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New Concept of External and Independent Next-to-the-Scope Intraluminal Grasping Device (EINTS)

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Rezumat

Un nou concept: dispozitive de prehensiune intraluminale, externe și independente asociate endoscopului

Context: Procedurile endoscopice intervenționale implică o serie de manevre complexe şi precise. Îmbunătățirea funcției instrumentelor endoscopice pentru a obține o tracțiune suplimentară s-a bazat pe experiența chirurgicală. Această idee a apărut folosind instrumente auxiliare, externe, aplicate în vecinătatea endoscopului pentru a urma conceptele chirurgicale. Scopul acestui studiu este evaluarea instrumentelor de prehensiune endoscopice flexibile în ceea ce priveşte funcția şi raza de acțiune a acestora, cu introducerea conceptului de pensă de prehensiune endoscopică intraluminală.

Metode: În acest studiu sunt evaluate pensele de prehensiune endoscopice (1: through-the-scope-grasper, TTS-G; 2:additional-working-channel-system AWC-S; 3:external-independent-next-to-the-scope-grasper EINTS-G) în ceea ce priveşte raza de acțiune, abilitățile de prehensiune, manevrabilitate şi capacitatea de a expune țesutul cu unghiuri variate.

Rezultate: Raza de acțiune a instrumentelor ataşate de sau în interiorul endoscopului (TTS-G şi AWC-S) beneficiază de mobilitatea telescopului, atingând 180-210 grade în retroflexie; EINTS-G este limitat la 110 de grade. Pensa robustă de tip EINTS are avantajul unei forțe de strângere mai puternice pentru prehensiune şi tracțiune, ceea ce permite manipularea obiectelor mai mari. Manevrabilitatea independentă în timpul disecției ESD oferă o mai bună expunere a țesuturilor prin schimbarea angulației de tracțiune.

Concluzie: Raza de lucru a instrumentelor ataşate la endoscop beneficiază de mobilitatea telescopului. Pensa EINTS are avantajul

unei forțe mai puternice de prehensiune şi tracțiune în tractul gastrointestinal, iar manevrabilitatea independentă permite o expunere superioară a țesuturilor.

Cuvinte cheie: endoscopie intervențională, ESD, EFTR, pense de prehensiune endoscopice, rază de lucru, instrumente endoscopice, endoscopie terapeutică

Abstract

Background: Interventional endoscopic procedures require complex manipulations and precise maneuvering of end-effectors. One focus in research on improved endoscopic instrument function was based on surgical experience to gain additional traction. The idea has emerged using assisting instruments by applying external tools next-to-the endoscope to follow surgical concepts. The aim of this study is the assessment of flexible endoscopic grasping instruments regarding their function and working-radius introducing the concept of an intraluminal "next-to the-scope" endoscopic grasper.

Methods: In this study endoscopic graspers are evaluated (1:through-the-scope-grasper, TTS-G;2:additional-working-channel-system AWC-S;3:external-independent-next-to-the-scope-grasper EINTS-G) regarding their working-radius, grasping abilities, maneuverability and the ability to expose tissue with varying angulation.

Results: The working radius of the tools attached or within the endoscope (TTS-G and AWC-S) benefit from the steering abilities of the scope reaching 180-210 degrees in retroflexion; EINTS-G is limited to 110-degrees. The robust EINTS-grasper has the advantage of stronger grip for grasping and pulling force, which enables manipulation of larger objects. The independent maneuverability during ESD-dissection provides better tissue-exposure by changing the traction-angulation.

Conclusion: The working radius of tools attached to the endoscope benefit from scope- steering. The EINTS-grasper has the advantage of stronger grasping force and pulling within the GI-tract and independent maneuverability enables improved tissue-exposure.

