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Functional Endoscopic Sinus Surgery (FESS)

Comparison of Three-Dimensional Endoscopy with the standard Two-Dimensional Endoscopy

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Zusammenfassung

Die funktionelle endoskopische Nasennebenhöhlenchirurgie (FESS) hat sich in den letzten Jahren für konservative, therapierefraktäre chronische Rhinosinusitis (CRS) mit oder ohne Polypen zur Therapie der Wahl entwickelt. Das Konzept von FESS besteht darin, die verlegten und/oder verengten Abflusswege der Nasennebenhöhlen zu rekonstruieren, die mukoziliäre Clearance wiederherzustellen und den Zugang für die topische medikamentöse Therapie der entzündeten Schleimhäute in der Nasenhöhle und den Nasennebenhöhlen zu schaffen und zu erweitern. Die Standard-Endoskopietechnik dieser Operation mit einem zweidimensionalen Endoskop 2D-HD (High-Definition mit Auflösung 1920×1080 Pixel) hat sich bis zu 2D-4K (Ultra-High-Definition mit Auflösung 3840×2160 Pixel) Auflösungskameras weiterentwickelt. Ein weiterer Fortschritt der endonasalen Endoskopietechnik besteht aus einem dreidimensionalen Endoskop, welches aus zwei Linsen in Kombination mit einer 3D-HD Kamera besteht. Dieses 3D-HD Endoskop soll dem Operateur verbesserte anatomische Informationen und chirurgische Orientierung bieten.

Ziel dieser Studie war der Vergleich der 2D-HD Endoskopie mit der neuen 3D-HD Endoskopie. Im Rahmen der übergeordneten Zielsetzung wurden folgende Fragen untersucht: Besteht ein Vorteil der 3D-HD Endoskopie in Bezug auf die Operationsdauer, Bilddarstellung und Benutzerfreundlichkeit gegenüber der 2D-HD Endoskopie. Darüber hinaus korreliert diese Studie die Bilddarstellung und Nutzbarkeit von 3D-HD, 2D-HD und 2D-4K Endoskopie an anatomischen Präparaten.

Der erste Teil der Studie (klinische Studie an Patienten) besteht aus einer teilweise doppelblinden, randomisierten, prospektiven, interventionellen Studie mit n=20 Patienten mit chronischer Rhinosinusitis (mit oder ohne Polypen). Bei diesen nicht voroperierten Patienten wurde jeweils eine beidseitige funktionelle endoskopische Nasennebenhöhlenoperation nach der Technik der Grazer Schule durchgeführt. Nach Einverständnis zur Studienteilnahme wurde eine Seite mit der neuen 3D-HD Endoskopie und die andere Seite mit der bisher angewandten 2D-HD Endoskopie operiert. Die Gesamtzeit der Operation für beide Techniken wurde gemessen. Zudem füllte der Chirurg nach der Operation einen für diese Studie entworfenen Fragebogen aus, der 20 Fragen zur Bilddarstellung und Benutzerfreundlichkeit umfasste.

Im zweiten Teil der Studie, Teil 1/2 der Laborstudie, wurde ein Präparat des anatomischen Instituts der Ludwig-Maximilians-Universität München während des Operations-Kurses „FESS MunichMasterClass 2018“ eingesetzt. 26 Teilnehmer/innen wurden gebeten, nach einer Nasennebenhöhlenendoskopie mit jeweils der 3D-HD und 2D-HD Endoskopie an einem anatomischen Präparat einen Fragebogen auszufüllen. Im Teil 2/2 der Laborstudie füllten weitere 20 Teilnehmer/innen nach einer Nasennebenhöhlenendoskopie und einer standardisierten, Zeit-gestoppten „Objekt-Bergung“ aus einer Nebenhöhle mit sowohl der 2D-4K als auch 3D-HD Endoskopie einen Fragebogen aus. Diese Teilnehmer/innen nahmen am Operations-Kurs „FESS MunichMasterClass 2019“ teil. Die subjektive Erfahrung der Teilnehmer/innen zur 3D-HD und 2D-4K Endoskopie sowie deren täglichen Routinetätigkeiten einschließlich langjähriger Erfahrung, bisher durchgeführte Gesamtoperationen und die Erwartungen an die zukünftige Bilddarstellung usw. wurden ermittelt.

In der klinischen Patienten-Studie lag das mittlere Patientenalter bei 42 Jahren und 35% der Patienten waren weiblich. Die Operationsindikation war bei n=20 Patienten eine chronische Rhinosinusitis mit Nasenpolypen. Das chirurgische Verfahren war auf beiden Seiten identisch und es wurden 18 Fronto-spheno-ethmoidektomien und 2 Fronto-ethmoidektomien durchgeführt. Die mittlere Operationsdauer mit der 3D-HD Endoskopie betrug 37,9 min und mit der 2D-HD Endoskopie 33,1 min ohne statistisch signifikanten Unterschied ($p=0,1814$). Bei der Bilddarstellung zeigte die 3D-HD Endoskopie bei der Erkennung von Details/anatomische Erkennung einen signifikanten Vorteil gegenüber 2D-HD ($p<0,001$), ebenso bei der Tiefenwahrnehmung ($p<0,001$) und dem 3D Effekt ($p<0,001$). Bei der Benutzerfreundlichkeit zeigte 3D-HD nur einen Vorteil gegenüber 2D-HD aufgrund des geringeren Gewichts von Endoskop und Kamera ($p=0,05$).

In der 3D-HD versus 2D-HD Endoskopie Laborstudie betrug die durchschnittliche Berufserfahrung der Teilnehmer/innen 7 Jahre, zwei Teilnehmer hatten bereits mehr als 10.000 Operationen durchgeführt. Bei der Bilddarstellung einigten sich die Teilnehmer/innen auf eine bessere Erkennung von Details ($p=0,002$), Farbdarstellung ($p=0,002$), Ausleuchtung ($p<0,001$) und Tiefenwahrnehmung ($p<0,001$) mit der 3D-HD Endoskopie; bei der Benutzerfreundlichkeit gab es einen Trend für eine höhere kognitive Belastung bei der 3D-HD Endoskopie ($p=0,08$). Für die Präparation aller Nasennebenhöhlen ($p<0,001$) wurde die 3D-HD Endoskopie im Vergleich zur 2D-HD Endoskopie präferiert.

Im Teil 2/2 der Laborstudie, zum Vergleich der 3D-HD versus 2D-4K Endoskopie, verwendeten 45% der Teilnehmer/innen eine HD-Kamera in ihrem beruflichen Alltag. Die Gesamtzeit der „Objekt-Bergungen“ war bei der 3D-HD Endoskopie etwas länger als bei der 2D-4K Endoskopie, jedoch nicht signifikant (Zeit zum Auffinden und Entfernen des Objekts: 3D-HD vs. 2D-4K $p=0,15$ bzw. $p=0,05$) und die Teilnehmer/innen, die bereits 3D-HD oder 2D-4K Endoskopie verwendeten, zeigten bei der Aufgabenerledigung mit Vorerfahrung der entsprechenden Kameras einen Trend zum etwas schnelleren „Objekt-Bergen“ im Vergleich zu Teilnehmern, die andere Kameras verwendeten (Gesamtaufgabenerledigung: alle anderen vs. 3D, $p=0,08$; alle anderen vs. 2D-4K, $p=0,38$). Alle Teilnehmer/innen waren sich über den Vorteil von 2D-4K gegenüber 3D-HD in allen Eigenschaften von Bilddarstellung einig.

Zusammenfassend lässt sich aus den Untersuchungen sagen, dass die 3D-HD Endoskopie von operativ tätigen HNO-Ärzten für eine bessere anatomische Erkennung und Tiefenwahrnehmung höher bewertet wurde, jedoch die gesamte subjektive Erfahrung und Handhabung mit 3D-HD Endoskopen bei Patienten im Vergleich zu 2D-HD Endoskopen als geringer eingeschätzt wird. Die 3D-HD Endoskopie könnte im Rahmen der Lehre/Ausbildung bei Medizinstudenten, Assistenzärzten und Operationsschwestern vorteilhaft sein, da diese eine realistischere und detailliertere Ansicht der Nasennebenhöhlen ermöglichen kann. Ein modularer Einsatz der unterschiedlichen optischen Endoskopie-Techniken in der klinischen Routine mit Einsatz von 2D-HD oder 2D-4K Endoskopie allein oder zur verbesserten räumlichen Orientierung in Kombination von 2D-4K mit 3D-HD Endoskopie (ergebend 3D-4K, dreidimensionale Ultra-High-Definition) könnte die Vorteile dieser Techniken zukünftig zum Wohle unserer Patienten zum Einsatz bringen.

Summary

Functional Endoscopic Sinus Surgery (FESS) has recently become the standard therapy for conservative, therapy-refractory chronic rhinosinusitis (CRS) with or without polyps. The main concept of FESS is to reconstruct the congested or narrow drainage pathways of the paranasal sinuses, to reestablish the mucociliary clearance and to broaden the access for topical medical therapy of the inflamed mucosa in the nasal cavity and paranasal sinuses. The standard endoscopy technique with a two-dimensional endoscope 2D-HD (high-definition with resolution 1920×1080 pixels) has lately advanced to a 2D-4K (ultra-high-definition with

resolution 3840×2160 pixels) resolution camera. The recent advancements in the field of endonasal endoscopy technique with a three-dimensional endoscope consists of two lenses combined with a 3D-HD camera providing improved anatomical information and surgical orientation to the surgeon according to the manufactures.

The objectives of this study are to compare this new 3D-HD endoscopy with the standard 2D-HD endoscopy, specifically whether the 3D-HD endoscopy offers the benefits for the surgeon in terms of duration of surgery, imaging properties and handling aspects in FESS. Furthermore, this study also correlated the imaging and usability of 3D-HD-, 2D-HD- and 2D-4K-endoscopy techniques between patient and specimen.

The first part of the study (a clinical study on patients) consisted of a partially double-blind, randomized, prospective, interventional study involving 20 patients (n=20) with chronic rhinosinusitis with or without polyps. These patients without history of previous surgery underwent bilateral functional endoscopic sinus surgery. The operations were performed using the Graz school FESS techniques. After informed consent to participate in the study, one side of the nasal cavity was operated with the new 3D-HD endoscopy technique, while the other side was operated with the standard 2D-HD endoscopy technique. The total taken for surgery using both techniques were recorded and at the end of the operation the surgeon filled in a questionnaire comprising 20 questions about imaging properties and usability aspects.

For the second part of the study (the first part of laboratory study) a human cadaver specimen of the Anatomical Institute of the Ludwig-Maximilian-University Munich was used during the cadaver dissection course (FESS MunichMasterClass 2018) was used. Twenty-six participants involving the dissection course were requested to fill up the questionnaire form after endoscopy the paranasal sinuses with the 3D-HD- and 2D-HD-endoscopy technique in a cadaver specimen. Additionally, twenty participants (the second part of the laboratory study) were requested to fill up the questionnaire form following paranasal sinuses dissection and a standardized, timed object retrieval using the 2D-4K- and 3D-HD-endoscopy technique. These participants were participating in the cadaver dissection course (FESS MunichMasterClass 2019). Subjective impressions of the participants about 3D-HD- and 2D-4K-endoscopy, and their experience of daily routine including years of experience, total surgeries so far performed and their expectations for future imaging etc. were recorded.

The results of the clinical study revealed that the patients mean age was 42 years and 35% of the patients were female. The indications for surgery were chronic rhinosinusitis with nasal polyps in all 20 patients. The surgical procedure was identical on both sides and 18 fronto-spheno-ethmoidectomies and 2 fronto-ethmoidectomies were performed. Mean duration of surgery with 3D-HD endoscopy was 37.9 minutes and with 2D-HD endoscopy 33.1 minutes, with no statistically significant difference between the groups ($p=0.1814$). For imaging properties, 3D-HD presented superiority over 2D-HD in heading of recognition of details ($p<0.001$), depth perception ($p<0.001$) and 3D effect ($p<0.001$) as rated according to the operating surgeon. For usability aspects, 3D-HD presented superiority over 2D-HD only in weight of endoscope ($p=0.05$).

In the 3D-HD versus 2D-HD endoscopy laboratory study, the average years of work experience of participants was 7 years, and two participants had already performed more than 10,000 related surgeries. For imaging properties, participants agreed about improved recognition of details ($p=0.002$), color brilliance ($p=0.002$), illumination ($p<0.001$) and depth perception ($p<0.001$) with 3D-HD endoscopy; and for usability aspects, there was a trend towards higher cognitive load with 3D-HD endoscopy ($p=0.08$). Similarly, for dissection of all the sinuses ($p<0.001$), the participants preferred 3D-HD endoscopy in comparison to 2D-HD endoscopy. In the 3D-HD versus 2D-4K endoscopy laboratory study in a specimen, 45% of participants were accustomed to using HD camera in their daily surgical routine. Total task completion time was slightly longer with 3D-HD-endoscopy than 2D-4K endoscopy, but was not statistically significant (time to locate and remove: 3D-HD vs 2D-4K, $p=0.15$ and $p=0.05$ respectively), and participants who were already using 3D-HD- or 2D-4K-endoscopy showed a trend towards slightly faster task completion using respective cameras in comparison to participants using other cameras (total task completion: all others vs 3D-HD, $p=0.08$; all others vs 2D-4K, $p=0.38$). For imaging properties, participants agreed about superiority of the 2D-4K over 3D-HD in all features.

To summarize, three-dimensional endoscopy technique was rated to be superior by professionals for improved anatomical understanding and depth perception, however the entire experience and handling with 3D-HD in patients was rated as inferior compared to 2D-HD. It might be more advantageous to share the 3D-HD-technique for teaching or training purposes for residents, medical students and nurses. Such implication will impart a realistic and detailed understanding of the paranasal sinuses to the trainees. Further, a modular endoscopy technique

with spatial orientation of 3D-HD endoscopy combined with superior resolution of 2D-4K endoscopy (resulting in 3D-4K, three-dimensional ultra-high-definition) could provide advantages for the surgeon and better results for patients.

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Glossary of abbreviations

ARS- Acute Chronic Rhino-Sinusitis

ASS- Acetylsalicylic Acid

CAS- Computer Assisted Surgery

CRS- Chronic Rhino-Sinusitis

CRSwNP- Chronic Rhino-Sinusitis with nasal polyposis

CT- Computer Tomography

ESS- Endoscopic Sinus Surgery

FESS- Functional Endoscopic Sinus Surgery

MRI- Magnetic Resonance Imaging

NSAIDs- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

NS- Not significant

OP- Operation

SEM- Standard Error of Mean

Tab.- Table

3D-HD- Three-Dimensional-High-Definition

2D-HD- Two-Dimensional-High-Definition

VAS- Visual Analog Scale

1. Introduction and Motivation

1.1 Anatomy and physiology of paranasal sinuses

The paranasal sinuses are pneumatic extensions that surround the nasal cavity (1). They are named according to the facial bones in which they are positioned. There are 2 frontal sinuses, 2 maxillary sinuses, 2 sphenoidal sinuses and many ethmoidal cells /units. They are separated in the midline by the nasal septum. Anatomical deviations from this are also possible. All the sinuses are lined by a ciliated pseudostratified epithelium with goblet cells which secretes mucus (2-4).

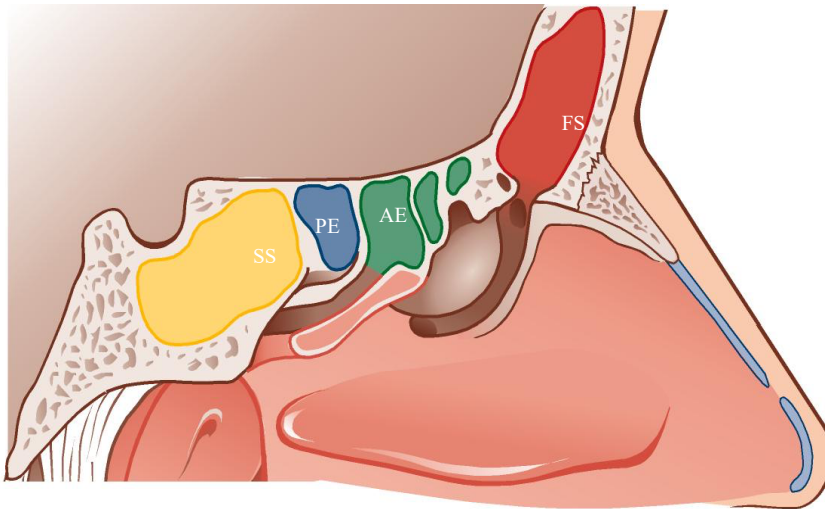


Figure 1. Diagram of the sinuses projected onto the cranial surface

(FS=Frontal sinus, AE=Anterior ethmoid, PE=Posterior ethmoid, SS=Sphenoid sinus)

Source: A. Leunig, Endoscopic surgery of the lateral nasal wall, paranasal sinuses and anterior skull base (3)

The function of the paranasal sinuses is yet still not fully elucidated. However, the following functions have been attributed to the paranasal sinuses so far:

- Air conditioning of the breathing air
- Thermal isolation of delicate structures
- Shock absorption during an accident
- Diminishing the weight of the head
- Growing the resonance of the voice
- Providing a sense of smell
- Supporting immune defense of the nasal cavity (5-7)

Though each paranasal sinus has a relatively simple anatomical structure by itself, but their association to other sinuses, to the lateral nasal wall and to the surrounding structures are highly variable and can be complex at times.

