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RHINOLOGY

A prospective, feasibility study to evaluate the efficacy and usability of a novel drivable endoscope in patients with chronic rhinosinusitis

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Abstract

Purpose To carry out a pilot study to evaluate the efficacy of a novel, drivable endoscope (the Peregrine™ Drivable ENT Scope), compared to standard rigid endoscopes in the access, visualization, and irrigation of the paranasal sinus anatomy.

Methods A prospective, multi-center, feasibility study was conducted on seventeen subjects who underwent primary functional endoscopic sinus surgery and were evaluated with the drivable endoscope and standard, rigid endoscopes (0°, 30° and 70°, as applicable). A CT scan was available for image guidance, as needed. The primary efficacy endpoint was the ability to access and visualize sinonasal anatomic landmarks. Secondary endpoints included device usability, as measured by a usability questionnaire given to surgeons postoperatively; the device's ability to irrigate the sinuses and patient reports of tolerability and pain during postoperative procedures.

Results The drivable endoscope success rate in visualizing all paranasal sinus anatomic landmarks was 55.6% better than the standard rigid endoscopes: 98.3% (178/181) versus 42.7% (76/178); $p < 0.001$. Surgeons rated scores of over 4 (on a 1–5 scale) for the usability of the drivable endoscope to enter the maxillary, frontal and sphenoid sinuses. The ability to irrigate the sinuses using the drivable endoscope was given a mean score of 4.3, and image quality was given a mean score of 3.4. The three patients evaluated postoperatively reported low pain and high tolerability scores with the drivable endoscope.

Conclusions These preliminary results indicate that the drivable endoscope is effective, easy to use and highly tolerable in sinonasal endoscopy.

Keywords Functional endoscopic sinus surgery (FESS) · Nasal endoscopy · Drivable endoscope · Chronic rhinosinusitis · Paranasal sinus

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Introduction

The rigid endoscope has transformed the field of rhinologic surgery since its development by Karl Storz in 1961, and is routinely used in otolaryngology practice. Over the past two decades, improvements in endoscopic techniques and instrumentation have enabled otolaryngologists to carry out major sinonasal surgery in a fully endoscopic manner [1]. Nevertheless, the paranasal sinuses, because of their anatomic position and potential for variability, can be difficult to visualize with standard rigid endoscopes.

Chronic rhinosinusitis (CRS) is one of the most common chronic illnesses in the United States and Europe, affecting approximately 14% of the US population [2] and 11% of the European population (with geographical variation ranging between 7 and 27%) [3, 4]. CRS is associated with a significantly reduced quality of life [5]. The currently accepted treatment for medically refractory CRS is functional

endoscopic sinus surgery (FESS). With advances in this procedure, it is now recognized that a structural preservation approach should be taken for the surgical treatment of sinus disease, and the least invasive procedure should be attempted first [6]. This has been shown to have clinical benefits for patients. For example, Patel and colleagues [7] found that both Draf 2B and Draf 3 procedures offer durable symptomatic improvement for patients with refractory frontal CRS, but the former less invasive procedure was associated with earlier postoperative symptom improvement.

Nasal endoscopy is essential for the diagnosis and treatment of sinonasal disorders [8]. Current standard rigid endoscopes perform well at allowing otolaryngologists to evaluate the nasal cavity and, when anatomy is favorable, also the sinus drainage pathways. However, due to the angled location of the sinuses in relation to the nasal cavity [9], it is technically difficult to visualize the sinus cavities in their entirety during or after endoscopic sinus surgery in order to ensure complete removal of pathology residing in, or stemming out of, the sinuses. Furthermore, such technical challenges prevent adequate inspection of possible disease recurrence in the postoperative setting, as well as potentially causing pain and discomfort to the patient. Consequently, there is significant clinical value in well tolerated and improved visualization of the sinus anatomy.

Often a CT scan is required to better assess intra-sinus pathology when a sinus cannot be visualized endoscopically, thus exposing patients to potentially harmful radiation. This risk may be limited or avoided if intra-sinus endoscopic visualization was available during diagnosis and follow-up [10–13].