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Key words: interventional endoscopy, ESD, EFTR, endoscopic graspers, working radius, endoscopic instruments, therapeutic endoscopy

Introduction

Interventional endoscopic procedures require complex technical manipulations and precise maneuvering of endoscopic end-effectors (1-3). Current commercially available endoscopic instruments such as graspers, snares as well as coagulation and cutting tools provide the necessary features for intraluminal work sufficiently, but improvements could be welcome in complex therapeutic procedures (4-6). Among experienced endoscopists, a controversial discussion continues about the optimization of these tools regarding the necessity of traction and countertraction, triangulation, maneuverability and steering options (7-9). The latter features are well-established principles in surgical dissection and precision-work on tissue (7,8,10,11).

The number of publications on the traction issue in flexible endoscopy may be a sign for some lack of instrumental functionality of current available endoscopic instruments (4,7, 8,9,12-16). Therefore, it could be anticipated that endoscopic experts may not need these options, since their vast experience will allow

for compensation of lacking instrument features. For novices and "average" endoscopists such a limitation of optimal instrument function may be critical and literature provides several examples of instrument optimization regarding interventional endoscopic procedures (17-22).

The retraction or lifting of tissue or the resected specimens require a sufficient grasping function, creating traction. Recently, several attempts were reported about additional assisting instruments using external tools outside the regular endoscope, based on a more surgical paradigm, to facilitate endoscopic procedures (21,22,23). As we gathered experimental experience with this idea, we planned to explore this option more systematically.

Therefore, the aim of this study is the assessment and comparison of different concepts of flexible endoscopic grasping instruments regarding their maneuverability, function and working-radius in various situations and introducing a new concept of an external intraluminal "next-to the-scope" endoscopic grasper.

Methods

As a basis of our study, we evaluated the currently available concepts of endoscopic grasping devices.

A first concept is the well-established through-the-scope grasping device (TTS-grasper), which is advanced through the working channel of the endoscope, thus being forced to always be manipulated in the axis of the scope and is available from different companies (Example: Olympus Medical Deutschland GmbH, Hamburg; Boston Scientific Deutschland GmbH, Düsseldorf).

A second concept of grasping instruments is the use of an Additional-Working-Channel grasper (AWC-system)(Ovesco GmbH, Tübingen), which uses an attachable system to the endoscope, which increases the triangulation component, however, the grasper is still connected to the working axis of the scope.

The third is an external independent next-to-the-scope (EINTS) flexible grasper (Fortimedix Surgical BV, Geleen, Netherlands), which can be manipulated independently from the scope.

Design of the Investigations

The design of the study consisted of the assessment of the chosen endoscopic grasping instruments following different concepts as to their function and grasping abilities as well as their maneuverability. The first test is the assessment of parameters regarding the working radius of the instruments in order to determine the applicability within the gut lumen.

The second test is the evaluation of the grasping ability as measured by the pulling force on a string held by the different grasping forceps of the flexible instruments.

The third test concerns the maneuverability of the different grasping instruments in the pre-clinical situation as tested in a porcine esophago-gastric explant-model.

The fourth test evaluates the ability of the graspers to expose tissue of the submucosa in a certain angle, which facilitates and helps to proceed with an ESD in an optimized way.

The Investigated Instruments

Three types of grasping instruments as basic tools were studied (*Fig. 1*): 1- the conventional through-the-scope-grasper (TTS-G); 2- the additional-working-channel-system (AWC-S) with a working-channel, externally attached to the scope for the use of an additional regular grasper; and 3- an external, independent, next-to-the-scope grasper (EINTS), which is placed outside the endoscope into the gut-lumen without connection to the scope, thus allowing for independent manipulations.

The traditional endoscopic grasping instrument TTS-grasper can be advanced through the working channel of any regular endoscope. No further preparation is necessary. A large number of such instruments are commercially available. Directional movements of the grasping instrument and scope are combined.