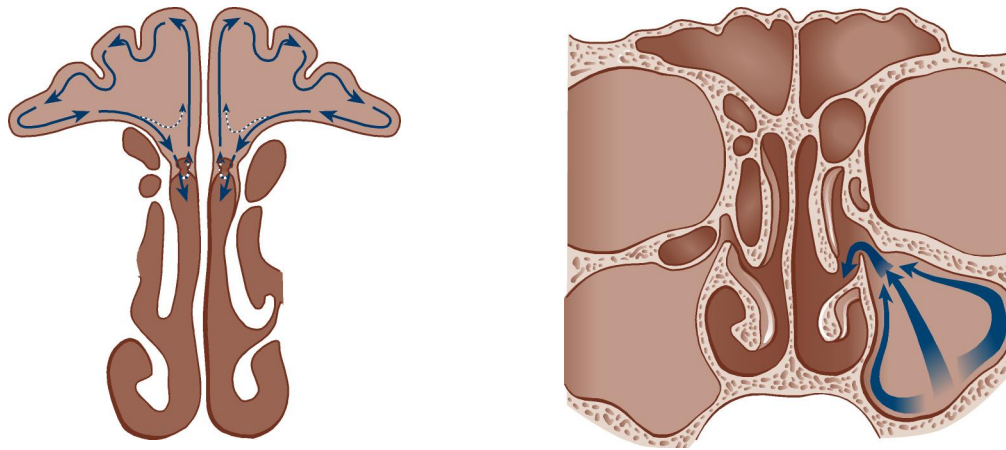


Figure 2. Secretion transport from the frontal- (left picture) and maxillary (right picture) sinus into the middle meatus.

Source: A. Leunig, Endoscopic surgery of the lateral nasal wall, paranasal sinuses and anterior skull base (3)

1.1.1 Ethmoid cells

The ethmoid cell system of the ethmoid bone can be divided into an anterior and a posterior segment by the basal lamella of the middle turbinate. The anterior ethmoid air cells drain into the middle nasal passage and are anatomically and functionally located in front of the maxillary and frontal sinuses. Lamina papyracea, which is an orbital plate of the ethmoid bone forms the lateral bony wall which divides the ethmoid air cells from the orbit. The posterior ethmoid air cells drain into the upper nasal passage.

1.1.2 Maxillary sinus

The maxillary sinuses are the largest of all paranasal air sinuses. They border the orbit cranially and the main nasal cavity medially, the pterygopalatine fossa and the retro-maxillary space dorsally. There is a relationship to the ethmoid cell system through the ethmoid recess. Their secretion runs through the semilunar hiatus into the middle nasal passage.

1.1.3 Sphenoid sinus

The sphenoid sinuses have an ostium on their anterior wall and drain into the sphenoid-ethmoidal recess which is located within the superior nasal passage. They border the anterior, middle and posterior cranial fossa and the Sella turcica. The optic canal is attached from above to the side walls of the sphenoid sinus and the internal carotid artery is attached posterior. In addition, the cavernous sinus and the second to sixth cranial nerves have a close anatomical relationship to the sphenoid sinus.

1.1.4 Frontal sinus

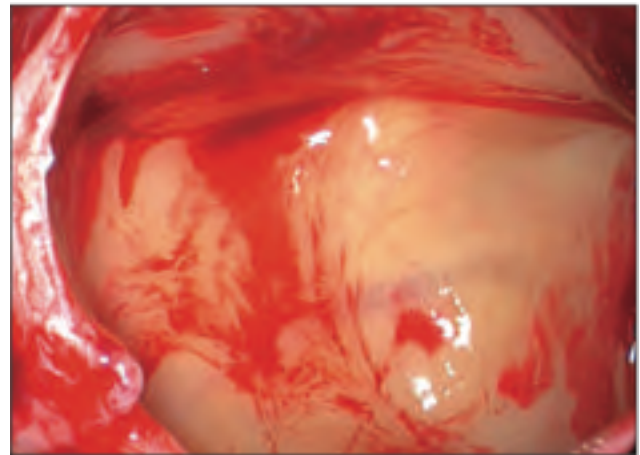
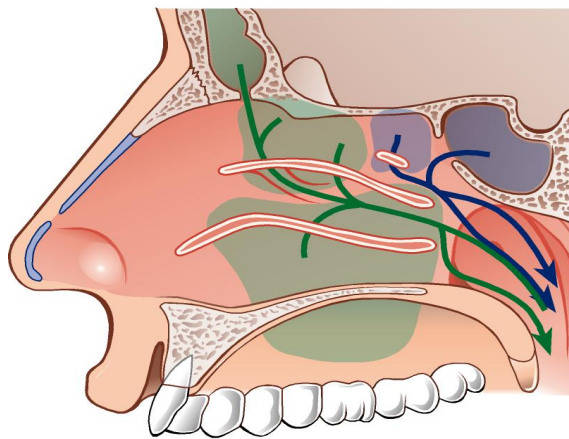
The frontal sinuses are situated in the frontal bone and cranial to the anterior ethmoid air cells. Their secretions drain into the frontal recess which is located on the anterosuperior part of ethmoid- and inferior to the opening of frontal sinus. Both the frontal sinuses are developed from the anterior ethmoid cells embryonically and pneumatize upwards into the frontal region.

1.2 Inflammatory diseases of the nasal cavities and paranasal sinuses

Inflammation of the paranasal sinuses (sinusitis) is a common disease throughout the globe. It is defined as an inflammation of the mucous membrane involving one or more paranasal sinuses. The inflammation is hardly limited to one paranasal sinus, and it often also involves the major nasal cavity. For this reason, it is often also designated as rhinosinusitis as well. A total number of 2.6 million cases were diagnosed as a “chronic rhinosinusitis” in Germany alone between July 2000 and June 2001 (8, 9).

The classification of rhinosinusitis is frequently based on the time period and progress of the symptoms into acute, chronic and intermittent. If the symptoms completely disappear within 12 weeks of onset of symptoms, it is called as acute rhinosinusitis. If the symptoms last more than 12 weeks, where symptoms of the illness are continuously present during this period, then it is called as chronic rhinosinusitis. Intermittent rhinosinusitis is defined when there are four or more episodes of acute symptoms of sinusitis annually with completely symptom-free intervals in between (10-13).

1.2.1 Pathophysiology



Mucociliary transport system of secretions in the paranasal sinuses which is directed towards the pharynx

Mucociliary transport in the maxillary sinus, displaying blood

Figure 3. Mucociliary transport of paranasal sinuses

Source: A. Leunig, Endoscopic surgery of the lateral nasal wall, paranasal sinuses and anterior skull base (3)

The osteomeatal complex describes the point of junction between the common drainage path of the maxillary sinus, frontal sinus and ethmoid cells, and also includes the ethmoid infundibulum, semilunar hiatus and the middle turbinate. Inflammatory modifications in these areas can lead to impairment and even interruption of the normal physiological drainage by relocating the natural ostium. Adequate opening of the paranasal sinuses and thus their natural drainage pathways is essential for the mucociliary transport of secretions and self-clearance of germs, because the direction of primary drainage is genetically determined. In the region of the paranasal sinuses, it is pointed towards the natural ostia (14-17). Studies have shown that fenestrations in the lower nasal passage with the indication of a better result are not long-term improvement, but even causes the reappearance of circulating mucus transport from the natural ostium through the newly created ostium back into the cavity (named as “missed ostium sequence”). The interference of drainage supports, formation of nidus, reproduction of pathogenic germs and thus the disease process (18, 19).

Chronic rhinosinusitis with the formation of polyps is considered a subclass of chronic rhinosinusitis (20-22). Polyps are mushroom like, pale-gray protrusions of the mucous

membrane, which arise mainly in the area of the ethmoid bone and the middle turbinate and are an expression of inflammation of the mucous membrane. It appears more often together with intolerance to non-steroidal anti-inflammatory drugs (NSAIDs- especially aspirin) and bronchial asthma, which is often referred to as the Samter's triad (23, 24). The prevalence of nasal polyps in general population is about 4% (25). This increases to 7-15% in patients with bronchial asthma and even to 36-60% among patients with intolerance to non-steroidal anti-inflammatory drugs (26).

1.2.2 Symptoms and Diagnosis

The symptoms of acute and chronic sinusitis differ primarily in their severity, their temporal course and the related general symptoms. Acute sinusitis is characterized by a quick onset, high fever, flush and intense symptoms (27). In difference, the beginning of chronic sinusitis often cannot be clearly defined, the symptoms are usually softer and the general symptoms that come earlier are tiredness, exhaustion, reduced performance and depression (10). As the name suggests the onset is often insidious in chronic rhinosinusitis.

The following clinical symptoms frequently suggest "chronic rhinosinusitis" (8, 23):

- Trouble during breathing through the nose
- Anterior and / or posterior rhinorrhea
- Headache, facial pain or pressure
- Hyposmia / anosmia

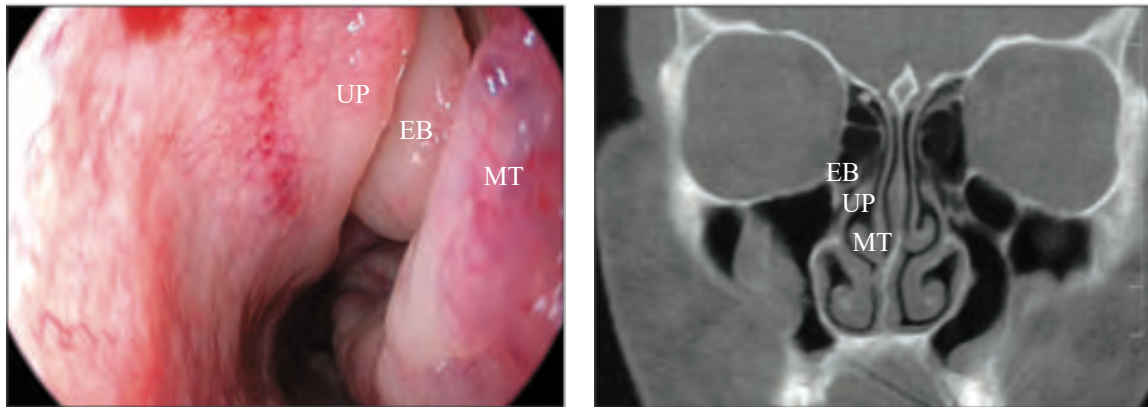
The localization of pain is reasonably characteristic in certain areas of the affected paranasal sinuses. The pain related to maxillary sinus projects on the cheek, the frontal sinus on the forehead, the ethmoid cells projects between the eyes and the sphenoid sinus projects onto the occipital-, temporal region or the inner side of the head (28).

The basic diagnosis of sinusitis comprises of taking a detailed history, clinical examination through nasal endoscopy (29) and the laboratory assessment of inflammatory parameters, allergy tests and/or imaging.

The following signs may be seen during endoscopic examination that point towards sinusitis (30):

- Nasal polyps
- Putrid discharge in the middle nasal passage
- Erythema and swelling of the mucous membrane in the middle nasal passage

The importance of the conventional X-ray examination (occipito-frontal, occipito-mental), especially for chronic rhinosinusitis, has been replaced by computer tomography (CT) examination in recent times. In addition to the superimposition-free display and thus better accessibility of the pathological processes, it also offers the advantage that it can also be used to plan and carry out the surgery; if that is necessary (10, 31-33).



Endoscopic view of middle meatus showing uncinete process (UP), ethmoid bulla (EB) and middle turbinate (MT) Radiological imaging (CT scan) showing the corresponding structures of endoscopy

Figure 4. Endoscopic and radiological analysis of paranasal sinuses

Source: A. Leunig, Endoscopic surgery of the lateral nasal wall, paranasal sinuses and anterior skull base (3)

1.2.3. Therapy

If the progression of the symptoms is uncomplicated, the acute rhinosinusitis is often treated conservatively. The therapeutic options are local vasoconstrictive agents (decongestant nasal drops), antihistamines for allergies, adequate analgesia and antibiotics in case of superinfection (10). While using antibiotics, the local resistance levels or antibiotic sensitivity must be considered generously (34).

According to the current guidelines, a conservative therapy is initially tried also in the case of chronic rhinosinusitis. In addition to adequate analgesia, the use of topical steroids can be suggested (35). Often no lasting success can be achieved in such a way (10, 11, 36).

In case of complicated rhinosinusitis or those that cannot be adequately controlled conservatively, an additional treatment option is sinus surgery. The objective of such an

operative procedure is the improved drainage and ventilation of the affected paranasal sinuses. So that the corresponding key regions of the osteomeatal unit are reestablished and natural course of flow resumes along the direction of transport of the ciliated epithelium (37). Regarding principle, these operations can be performed microscopically or endoscopically, although functional endoscopic sinus surgery (FESS) is progressively emerging into a standard therapy for the management of chronic rhinosinusitis (10, 37-41).

1.2.4 Surgical Techniques

The major principle of surgical treatment for the inflammatory diseases of paranasal sinuses was centered primarily on the paranasal sinuses for a long time. This is due to the fact that limited diagnostic and therapeutic facilities were available, and the pathophysiological principles of the fundamental disease were not understood in detail. The most common intervention for a long time was fenestration in the lower nasal passage for a long time and a transfacial sinus surgery, for example transoral opening of the maxillary sinus with removal of the entire mucous membrane (operation according to “Caldwell-Luc”) (42). These types of extranasal interventions were slowly replaced with the development of appropriate endoscopic optics and instruments, with the growing understanding of the mucociliary transport system. On a historical note, Professor Walter Messerklinger from Graz wrote a landmark manuscript on this regard in 1970, for which he initially did not even find a publisher due to the lack of interest from the local community (43).

Since the introduction of “Functional Endoscopic Sinus Surgery (FESS)” in 1985 by Professor Heinz Stammberger and David W. Kennedy, this procedure has become more and more popular and is now considered to be the gold standard in the treatment of chronic inflammatory sinus diseases. It serves for both diagnostic and therapeutic purposes. The main concept and objective of the FESS is to reconstruct the drainage pathways, with expansion of the natural ostium, if necessary, without damaging healthy mucous membranes unnecessarily. The focus here is primarily on the ostiomeatal complex, the entry room of the frontal and maxillary sinuses in the anterior ethmoidal area and not into the sinus itself (44). Computer-aided navigation systems (“computer-aided surgery”, CAS) are also being used in intraoperative setup more and more frequently nowadays. The surgery was first used in ENT field in the year 1986 (45).

Surgical interventions through the FESS have shown that they significantly reduce the symptoms of chronic rhinosinusitis (46, 47). They have a success rate between 76 and 98% (48) and are indicated when the conservative therapy remains unsuccessful. Patients with or without nasal polyps seem to benefit uniformly from the procedure (49-51). If the symptoms cannot be controlled with medicine even after the surgery, around 10 to 20 % patients are re-operated due to persistent or repetitive symptoms. Patients with nasal polyposis can be mainly affected by the repetition of the polyps sometimes (52). For the difficult to treat patient, monoclonal antibodies are approved for the treatment of Chronic rhinosinusitis with nasal polyposis (CRSwNP). During surgery modern imaging using navigation seems to reduce the injury of critical structures in the paranasal sinuses (53).

1.2.5 3D-HD endoscopic visualization in FESS

Surgeries through endoscopic techniques have advanced the management of diseases in many medical fields, including rhinology, over the past two decades. Previously used high-resolution (HD) cameras show an image that is "two-dimensional" (2D-HD technology), just like on a normal television set (54). Further development of technology has now made it possible to provide the endoscopes with two lenses, which allows the use of a "three-dimensional" camera which presents a three-dimensional image with a spatial effect (3D-HD technology) (55, 56). This new technique can potentially be an advantage for the surgeon, who can perform the surgery in a better way. These new advancements of 3D-HD are already being used as standard techniques in abdominal surgeries. The advantage of this technique lies in the better visualization of the spaces between the anatomical structures (57).

