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A 3D-printed pedal fixator for connecting different pedal-operated tools reduces the number of mistakes during endoscopic submucosal dissection

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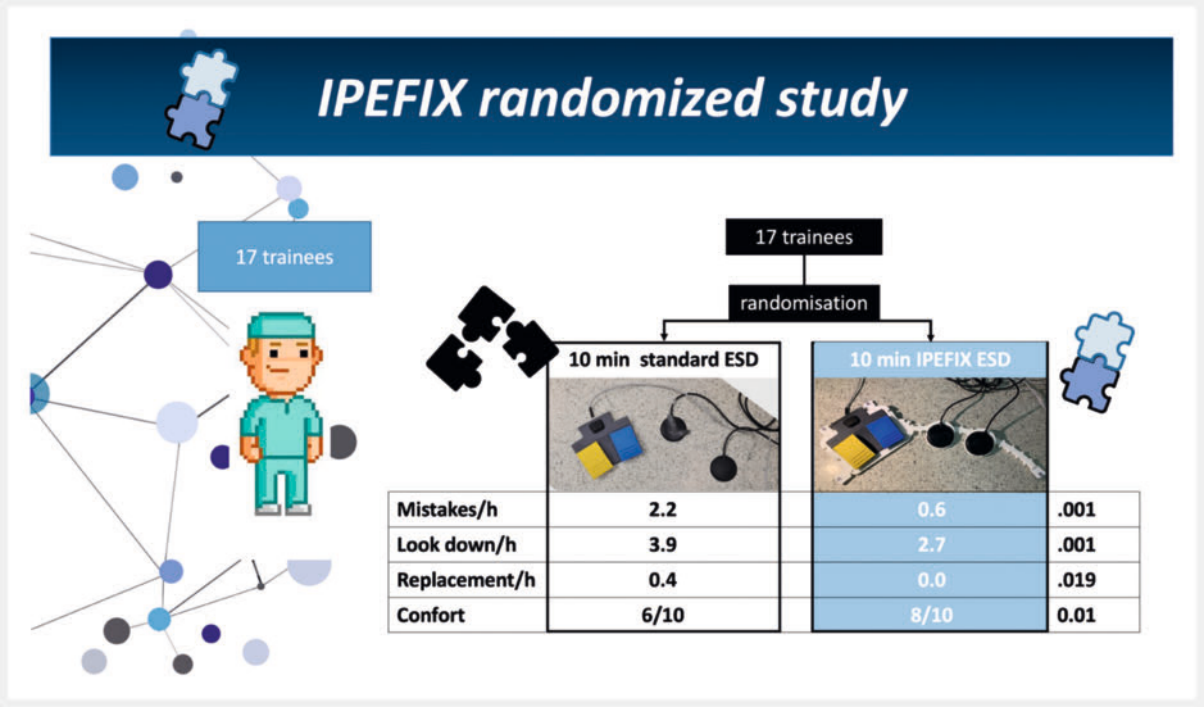
GRAPHICAL ABSTRACT



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Bibliography
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ABSTRACT

Background and study aims What distinguishes endoscopic submucosal dissection (ESD) from endoscopic mucosal resection is the need for three foot pedals to activate the electrosurgical unit, flushing and knife injection. The lack of connection between the various pedals of different shapes and brands leads to numerous pedals displacements and potential mistakes. The aim of this study was to evaluate an Innovative PEdal FIXator (IPEFIX) to reduce pedal mistakes during ESD.

Methods This was a prospective, multicenter, randomized study. Consecutive ESD procedures were randomly assigned to two groups: a control group with the three pedals free and the IPEFIX group in which the three pedals were linked by IPEFIX. The main outcome evaluated was the number of foot mistakes (wrong pedal, foot push beside the pedal).

Results A total of 107 ESDs were performed by eight experts in five centers. The median number of mistakes per hour of ESD procedure was 0/h in the IPEFIX group and 1.9/h in the control group (P <0.001). The mean number of times to look down to control the position of the pedals was 2.2/h the IPEFIX group and 7.7/h in the control group (P <0.001). Mean replacements of the pedals were 0./h in the IPEFIX group and 1.7/h in the control group (P <0.001). Similar results were obtained in trainees in simulated ESD on animal models.

Conclusions IPEFIX is a simple device to connect different pedals during endoscopic procedures. It helps to reduce the numbers of foot mistakes during ESD and improves operator comfort.