The Peregrine™ Drivable ENT Scope is intended to visualize the internal cavities of the ear, airways, nose and sinus cavities during diagnostic and therapeutic endoscopic procedures. This clinical study is a pilot, first-in-man explorative study that aimed to evaluate its efficacy and usability compared to standard rigid endoscopes, in visualizing the paranasal sinus anatomy in patients with CRS, as well as its irrigation capability.

Methods

Patients

This was a prospective, open-label, non-randomized feasibility study that took place at the University of Ghent Hospital (Ghent, Belgium), Rabin Medical Center (Petach Tikva, Israel), and Assuta Medical Center (Tel Aviv-Yafo, Israel). Adult patients who were scheduled for primary FESS were consecutively enrolled to participate in the study from September 21st, 2015 through to January 26th, 2017. Patients were excluded from the study if they were indicated for a tumor excision or had a history of any significant medical disorder that contraindicated study participation, such as any known current or past bleeding disorders that required anticoagulants (e.g. chronic coumadin treatment). All study participants provided written informed consent. The study was performed according to the Declaration of Helsinki ethical guidelines and was approved by the hospitals' Institutional Review Boards and by the Ministries of Health of Belgium and Israel.

Instruments

The Peregrine™ Drivable ENTScope (3NT Medical Ltd) evaluated in the study is a miniature endoscope measuring 2.3 mm in diameter with a built-in channel for irrigation, and a color distal camera chip at its distal tip, located in a disposable shaft; the disposable shaft is fitted into a reusable metallic handle (see Fig. 1). The tip of the endoscope can angulate at 0°–125° at a turning radius of 3 mm; once the

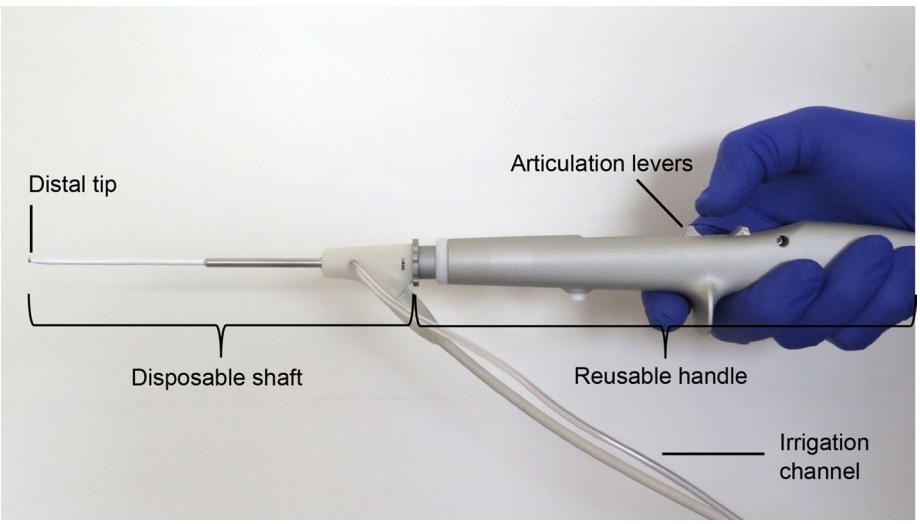

Fig. 1 The Peregrine™ drivable ENT scope. The device evaluated in the study is an endoscope measuring 2.3 mm in diameter with a camera at its distal tip and a built-in channel for irrigation. It is comprised of a disposable shaft fitted into a reusable handle. The distal tip of the endoscope can angulate and advance over the angulation

desired angle is reached, the tip can then extend beyond the set angulation and advance into the anatomy (see Fig. 2 and Supplementary Video 1).

Standard rigid endoscopes. The FESS procedures were performed with standard 4 mm 0°, 30°, 45°, and 70° rigid endoscopes, connected to a high definition camera and monitor system, according to the surgeon's discretion as applicable.