1.3 Aims and objectives of the study

Paranasal sinus surgery has been truly changed by the development of newer endoscopic technologies in recent days. The microscopic techniques used earlier permitted only a straight view into the nose. More complex transnasal interventions of the frontal or maxillary sinus were not possible with previous techniques. After the invention of endoscopic angled optics (30 °, 45 °, 70°) which ensured the breakthrough in endoscopic technology, these are now considered the gold standard for surgical procedure in sinus and skull base surgery. These endoscopes allow the surgeon to look around the corners, to see all parts of the surgical site and further to work more precise with suitably curved instruments and more extensive procedures with increased practice (43).

Largely, the key difference to the microscopic technique used previously is the two-dimensional field of view. The normal 4mm thick endoscope allow only one viewing channel, the image of which can now be displayed on a monitor with resolutions up to 2D-4K. Over the past few years, endoscopes with two optical channels have been developed that are already used as standard in laparoscopy (58). The constantly improving technical development recently also led to the development of three-dimensional endoscopy in FESS. Overall, this technology is new and is used only at a few centers due to its high costs and less known outcomes so far. The primary objective of this study is to compare the possible superiority of 3D-HD endoscopy over 2D-HD endoscopy technique. In accordance with its primary objective the following questions had to be answered:

- How long is the duration of the surgery using 3D-HD-endoscope compared to the duration of the surgery using 2D-HD-endoscope?
- Is the surgery with new commercially available 3D-HD-endoscopic technique faster than the standard 2D-HD-endoscopic surgical technique?
- Is 3D-HD-endoscopic technique better to 2D-HD-endoscopic technique in terms of recognition of details/anatomical understanding, depth perception and optical image quality?
- Which technique has improved ergonomics?
- How is the intraoperative handling of the camera with 3D-HD technique?
- Which method provides subjective advantages for the surgeon?
- Is there any correlation between results from a specimen and from patients regarding 3D-HD- and 2D-4K-endoscopy systems?

2. Materials and methods

The present work describes in its first part, a randomized, prospective, partially double blind (in which only the surgeon knows which endoscopy technique the patient is receiving), interventional study designed to compare the standard 2D-HD-endoscopic surgical technique with the new commercially available 3D-HD-endoscopic technique in the context of paranasal sinus surgery. The study was carried out from May to October 2018 at the ENT Clinic Dr. Gaertner Bogenhausen (Munich, Germany).

In second part of the study, 26 participants were asked about the 3D-HD-endoscopic techniques, and 20 participants were asked about 2D-4K-endoscopic techniques who also participated on the endoscopic sinus surgery exercise course “FESS *MunichMasterClass 2018* (28-29.06.2018)” and “FESS *MunichMasterClass 2019* (04-05.07.2019)” respectively at Institute of Anatomy of the Ludwig Maximilian University (LMU) Munich.

2.1 Diagnostic tools: Staging of rhinosinusitis

There are many imaging modalities like conventional X-ray, CT or MRI for the diagnosis of rhinosinusitis and related disorders. However, CT scan denotes the gold standard for the radiological assessment of chronic rhinosinusitis. Unlike for acute rhinosinusitis, investigations or imaging techniques may not be required. The diagnosis is primarily based on clinical findings. Since the mid 1990s, the severity of rhinosinusitis has been re-defined with the help of the Lund-Mackay Scoring (LMS) system (59, 60). It is primarily based on radiological findings and because of its simplicity it is more used in comparison to the much more complex classifications of Friedman (61), May (62) and Kennedy (63).

Depending upon the degree of the appearances on the CT-scan, the Lund-Mackay system assigns 0 point for no abnormalities, one point for partial opacification and two points for total opacification of the sinus to be assessed. It is difficult to use this grade system in the area of ostiomeatal unit, so they were rated simply with point 0 (not obstructed) or 2 (obstructed). The number of points (score) that can be calculated in this way is between 0 and 24, or between 0 and 12 when considered separately (63). An LMS ≤ 2 indicates an excellent negative predictive value and LMS ≥ 5 indicates an excellent positive predictive value, which reflects true disease.

Table 1: Lund-Mackay radiological grading system (copied from Lund et al (59))

Lund-Mackey system.

Sinus	Right sinus	Left sinus
Frontal	0-2	0-2
Anterior ethmoids	0-2	0-2
Posterior ethmoids	0-2	0-2
Maxillary	0-2	0-2
Sphenoid	0-2	0-2
Ostiomeatal complex	0 or 2	0 or 2

For the sinuses: 0 = no inflammation; 1 = partial inflammation; 2 = 100% inflammation.

For the ostiomeatal complex: 0 = not occluded; 2 = occluded.

Maximum total score: 24.

2.2 Operational terminology and nomenclature of the surgical interventions

A good catalogue of standard terminologies for anatomical categorization about the paranasal sinuses was published by H. Stammberger, W. Hosemann and W. Draf (1997), while the different endoscope-controlled sinus surgeries were classified by D. Simmen and N. Jones (2005)(64). Their categorization has been summarized below:

Table 2: Standard terms and definitions for paranasal sinuses

Standard terms and definitions for paranasal sinuses operations, according to D. Simmen and N. Jones (2005):	
Infundibulotomy	Removal of the uncinate process with exposure (and possible enlargement) of the natural maxillary sinus ostium. The outflow tract of the frontal recess is preserved.
Partial anterior ethmoidectomy	Infundibulotomy with removal of the ethmoid bulla. This procedure may include removal of an Agger nasi cell, but the frontal recess outflow tract is preserved.
Ethmoidectomy	Partial anterior ethmoidectomy is extended by opening the posterior ethmoid cells.
Spheno-ethmoidectomy	Partial anterior ethmoidectomy is extended by opening the posterior ethmoid cells and opening or enlarging the sphenoid sinus.

Fronto-ethmoidectomy	The ethmoid cells and maxillary sinus are opened, and the frontal sinus is opened while preserving its mucosa. <i>Draf</i> described three procedures for enlarging the frontal sinus outflow tract: type I (superior resection of the uncinate process), type IIa and IIb (partial to maximal opening of the frontal sinus between the septum and lamina papyracea), and type III (median drainage procedure).
Fronto-spheno-ethmoidectomy	Opening all the paranasal sinuses.
Antrostomy, frontal sinusotomy, or sphenoidotomy	The natural ostium of the maxillary, frontal or sphenoid sinus is enlarged in varying degrees.
<i>The author recommends the use of a nationally or internationally standardized nomenclature and terminology for paranasal sinus operation (taken as a Verbatim from Simmen et al (64))</i>	

2.2.1 Infundibulotomy

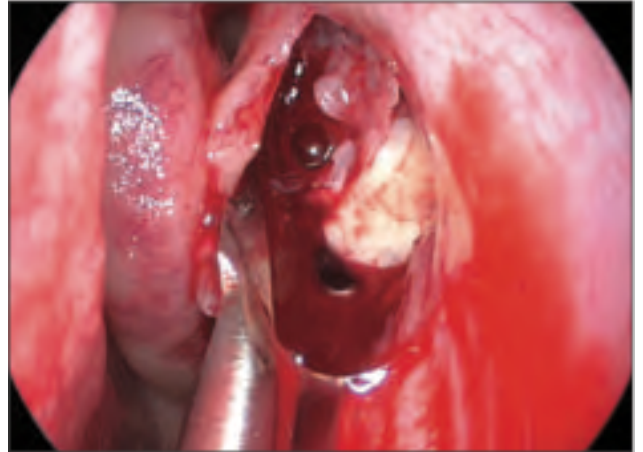
Infundibulotomy is also called as uncinectomy. During this process, the uncinate process (medial wall of the ethmoid infundibulum) is removed, so that the natural ostium of the maxillary sinus can be seen. A sickle blade is used to cut in the area of the upper edge of the uncinate process and the cut is redirected into the sagittal plane downwards so that the uncinate process can be completely removed (64, 65).

During the process of expansion of the maxillary sinus opening, a distinction is generally made between three types (64):

- Maxillary sinusotomy type I: extension of the natural ostium posterior up to 1 cm. Connection of an accessory ostium with the natural one
- Maxillary sinusotomy type II: extension of the natural ostium posterior and inferior up to 2 cm
- Maxillary sinusotomy type III: maximum extension of the natural ostium up to the posterior wall of the maxillary sinus (dorsal), crista lacrimalis (anterior) and base of the middle turbinate (inferior)



Incision in the uncinete process using a sickle knife



Sight of the ethmoid infundibulum, exposing maxillary ostium with retained secretions

Figure 5. Infundibulotomy of the left side, endoscopic view

Source: A. Leunig, Endoscopic surgery of the lateral nasal wall, paranasal sinuses and anterior skull base (3)

2.2.2 Ethmoidectomy

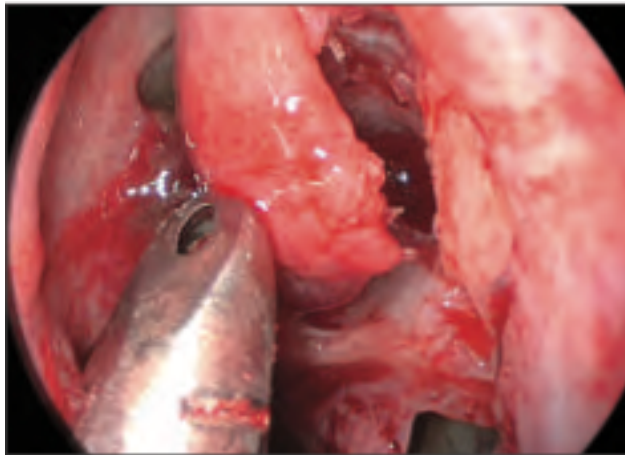
A partial anterior ethmoidectomy combines an infundibulotomy plus the removal of the anterior ethmoid cells to the basal lamella of the middle turbinate. Partial removal of the agger nasi cell can also include this procedure. In posterior ethmoidectomy, the posterior ethmoid cells are also opened up to the sphenoid sinus. Both procedures proceed the infundibulotomy plus the opening of the ethmoid cells situated medial to the maxillary sinus wall. Then the ethmoid bulla is removed. After the retrobulbar space and the basal lamella of the middle turbinate are seen, the procedure is considered complete (64).



Ethmoid bulla and ostium of maxillary sinus



Taking down of anterior wall



Taking down of medial wall



Showing basal lamella after the removal of ethmoid bulla

Figure 6. Ethmoidectomy

Source: A. Leunig, Endoscopic surgery of the lateral nasal wall, paranasal sinuses and anterior skull base (3)

2.2.3 Fronto-ethmoidectomy

The frontal sinus is the most complex area for the endoscopic sinus surgery because of its complex anatomy and direct relation with the brain. The European Position Paper (EPOS) on the Anatomical Terminology of the Internal Nose and Paranasal Sinuses classified the frontal sinus anatomy into anterior- or posterior- or medial- or lateral cells (53).

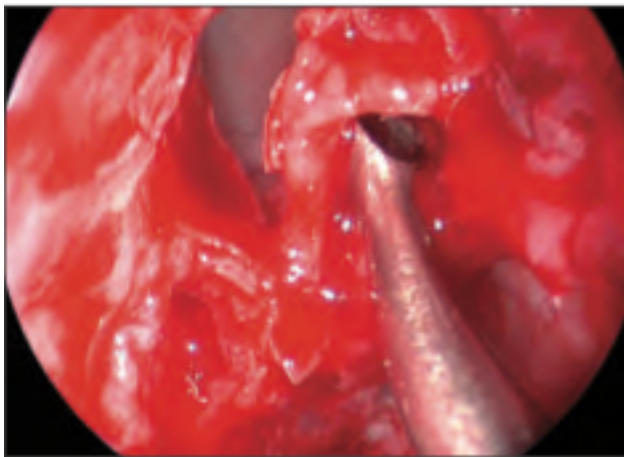
Table 3: International Frontal Sinus Anatomy Classification (IFAC) (*taken as a Verbatim from Wormald et al (66)*)

Cell type	Cell name	Definition	Abbreviation
Anterior cells (push the drainage pathway of the frontal sinus medial, posterior or posteromedially)	Agger nasi cell	Cell that sits either anterior to the origin of the middle turbinate or sits directly above the most anterior insertion of the middle turbinate into the lateral nasal wall.	ANC
	Supra agger cell	Anterior-lateral ethmoidal cell, located above the agger nasi cell (not pneumatizing into the frontal sinus).	SAC
	Supra agger frontal cell	Anterior-lateral ethmoidal cell that extends into the frontal sinus. A small SAFC will only extend into the floor of the frontal sinus, whereas a large SAFC may extend significantly into the frontal sinus and may even reach the roof of the frontal sinus.	SAFC
Posterior cells (push the drainage pathway anteriorly)	Supra bulla cell	Cell above the bulla ethmoidalis that does not enter the frontal sinus.	SBC
	Supra bulla frontal cell	Cell that originates in the supra-bulla region and pneumatizes along the skull base into the posterior region of the frontal sinus. The skull base forms the posterior wall of the cell.	SBFC
	Supraorbital ethmoid cell	An anterior ethmoid cell that pneumatizes around, anterior to, or posterior to the anterior ethmoidal artery over the roof of the orbit. It often forms part of the posterior wall of an extensively pneumatized frontal sinus and may only be separated from the frontal sinus by a bony septation.	SOEC
Medial cells (push the drainage pathway laterally)	Frontal septal cell	Medially based cell of the anterior ethmoid or the inferior frontal sinus, attached to or located in the interfrontal sinus septum, associated with the medial aspect of the frontal sinus outflow tract, pushing the drainage pathway laterally and frequently posteriorly.	FSC

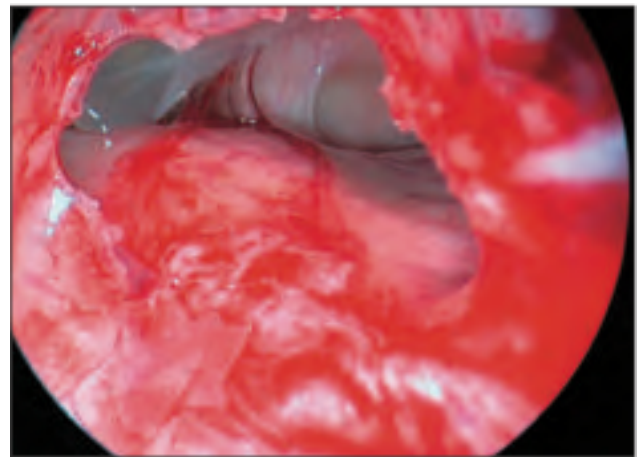
Fronto-ethmoidectomy combines an anterior ethmoidectomy plus an opening of the frontal sinus. In this process a circular mucosal wound due to excessive mucosal removal must be prevented.

There are three types of frontal sinusotomy:

- Frontal sinusotomy type I: Removal of the uncinate process near to the base of the skull base or the middle turbinate is performed. Examination of the frontal sinus is possible.
- Frontal sinusotomy type II: Additional frontoethmoidal cells must be removed, where uncinate process type A is present. Depending on the degree of extension of the frontal sinus opening, a difference is made between a type IIA (approx. 5mm) or a type IIB-sinusotomy (> 5mm).
- Frontal sinusotomy type III: The frontal recess is widened extensively, extending to the midline and with removal of the entire floor of the frontal sinus and parts of the interfrontal sinus septum (64).



Removing bony lamellae using the Kuhn curette



Opening of frontal sinus after removal of bony lamellae

Figure 7. Frontoethmoidectomy

Source: A. Leunig, Endoscopic surgery of the lateral nasal wall, paranasal sinuses and anterior skull base (3)

2.2.4 Spheno-ethmoidectomy

This procedure describes an anterior ethmoidectomy plus an opening of the posterior ethmoid cells and the sphenoid sinus. There is no dissection in the area of the frontal recess.

There are three types of sphenoid sinusotomy:

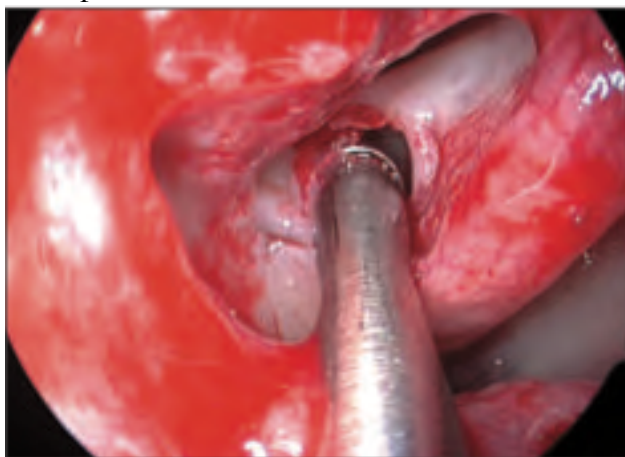
- Sphenoid sinusotomy type I: Only the exposure of sphenoid ostium is performed.
- Sphenoid sinusotomy type II: Removal of the upper half of the front wall is performed.
- Sphenoid sinusotomy type III: Removal of the entire front wall from the floor to the base of the skull, and from the septum to the sphenoid sinus wall in a lateral direction is done (64).



