

# Can single-use versus standard duodenoscope improve ergonomics in ERCP? A comparative, simulation-based pilot study



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## ABSTRACT

**Background and study aims** Musculoskeletal disorders (MSDs) and injuries (MSIs) are frequent in gastrointestinal endoscopy. The aim of this study was to assess potential ergonomic advantages of a lighter single-use duodenoscope compared with a standard reusable one for endoscopists performing endoscopic retrograde cholangiopancreatography (ERCP).

**Methods** Three experienced endoscopists performed an ergonomic, preclinical, comparative protocol-guided simulation study of a single-use and a standard reusable duodenoscope using an anatomic bench model. Surface EMG signals from left forearm and arm muscles were recorded. A commercial inertial sensor-based motion capture system was applied to record body posture as well.

**Results** A significant lowering of root mean square amplitude and amplitude distribution of biceps brachii signal (ranging from 13% to 42%) was recorded in all the participants when using a single-use duodenoscope compared with a reusable one. An overall reduction of muscle activation amplitude and duration was also associated with the single-use duodenoscope for forearm muscles, with different behaviors among subjects. Participants spent most of the time in wrist extension (> 80%) and ulnar deviation (> 65%). A consistent pattern of functional range of motion employed for completing all procedures was observed.

**Conclusions** Our study showed that a lighter scope has a promising effect in reducing upper arm muscle activity during ERCP with potential benefit on musculoskeletal health in the ERCP setting.

## Introduction

Musculoskeletal disorders (MSDs) and injuries (MSIs) are frequent in gastrointestinal endoscopy: previous studies show an incidence of MSIs ranging from 37% to 89% among gastrointestinal endoscopists [1]. When focusing on endoscopic retrograde cholangiopancreatography (ERCP), the majority of endoscopists who perform ERCP, in a range from 67% to 91%, suffer from a musculoskeletal pain symptom [2, 3], and up to 48% report a musculoskeletal injury [2].

Gastrointestinal endoscopic procedures such as ERCP are characterized by a demanding physical interaction between the clinician and the endoscope. Furthermore, the ERCP operator is burdened with an increase in static load on the neck, shoulders, and back because of the use of lead aprons, which can weigh as much as 9.1 kg [3, 4]. Repeated pinching or gripping of the endoscope, as well as pushing, pulling, and torquing of the insertion tube in potentially awkward postures, have been shown to be risk factors for work-related MSIs [4]. The instrument control head is designed to be held and operated by the endoscopist's left hand. Heavier endoscopes have been shown to produce an increased static load on the left hand and wrist [5]. Static loading leads to decreased muscle perfusion and accumulation of lactic acid resulting in muscle fatigue and pain. Regardless of procedure complexity, operator fatigue appears to be an important predictor of outcome in ERCP. Although there have been substantial advances in endoscopic imaging technology, the basic shape, weight, and layout of the instrument are essentially unchanged since the endoscope was first introduced.

EXALT Model D single-use duodenoscope (Boston Scientific, Marlborough, Massachusetts, United States) is a single-use duodenoscope first developed to reduce the duodenoscope-associated infection rates. The EXALT device is comparable to reusable duodenoscopes in terms of feasibility, safety, and performance in a clinical setting [6]. Notably, although the EXALT model does not present significant design changes, it is much lighter than reusable duodenoscopes and may help reduce muscle load and fatigue during ERCP.

The aim of this pilot study was to evaluate potential ergonomic advantages of lighter single-use duodenoscopes compared with standard reusable ones by means of objectively measured parameters extracted from electromyographic signals and wearable inertial sensors in a preclinical comparative protocol-guided simulation study using an anatomic bench model.

## Methods

### Population

Three experienced endoscopists (> 5 years of practice) were recruited from the Gastroenterology and Interventional Endoscopy Unit of Local Health institution of Bologna. Current and previous musculoskeletal disorders were assessed using a standardized questionnaire including The Italian version of The Nordic Musculoskeletal Questionnaire [7]. Individuals were also



► Fig. 1 ERCP anatomic bench model.

asked to report recent hand or wrist injuries, previous surgery in the hand-wrist, elbow, or shoulder.

The study was approved on June 16th, 2022, by the Central Emilia Outer Area Ethical Committee of the Emilia-Romagna Region.