Endoscope usability questionnaire. This questionnaire was completed by the otolaryngologists upon completion of each FESS procedure. Here, the surgeons scored their subjective ratings of the access and lavage (where applicable) of the sinuses by the drivable endoscope, and their subjective impression of its image quality. A scale between 1 (worst) and 5 (best) was employed.

Postoperative clinic questionnaire. For patients evaluated in the postoperative clinic, subjective scores on tolerability (on a scale of 1–10, where 1 = highly tolerable and 10 = not at all tolerable) and pain (on a scale of 1–10, where 1 = no pain and 10 = worst pain) were recorded.

Procedure

Screening of patients took place within 2–30 days before the FESS procedure to determine whether they were otherwise healthy and eligible for the study. Four otolaryngologists performed all FESS endoscopic procedures under general or local anesthesia. Standard rigid endoscopes (0°, 30°, 45° and 70°, as applicable) were used during the surgical procedures. The drivable endoscope was then used at different levels of surgical resection to assess its ability to visualize the intrasinus anatomic landmarks in comparison to the appropriate rigid endoscope for the surgical situation as decided by the surgeon. A CT scan was available for image guidance, as needed. The occurrence of adverse events (AEs) during the procedure was recorded. After each procedure, the otolaryngologists filled out a usability questionnaire.

All subjects underwent follow-up 4–20 weeks after the procedure in accordance with their center's standard of care. At the University of Ghent Hospital, in order to preliminarily explore the postoperative applicability of the drivable endoscope, the otolaryngologist selected the last 3 study participants for evaluation with the drivable endoscope during the postoperative visit. This was carried out under topical anesthesia in the outpatient clinic. The subjects reported on any discomfort and pain felt during this procedure and their general tolerability of the procedure. Upon completing each postoperative procedure, the otolaryngologist completed the endoscope usability questionnaire and recorded any AEs.

Outcome measures

The primary efficacy endpoint was the ability to visualize the paranasal sinus anatomy by directly observing: the maxillary sinus natural ostium, floor, lateral recess, and anterior wall; the frontal sinus ostium, posterior table, anterior table, and lateral recess; and the sphenoid sinus ostium, posterior wall, floor, and lateral recess. Secondary endpoints included the device usability as measured by the endoscope usability questionnaire; the device's ability to irrigate the sinuses; and for subjects evaluated in the postoperative clinic, patient-reported procedure tolerability and pain scores. The incidence of unanticipated device- or procedure-related AEs was also noted.

Statistical analysis

An independent statistician analyzed study data with IBM SPSS Statistics version 23.0 (IMB SPSS, Armonk, NY, US). Subject characteristics were summarized by the appropriate descriptive statistics. Student *t* tests were employed to analyze the continuous measures and Chi-square or Fisher's exact tests compared categorical parameters. Statistical significance was taken at the $p < 0.05$ level. Considering the exploratory nature of this pilot study and the corresponding relatively small subject sample, statistical analysis was only carried out where the statistician deemed it relevant.

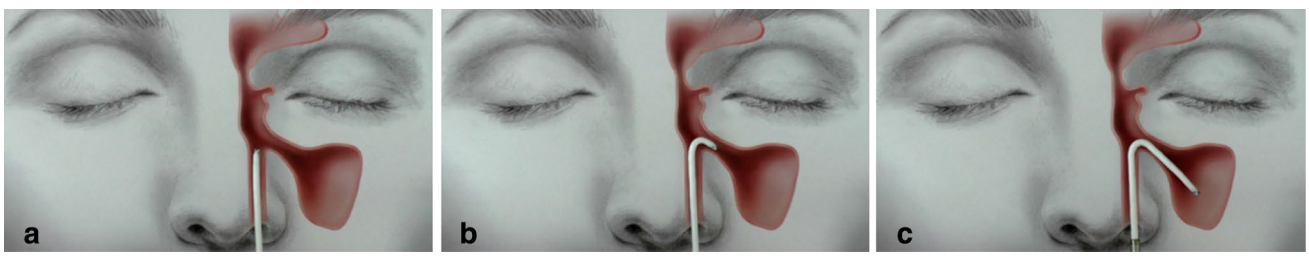

Fig. 2 Angulation and advancement of the Peregrine™ drivable ENT scope. The actual drivable endoscope is photographed from above, as it is advanced over an illustration of the nasal cavity (**a**), angulated until the maximal angle is reached (**b**) and advanced over the turn, over the illustrated maxillary sinus (**c**)