Showing the ostium of sphenoid sinus medial to the superior turbinate



Opening sphenoid sinus through transethmoidal route



Widening the opening by using circular-cutting punch



View of ostium of maxillary and sphenoid sinus after spheno-ethmoidectomy

Figure 8. Spheno-ethmoidectomy

Source: A. Leunig, Endoscopic surgery of the lateral nasal wall, paranasal sinuses and anterior skull base (3)

2.3 Patients and study design

Patients who were advised for a bilateral Functional Endoscopic Sinus Surgery (FESS) received a FESS procedure with the 2D-HD-endoscopic technique on one side of the nose. The contralateral side was operated using the 3D-HD-endoscopic technique. The side to be operated was randomized preoperatively by tossing a coin by surgeon in order to choose between two alternatives: 2D-HD or 3D-HD endoscopic technique. The patients were unaware of which side was chosen for 2D-HD or 3D-HD. A prior written informed consent was taken from all the participants.

Follow-up examinations of the patients were carried out on the first day, two week and four weeks, and three months after the completion of surgery. Long term surgical outcomes were not evaluated in this study.

The total time period of the surgery using both techniques was measured on each side separately. A questionnaire-form was filled up by the surgeon after the surgery comparing the imaging quality and usability of the 3D-HD-endoscopic technique and the 2D-HD-endoscopic technique. The images from the surgery were recorded and questionnaires were filled out. The questionnaire contained a total of 20 questions using an ordinal likert scale from 1-5. The central neutral reference point was kept as 3 to compare the 2D-HD endoscope with 3D-HD endoscope system. Here, 1 meant that 3D-HD remained much worse than 2D-HD, and 5 meant that 3D-HD remained much better than 2D-HD.

A different set of questionnaires was used for the 3D-HD- and 2D-4K-endoscopy performed in a cadaver in the laboratory setting.

2.3.1 Inclusion and exclusion criteria

A total of 20 patients with chronic rhinosinusitis with or without polyps were included in the study. They were recommended for surgery as they were less responsive to the conservative treatment and therefore were suggested for a bilateral functional endoscopic sinus surgery (FESS). The requirement that had to be met was the patients must be fully capable of understanding the information regarding the operation, willingness to give permission to the study and finally agreed to sign the coin-tossing process and randomization for selection of side.

Those patients were excluded from participating in the study who were under 10 years of age, past history of surgery on paranasal sinuses, with other comorbidities as bleeding disorders and were unable or refusal to give permission for the study. Patients with asymmetric or unilateral diseases like one sided polyp, antrochoanal polyp, inverted papilloma, diagnosis with doubt of malignancy were excluded from the study because these conditions created difficulty for comparison of contralateral side.

For the present study in the laboratory setup, there were no sets of specific inclusion and exclusion criteria. All participants of the FESS MunichMasterClass 2018 and 2019 course were allowed to participate in the 3D-HD and 2D-4K study. Some of the surgeons were experienced and some of them were novice, which allowed us to make a comparison between them regarding the subjective experience of new technique.

2.3.2 Conducting the study

After all the inclusion criteria were successfully checked, the patient was informed one or two days before the operation about the operation procedure and the procedural details of the study. With their permission to the random side selection and partially double blinded study, they were finally taken into the study group.

Before the surgery had started, the side to be operated by 3D-HD-endoscopic technique was determined by coin-tossing. For this purpose, heads side was assumed for the 3D-HD and tails side was assumed for the 2D-HD. The side to be operated with 3D-HD technique was decided when the coin landed. The surgeon operated always from right side to left side inside the nasal cavity to maintain uniformity. In this way, a random distribution of the surgery was achieved. During the surgery with the 3D-HD-endoscopic technique, both the surgeon and assistant-nurses used a polarized glass to view the 3D-HD images on a polarized monitor. The surgery on both sides was performed by the same surgeon for better comparability. It was done to open the congested or blocked paranasal sinuses in the osteomeatal junction or to remove the polyps. The surgeon tried to operate smoothly as possible to save the remaining mucous membrane. Thus, at the end the natural anatomy with ventilation and drainage of the paranasal sinuses could be restored.

The surgery was documented separately in the appropriate nomenclature. Photos and videos of the surgery were documented accordingly. A distinction was made between infundibulotomy,

partial anterior ethmoidectomy, ethmoidectomy, spheno-ethmoidectomy, fronto-ethmoidectomy and fronto-spheno-ethmoidectomy. Additionally, septoplasty and turbinoplasty were performed if needed.

In the second part of study, participants from FESS *MunichMasterClass 2018 and 2019* were involved. FESS *MunichMasterClass* is a course regarding endoscopic sinus surgery training for young ENT resident-doctors where they learn surgery in paranasal sinuses on cadavers. This course takes place annually at the Anatomical Institute of LMU Munich. As part of this advanced training event, ENT resident-doctors were introduced to the precise basics of functional endoscopic sinus surgery (FESS) in accordance with the Graz School through lectures and videos in a practical and detailed approach by experts from Germany and abroad. Here they acquire the opportunity to learn or extend the various surgical techniques, access routes as well as practical tips and tricks of paranasal sinus surgery. They are guided in a “step by step” manner under direct personal guidance of experienced lecturers in 2D-HD, 3D-HD and 2D-4K technologies on specially fixed anatomical specimens.

Participants from FESS *Munich Master Class 2018* (28.-29.06.2018) were requested to dissect into the cadaver, one side with 2D-HD-endoscopic technique and other side with 3D-HD-endoscopic technique. After the procedures were completed with both the techniques, a questionnaire was filled up regarding their work experiences, total surgeries performed till date and benefits of 3D-HD-technique in comparison to the 2D-HD-technique concerning imaging properties, usability aspects and accessibility of dissection in different paranasal sinuses.

Participants from FESS *Munich Master Class 2019* (04.-05.07.2019) were requested to dissect into the nasal cavity of the cadaver, one side with 3D-HD-endoscopic technique and the other side with 2D-4K-endoscopic technique. After the procedures were completed with both the techniques, a questionnaire was filled up in Google Forms about the different types of cameras they have been using, their selection for future imaging system, task completion time and advantages of 2D-4K-technique regarding imaging properties.

The results from all different questionnaires in patients and in laboratory specimen have been evaluated separately.

2.3.3 Overview of clinical and laboratory study

The following table displays the overview of clinical and laboratory study included in this dissertation.

Table 4: Overview of clinical and laboratory studies included in this dissertation

Study type	Participants	Study design	Outcome measures
Clinical			
3D-HD vs 2D-HD	20 patients 1 surgeon	Randomized, prospective, partially double blind, comparative, interventional study; FESS	Operative time, imaging- and usability properties
Laboratory			
3D-HD vs 2D-HD	26 participants, 1 specimen	Randomized, comparative study; FESS	Subjective experience of participants, imaging- and usability properties, advantages of 3D-HD for dissection of particular sinuses
3D-HD vs 2D-4K	20 participants, 1 specimen	Randomized, comparative study; FESS	Personal experience of participants, task completion time, imaging properties
Total	Data from 66 individuals		

2.4 Data processing and evaluation

2.4.1 Databank

Clinical study:

A databank was created with the program “Microsoft Forms 2014” for the registration and further processing of the collected data. The total time period of the surgery using both the techniques were measured each side separately. A questionnaire-form concerning the comparison of 3D-HD endoscopy to 2D-HD endoscopy was filled up by the surgeon after each surgery which contained total eight questions regarding imaging qualities and total ten questions about usability aspects.

A total of 20 patients were operated by an experienced surgeon at ENT Clinic Dr. Gaertner Bogenhausen from 08.05.2018 to 19.10.2018.

Laboratory study:

Regarding laboratory study, 2D-HD vs 3D-HD endoscopy of 2018 and 3D-HD vs 2D-4K endoscopy of 2019 at the Anatomical Institute of LMU Munich were analyzed.

In both parts of the study, for 2D-HD endoscopy standard KARL STORZ® 2D-HD/HD endoscopic camera and for 3D-HD endoscopy TIPCAM®1 S 3D-HD, 0°, 4mm; TIPCAM®1 S 3D-HD, 30°, 4mm; and TIPCAM®1 S 3D-HD, 45°, 4mm endoscopic camera produced by Karl Storz® GmbH were used.

2.4.2 Statistical analysis

The data so obtained were entered on Microsoft Excel 2018.

For all continuous variables, absolute values, percentages, mean values (μ), standard deviations (σ), standard error of mean (SEM), 95% confidence interval, medians and quartiles were calculated. For categorical variables, frequencies were calculated. The results of the imaging and usability of both the techniques were compared by means of arithmetic mean, standard deviation and 95% confidence interval of the mean. The statistical significance of the individual properties was analyzed by using one sample t-test and the time duration of the surgery by the both techniques were calculated using the two-tailed student t-test.

The significance level was set at $p < 0.05$ for the tests mentioned (5% margin of error). For all statistical analyses, the Statistical Program GraphPad Prism version 9.0.0 (GraphPad Prism Inc, California, USA) was used. The results obtained were illustrated with the help of histogram, bar charts, column and graphs.

3. Results

3.1 Socio-demographic profile of the patients

The various socio-demographic profiles of the patients were documented in the study. The following data and analyses represent these variables.

3.1.1 Age and Gender distribution of patients

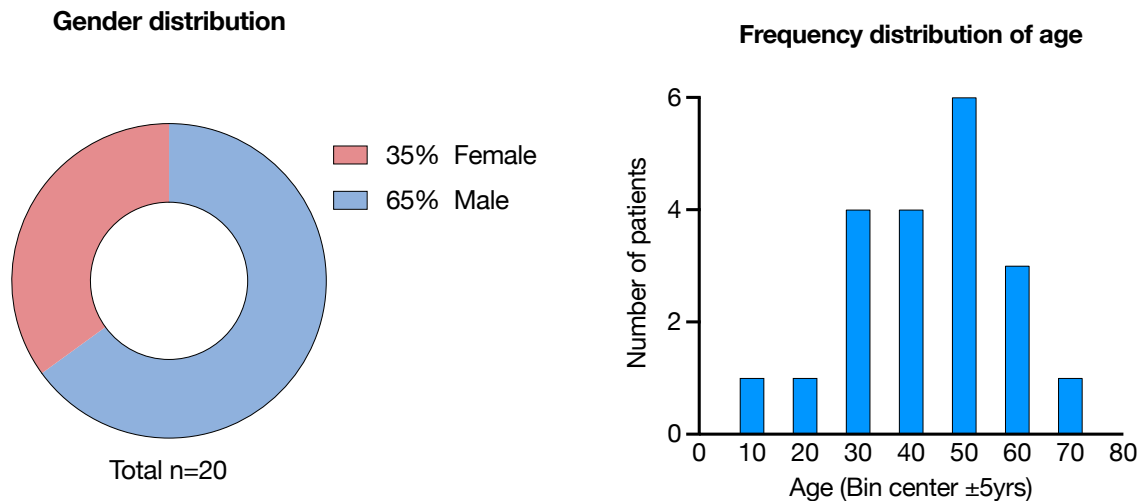


Figure 9. Age- and gender distribution of patients (total patient n=20)

From May to October 2018, a total of 20 patients were included in the study. Among them, 7 were female and 13 were male (Fig 9) shown in the form of a pie-chart. The mean age of the patients was $41,8 \pm 14,3$ (mean \pm standard deviation) years (Range = 12-69 years) shown in the form of a histogram with gaussian frequency distribution curve.

3.1.2 Preoperative endoscopic and radiological Diagnosis

Endoscopic Diagnosis:

As a part of the preoperative diagnosis, adrenaline-moistened cotton swabs were used as a local vasoconstrictor to limit the bleeding and to improve the quality of surgical field during functional endoscopic sinus surgery (FESS). Following the use of adrenaline-moistened cotton swabs, a nasal endoscope was inserted for the visualization of the sinuses. In order to plan the surgery, in all cases a prior computer tomography scan (CT scan) of the paranasal air sinuses was performed.

Figure 10 below represents the various diagnoses made among the 20 subjects.

Preoperative endoscopic findings

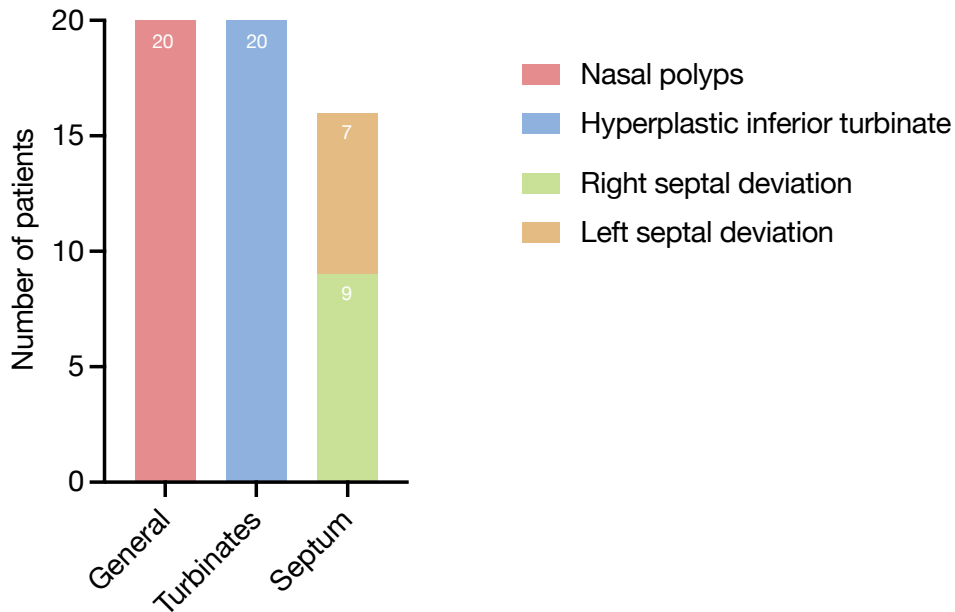


Figure 10. Preoperative endoscopic findings (total patient n=20), the number in the bar diagram represents the number of patients with corresponding endoscopic findings (number of diagnoses=56)

During preoperative nasal endoscopy, the following findings were representative of patients with chronic rhinosinusitis and nasal breathing difficulties: nasal polyposis, right or left septal deviation, and hyperplastic inferior nasal turbinate. Among all 20 patients (100%), nasal endoscopy showed a narrow middle nasal passage with polyps and hyperplastic inferior nasal turbinate. The endoscopic examination furthermore showed a right septal deviation among 9 patients (45%) and a left septal deviation among 7 patients (35%). There was no septal deviation among 4 patients (20%) (Fig 10).

Radiological Diagnosis: A CT-scan of the paranasal sinuses with its three-dimensional (3D-HD) reconstruction was performed preoperatively as a plan for the use of intraoperative navigation among all patients. Moreover, the methodical analysis of the available CT-scan film was carried out by the surgeon. The evaluation of such preoperatively made imaging using a precisely applied checklist is of utmost importance. The extent of sinus inflammation in such image could improve the safety and efficiency in sinus surgery according to Lund and Mackay radiological staging system. Among all patients, the CT-scan showed signs of sinus

inflammation with features of swelling of the mucous membrane with partial or complete opacification of the affected paranasal sinuses.