The AWC-system consists of an additional

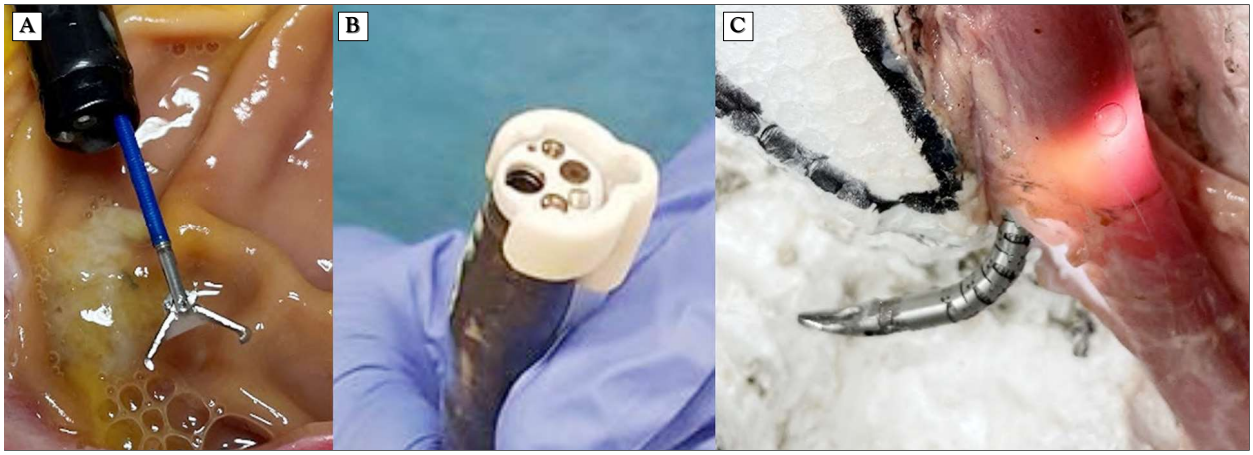


Figure 1. **(A)** - The traditional flexible grasper TTS-G; **(B)** - The additional-working-channel-system (AWC-S) for passage of a regular flexible grasper through an additional working channel attached to the scope; **(C)** - external independent intraluminal next-to-the-scope grasper (EINTS-grasper)

working channel, which was developed, designed and manufactured for the application on a regular commercially available endoscope (23). A plastic tube system (AWC) with a proximal valve opening at the level of the working channel entrance of the scope and a distal clip-like fixation of the channel on the scope-tip was attached to the endoscope. The distal tip of the AWC follows the movements of the scope, thus the manipulation of the grasper is combined with the manipulation of the scope.

The external, independent instrument (EINTS-grasper) should be handled by an endoscopist and an assistant. The 5 mm instrument was designed following established laparoscopic principles (21). The flexible shaft has currently a length of 80 cm, and the end-effector is capable of articulation in all directions via movement of the handle outside the body. The instrument is anchored externally via fixation to a StrongArm™ Surgical Holder (Mediflex), attached to the operating table. The end-effector could be turned using triangulation under direct visualization by the scope. The EINTS-grasper can be maneuvered in and out of the esophagus independently from the scope without limitation, but should be advanced under endoscopic vision. In order to facilitate repetitive passage through the oropharynx, an overtube (Guardus®-overtube, US-Endoscopy, USA; outer diameter:18,5 mm) was used.

Study Procedures

In a first test-series, the working radius of the instruments were measured on millimeter-paper, calculating the angles of turning of the instruments in combination with or without the scope as well as measuring the actual radius of turning the instrument-tip in centimeters (*Fig. 2*). The measurement parameters were:

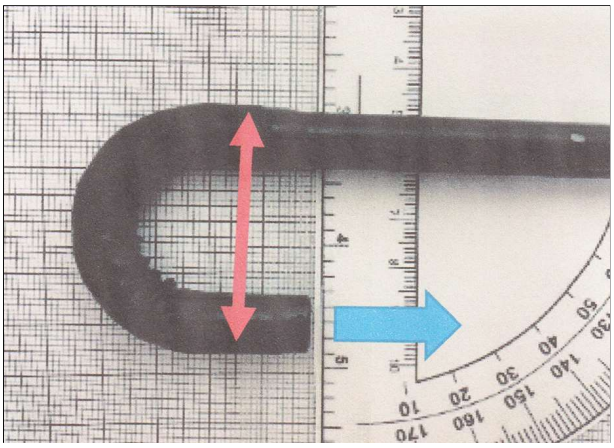


Figure 2. Measurements of working radius of the different instruments: blue: degree of angulation of tip; red: necessary lateral space (cm) under retroflexion

1. the maximum possible angulation of the instrument tip to demonstrate the steering ability, created by the instrument and the scope or the instrument, measured in degrees of angulation (blue arrow);
2. the distance or space of the lateral retroflexion of the scope and/or the instrument (red line).