### ERCP anatomic bench model

The study was carried out on a fully synthetic ERCP anatomic bench model (► Fig. 1), previously used by procedure experts [8] to simulate four ERCP tasks in an anatomic model, comparing performance ratings and completion times of a single-use duodenoscope (EXALT Model D Single-Use Duodenoscope, Boston Scientific, United States) with a reusable duodenoscope (Olympus TJF-Q180V, Olympus Corporation, Japan). The bench model simulates relevant anatomy and mechanical properties of the normal human digestive tract from mouth to distal duodenum, including a pseudo-papilla and bile duct. It was constructed from Ecoflex 10 silicone (Smooth-On, Inc, Macungie, Pennsylvania, United States)-impregnated fabric of varying thickness to simulate differences in elastic properties in different regions of the intestinal tract. Synthetic mucus was applied to simulate lubricity provided by normal mucosa of the intestinal tract.

### Experimental procedure

Each endoscopist performed two identical simulated ERCP sessions of four procedures, wearing lead aprons, in the routinely used standard endoscopy room.

The participants were requested to replicate type and durations of ERCP standard tasks according to previous data recorded in four real cases randomly selected among 54 procedures in a time and motion analysis [9]. Simulated ERCP procedures, related tasks, and their duration are summarized in ► Table 1.

A single-use duodenoscope and a standard reusable duodenoscope were used during the first and second sessions, respectively. The two duodenoscopes were similar in shape and size. The length of the head of the EXALT duodenoscope was 296 mm, the handle transverse dimension was 120 mm, and the diameters of the two control dials were 64 mm and 42 mm. The length of the head of the Olympus duodenoscope was 290 mm, the handle transverse dimension was 130 mm, and the

► **Table 1** Simulated ERCP procedures, related tasks and their duration (minutes).

Number of ERCP procedures per task description	1°	15 min break	2°	15 min break	3°	15 min break	4°
Duodenal intubation and ampulla visualization	1		1		1		1
Biliary cannulation attempts	12		5		25		15
Sphincterotomy	2		2		3		1
Common bile duct stones removal	6		6		20		10
Stent placement	6		3		10		10
Duodenoscope removal	1		1		1		1
<b>Single ERCP procedure duration (min)</b>	<b>28</b>		<b>18</b>		<b>60</b>		<b>38</b>
<b>Session duration (min) – [including breaks (min)]</b>	<b>144 – [189]</b>						

ERCP, endoscopic retrograde cholangiopancreatography.

diameters of the two control dials were 67 mm and 46 mm. The EXALT and the Olympus duodenoscopes weighed 750 and 1500 g, respectively.

The two sessions performed by each endoscopist were scheduled 7 days apart to minimize the carryover effect of muscle fatigue developed from the previous condition. Before and after each experimental session, endoscopists performed their daily job routine.

At the beginning of each session participants were equipped with surface electromyographic (sEMG) and kinematic measurement apparatus and the calibration procedures were performed. Each procedure was separated by 15 minutes, corresponding to the mean room turnover time resulted in the aforementioned study [9].

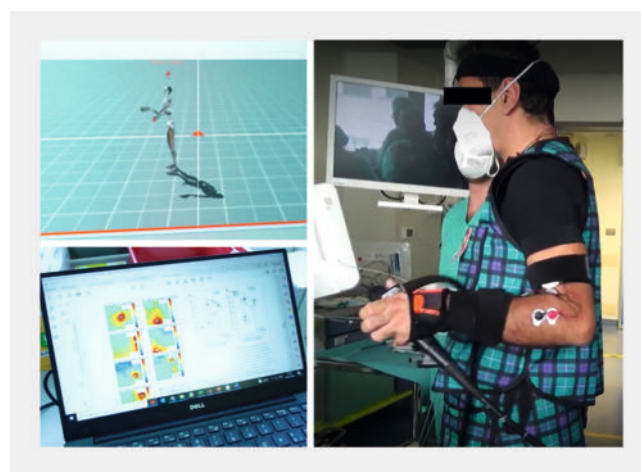
A repeated measures experimental design was used in which the dependent variables were measured on each participant for each of the two levels of the independent variable. The two levels of the independent variable were: using the single-use duodenoscope and the reusable duodenoscope during task performance (► **Fig. 2**).