3.1.3 Indications for surgery

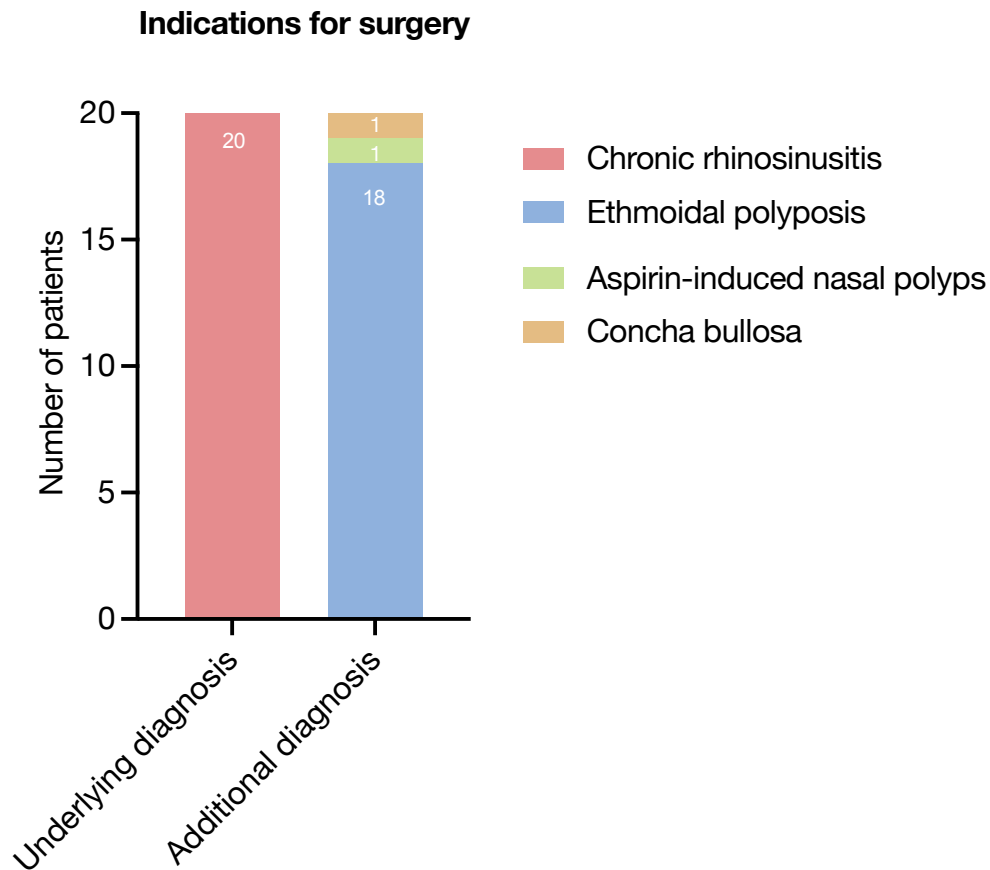


Figure 11. Representation of distribution of the surgical indications (total patient n=20), the number in the bar diagram represents the number of patients and the surgical indications

The indication for surgical procedure was chronic rhinosinusitis (CRS) with nasal polyps in all patients (100%). Regarding the distribution of nasal polyps, 18 of them with ethmoidal polyposis (90%), one case was of aspirin-induced nasal polyps (5%) and a single case was of concha bullosa with a solitary polyp arising from the uncinata process (5%) (Fig 11). Additionally, one patient of chronic rhinosinusitis showed features of sphenoid sinus fungal ball in the sphenoid sinus.

3.1.4 Surgical procedures

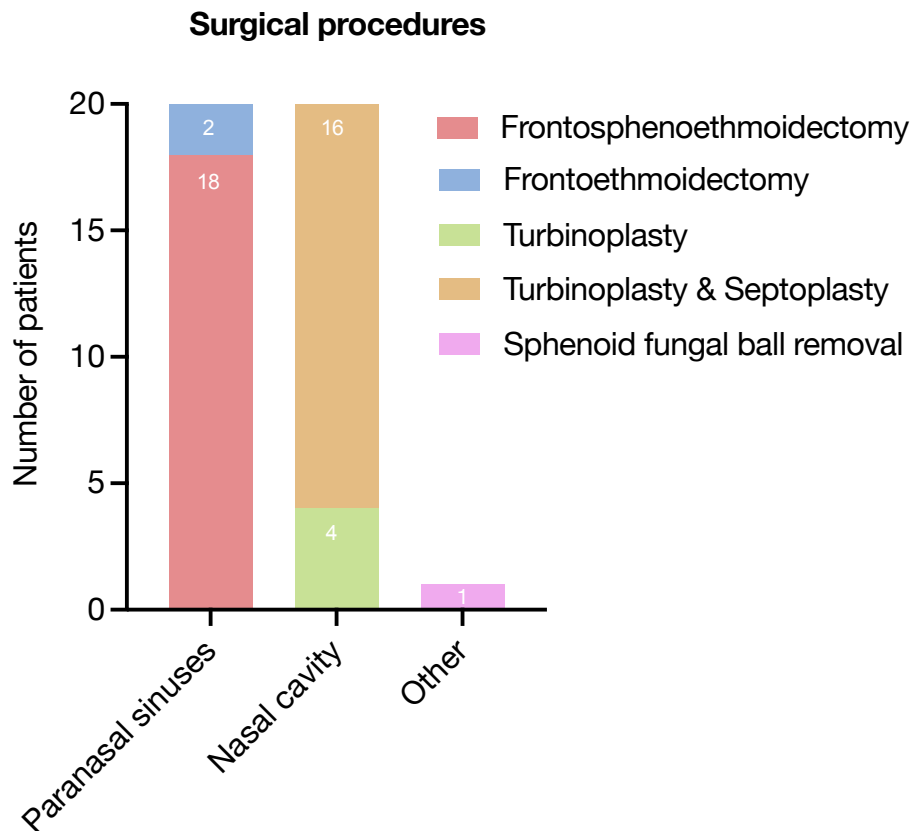


Figure 12. Distribution of patients according to type of surgery performed (total patient n=20), the number in the bar diagram represents the number of surgical procedures performed (number of intra-operative procedures=57, total operations n=20)

Figure 12 represents the total number of procedures performed among the 20 patients. A total of 20 turbinoplasty, 18 fronto-spheno-ethmoidectomy, 16 septoplasty, 2 fronto-ethmoidectomy and one removal of sinus fungal ball were performed (Fig 12). In all patients, identical endoscope was carried on both sides; one side with a 2D-HD-endoscopic technique, while the other side with a 3D-HD-endoscopic technique. In addition, in one case a bilateral removal of a concha bullosa was performed.

3.1.5 Histopathology of chronic rhinosinusitis

Eosinophilic CRS expressed as eosinophil percentage in tissue

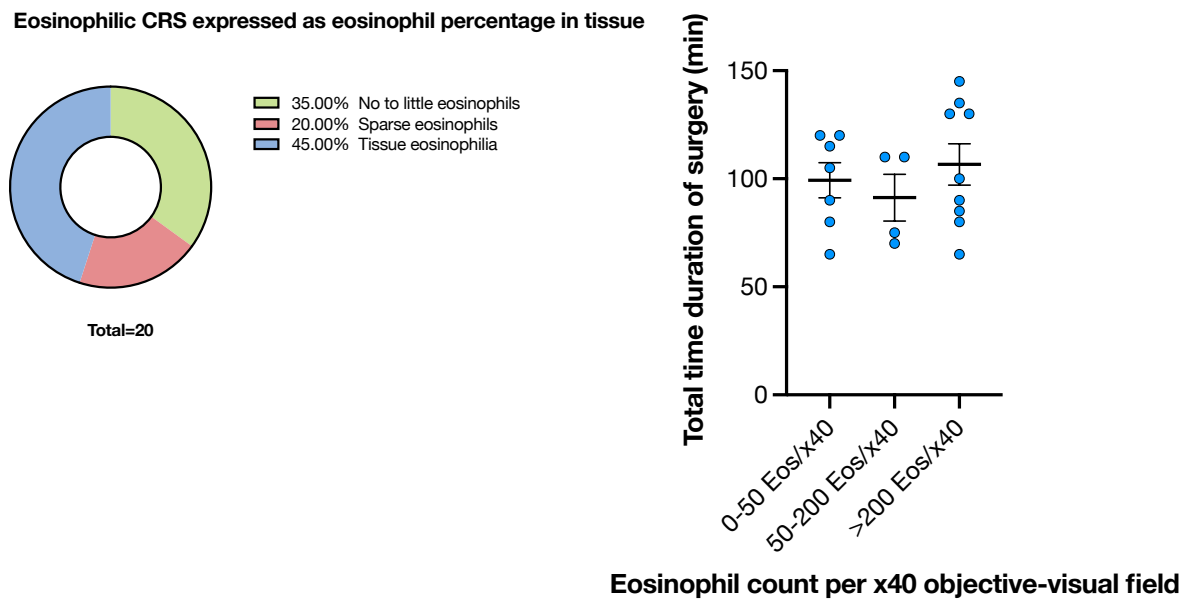


Figure 13. Left: Representation of distribution of the eosinophil percentage in tissue (the percentage in the legend represents the eosinophil count per x40 objective-visual field; no to little eosinophils: 50 eosinophils, sparse eosinophils: 51-200 eosinophils, tissue eosinophilia: >200 eosinophils); Right: Results of comparison of total time duration of surgery with increases number of eosinophils. Data are shown with mean \pm SEM

Figure 13 shows the histopathological correlation of chronic rhinosinusitis. Microscopic examination of tissues removed from the surgery was performed, which revealed 7 cases with less than 50 eosinophils, 4 cases with 51-200 eosinophils and 9 cases with more than 200 eosinophils (eosinophilia) per x40 objective-visual field. There were no cases with fungus and malignancy in pathological examination. Furthermore, cases having eosinophilia took longer time duration during the surgery (Fig 13, right).

3.1.6 Total time of surgery

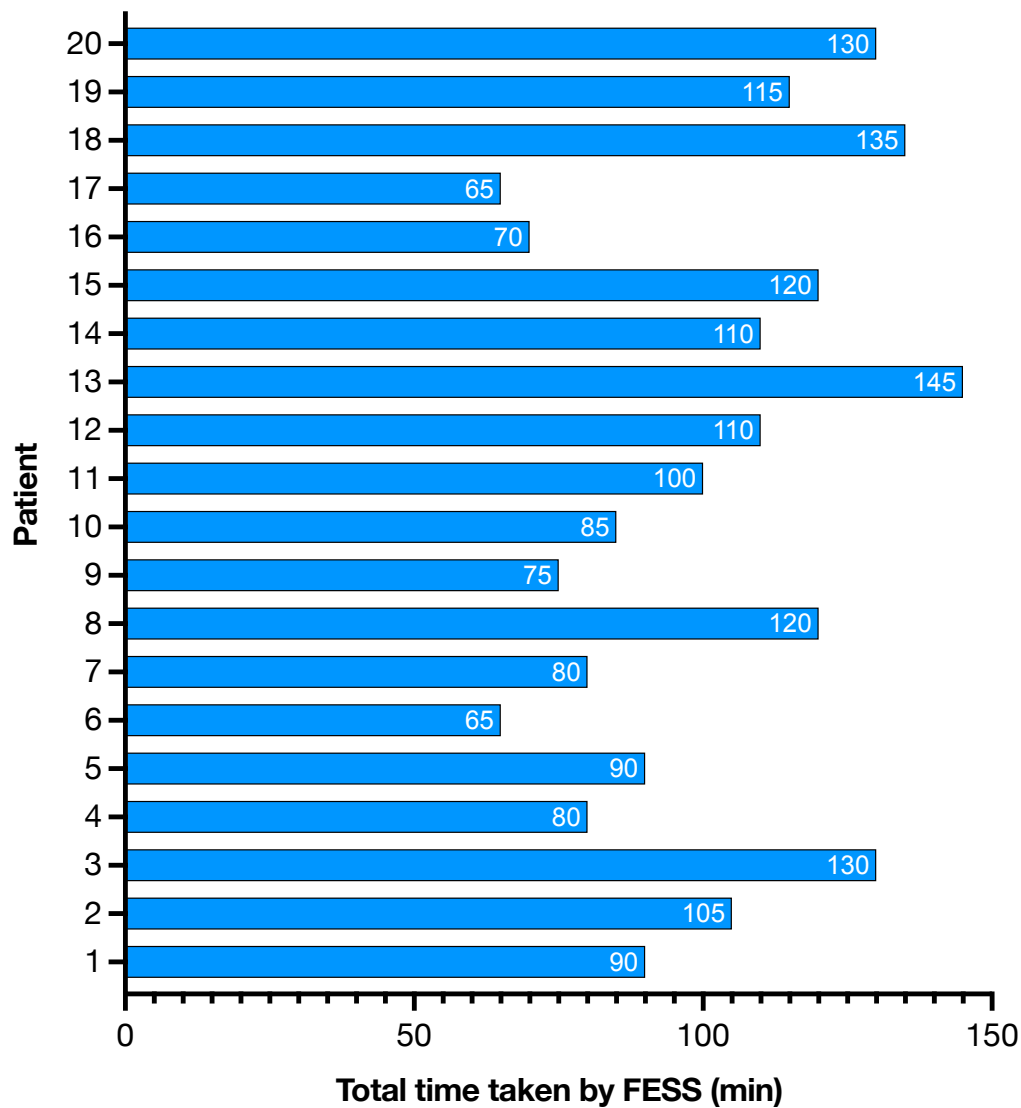


Figure 14: Total time of surgery of individual patients (n=20), the number in the bar diagram represents the total time of surgery

Figure 14 reveals the time taken for individual surgery in minutes. The shortest surgery took 65 minutes while the longest surgery among all took 145 minutes. The mean total time of the surgery was 101 ± 24 minutes (mean \pm standard deviation) (Fig 14).

3.2 FESS with 3D-HD- and 2D-HD-Endoscopy

3.2.1 Time of surgery with 3D-HD- and 2D-HD-techniques

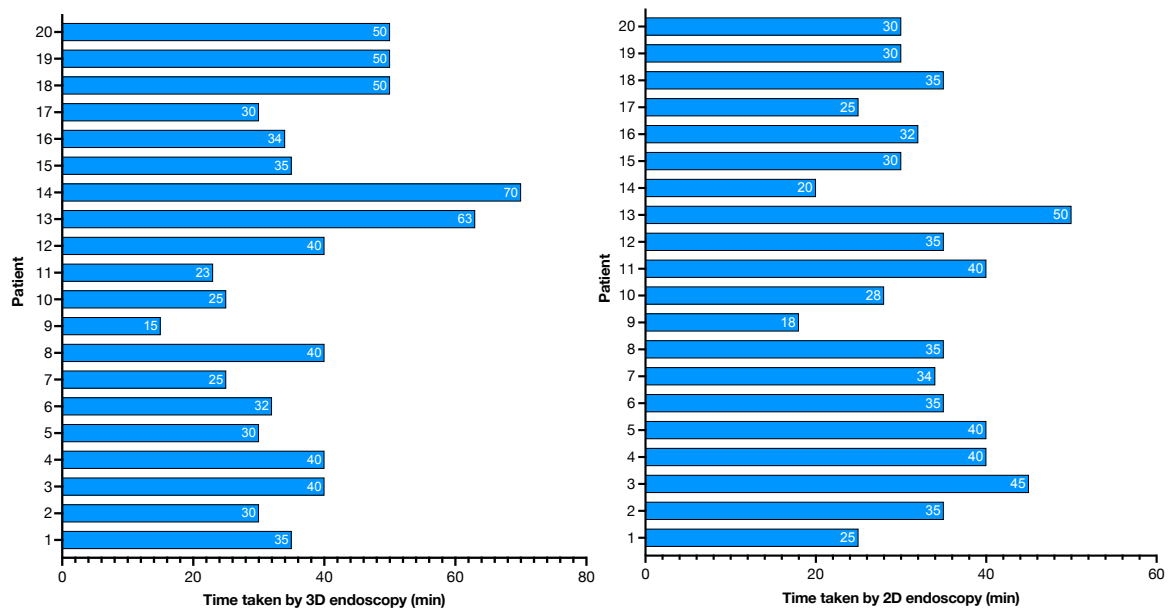


Figure 15. Duration of surgery in individual patient with 3D-HD- and 2D-HD-techniques (n=20), the number in the bar diagram represents the time of surgery

The shortest surgery with 3D-HD-techniques took 15 minutes while the longest surgery among all took 70 minutes. The average time of the surgery was $37,9 \pm 13,5$ minutes (mean \pm standard deviation) (Fig 15).

The shortest procedure with 2D-HD-technique took 18 minutes while the longest surgery among all took 50 minutes. The average time of the surgery with the 2D-HD-technique was $33,1 \pm 7,9$ minutes (mean \pm standard deviation) (Fig 15).

3.2.2. Comparison of total time of surgery with 2D-HD- and 3D-HD-endoscopy

Operative time with 2D- and 3D-endoscopy

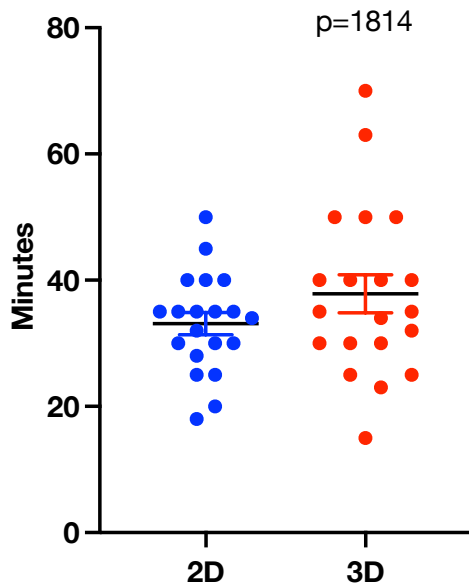


Figure 16. Results of total surgical time with 2D-HD- and 3D-HD-endoscopy; unpaired two-tail student t-test was used (n=20). Data are shown with mean \pm SEM, $p=0.12$ (ns)

The mean time of surgery was 33.1 min (± 1.6 SEM) for 2D-HD method and 37.9 min (± 3.0 SEM) for 3D-HD method. Although the total time of surgery with the 2D-HD endoscopy technique was shorter than with the 3D-HD technique; the comparison did not demonstrate statistical significance at 5% margin of error ($p=0.1814$).