Results

Seventeen subjects (9 females; 8 males) were screened, determined eligible, and enrolled in the study. Their mean age was 46 ± 10.8 years (range 25–60 years). All the patients successfully underwent FESS using the standard and drivable endoscopes and completed their postoperative follow-up visits. Three patients out of the 17 were also evaluated by the drivable endoscope and standard rigid and flexible endoscopes in the postoperative clinic setting.

The levels of surgical resection at which comparisons between the drivable endoscope and a rigid endoscope were made were as follows. For the 27 maxillary sinuses attempted (16 left, 11 right), 18 sinuses underwent an antrostomy, 5 underwent an uncinectomy, and 4 were visualized through an accessory ostium without any resection; for the 17 frontal sinuses attempted (12 left, 5 right), 13 underwent Draf 2a, 1 underwent Draf 1, 2 underwent Draf 3, and 1 was visualized after resection of an agar nasi cell; and for the 3 sphenoid sinuses attempted, 1 underwent superior turbinectomy and 2 were visualized without any resection.

The ability to directly visualize the different sinus anatomic landmarks at the same level of surgical resection is summarized for the drivable and standard endoscopes in Table 1. At the same level of surgical resection, the drivable endoscope was superior in visualizing the maxillary, frontal and sphenoid sinuses anatomic landmarks compared to standard rigid endoscopes, with an overall visualization success rate of 98.3% (178/181) versus 42.7% (76/178), respectively; $p < 0.001$, an improvement of > 55%. Figure 3 shows examples comparing sinus anatomy visualization between the drivable endoscope and a standard 30° endoscope, at the same level of surgical resection.

Table 2 summarizes the findings reported by the otolaryngologists regarding device usability. On the usability of the drivable endoscope in entering the maxillary, frontal and sphenoid sinuses, mean scores were consistently over 4 on a 1–5 scale, demonstrating high subjective usability of the study device. Image quality was given a mean score of 3.4 on a 1–5 scale, showing adequacy for the observed anatomic landmarks.

The three subjects who underwent a postoperative procedure reported scores for pain and tolerability during the procedure (on 1–10 scales). They graded mean scores of 1.6 and 5.5 for pain felt during drivable endoscope and standard rigid endoscope use, respectively. Similarly, they graded respective mean scores of 1.6 and 7.5 for procedure tolerability. (Supplementary Video 2 provides an example of a postoperative procedure showing a side-by-side comparison

Table 1 Visualization success rates of sinus anatomy landmarks

Anatomic landmark	Visualization success rate of drivable endoscope, (success/total) (%)	Visualization success rate of standard endoscope (success/total) (%)	Difference in visualization success rate between the endsocopes (% difference)
Maxillary sinus natural ostium	21/23 (91.3%)	18/23 (78.3%)	13
Maxillary sinus floor	26/27 (96.3%)	8/27 (29.6%)	66.7
Maxillary sinus lateral recess	27/27 (100%)	8/25 (32%)	68
Maxillary sinus anterior wall	26/26 (100%)	5/24 (20.8%)	79.2
Total for maxillary sinus landmarks	100/103 (97.1%)	39/99 (39.4%)	57.7[a]
Frontal ostium	17/17 (100%)	16/18 (88.9%)	11.1
Frontal sinus posterior table	17/17 (100%)	11/17 (64.7%)	35.3
Frontal sinus anterior table	16/16 (100%)	2/14 (14.3%)	85.7
Frontal sinus lateral recess	15/15 (100%)	0/15 (0%)	100
Total for frontal sinus landmarks	65/65 (100%)	29/64 (45.3%)	54.7[a]
Sphenoid sinus ostium	4/4 (100%)	4/5 (80%)	20
Sphenoid sinus—sella/clivus	3/3 (100%)	2/4 (50%)	50
Sphenoid sinus floor	3/3 (100%)	1/3 (33.3%)	66.7
Sphenoid sinus lateral recess	3/3 (100%)	1/3 (33.3%)	66.7
Total for sphenoid sinus landmarks	13/13 (100%)	8/15 (53.3%)	46.7
Total for all sinus landmarks	178/181 (98.3%)	76/178 (42.7%)	55.6[a]