## Measuring systems

### Acquisition of myoelectric signals

sEMG signals were detected in bipolar configuration with a modular and wireless sEMG amplifier (DuePro, OT Bioelettronica, Torino, Italy). Signals were sampled at 2048 Hz (bandwidth 10–500 Hz), with 16-bit resolution and transmitted through a Bluetooth link to a personal computer (BP software, LISiN, Politecnico di Torino, Italy). The following muscles of the left forearm and arm were considered: abductor pollicis longus (APL), extensor carpi radialis, flexor carpi radialis, biceps brachii (BB). Pre-gelled Ag/AgCl electrodes (Arbo H1245G, Kendall) were used. Before electrode positioning, the skin was cleaned with conductive and abrasive paste (Every, Spes Medica, Italy) to improve the electrode-skin contact [10].

After electrode placement, participants were asked to perform some test contractions for signal quality inspection. In



► **Fig. 2** Performing ERCP procedure and data recording.

this phase signals were also recorded under standard conditions to quantify the noise level and the maximal sEMG amplitude for each muscle. Specifically, the baseline noise level was measured by asking participants to rest their forearm on a support and relax the arm and forearm muscles, whereas the maximal sEMG amplitude was recorded during a maximal isometric contraction preformed against manual resistance.

### Inertial measurement unit (IMU)

Recording of body postures was performed using a commercial inertial sensor-based motion capture system, the Xsens MTw Awinda (Xsens, Enschede, the Netherlands), consisting of 17 IMUs secured on each participant according to the user manual. Data were processed with the dedicated MVN Analyze software (Xsens, Enschede, the Netherlands).

## Data analysis

### sEMG signals

The following procedure was applied to analyze sEMG signals of each muscle and task. The root mean square (RMS) amplitude was computed for each 30-ms epoch of the sEMG signal. The sequence of RMS values was then compared with the baseline noise threshold. The noise threshold was set to 3 standard deviations of the RMS amplitude distribution of the rest signal detected immediately before the first procedure. The number of epochs with RMS values exceeding the noise threshold were regarded as active epochs. This procedure allowed to compute the two sEMG variables of interest: (1) muscle activation duration, (i.e. the percentage of active epochs with respect to the total number of epochs); and (2) degree of muscle activation (i.e. the average RMS amplitude across active epochs [11]). Each sEMG variable was computed for each task ( $n = 6$ ) of each procedure ( $n = 4$ ) in both experimental conditions (single-use vs. standard duodenoscope), leading to two sets of 24 values for each variable. Paired comparisons using the Wilcoxon signed-rank test were performed to quantify the effect of the duodenoscope device on sEMG variables.

### Posture analysis

The recorded data were first processed in the MVN Analyze software, provided by Xsens Technologies. Because the left hand usually holds the control part of the endoscope, for the purpose of this analysis, postures of the left upper limb were calculated, focusing on wrist and elbow joint angles. Summary measures are calculated as percentage of time spent in each wrist posture according to the following intervals for pronation/supination and flexion/extension: 0°- 15° (central/neutral

posture), 15°-45° (mid posture), 45°-60° (extreme posture), > 60° (out of range posture). For radial/ulnar deviation, the following intervals were applied: 0°-15° (central/neutral posture), 15°-30° (mid posture), 30°-45° (extreme posture), > 45° (out of range posture). For elbow joint central/neutral posture was considered between 60° and 100° of flexion.

## Results

Among the participating endoscopists, there were two males and one female aged 45, 43, and 51 years, respectively. All the endoscopists had more than 5 years of experience in ERCP; they also did not report any musculoskeletal pain or discomfort at the beginning of the experiment, nor recent hand or wrist injuries, previous surgery in the hand-wrist, elbow, or shoulder.

### Muscle activation

sEMG results indicate an overall reduction in muscle activation, both in terms of amplitude and timing. ► **Table 2** and ► **Table 3** show the percentage differences in sEMG variables estimated in the two experimental conditions, computed with respect to the condition ("standard reusable duodenoscope"). Negative values indicate a reduction in the sEMG variable when the single-use duodenoscope was used. The degree of muscle activation (RMS amplitude) of BB was significantly lower in all the participants when using the single-use duodenoscope, with reduction ranging from 13% to 42% (► **Table 2**). The other muscles displayed different behaviors in different subjects, with an overall amplitude reduction associated with the single-use duodenoscope, although a significant amplitude increase was observed in one case (wrist extensor of Participant 2). Similar results were obtained when the muscle activation duration was considered (► **Table 3**).

► **Table 2** EMG amplitude estimations (RMS) and their changes between the two tested conditions (standard and single-use duodenoscope).