3.2.3 Imaging properties

The subjective perception of the surgeon of the imaging after the surgery has been described in the following paragraphs. Here, we have discussed all individual sinuses at first separately then at the end a combined outline of all sinuses has been described. The graph shown beneath is similar to the forest plot where 3 points on the x-axis indicates equivalence of 2D-HD technique with 3D-HD technique. Similarly, in this 5-point Likert scale, less than 3 represent superiority of 2D-HD method while value more than 3 represents superiority of 3D-HD technique.

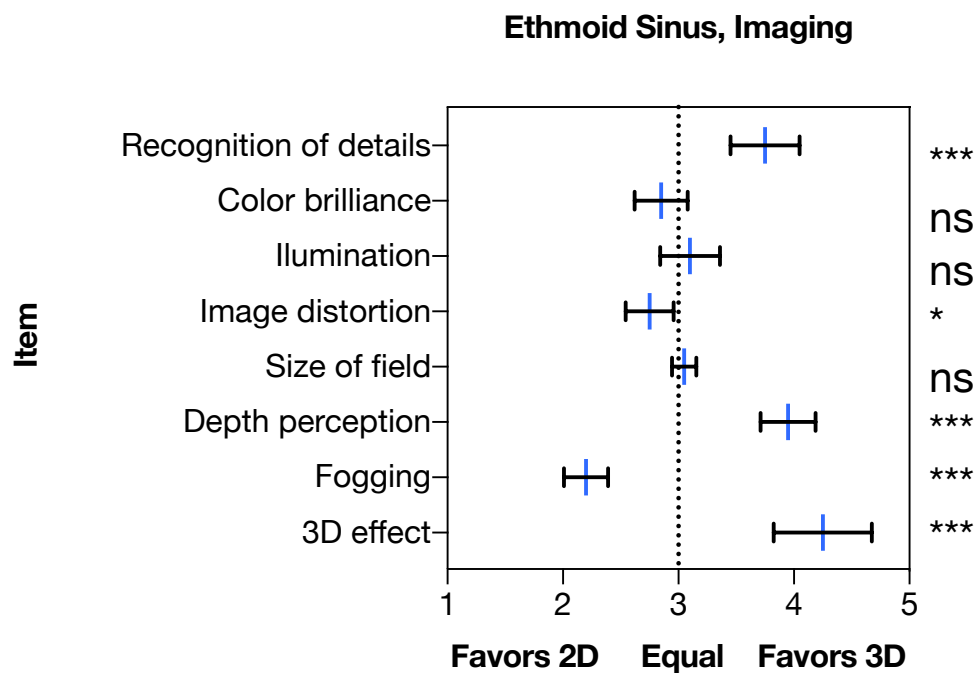


Figure 17. Results for imaging properties of the ethmoid sinus with 3D-HD endoscopy compared to 2D-HD endoscopy (n=20). Data are shown with mean and mean with 95% CI, $p > 0.05$ (ns: non-significant), $p \leq 0.05$ (*), $p \leq 0,001$ (***); one sample t-test with a hypothetical mean of 3.0 was used

As we assessed the imaging properties of the ethmoid sinus (Fig 17), following conclusions were obtained from the descriptive analysis of the data: 3D-HD was superior to the 2D-HD technique in headings of “recognition of details/anatomical understanding” (mean 3.8; 95% CI [3.45, 4.05]), “depth perception” (mean 4.0; 95% CI [3.71, 4.19]) and “3D effect” (mean 4.3, 95% CI [3.82, 4.68]). The 3D-HD technique has also shown improved results in “illumination” (mean 3.1; 95% CI [2.84, 3.36]) and “size of field” (mean 3.1; 95% CI [2.95, 3.15]) in comparison to the 2D-HD technique.

We further performed statistical analysis of the data and yielded subsequent results. In headings, recognition of details ($p < 0.001$), depth perception ($p < 0.001$) and 3D effect ($p < 0.001$), the sample mean deviated significantly from the hypothetical mean of 3 (towards 3D-HD value). Which shows that during surgery these three features were better reflected in 3D-HD endoscopy than in 2D-HD endoscopy. In contrast image distortion ($p < 0.020$) and fogging ($p < 0.001$) were significantly better in 2D-HD. There were no significant differences in parameters as color brilliance, illumination and size of the field.

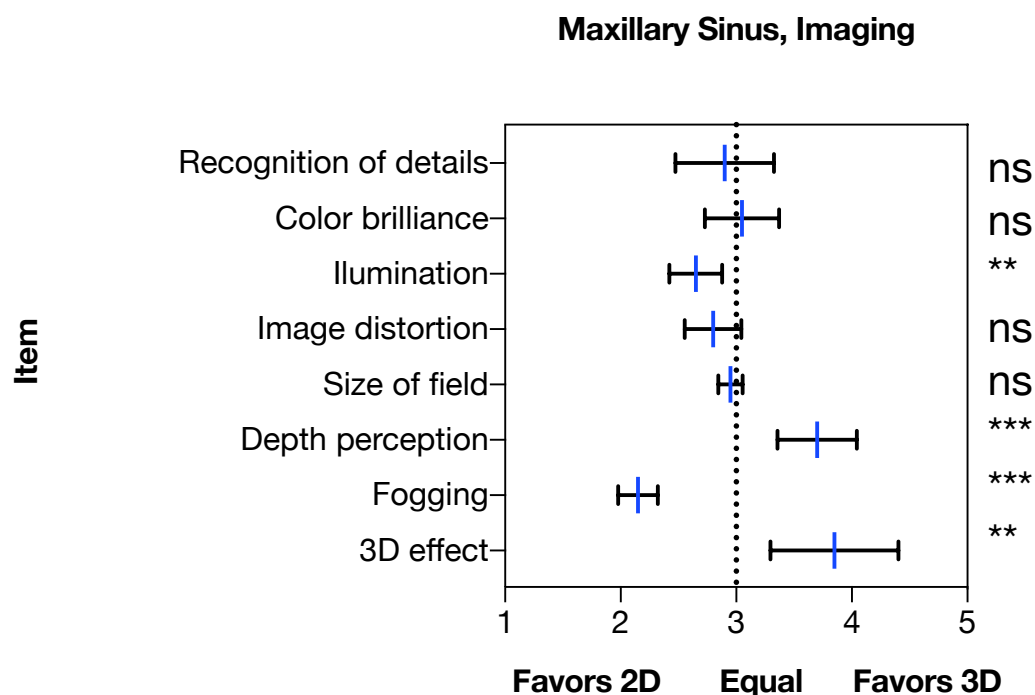


Figure 18. Results for imaging properties of the maxillary sinus with 3D-HD endoscopy compared to 2D-HD endoscopy ($n=20$). Data are shown with mean and mean with 95% CI, $p > 0.05$ (ns: non-significant), $p \leq 0.01$ (**), $p \leq 0.001$ (***); one sample t-test with a hypothetical mean of 3.0 was used

The descriptive analysis used for imaging properties of maxillary sinus (Fig 18) revealed the following results: 3D-HD was much better to 2D-HD in headings of “depth perception” (mean 3.7; 95% CI [3.36, 4.04]) and “3D effect” (mean 3.9, 95% CI [3.30, 4.40]). The 3D-HD technique also has shown slight dominance in “color brilliance” (mean 3.1; 95% CI [2.73, 3.37]). One noticeable difference for maxillary sinus with other sinuses is that the “recognition of details” (mean 2.9; 95% CI [2.47, 3.33]) in 3D-HD technique was perceived almost equivalent to that of the 2D-HD technique.

We additional executed statistical analysis of the data and acquired successive results. In headings of depth perception ($p<0.001$) and 3D effect ($p=0.005$), sample mean was deviated significantly away from the hypothetical mean of 3 towards 3D-HD technique. We hence concluded that during the surgery these features were better reflected in 3D-HD endoscopy than in 2D-HD endoscopy technique. However, in headings of contrast illumination ($p=0.005$) and fogging ($p<0.001$) significance was perceived better in 2D-HD technique. No significant differences between 2D-HD and 3D-HD techniques were demonstrated in recognition of details, color brilliance, image distortion, and size of the field for the maxillary sinus.

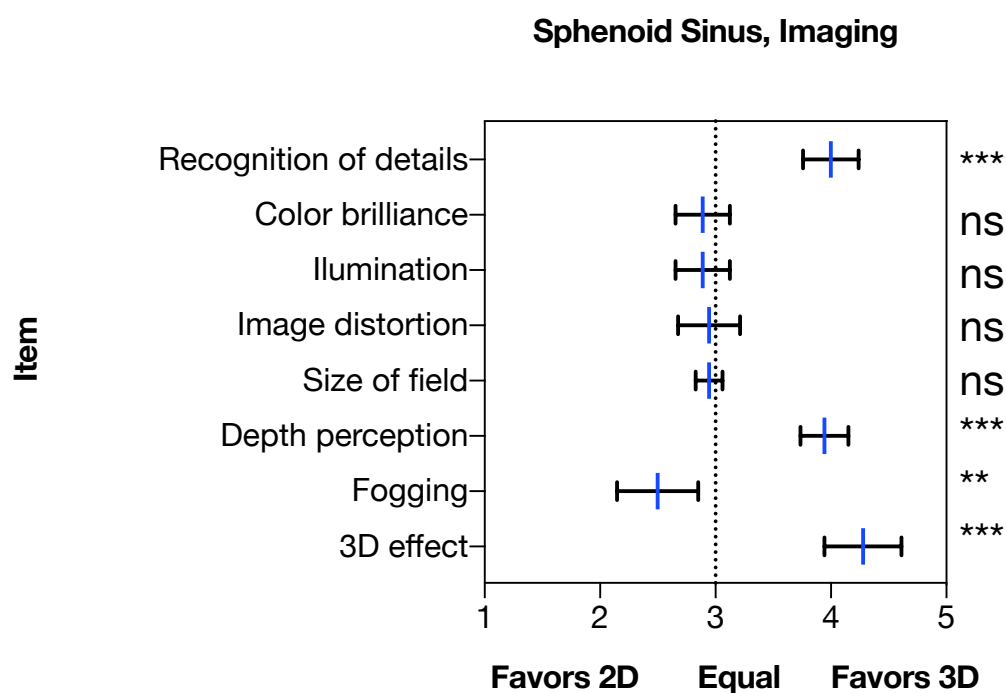


Figure 19. Results for imaging properties of the sphenoid sinus with 3D-HD endoscopy compared to 2D-HD endoscopy (n=20). Data are shown with mean and mean with 95% CI, $p>0.05$ (ns: non-significant), $p\leq 0.01$ (**), $p\leq 0.001$ (***); one sample t-test with a hypothetical mean of 3.0 was used

We used the descriptive analysis for imaging properties of sphenoid sinus (Fig 19) and found the subsequent results: The 3D-HD technique was superior to 2D-HD in headings of “recognition of details/ anatomical understanding” (mean 4.0; 95% CI [3.76, 4.24]), “depth perception” (mean 3.9; 95% CI [3.74, 4.15]) and “3D effect” (mean 4.3, 95% CI [3.95, 4.61]). In headings of color brilliance and brightness 2D-HD technique showed better results.

Further in the headings of recognition of details ($p < 0.001$), depth perception ($p < 0.001$) and 3D effect ($p < 0.001$), the sample mean significantly deviated away from the hypothetical mean of 3 towards 3D-HD technique. We hence concluded that during the surgery these features were better reflected in 3D-HD endoscopy than in 2D-HD endoscopy. In contrast, fogging ($p = 0.008$) was significantly better in 2D-HD endoscopy technique. There were no significant differences between 2D-HD and 3D-HD in headings of color brilliance, illumination, image distortion and size of the field.

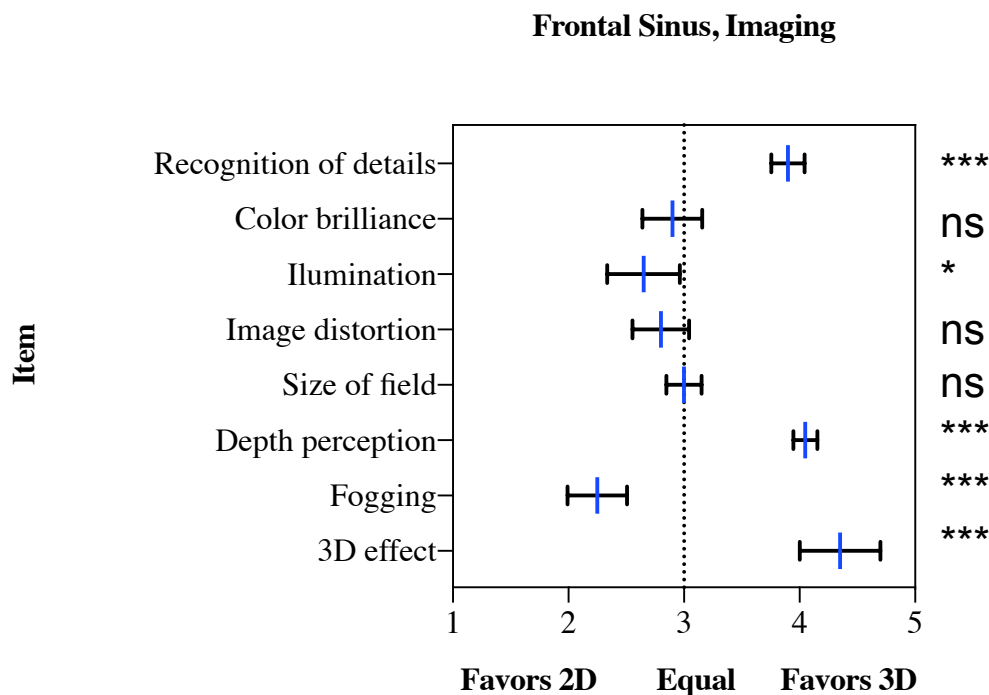


Figure 20. Results for imaging properties of the frontal sinus with 3D-HD endoscopy compared to 2D-HD endoscopy ($n = 20$). Data are shown with mean and mean with 95% CI, $p > 0.05$ (ns: non-significant), $p \leq 0.05$ (*), $p \leq 0.001$ (***) ; one sample t-test with a hypothetical mean of 3.0 was used

For the frontal sinus, the imaging properties of frontal sinus (Fig 20) showed the following results after the descriptive analysis. The 3D-HD technique was superior to 2D-HD in headings of “recognition of details/ anatomical understanding” (mean 3.9; 95% CI [3.76, 4.04]), “depth perception” (mean 4.1; 95% CI [3.95, 4.15]) and “3D effect” (mean 4.4, 95% CI [4.00, 4.70]). Surprisingly, the heading “size of field” (mean 3.0; 95% CI [2.85, 3.15]) revealed same score in both the techniques.

Statistical analysis showed that in headings of recognition of details ($p<0.001$), depth perception ($p<0.001$) and 3D effect ($p<0.001$), sample mean deviated significantly from the hypothetical mean of 3. We hence concluded that during the surgery these features were better reflected in 3D-HD endoscopy than in 2D-HD endoscopy. However, in headings of contrast illumination ($p<0.03$) and fogging ($p<0.001$), the results were significantly better in 2D-HD endoscopy technique. The results of maxillary and sphenoid sinus showed similar result as of the frontal sinus in headings of color brilliance, image distortion and size of the field, which revealed no statistically significant differences between 2D-HD and 3D-HD endoscopy technique.