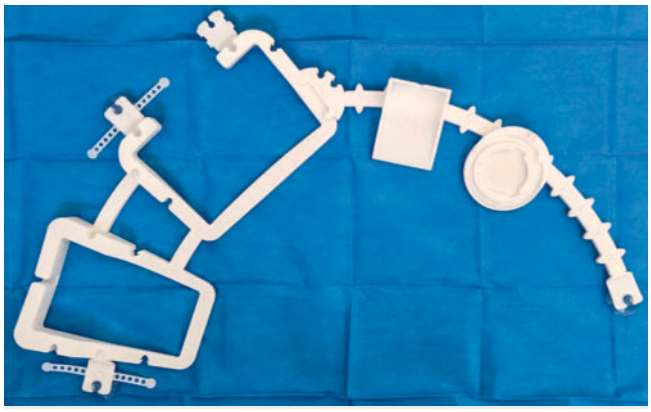
Introduction

Recent techniques in diagnostic and therapeutic endoscopy require the use of different foot-controlled devices. For example, water immersion colonoscopy and underwater endoscopic mucosal resection require the parallel use of two foot pedals to control both the electrosurgical unit and the peristaltic pump to fill the colon with water. For endoscopic submucosal dissection (ESD), the problem is more complex with three pedals to be managed in parallel, since the pump that activates the knife injection must be added to the electrosurgical unit pedal and the flushing one.

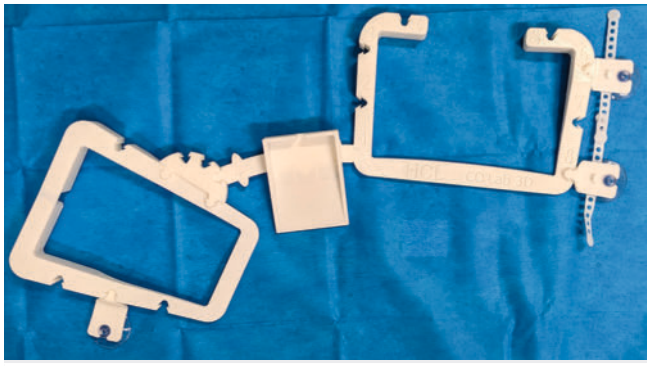
Although quite difficult to measure, the lack of connection between the various pedals of different shapes and brands leads most teams to place them on the floor without fixing them, leading to numerous displacements of these devices during the procedure, forcing the operator to look away from the operating field to replace his feet. These wanderings to find the pedal could be a source of time loss, additional stress, dangerous mistakes when the electrosurgical pedal is activated instead of the flushing one and, for beginners, a change of position that forces them to reposition themselves with the scope. This can be a problem when controlling a bleeding, for example, where holding a fixed position in front of the bloody vessel is important.

To reduce these difficulties, we have designed a 3 D printed fixator (IPEFIX Innovative PEdal FIXator, Hospices civils de Lyon, France) allowing the connection between the electrosurgical unit, the peristaltic pump and the knife injection pedals whatever their shape and brand (▶ **Fig. 1**) [1]. This device was designed to be versatile (▶ **Fig. 2, Video 1**), allowing an operator to choose the distance between the pedals, the angulation but also the position (right/left) and to prevent it from moving thanks to anti-slip systems.

We designed this prospective multicenter evaluation of the benefits of this IPEFIX pedal connector to reduce the foot pedal mistakes while performing ESD in two different group of endoscopists (experts and trainees).



▶ **Fig. 1** IPEFIX example.



▶ **Fig. 2** IPEFIX different configuration.

VIDEO

▶ **Video 1** Parallel between feet movement and endoscopic view of the procedure with and without the IPEFIX device.

Methods

Expert evaluation

We designed a prospective randomized (1/1) study to evaluate the benefits of the IPEFIX connector in five French expert centers in endoscopic submucosal dissection (4 university hospitals and one private hospital) with eight physicians involved.

Consecutive ESD procedures during the 3 months of evaluation were randomized to allocate the procedure in the two study groups: a control group that used standard ESD with the three pedals free (electrosurgical unit block of 2 pedals (cut and coag), flushing pump, injection pump for the knife) and an IPEFIX group that performed ESD with the three pedals connected with the fixator, but the position of the four different pedals was left to the preference of each physician (right-left, distance between pedals) ().

At least 10 ESD procedures per physician (5 with IPEFIX and 5 without) were expected during the study period.

Procedures

Consecutive conventional digestive ESDs were performed, using a conventional gastroscope or colonoscopes, a cap at the distal end, a ESD knife (left to the choice of the physician) and the three pedals. The use of a counter traction strategy was left as the discretion of the operator. The precise position of the pedals was left to the preference of each physician to choose the side of the pedals (right/left) and the precise distance between pedals. The IPEFIX was settled up after the randomization.