Muscle	Subject #	RMS amplitude [median (IQR)] ( $\mu\text{V}$ )		% changes of RMS amplitude w.r.t. standard duodenoscope	P (Wilcoxon signed rank test)
		Standard duodenoscope	Single-use duodenoscope		
Abductor pollicis	1	<b>239 (38)</b>	<b>193 (23)</b>	<b>-19.2 %</b>	**
	2	86 (23)	92 (26)	+6.9 %	NS
	3	<b>136 (46)</b>	<b>108 (43)</b>	<b>-20.6 %</b>	*
Wrist ext.	1	451 (186)	439 (89)	-2.7 %	NS
	2	<b>64 (41)</b>	<b>79 (25)</b>	<b>+23.4 %</b>	*
	3	<b>152 (94)</b>	<b>118 (37)</b>	<b>-22.4 %</b>	*
Wrist flex.	1	178 (30)	166 (10)	-6.7 %	NS
	2	61 (24)	59 (25)	-3.3 %	NS
	3	<b>99 (54)</b>	<b>80 (33)</b>	<b>-19.2 %</b>	*
Biceps Brachii	1	<b>214 (61)</b>	<b>177 (35)</b>	<b>-17.3 %</b>	**
	2	<b>194 (29)</b>	<b>169 (26)</b>	<b>-12.9 %</b>	*
	3	<b>275 (82)</b>	<b>156 (62)</b>	<b>-43.3 %</b>	**

\*  $P < 0.05$ ; \*\*  $P < 0.01$ .

IQR, interquartile range; NS, not significant (Wilcoxon signed rank test).

► **Table 3** Muscle activation durations (expressed as % of the total task duration) and their changes between the two tested conditions (standard and single-use duodenoscope).

Muscle	Subject #	Activation duration [median (IQR)] (% of the task duration)		% changes w.r.t. standard duodenoscope	P (Wilcoxon signed rank test)
		Standard duodenoscope	Single-use duodenoscope		
Abductor pollicis	1	<b>85 (10)</b>	<b>61 (24)</b>	-28.2 %	**
	2	28 (15)	31 (12)	+10.7 %	N.S.
	3	<b>58 (12)</b>	<b>38 (13)</b>	-34.4 %	**
Wrist ext.	1	91 (10)	94 (8)	+4.3 %	N.S.
	2	<b>47 (22)</b>	<b>61 (19)</b>	+29.8 %	*
	3	<b>60 (18)</b>	<b>51 (12)</b>	-15.0 %	*
Wrist flex.	1	<b>11 (7)</b>	<b>19 (9)</b>	+72 %	*
	2	<b>13 (16)</b>	<b>9 (6)</b>	-30.7 %	*
	3	<b>34 (12)</b>	<b>16 (9)</b>	-52.9 %	**
Biceps Brachii	1	<b>84 (19)</b>	<b>70 (18)</b>	-16.6 %	**
	2	<b>83 (10)</b>	<b>76 (11)</b>	-8.4 %	*
	3	<b>89 (13)</b>	<b>65 (10)</b>	-26.9 %	**

\* $P < 0.05$ ; \*\* $P < 0.01$ .

IQR, interquartile range; NS, not significant (Wilcoxon signed rank test).

## Joint angles

We observed that all participants had a tendency to spend the most time in wrist extension (>80%) and ulnar deviation (>65%). In addition, with the both single-use duodenoscope and the standard reusable duodenoscope, more than 60% of the total recorded time during ERCP procedures was spent within the range 0°–15° (central/neutral posture) for wrist radial/ulnar deviation and pronation/supination. Conversely, wrist extension deviated from the central/neutral range for more than 40% of the time, with the mid-range 15°–45° of extension being the prevalent position during all the procedures. Out-of-range postures were reached only occasionally (less than 5% of the time) by all participants for ulnar deviation and wrist flexion/extension.

Comparing endoscopists, we observed different total functional range of motion employed for completing all procedures, with Participant 2 having a wider distribution for all wrist postural planes of motion. By contrast, similar patterns were detected for each subject comparing procedures performed with the single-use duodenoscope with others with standard reusable duodenoscope. ► **Table 4** summarizes these results.

Throughout both experimental sessions, participants' mean elbow flexion ranged between 90° and 100°, while more extreme joint angles (>120° of elbow flexion) were recorded less than 10% of the time.

## Discussion

To our knowledge, this is the first (albeit preliminary) study in ERCP to evaluate potential ergonomic advantages for endoscopists of a newly designed single-use endoscope compared with a standard reusable duodenoscope, by means of objectively measured parameters of upper-limb postures and muscle activity.