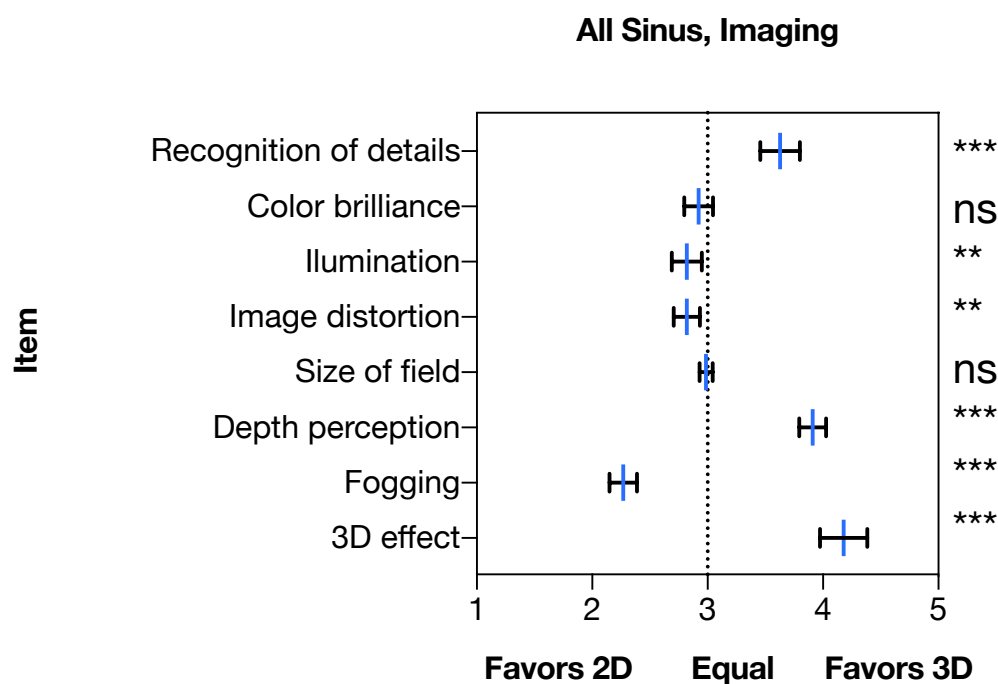


Figure 21. Results for imaging properties of all sinuses with 3D-HD endoscopy compared to 2D-HD endoscopy (n=20). Data are shown with mean and mean with 95% CI, $p>0.05$ (ns: non-significant), $p\leq 0.01$ (**), $p\leq 0.001$ (***); one sample t-test with a hypothetical mean of 3.0 was used

A total of 78 sinuses were evaluated altogether as follows: 20 ethmoid sinus, 20 maxillary sinus, 18 sphenoid sinus and 20 frontal sinuses. Descriptive analysis of all sinuses for imaging properties (Fig 21) showed superiority of 3D-HD over 2D-HD in headings of “recognition of details/ anatomical understanding” (mean 3.6; 95% CI [3.46, 3.80]), “depth perception” (mean 3.9; 95% CI [3.79, 4.03]) and “3D effect” (mean 4.2, 95% CI [3.97, 4.38]). Other aspects of visualization for example color brilliance; brightness and size of the field were superior in 2D-

HD in contrast to 3D-HD. Additionally, images were distorted and defogged with 2D-HD in comparison to 3D-HD technique.

Statistical analysis showed that in headings of recognition of details ($p < 0.001$), depth perception ($p < 0.001$) and 3D effect ($p < 0.001$), sample mean was deviated significantly away from the hypothetical mean of 3 towards 3D-HD technique. We hence concluded that during the sinus surgery these features were better reflected in 3D-HD endoscopy than in 2D-HD endoscopy. In contrast headings as illumination ($p = 0.007$), image distortion ($p = 0.002$) and fogging ($p < 0.001$) were significantly better in 2D-HD endoscopy technique. There was no statistically significant difference between two techniques in headings of color brilliance and size of the field.

3.2.3 Usability aspects

The subjective perception of usability following the surgery has been described in the coming paragraphs. Here we have discussed all individual sinuses separately and at the end a combined outline of all sinuses has been presented.

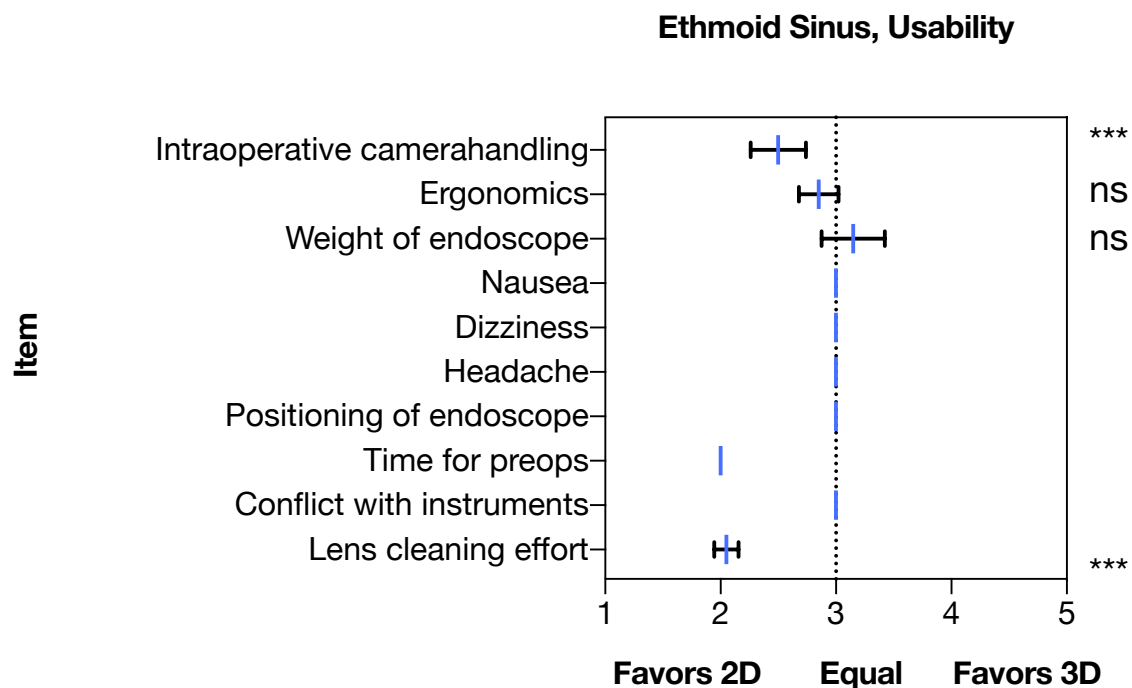


Figure 22. Results for usability properties of the ethmoid sinus with 3D-HD endoscopy compared to 2D-HD endoscopy ($n = 20$). Data are shown with mean and mean with 95% CI, $p > 0.05$ (ns: non-significant), $p < 0.001$ (***), na = not applicable (sample difference has zero SD); one sample t-test with a hypothetical mean of 3.0 was used

The usability properties of ethmoid sinus (Fig 22) were evaluated using descriptive analysis. The results of which have shown that 3D-HD technique was better to 2D-HD technique only in headings of “weight of endoscope / camera (mean 3.2; 95% CI [2.88, 3.42])”. In other headings as in “intraoperative handling of the camera” (mean 2.5; 95% CI [2.26, 2.74]), “ergonomics/changing of endoscopes” (mean 2.9; 95% CI [2.68, 3.02]) and “lens cleaning effort” (mean 2.1; 95% CI [1.95, 2.15]) 2D-HD technique was found to be superior to 3D-HD technique. The preoperative preparation time was also shorter in 2D-HD endoscopy technique. Headings related to surgeon’s symptomatology and comfort as nausea, dizziness, headache, positioning of endoscope and conflicts with instruments were found to be almost equal in both the techniques.

Statistical analysis has also revealed the following facts. In headings as intraoperative handling of the camera ($p < 0.001$) and lens cleaning effect ($p < 0.001$), the sample mean was deviated significantly from the hypothetical mean of 3 towards the 2D-HD spectrum. We can thus conclude that these two intraoperative features were better reflected in 2D-HD endoscopy than in 3D-HD endoscopy technique. There was no statistically significant difference between two techniques regarding the headings of ergonomics and weight of endoscope.

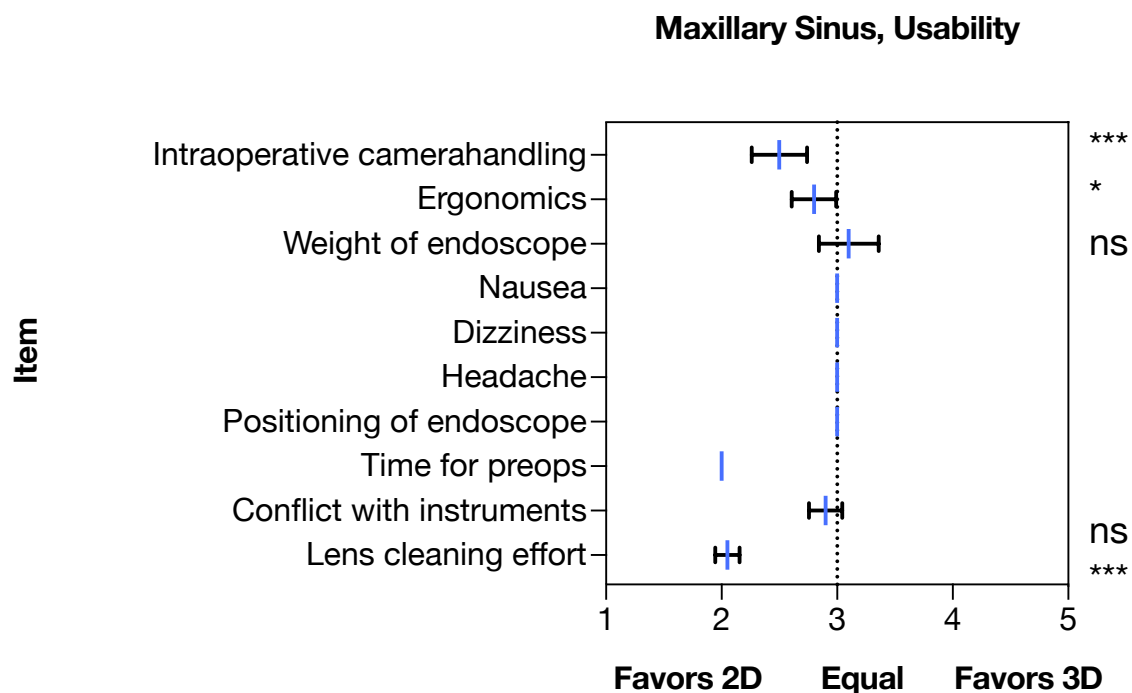


Figure 23. Results for usability properties of the maxillary sinus with 3D-HD endoscopy compared to 2D-HD endoscopy (n=20). Data are shown with mean and mean with 95% CI,

$p > 0.05$ (ns: non-significant), $p \leq 0.05$ (*), $p \leq 0.001$ (***), na=not applicable (sample difference has zero SD); one sample t-test with a hypothetical mean of 3.0 was used

Regarding the usability properties of maxillary sinus, descriptive data analysis generated has shown the superiority of 3D-HD over 2D-HD technique (Fig 23) only in heading of “weight of endoscope / camera” (mean 3.1; 95% CI [2.84, 3.36]). In other headings viz. “intraoperative handling of the camera” (mean 2.5; 95% CI [2.26, 2.74]), “ergonomics/changing of endoscopes” (mean 2.8; 95% CI [2.61, 2.99]), “conflict with instruments” (mean 2.9; 95% CI [3.46, 3.04]) and “lens cleaning effort” (mean 2.1, 95% CI [1.95, 2.15]), 2D-HD technique was found to be superior to the 3D-HD technique. The preoperative preparation time also favored 2D-HD endoscopic technique. Headings concerning surgeon’s symptomatology and comfort namely nausea, dizziness, headache and positioning of endoscope were equivalent in both the techniques.

Certain headings as intraoperative handling of the camera ($p < 0.001$), ergonomics ($p = 0.04$) and lens cleaning effect ($p < 0.001$), favored the 2D-HD technique as the sample mean deviated significantly from the hypothetical mean value of 3. We can thus conclude that during the surgery these features were better perceived in 2D-HD endoscopy than in 3D-HD endoscopy technique. Although the weight of endoscope was lighter in 3D-HD technique, there was no statistically significant difference between 2D-HD and 3D-HD techniques concerning it.

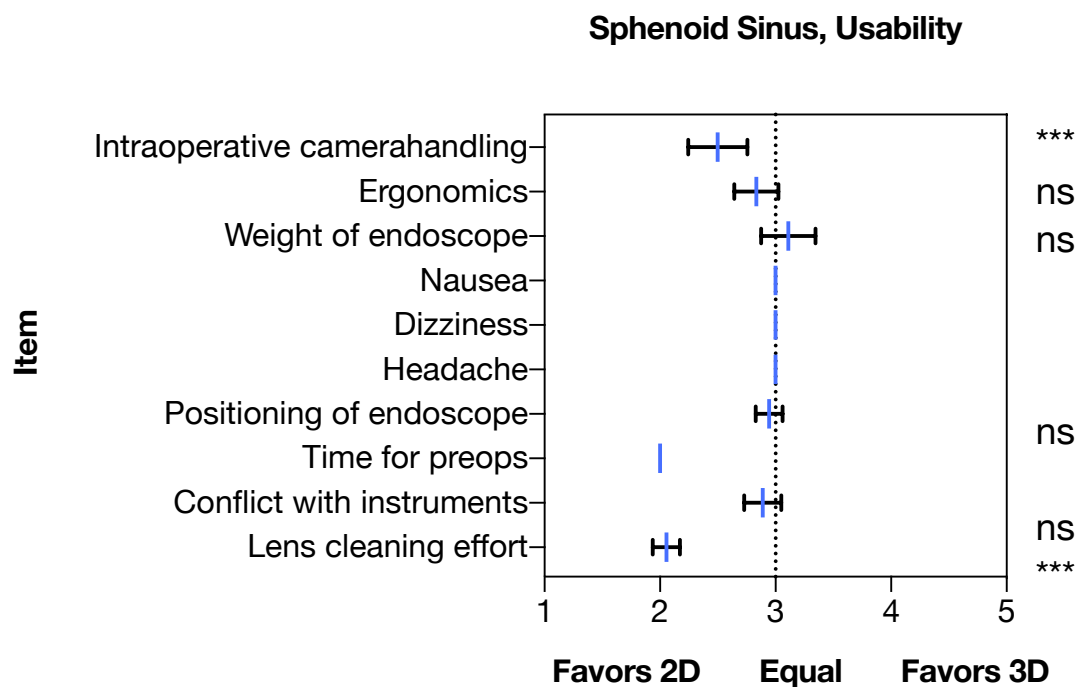


Figure 24. Results for usability properties of the sphenoid sinus with 3D-HD endoscopy compared to 2D-HD endoscopy (n=20). Data are shown with mean and mean with 95% CI, $p > 0.05$ (ns: non-significant), $p \leq 0.001$ (***), na=not applicable (sample difference has zero SD); one sample t-test with a hypothetical mean of 3.0 was used

The descriptive analysis for usability properties of sphenoid sinus (Fig 24) has shown lighter “weight of endoscope” (mean 3.1; 95% CI [2.88, 3.35]) with 3D-HD in comparison to 2D-HD. But in other headings as “intraoperative handling of the camera” (mean 2.5; 95% CI [2.24, 2.76]), “ergonomics/changing of endoscopes” (mean 2.8; 95% CI [2.64, 3.02]), “positioning of endoscope” (mean 2.9; 95% CI [2.83, 3.06]), “conflict with instruments” (mean 2.9; 95% CI [2.73, 3.05]) and “lens cleaning effort” (mean 2.1; 95% CI [1.94, 2.17]), 2D-HD was superior to 3D-HD technique. Headings as preoperative preparation time, nausea, dizziness, headache and conflict with instruments were comparable in both the techniques.

Further statistical analysis for usability properties of sphenoid sinus has shown significant differences in intraoperative handling of the camera ($p < 0.001$) and lens cleaning effect ($p < 0.001$), as sample mean was deviated significantly from the hypothetical mean of 3 towards 2D-HD technique. We thus concluded that during the surgery these features were better perceived in 2D-HD endoscopy than in 3D-HD endoscopy. Regarding headings such as ergonomics, weight and positioning of endoscope and conflict with instruments, there were no significant differences between the techniques.