In a second test-series, the force was measured for each grasping instrument, with which they could pull on a string attached to the gauge, when turning in an opposite direction, simulating traction on a tissue. For the measurement, a Digital Force Gauge PCE-DFG-500 (PCE Deutschland GmbH, Meschede, Germany) was used. This force was expressed in N (Newton).

In the third test, a dry-set Styrofoam model of the upper GI-tract placing was created with an excavated space for an esophago-gastric porcine-explant, which could be entered by scopes and instruments. Seven measurements (in sec) were taken for each task in order to quantitatively evaluate the performance of the instruments. A first measurement was the time needed to advance the instrument tip with the scope from the pharynx to a prefabricated esophageal lesion. A second time-measurement was taken maneuvering the tip of the grasper from an intraluminal prefabricated perforation outside in the "mediastinum" (*Fig. 3*). A third time-measurement was taken to remove an intraluminal placed sponge from the esophageal lesion to the pharynx and outside under endoscopic vision by pull-back of the scope. The number of necessary re-grasping in case of loss of the sponge during retrieval was also counted.

In a fourth test series focusing on more detailed traction abilities, the different necessary directions of traction were evaluated in an ESD-model. In a gastric porcine explant, an ESD of a lesion on the posterior gastric wall was simulated, measuring the angles or direction of traction, which could be established with the different instruments, compared to the axis of the endoscope (*Fig. 4*). As dissection of tissue can be facilitated by using changing angles of traction and changing tension of the tissue, thus, improvement of the dissection process could be facilitated by exposing changing areas of submucosa under traction and applying changing tension on the tissue. The applied angulations of traction were evaluated by measuring the possible angulation between the axis of the tip of endoscope and the axis of the tip of the instruments. For each instrument 7 samples were taken. All evaluation criteria were prospectively measured and documented.



Figure 3. EINTS-grasper with sponge at the prefabricated esophageal lesion, providing superior grasping and pulling force

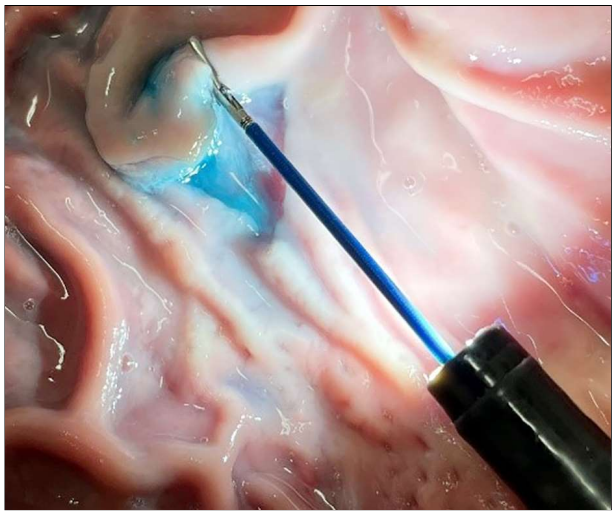


Figure 4. In-vitro ESD model: the axis of the tip of the TTS-grasperis identical with the axis of the tip-segment of the scope. Any change in scope direction will also change the direction of the grasper.

Results

The results of the different test series concern: 1: working radius and necessary intraluminal space; 2: assessment of pulling force established by scope and different grasping instruments; 3: time-consumption of different tasks in an esophageal-explant-leak-model. 4: differences in angulation of instruments during traction.