An independent observer was in the intraoperative room to observe and count the number of mistakes and replacement.

Parallel additional trainee evaluation

In parallel, a prospective randomized study was done involving ESD trainees during the national ESD training program of the French society of digestive endoscopy. The 17 trainees were evaluated during two phases of ESD on simulated 3-cm lesions on living pigs during 10 minutes for each phase of evaluation (one phase with IPEFIX and one without). The order of the two phases was randomly decided.

Outcomes

The main outcome was the evaluation of the number of foot mistakes (wrong pedal, foot push beside the pedal) during the ESD procedure ().

The secondary outcomes were: 1) the number of look down to control the position of the pedals during ESD procedure; 2) the number of pedal replacements by the physician or his assistant during ESD procedure; and 3) The subjective evaluation of the comfort during ESD procedure using a numeric scale from 0 (uncomfortable) to 10 (maximal comfort).

The evaluation of the system was recorded by an independent observer (nurse or fellow student).

Sample size for expert evaluation

We hypothesized a reduction in mistakes by a factor three going from six mistakes/hour to two using the IPEFIX connector. With a standard deviation of 2.5, an alpha risk of 0.05 and a power (1-Beta) of 0.9, we calculated a need for 33 procedures per arm. In order to increase the number of experiences with different physicians, we decided to include eight physicians performing at least 10 cases.

Statistical analysis

The data are presented as frequencies and percentages for categorical variables. Normally distributed data are expressed as means (standard deviations) and non-normally distributed data are expressed as medians (interquartile range [IQR]). Linked samples were compared using the two-tailed nonparametric Wilcoxon test because a standardized normal distribution could not be assumed due to the small sample size. Chi square and Fisher's exact tests were used to analyse qualitative data. P <0.05 was considered to indicate statistical significance.

▶ **Table 1** Comparison of ESD performance with or without IPEFIX device.

Characteristics	IPEFIX n = 53	NO IPEFIX n = 54	*P* value
Site of ESD			
▪ Rectum	18 (33.4)	20 (37)	0.8
▪ Sigmoid colon	9 (17)	11 (20.4)	0.8
▪ Left colon	2 (3.8)	4 (7.4)	0.49
▪ Transverse colon	2 (3.8)	2 (3.7)	1
▪ Right colon	11 (20.8)	5 (9.2)	0.17
▪ Cecum	5 (9.4)	5 (9.2)	1
▪ Appendix	1 (1.9)	0 (0)	0.49
▪ Ileocecal valvula	1 (1.9)	1 (1.8)	1
▪ Esophagus	3 (5.7)	2 (3.7)	1
▪ Stomach	1 (1.9)	3 (5.6)	0.6
Lesion size in mm (median, IQR)	50 (40–60)	57.5 (45–70)	0.067
Lesion surface in mm^2 (median, IQR)	15.7 (9.4–23.5)	19.6 (11.8–34.1)	0.067
ESD duration (minutes) (median, IQR)	35 (25–60)	50 (30–75)	0.035
Dissection speed in mm^2/min (median, IQR)	38.6 (23.3–70.6)	41.7 (26.2–64.6)	0.84
No. times per hour to look down to control pedal position (median, IQR)	2.2 (1.1–5)	7.7 (4.1–12)	<0.001
Number of replacements of the pedals per hour (median, IQR)	0 (0–0)	1.7 (0.8–3.2)	<0.001
Number of foot mistakes per hour (median, IQR)	0 (0–0.4)	1.9 (0–3.8)	<0.001

IPEFIX, Innovative PEdal FIXator; ESD, endoscopic submucosal dissection; IQR, interquartile range; s, second.

Ethics

No specific institutional review board or written consent were needed for this study. Patients are included prospectively in a maintained database for ESD cases (registered NCT 04592003).

Results

Expert group

A total of 107 procedures (53 IPEFIX, 54 control) were performed by eight physicians. One physician performed 20 procedures, two did 19 procedures, four did 10 procedures and one could only perform nine procedures during the study period.

The majority (91.6%) of the ESDs were performed for colorectal lesions (▶ **Table 1**). The median size of the lesion and duration of the procedure were 50 mm (IQR 40–65) and 40 minutes (IQR 26–71), respectively. They were no statistical differences between the two groups for lesions localization and ESD speed but procedure duration was significantly shorter in the IPEFIX group (35 vs 50 min, $P = 0.039$) (▶ **Table 1**,).

