= equipment failure)



|  | N° of malfunctions | Rate of malfunction (%) |
|--|--------------------|-------------------------|
| <b>Fluid and gas circuit</b>           | <b>12</b>          | <b>13%</b>              |
| Laparoscopic suction/irrigation system | 10                 | 10.9%                   |
| Insufflator                            | 2                  | 2.1%                    |
| <b>Instruments</b>                     | <b>44</b>          | <b>48%</b>              |
| Bipolar forceps                        | 14                 | 15.3%                   |
| Optical system                         | 0                  | -                       |
| Uterine manipulator                    | 0                  | -                       |
| Laparoscopic morcellator               | 1                  | 1.1%                    |
| Insufflation switch                    | 0                  | -                       |
| Extraction bag                         | 1                  | 1.1%                    |
| Sheath                                 | 5                  | 5.5%                    |
| Niddle holder                          | 10                 | 11%                     |
| Monopolar needlepoint or loop          | 1                  | 1.1%                    |
| Forceps for tissue fusion              | 4                  | 4.4%                    |
| Monopolar scissors                     | 1                  | 1.1%                    |
| Scissors                               | 1                  | 1.1%                    |
| Suspension device                      | 2                  | 2.2%                    |
| Fascia closure device                  | 4                  | 4.4%                    |
| <b>Electrical circuit</b>              | <b>22</b>          | <b>24%</b>              |
| Bipolar forceps                        | 1                  | 1.1%                    |
| Bipolar cable                          | 14                 | 15.3%                   |
| Diathermy foot pedal                   | 1                  | 1.1%                    |
| Monopolar scissors                     | 0                  | -                       |
| Monopolar cable                        | 6                  | 6.6%                    |
| Generator                              | 0                  | -                       |
| <b>Video circuit</b>                   | <b>13</b>          | <b>14%</b>              |
| Cold light cable                       | 2                  | 2.2%                    |
| Monitor                                | 2                  | 2.2%                    |
| Optical system                         | 9                  | 9.9%                    |
| Digital camera                         | 0                  | -                       |
| <b>Total of EF</b>                     | <b>91</b>          | <b>100%</b>             |

Table 3. Catalogue of endoscopic equipment and related rate of malfunction  
(EF=equipment failures)