The measurements of the working radius of the 3 grasping instruments are summarized in *Table 1*, indicating a larger possible angulation of the instruments, which are connected to the endoscope e.g., the TTS-G and the AWC-S, based on the bending abilities of the scopes. The steel-made EINTS-grasper has less maneuverability than the scope. The advantage is its ability to independently maneuver the tip. The possible pulling force of different instruments shows a certain superiority of the steel-made EINTS-grasper, based on the robust structure (*Table 2*).

The results of the third series are demonstrated in *Table 3*. It is shown that the superior force of grasping with the external instrument can provide an improved manipulation of a sponge because of greater strength of gripping. The time consumption of several tasks such as inserting a sponge into a leak-cavity and the retrieval of a sponge from the "mediastinal leak-cavity" is significantly shorter than for regular smaller size grasping instruments of the TTS-grasper or the AWC-system.

The results of the fourth test show that with an independent next-to-the-scope and steerable instrument different angulations can be achieved between the EINTS-grasper from the tip of the scope, compared to the other "scope-dependent" instruments (*Table 4*).

Table 1. Results of test-series 1 showing the working radius

Device	complete angulation of tip (retroflexion)(degree) above / below		Necessary lateral space (distance cm) under max retroflexion
Gastroscope diameter 9.2 cm	210	90	3
Scope + TTS grasper	180	60	3.4
Scope + AWC-System	190	70	3.5
EINTS-grasper (scope separate)	110	60	5

Table 2. Results of test-series 2 with assessment of force involved in pulling with different instruments on simulated tissue (Force gauge)

Device	median result (Newton)	IQR (N)
Scope and conventional grasper TTS	7.675	Q3 8.44 Q2 7.67 Q1 7.05
EINTS- grasper	9.9	Q3 10.7 Q2 9.9 Q1 8.5
Laparoscopic grasper (as control)	11.975	Q3 12.76 Q2 11.97 Q1 11.27

Table 3. Results of test-series 3 with comparison of different grasping instruments

Tasks	Median time and time-range in sec			Special notes
	TTS-grasper	AWC-grasper	EINTS-grasper	
Advancement of grasper to esophageal lesion	15 (11-30)	14 (13-32)	12 (10-23)	No problem
Transport of sponge in para-esophageal cavity	290 (110-600)	280 (100-550)	250 (60-500)	Loss of sponge at ostium, bending function
Endoscopic assisted retrieval of sponge	260 (190-500)	270 (180-490)	180* (50-260)	$p<0.05$
Necessary regrasping maneuvers	5 (2-20)	5 (3-18)	1* (0-4)	*$p<0.05$

Table 4. Results on test-series 3 on measurements of angulation of EINTS versus axis of scope

tool	1	2	3	4	5	6	7	median
TTS versus scope	0	5	0	5	0	5	0	0
EINTS versus scope	30	35	40	40	30	40	40	40

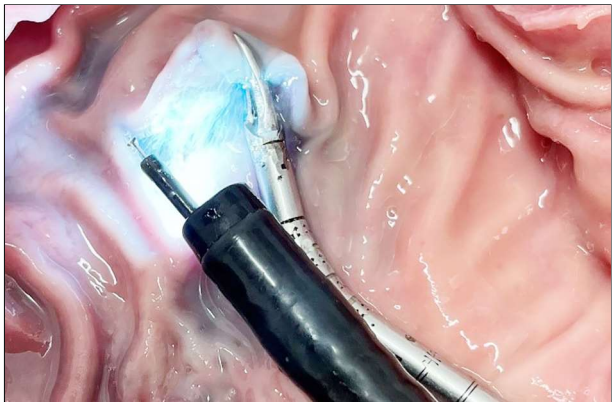


Figure 5. With the independent EINTS-grasper, a change in angulation of traction of the flap compared to the scope-axis can be established.