Our study showed that a lighter endoscope, although it had no substantial change in shape, could decrease static and dynamic load during ERCP procedures.

Results showed that the single-use duodenoscope session was associated with lower induced muscle activity. Conversely, reusable heavier duodenoscopes led to increased sEMG activity in the BB for all subjects; the same trend was recorded in the left APL in two subjects. Besides, the increase in sEMG amplitude was always associated with an increase in activation intervals because the muscle was active for a longer period.

Although ergonomics is an emerging issue in endoscopy, studies published so far have mainly focused on colonoscopy to evaluate hand forces and muscle load in laboratory research settings as well as real-life scenarios [5]. Toward this goal, Shergill et al. used sEMG and pressure sensors to show that the right-thumb peak pinch forces required during left and right colon insertion exceeded the threshold value of 10 N repeatedly, leading to an increased risk of musculoskeletal injury of the thumb and wrist of colonoscopists [1]. Furthermore, left-wrist extensors, left-thumb extensors, and right-wrist extensors exceeded the American Conference of Industrial Hygienists hand activity level action limit during routine colonoscopy [1].



In another study on colonoscopy, sEMG data demonstrated increased muscular activation specifically in the right trapezius, right deltoid, and right posterior forearm [12].

Notably, colonoscopy technique strongly differs from ERCP technique in regard to forearm muscle involvement and posture load. Indeed, colonoscopists hold the body of the endoscope and manipulate the dials with their left hand and advance the endoscope forward with their right hand [12]; therefore, high forces are also required in the right forearm and right hand due to the need to apply torque during insertion or the force required to reduce or overcome loops in the colonoscope while attempting to reach the cecum [1].

In contrast, during ERCP, a lower applied force is generally required for the right forearm and right hand to manipulate the duodenoscope to advance and withdraw the shaft with the scope hooking on the duodenal angle and to place the scope in the right position to correctly visualize the ampulla [13]. Furthermore, high force is required to maintain the scope in unusual stable positioning with the left forearm while static load stress due to protective lead aprons is applied, often for longer procedures than during colonoscopy [12, 13, 14].

As results with the different techniques in regards to endoscopists performing colonoscopy show that static load seems to be the main issue for endoscopists performing ERCP, due to long duration of keeping the scope in a stable but awkward position, and the overload of lead aprons [3, 4].

To our knowledge, this is the first study to evaluate muscular electrical activity extracted from sEMG along with postures derived from inertial sensors in ERCP. We evaluated upper-extremity muscular activation and compared the effect of hand gripping of two different scope systems in simulated procedures.

Therefore, we focused on the left arm and hand-forearm muscles involved in holding the shaft and manipulating the gear, as required in the ERCP procedure.

Our sEMG results show the impact of a lighter duodenoscope in reducing left upper arm muscular activity, both in terms of activation degree and timing (► **Table 2** and ► **Table 3**). Statistically significant reduction in muscle was consistently observed in BB across subjects, and in two subjects for abductor pollicis. Wrist flexions and extensors showed different behavior, with an overall reduction trend, although not statistically significant in all cases. The observed inter-subject variability in the sEMG results was somehow expected and may be attributed to the differences in individual posture and movements during the procedures. It is plausible that the consistent decrease in BB activation is linked to firm grasp of different-weight objects, as well as to its fundamental role in elbow flexion, a motion that is common across subjects and tasks, likely less influenced by specific participant postures.

Concerning the possible influence of posture on sEMG parameters, we are aware that wrist range of motion is strictly related to hand grip and pinch strength [15]. Despite the fact that experimental design and results varied among studies, grip strength is most often greatest in the neutral position if compared with supination and pronation or ulnar deviation > 15°; furthermore, significant deviation (> 45°) from the neutral

wrist posture has been associated with reduced grip strength [16].

However, research has also shown that spontaneous and reproducible wrist postures, in addition to neutral, were associated with maximum grip force, highlighting the complex interaction between posture, muscle capacities, and task performance. Lower forces were observed when other wrist postures, such as flexion or extension, were imposed reflecting changes in muscle-force generating capacities induced by wrist position [17].