Success rate is calculated as the frequency of successful visualization attempts (success) of a specific landmark, divided by the frequency of visualization attempts (successful and failed), across different patients

[a]For maxillary, frontal and the total of all sinus anatomic landmarks, the drivable endoscope had a significantly higher visualization success rate compared to the standard endoscope ($p < 0.001$)

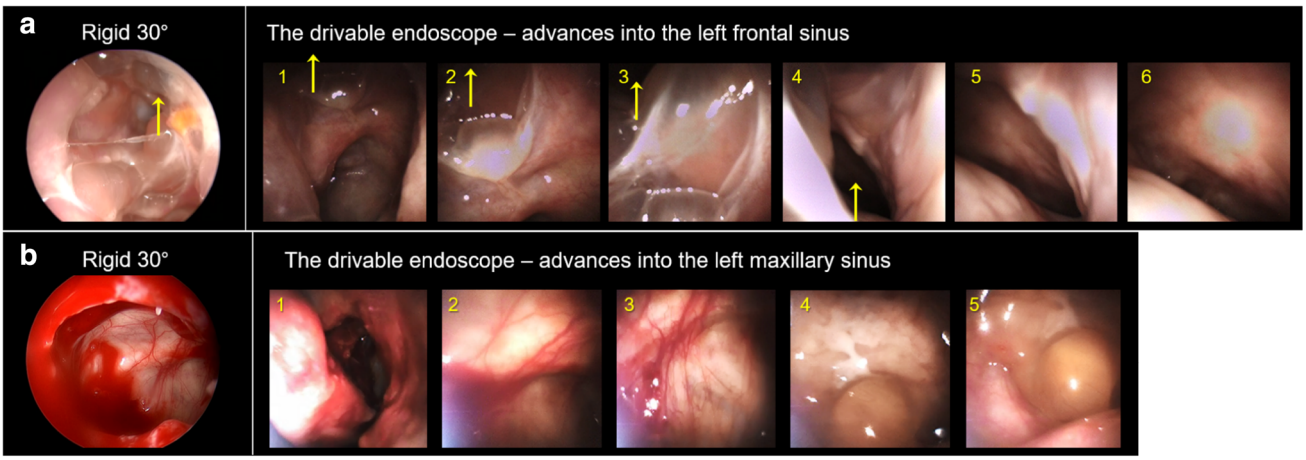

Fig. 3 Examples comparing sinus anatomy visualization between the drivable endoscope and a standard 30° endoscope. Postoperative evaluation of a left frontal sinus of a 55-year-old woman following Draf 2a (**a**). A rigid 30° endoscope (left) advances as close as possible toward the frontal recess (indicated with a yellow arrow). The drivable endoscope (right) advances through the frontal ostium (indicated with a yellow arrow in 1–4) and visualizes the lateral recess and anterior table of the frontal sinus (5–6). Intraoperative evaluation of the left maxillary sinus of a 39-year-old woman following an antrostomy (**b**). A rigid 30° endoscope (left) advances as close as possible to the antrostomy. The drivable endoscope (right) advances toward the antrostomy (right, 1) and into the maxillary sinus and visualizes the posterior wall (right, 2–3) and floor (right, 4–5)

Table 2 Usability of the drivable endoscope

Function	No. of procedures scored (% of total procedures)	Mean usability score (range)
Image quality	20 (100%)	3.4 (3–5)
Maxillary access	14 (70.0%)	4.1 (3–5)
Frontal access	13 (65.0%)	4.3 (3–5)
Sphenoid access	2 (10.0%)	4.0 (3–5)
Irrigation	8 (40.0%)	4.3 (3–5)

Scores were rated on a 1–5 scale, where 1 = worst and 5 = best usability

of the ability of the different endoscopes to visualize the frontal sinus anatomic landmarks).