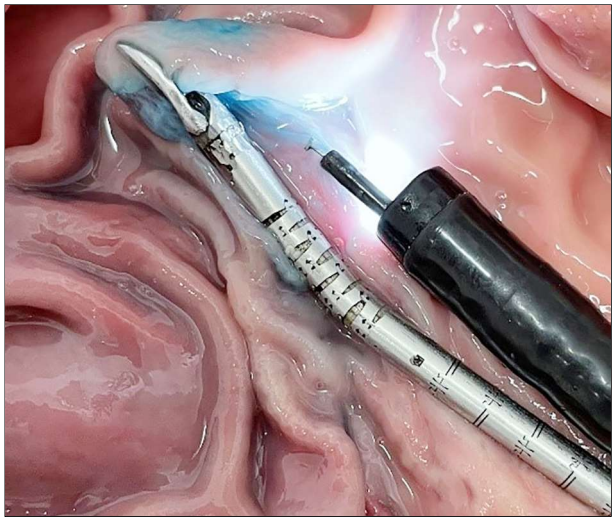


Figure 6. When using the EINTS in the corner of the incision, the submucosal tissue can be exposed by manipulation of the traction-angle and tension.

The difference in traction angulation compared to the scope-axis allows for improved tissue handling in the plane of dissection, demonstrated in *Fig. 5* and *Fig. 6*.

The possible angulation with the TTS-grasper and the AWC-system cannot be increased above 5 degrees, since the axis of the instruments and the axis of the scope are attached together. They can only be influenced by torsion of the scope. The EINTS-grasper can be manipulated by the steering mechanism and its independent maneuvers to reach different angulation between the scope-axis and the tip of the instruments between 30-40 degrees (*Table 4*). This allows for improved exposure of the dissection layers (*Fig. 6*).

In summary, the working radius of the tools attached or within the endoscope (TTS-G and AWC-S) benefit from the additional support of the flexibility and steering abilities of the scope. The external independent robust structured EINTS-grasper has the advantage of stronger possible grip for grasping and pulling force, which enables quick and efficient movement of larger objects within the GI-tract. The independent maneuverability provides the possibility during ESD-dissection to better expose the tissue by changing the traction-angulation.

Discussion

There is a discussion among endoscopists performing high-end interventional endoscopy about the usefulness of additional instruments in therapeutic procedures as well as the potential improvement, when applying certain surgical principles for dissection (2,3,5-8,12, 13,23). Sophisticated ideas have emerged regarding the option to use additional instruments for traction-countertraction during these procedures (5,6,8,12,13,23). In surgery, the principle of precise dissection of important structures relies on traction and countertraction of tissue to find the optimal layer of dissection with a minimum of necessary hemostasis (7,10,11). The issue of triangulation is another point of discussion, which is assumed by most gastroenterological endoscopists to play a minor role, especially in intraluminal work (4,9). Nevertheless, precise dissection with an energy device, also endoscopic dissection, can be enhanced by the retraction of the tissue in question to better expose the right layer of dissection, especially in oncologic work.

The basic design of endoscopes for the GI-tract has been unchanged in the last 50 years, initially carrying a camera for the diagnostic vision function. Integrating options for therapeutic action led to working channels, which allows for easy handling and the use of a large availability of different instruments. The disadvantage is the dependency of the working

radius of the instrument and limitation of the axis of action on the axis of the scope. The latter may be not important in routine intraluminal work such as an "routine" ESD, but may be of importance in larger lesions and/or lesions in difficult locations, where changing angles of action could be of advantage or intermittent traction could be quite helpful if not essential. Additional functions could be provided by a dual channel scope or an additional external working channel as reported, to bring in further assisting instruments such as a grasper for traction (8,12, 23,24). Another idea could be a combination of instrument-functions in one tool. This idea was tested 10-15 years ago during the NOTES-hype (7-11).

Our results show that the majority of tasks can be provided by the commercially available TTS-graspers via the working channel of the scope or as an external option with the AWC-system (23,24). The results also demonstrate that these two instrument options, supported by the flexibility of the endoscope tip, can be maneuvered with an excellent working radius within the lumen of the gut.