Moreover, up to 30° of wrist extension, commonly recorded in our study throughout ERCP procedures for all subjects, has been associated with maximal grip strength in experimental studies, especially when self-selected position was allowed. [15]. Therefore, when comparing muscle activities between ERCP sessions, the increased sEMG activity in the left forearm muscles seems not to have been influenced by wrist posture, which in our study, was held within extreme range of motion for less than 20% of the time and almost never exceeded out-of-range values with either type of duodenoscope. Also, a consistent pattern of functional range of motion employed for completing all procedures was observed for each subject with both the single-use duodenoscope and the standard reusable duodenoscope, supporting this conclusion. Our findings seem to highlight a biomechanical advantage for the single-use duodenoscope that could be considered among the basic ergonomic principles applied to reduce musculoskeletal strain. Indeed, well-established preventive precautions and recommendations for avoiding endoscopy-related pain and injuries are based more on ergonomic principles than on high-quality evidence, given the limited number of studies examining the outcome of selected objective measures of musculoskeletal parameters to assess the effectiveness of ergonomic interventions for preventing MSDs and MSIs [4, 18].

Preventive approaches include optimizing monitor size, height, and distance and the height of the treatment bed [4, 5], intermittent work-rest periods during fluoroscopic endoscopic treatment [19], and rehabilitation programs that include equipment/posture correction and stretching.

In the particular setting of ERCP, wearing two-piece lead aprons has been suggested, considering the theoretical advantage shown in a pilot study with a crossover design, which involved just five radiographers comparing two-piece, one-piece, and one-piece lead aprons with a waist belt [20].

Our study showed a potential role for a single-use duodenoscope in reducing static and dynamic loading during ERCP likely because of its lighter weight compared with the classic duodenoscope, as the differences in design do not seem to be so significant as to affect the posture and grip of the instrument.

The importance of endoscope weight and overload due to holding a heavy duodenoscope for a long time during ERCP is a well-known issue. Mechanical devices and a support stand specifically designed to reduce static load by holding part or all of the weight of reusable duodenoscopes have not gained traction for a variety of reasons, including limited mobility and issues with disinfection [21, 22, 23].

One limitation of our preliminary single-center study is lack of generalizability of the results due to the small sample size. However, all the experienced endoscopists performing ERCP at the Gastroenterology and Interventional Endoscopy Unit were enrolled, as ERCP is an advanced endoscopic procedure that requires considerable training and experience to perform effectively and safely. Furthermore, small sample sizes are often selected when comparing different ergonomic conditions, because assessing the same participants helps minimize risk of bias. This was recently discussed in a meta-analysis of studies comparing muscle activation between traditional laparoscopic surgery and robotic-assisted laparoscopic surgery [24]. Furthermore, previous studies published on ergonomics in endoscopy also involved small sample sizes of participants [25, 26].

Despite the small sample size of three subjects, a total of 24 ERCP procedures were analyzed, four with both duodenoscopes for each participant respectively. Overall, more than 3 hours of data recording were provided for each endoscopist.

Another possible limitation is that the study was performed on an anatomic bench model instead of a real patient. This choice was made to ensure similar conditions across participants. However, it is worth noting that the study protocol was designed to replicate as much as possible a realistic scenario. Indeed, the test was performed in the standard endoscopy room, with usual settings of monitors and bed; the endoscopists wore their own personal lead aprons and simulated ERCP replicating the type and duration of a real cases.

On the other hand, the strength of this work is that it is the first study dealing with ergonomic measurements in ERCP by means of wearable sensors, aimed to compare a new model of single-use duodenoscope with a reusable one.

## Conclusions

In conclusion, our study showed that the tested single-use duodenoscope encompasses properties such as lower mass, which has a promising effect in reducing upper arm muscle activity during ERCP with potential benefit on preventing MSI in the ERCP setting.

Further studies with larger sample sizes and that address gender issues in real-life scenarios are needed to confirm the impact of our measured potential ergonomic advantage on daily practice. Prospective study design is also required to measure the effectiveness of lighter duodenoscopes in preventing musculoskeletal disorders among endoscopists performing ERCP. However, it should be noted that this type of study may be very challenging to perform because ERCP is performed by a few selected physicians in each center, and therefore, a large number of hospitals should be involved. Furthermore, the study would be expensive because of the multiple measurement systems and the high number of disposable duodenoscopes that should be used continuously to determine their real benefits over repetitive and prolonged effort.

## Conflict of Interest

Vincenzo Cennamo: Olympus Italia, Olympus Europa, Euromedical, Novità Medicali. Other authors have any conflict of interest to declare

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