The median number of mistakes per hour of ESD procedure was 0.0/h in the IPEFIX group and 1.9/h in the control group ($P < 0.001$) (▶ **Table 1** and ▶ **Table 2**). The number of times to look down to control the position of the pedals was 2.2/h the IPEFIX group and 7.7/h in the control group ($P < 0.001$). The median number of replacements of the pedals by the physician or the nurse was 0.0/h in the IPEFIX group and 1.7/h in the control group ($P < 0.001$).

Subjective evaluation of comfort of the pedals control during the procedure with IPEFIX was 9/10 versus 7/10 in the control group ($P = 0.015$).

Trainee group

A total of 17 procedures were performed by 17 trainees. For each procedure, they were randomly evaluated 10 minutes with the IPEFIX connector and 10 minutes without. The number of mistakes per 10 minutes of ESD procedure was 0.6 (IQR 0–1) in the IPEFIX group and 2.2 (IQR 1–3) in the control group ($P < 0.01$). The number of times to look down to control the position of the pedals was 2.7 (IQR 1–4) in the IPEFIX group and 3.9 (IQR 1–4) in the control group ($P = 0.51$). The median number of replacements of the pedals by the trainee or the nurse was 0 (IQR (0–0) in the IPEFIX group and 0.4 (IQR 0–1) in the control group for the 10 minutes period ($P = 0.019$).

Subjective evaluation of comfort in the two groups was 8.2/10 in the IPEFIX group and 6.2/10 in the control group ($P = 0.001$).

▶ **Table 2** Comparison of ESD performance by each operator with or without IPEFIX device.

Operator	No. times per hour to look down to control pedal position (median, IQR)		*P* value	No. pedal replacements per hour (median, IQR)		*P* value	No. foot mistakes per hour (median, IQR)		*P* value
	IPEFIX	Control		IPEFIX	Control		IPEFIX	Control	
1 = 20 procedures	0.250 [0; 1.21]	7.31 [5.08; 9.94]	**<0.001**	0 [0; 0]	5.21 [1.79; 7.76]	**<0.001**	0 [0; 0]	7.28 [3.30; 10.4]	**<0.001**
2 = 10 procedures	2.00 [1.33; 2.00]	4.00 [2.40; 7.50]	0.21	0 [0; 0]	0.745 [0.600; 1.00]	0.18	0.333 [0; 1.00]	2.67 [1.12; 4.50]	0.059
3 = 9 procedures	2.91 [1.67; 5.00]	2.14 [1.07; 3.21]	0.71	0 [0; 1.1]	0 [0; 0]	0.37	0 [0; 1.1]	0 [0; 0]	0.37
4 = 10 procedures	0 [0; 0.451]	2.86 [1.83; 3.33]	0.11	0 [0; 0.652]	2.86 [2.75; 3.00]	**0.011**	0 [0; 0.451]	1.83 [0; 3.00]	0.37
5 = 10 procedures	5.14 [4.80; 9.60]	3.69 [3.43; 6.63]	0.22	0 [0; 1.00]	0.806 [0.800; 1.29]	0.52	0 [0; 0]	0 [0; 0.36]	0.79
6 = 10 procedures	5.33 [4.80; 6.86]	11.2 [8.00; 12]	0.15	0 [0; 0.667]	2.00 [0.750; 2.00]	0.1	0 [0; 0]	0 [0; 0]	0.42
7 = 19 procedures	2.33 [2.01; 6.33]	12.1 [10.4; 18.3]	**<0.01**	0 [0; 0]	1.50 [0.900; 2.70]	**<0.01**	0 [0; 0]	1.73 [0.600; 2.40]	**0.012**
8 = 19 procedures	3.83 [2.40; 5.00]	10.0 [7.07; 12.3]	**<0.01**	0 [0; 0]	1.82 [0.300; 3.14]	**0.013**	1.28 [0; 2.50]	3.30 [2.66; 4.74]	**0.03**

ESD, endoscopic submucosal dissection; IPEFIX, Innovative Pedal FIXator; IQR, interquartile range.

Discussion

The IPEFIX device reduces the number of mistakes during ESD procedures with fewer pedal errors, times to look down, and pedal replacements whether an operator is an expert or trainee. It could also reduce procedure duration, although further studies are needed to compare parameters in homogenous procedures (one organ, similar size and difficulty).

Procedure duration was significantly shorter thanks to the device, but this study did not show an improvement in speed of dissection. This can be explained by the fact that the ESDs were performed by experts that do not make a lot of mistakes during their procedures. However, we could hypothesize that this device will be much more helpful for young ESD practitioners. In our study, we showed that trainees using the IPEFIX were more likely to keep their eyes on the endoscopic screen and made fewer mistakes compared to when a procedure was done without the device. By using this device, the learning curve for ESD trainees could be accelerated by avoiding false movements and position loss. It is also probably better for our brain to always find the pedals in the same position in order to keep concentration on the endoscopic field and not on the feet.