However, whenever extra force for grasping and/or additional traction in different angulations is required by the anatomy or local situation at the lesion, the EINTS-grasper seems to be superior based on the experimental results. Manipulating more spacy objects such as a sponge with a friction component in the gut, more force and grasping strength is needed, which could be handled by the EINTS-grasper.

Furthermore, the EINTS-grasper can be selectively used as an external instrument at the choice of the endoscopist without changing the general approach. The advantage of an external, intraluminal instrument, which can be operated independent from the scope as an additional grasper, is the freedom of individual manipulations in different angulations and distances from the scope in contrast to scope-attached instruments, providing the possibility of traction and countertraction. This may facilitate assistance in endoscopic resections, ESD, EFTR, endoscopic placement of therapeutic tools such as a sponge in an abscess-cavity, endoscopic assistance in retrieval of tools or foreign bodies or it may be helpful in endoscopic suturing (25,26).

Technical shortcomings during therapeutic endoscopy have stimulated the search for new ideas to improve these technical steps. One idea was the use of additional instruments through double channel scopes and furthermore, the development of complex endoscopic platforms to perform surgical tasks (1,7-11, 23,24). The transluminal endoscopic activities 10-15 years ago produced valuable spin-off ideas such as the creation of independent instruments or independent vision from other instruments to possibly improve complex endoscopic approaches (5,7-11,21). Early experimental and clinical experience have shown the limitations and vast expenses for such systems, creating a new search for alternative and more reasonable solutions. The idea emerged to create and use an external instrument, which can be used intraluminal parallel to a regular endoscope to assist and improve the necessary endoscopic tasks (5,8,21,22). This study shows an experimental evaluation of this idea by testing the EINTS-grasper in different circumstances. The results show a helpful alternative when performing interventional endoscopy.

These considerations were discussed when developing multitasking endoscopic platforms during the NOTES-hype (7-11,24-26). Searching for the optimal solution for an independent component among the three most important instrumental endoscopic functions, i.e., vision, dissection, traction, in our theoretical simulation, we found for the necessary tasks in an intraluminal setting the combination of vision and dissection optimal for safe interventional endoscopic procedures, because precise application of energy during dissection should be followed closely by optimal vision. Therefore, the independent instrument could be the traction function. This is also reflected by the number of reports on additional systems and instruments for traction in interventional endoscopy, which have been published in recent years (4-6).

One of the important spin-off ideas of these

considerations was the option of an independent external and intraluminal instrument for additional assistance in therapeutic endoscopic procedures (21,27,28). Furthermore, the analysis of technical shortcomings in endoscopic procedures is essential, because these results can lead to further investigations to find reasons and improve the concepts, the design and functions of endoscopic instruments for the advantage of endoscopic procedures (29,30).

Conclusions

In conclusion, during major endoscopic resection procedures, the vision and dissection function are most important and can be assisted by traction in special situations. Different concepts of grasping instruments have been tested and show that the working radius of the tools attach to or within the endoscope (TTS-G and AWC-S) benefit from the additional support of the flexibility and steering abilities of the scope. The external independent robust structured EINTS-grasper has the advantage of stronger grip with grasping and pulling force, which enables quick and efficient movement of larger objects within the GI-tract. The independent maneuverability provides the possibility during ESD-dissection to better expose the tissue by changing the traction-angulation.

Conflict of Interest and Financial Disclosure

AM is consultant of Ovesco GmbH, Tübingen, Germany. KHF was (2016-2019) a consultant of Fortimedix Surgical BV, Geleen, The Netherlands. BS, SJT and AH declare that they do have no conflict of interest for this project.

Author's Contributions

All authors, KHF, BS, JT, AH, and AM have had substantial contributions to the conception and design of the work, the analysis and interpretation of data for the work. All authors have made substantial contributions to the drafting the manuscript, its revisions for critically improving the intellectual content. All authors were involved in the final approval of the version to be published. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved and that they can accept public responsibility for the report.

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