Only one adverse event was observed (an incidence of 5.9%) which was not related to the procedure or device. This patient developed recalcitrant CRS two months postoperatively which was unresolved at the time of study termination.

Discussion

This was a pilot clinical feasibility study to evaluate the efficacy and usability of Peregrine™ Drivable ENT Scope. These initial findings demonstrate that this endoscope is superior (> 55%) in its ability to visualize anatomic landmarks within the paranasal sinuses when compared to standard rigid endoscopes. Furthermore, surgeons scored highly on the drivable endoscope's usability, and the patients who were evaluated with it in the postoperative clinic rated high levels of tolerance and low levels of pain.

The findings from this pilot study indicate that the drivable endoscope overcomes the current technological limitations of standard endoscopes and provides maximal direct visualization of the paranasal sinus anatomy. In patients with sinonasal disease, good endoscopic visualization is essential both during diagnosis and during surgical procedures to allow complete assessment and treatment of intra-sinus pathologies [1, 14–18]. In addition, good endoscopic visualization of the paranasal sinuses may potentially obviate the need for CT imaging and its associated harmful radiation exposure [10–13]. For example, in patients with allergic fungal rhinosinusitis, good visualization of the entirety of the sinus cavities may spare tissue yet allow complete removal of all mucin and debris to eliminate the antigenic-inciting factor, which is crucial for these patients [19]. Complete sinus visualization is also useful in the assessment of complete excision of sinonasal tumors such as inverted papillomas, and in the evaluation of potential recurrence during postoperative follow up [1, 11, 12, 20]. Specifically, complete visualization of the tumor origin [10, 12, 15] may minimize damage to surrounding structures and facilitate less aggressive tissue resection, which in many cases is typical for purposes of exposure [10–12, 15, 20].

Surgeons in the current study consistently reported that the drivable endoscope was highly usable in accessing maxillary, frontal and sphenoid sinuses, and when required, in irrigating these sinuses through its built-in irrigation channel. However, a limitation of the device used in this study was that it was designed for operation

using the dominant hand, which limited the ability of the surgeon to use tools alongside the endoscope. Furthermore, although image quality was rated as adequate, we are aware it is currently not as good as that of the high definition system used with the standard rigid endoscopes These important insights gained during the study have contributed towards the development of a product version for the non-dominant hand with an improved image quality, which may complement standard rigid endoscopes during surgery and in the clinic setting; however, it is reasonable to assume that with constant improvements in distal chip image quality, such endoscopes may eventually replace the standard rigid endoscopes.

Since the drivable endoscope used in this study was an investigational device, the ethical committees required all procedures to be performed in the operating room during the study. However, once surgeons gained experience and confidence using the drivable endoscope in the operating room, the protocol was amended to include a few patients during their postoperative clinic visit to explore this important indication. All three patients evaluated with the drivable endoscope during postoperative follow-up found the procedures to be highly tolerable with low levels of pain felt, compared to standard rigid and flexible endoscopes. Further applicability of this device in the postoperative setting should be evaluated in future studies.

The small patient sample of the current study limits the comprehensive evaluation of the safety of the drivable endoscope. Nonetheless, we observed only one moderate unrelated adverse event of chronic rhinosinusitis during the course of the study. Thus, overall, the drivable endoscope does not seem to pose any further risks additional to the minor risks already associated with standard sinonasal endoscopy. In fact, the risks of bleeding and pain may likely be reduced due to the flexibility and small diameter of the device.

In conclusion, this feasibility study showed that directly visualizing the paranasal sinuses in patients with the Peregrine™ drivable endoscope is not only feasible but also superior to that of current standard endoscopes, and is highly tolerable. Such intra-sinus visualization has significant implications both during surgery and for postoperative follow up and can potentially improve patient outcomes. This should be further explored in future studies.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Informed consent The research involved human participants who all provided written informed consent.

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