Our study also evaluated the comfort of pedal control during ESD procedures and showed a significant improvement with use of the fixator for experts and trainees. Therapeutic endoscopic procedures such as ESD are known to require prolonged procedure times, which can lead to endoscopist discomfort [2, 3]. The duration of a procedure may predispose endoscopists to a loss of focus, risk of mistakes during the procedure, and in the long term, to musculoskeletal injuries. Stable positioning during the procedure can facilitate fluid movement and efficiency. What distinguishes ESD from endoscopic mucosal resection is the need for a third foot pedal to activate the knife injection. This leads to multiple movements of the foot and pelvis, which result in an unnatural twisted position, a possible loss of focus and possible future musculoskeletal disorders. For better, more ergonomic positioning, it has been recommended that surgeons keep the pedal near their feet and aligned in the same direction as the instruments, toward the target quadrant and laparoscopic monitor [4, 5]. The main problem is that because the pedals are not fixed, they can move during the procedure, leading the surgeon to become unbalanced while replacing the pedal with the foot and breaking concentration. By fixing the pedals in a stable position, physicians were more comfortable during the procedure. In the long term, using IPEFIX to reduce unusual movement could also prevent future musculoskeletal disorders.

Our study has some limitations. First, ESDs were performed by experts. Consequently, procedure duration was shorter, which may have resulted in fewer mistakes. Second, trainees were evaluated on a porcine model for only 10 minutes per phase. In this model, uncontrolled bleeding cannot be simulated. It was also not possible to evaluate stress in this situation, thus leading to potential underestimation of mistakes and overall results. Finally, the operators were not blind during the evaluation. However, our study has strengths in that we evaluated more than 100 ESDs in a randomized way performed by eight

experts and 17 trainees during their ESD training program. Results from experts and trainees were consistent and reinforce the benefit of our device.

Conclusions

To conclude, IPEFIX is a simple device for connecting different pedals during endoscopic procedures. It helps reduce the numbers of foot mistakes during ESD and improves operator comfort. Future studies are needed to confirm its advantages for improving procedure speed and preventing musculoskeletal disorders.

Acknowledgement

The IPEFIX device received the price of the European best innovative device by the ESGE during ESGE days 2022.

Conflict of Interest

Dr YZET Clara have financial disclosures with ABBVIE, GALAPAGOS and JANSSEN. Pr PIOCHE Mathieu have participated to training session with Olympus, Pentax, Cook Dr RIVORY Jérôme have participated to training session with Olympus, Cook Dr LEPILLEZ Vincent have participated to training session with Olympus. Dr LEBLANC Sarah have participated to training session with Olympus, Norgine and Ovesco, and gave lecture to Alfasigma Pr JACQUES Jérémie have participated to training session with Olympus, Fuji, Erbe, Pentax and Lumendi, and gave lecture to Abbvie, Janssen, Norgine. Dr WALLENHORST Timothée, GRAINVILLE Thomas, LEGROS Romain, FIGUEIREDO Mariana, PERRON Léa, LAFEUILLE Pierre, MOCHET Mikael, VIRELY Mélia, LEPLAT-BONNEVIALE Peggy have no conflicts of interest or financial ties to disclose

References

[1] Yzet C, Rivory J, Mochet M et al. A 3D-printed innovative pedal fixator for connecting different pedal-operated tools to improve work ergonomics during advanced diagnostic and therapeutic endoscopic procedures. Endoscopy 2022; 54: E650–E651

[2] Matsuzaki I, Ebara T, Tsunemi M et al. Effects of endoscopy-related procedure time on musculoskeletal disorders in Japanese endoscopists: a cross-sectional study. Endosc Int Open 2021; 09: E674–E683 doi:10.1055/a-1352-3850

[3] Morais R, Vilas-Boas F, Pereira P et al. Prevalence, risk factors and global impact of musculoskeletal injuries among endoscopists: a nationwide European study. Endosc Int Open 2020; 08: E470–E480

[4] Berguer R. Surgical technology and the ergonomics of laparoscopic instruments. Surg Endosc 1998; 12: 458–462 doi:10.1007/s004649900705

[5] Sánchez-Margallo FM, Sánchez-Margallo JA. Ergonomics in Laparoscopic Surgery. In: Malik A (eds.) Laparoscopic Surgery. InTech; 2017