Frontal Sinus, Usability

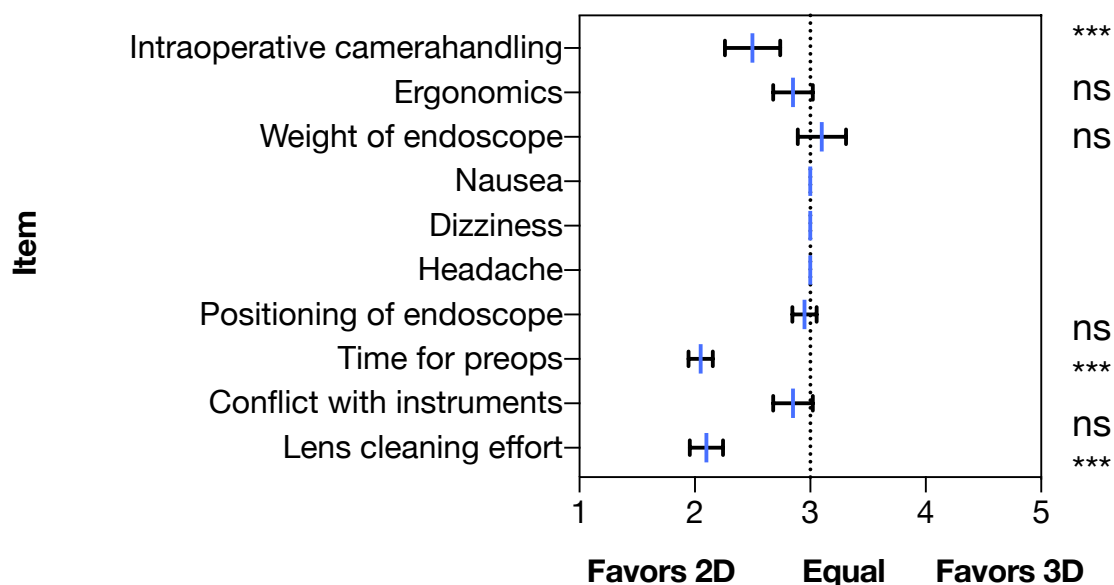


Figure 25. Results for usability properties of the frontal sinus with 3D-HD endoscopy compared to 2D-HD endoscopy (n=20). Data are shown with mean and mean with 95% CI, $p > 0.05$ (ns: non-significant), $p \leq 0.001$ (***), na=not applicable (sample difference has zero SD); one sample t-test with a hypothetical mean of 3.0 was used

The descriptive analysis for usability properties of frontal sinus (Fig 25) has demonstrated better results for 3D-HD endoscope over 2D-HD endoscope in heading of “weight of endoscope” (mean 3.1; 95% CI [2.89, 3.31]). In other headings concerning usability, 2D-HD technique was found to be superior to 3D-HD technique as follows “intraoperative handling of the camera” (mean 2.5; 95% CI [2.26, 2.74]), “ergonomics/changing of endoscopes” (mean 2.9; 95% CI [2.68, 3.02]), “positioning of endoscope” (mean 2.9; 95% CI [2.85, 3.05]), “time for preoperative operation” (mean 2.1; 95% CI [1.95, 2.15]), “conflict with instruments” (mean 2.9; 95% CI [2.68, 3.02]) and “lens cleaning effort” (mean 2.1, 95% CI [1.96, 2.24]). Headings concerning surgeon’s symptomatology and comfort including nausea, dizziness and headache didn’t have any significant difference.

In contrast to the analysis of other sinuses, preoperative preparation time was recorded to be different for frontal sinus. Analysis has shown significant difference in headings of intraoperative handling of the camera ($p < 0.001$), time for preoperative preparation ($p < 0.001$) and lens cleaning effect ($p < 0.001$), as the sample mean deviated significantly from the

hypothetical mean of 3, towards 2D-HD technique. We can thus conclude that during the surgery these features were better perceived in 2D-HD endoscopy than in 3D-HD endoscopy technique. Similarly, there were no significant differences between the 2D-HD and 3D-HD techniques concerning headings such as ergonomics, weight and positioning of endoscope and conflict with instruments.

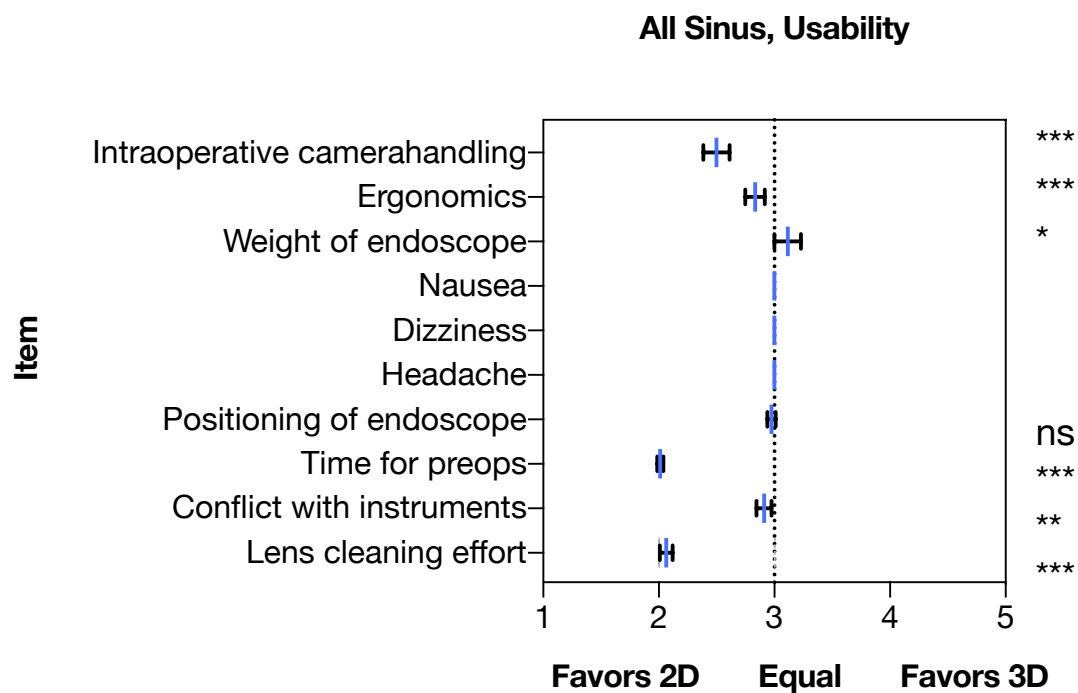


Figure 26. Results for usability properties of all sinuses with 3D-HD endoscopy compared to 2D-HD endoscopy (n=20). Data are shown with mean and mean with 95% CI, $p > 0.05$ (ns: non-significant), $p \leq 0.05$ (*), $p \leq 0.01$ (**), $p \leq 0.001$ (***), na=not applicable (sample difference has zero SD); one sample t-test with a hypothetical mean of 3.0 was used

A total of 78 sinuses were evaluated summing up 20 ethmoid sinuses, 20 maxillary sinuses, 18 sphenoid sinuses and 20 frontal sinuses. The descriptive data analysis with regard to the handling aspects of all sinuses showed superiority of 3D-HD technique over 2D-HD technique only in heading of “weight of endoscope” (mean 3.1; 95% CI [3.00, 3.23]) (Fig 26). All other features were better with 2D-HD technique as follows “intraoperative handling of the camera” (mean 2.5; 95% CI [2.39, 2.61]), “ergonomics/changing of endoscopes” (mean 2.8; 95% CI [2.75, 2.92]), “positioning of endoscope” (mean 2.9; 95% CI [2.94, 3.01]), “time for preoperative operation” (mean 2.0; 95% CI [1.99, 2.04]), “conflict with instruments” (mean 2.9; 95% CI [2.85, 3.298]) and “lens cleaning effort” (mean 2.1, 95% CI [2.01, 2.12]). Overall,

results have clearly shown a tendency of longer preoperative preparation time and extra lens cleaning effort with 3D-HD endoscopy. No change on surgeon's symptomatology and comfort in headings of nausea, dizziness, and headache were experienced during or after surgery with both the techniques.

Further statistical analysis for usability of all sinuses between the two techniques showed significant difference in headings of intraoperative handling of the camera ($p < 0.001$), ergonomics ($p < 0.001$), time for preoperative preparation ($p < 0.001$), conflict with instruments ($p = 0.007$) and lens cleaning effect ($p < 0.001$). The representative mean deviated significantly from the hypothetical mean of 3 towards 2D-HD endoscopy. Hence, we can conclude that during the surgery these features were better perceived in 2D-HD endoscopy than in 3D-HD endoscopy. In contrast, heading as weight of endoscope ($p = 0.05$) was significantly better with 3D-HD endoscope than 2D-HD endoscope. To conclude, we can see that only the weight of endoscope was a favored factor in 3D-HD endoscopy compared to 2D-HD endoscopy regarding its usability features.

3.2.4 Intraoperative pictures of paranasal sinuses with the 2D-HD- and 3D-HD-endoscope

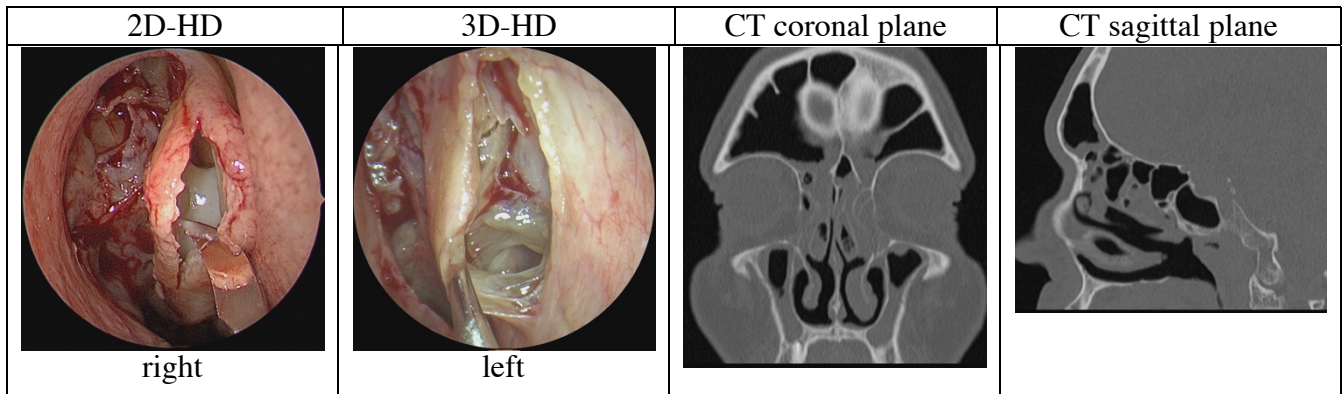


Figure 27. Images of different parts of the paranasal sinuses showing the comparison of 2D-HD- and 3D-HD endoscopy in patients

2D-HD images where color brilliance and illumination were superior to 3D-HD

3D-HD images where recognition of anatomical structures and depth perception were superior to 2D-HD

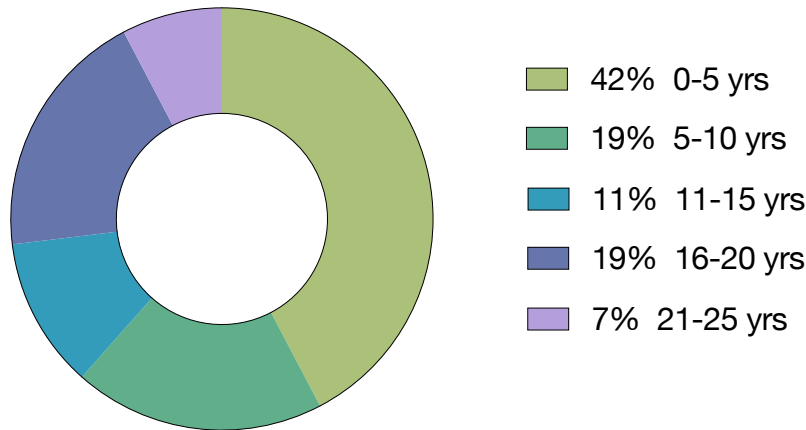
Coronal CT-images shows characteristics of sinusitis with mucosal thickening, opacification and bone-remodeling

Sagittal CT-images used mainly for the assessment of frontal recess

3.3 Cadaver dissection course 2018 /Study on specimen 3D-HD vs 2D-HD

3.3.1 Work experience of participants

Work experience of participants



Total n=26

Figure 28. Work experience of the participants in the form of a pie chart (total participants, n=26)

There were a total of 26 participants with varying degrees of work experience (ranging from less than a year to over 25 years). The average work experience of participants on the day of the surgery was $7,0 \pm 8,3$ years (mean \pm standard deviation) (Fig 28). With them 11 of the participants had with work experience less than 5 years, among which 4 participants performed the FESS-surgery for the first time in their life. Among other participants, 5 of them had work experience of 5-10 years, 3 of them had 11-15 years, 5 of them had 16-20 years and 2 of them had 21-25 years. This showed that only 2 participants were performing FESS surgeries routinely for more than 20 years.

3.3.2 Total surgeries so far performed

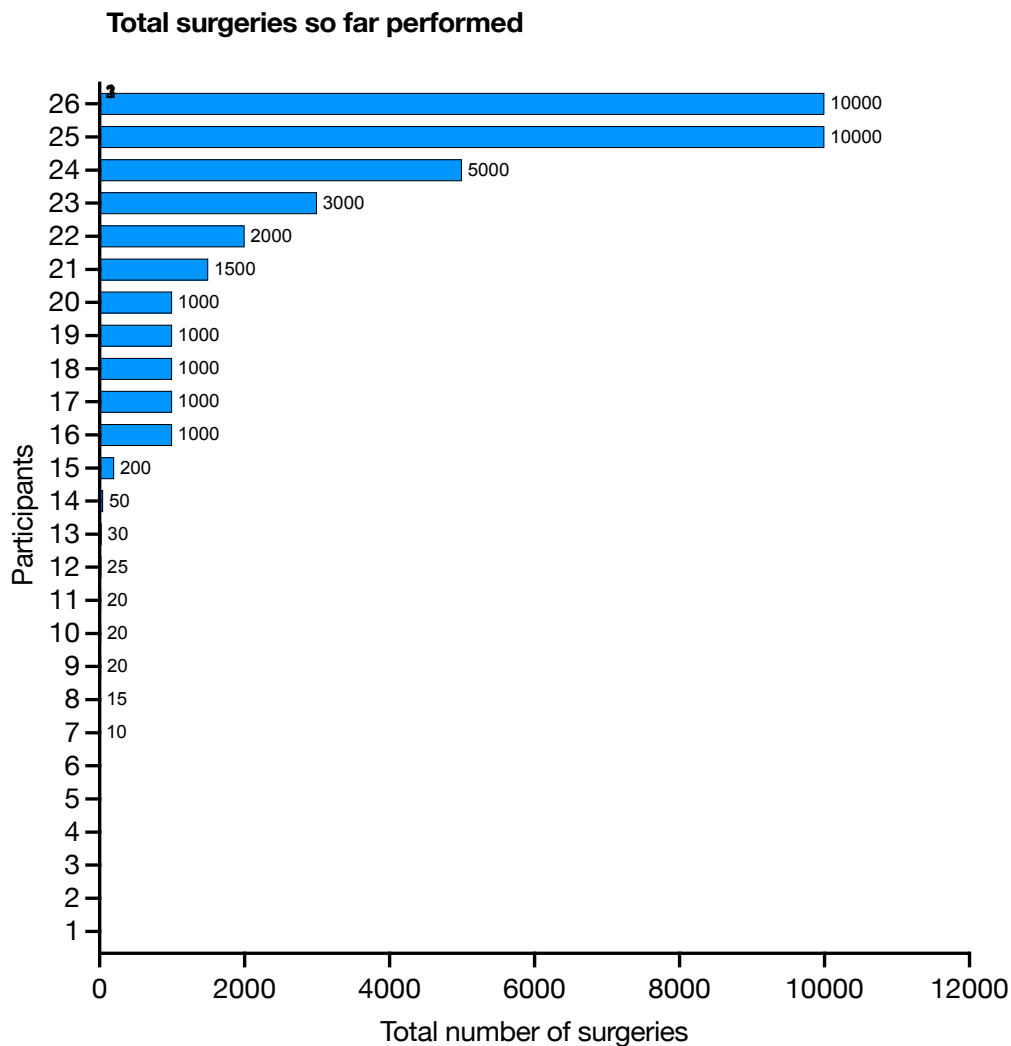


Figure 29. Total surgeries so far performed (total participants, n=26), participants with less than 10 surgeries performed was not shown in bar diagram

Among the total 26 participants, there was varying experience of FESS surgeries performed (ranging from single surgery to more than 10,000 surgeries). The average number of surgeries performed so far on the day of surgery was $1768,1 \pm 2778,0$ (Fig 29).

Out of all participants 57,7 % performed less than 200 surgeries so far, in which 26,7 % from them performed a FESS surgery for the first time in their life. Among other participants, 19,2% performed around 1.000 surgeries, 15,4% performed up to 5.000 surgeries and 7,7% performed more than 10.000 surgeries so far. This showed that only 2 participants performed more than 10.000 FESS surgeries so far.

3.3.3 Correlation between work experience of surgeons and different features of imaging

Relationship between work experience of participants and size of the field

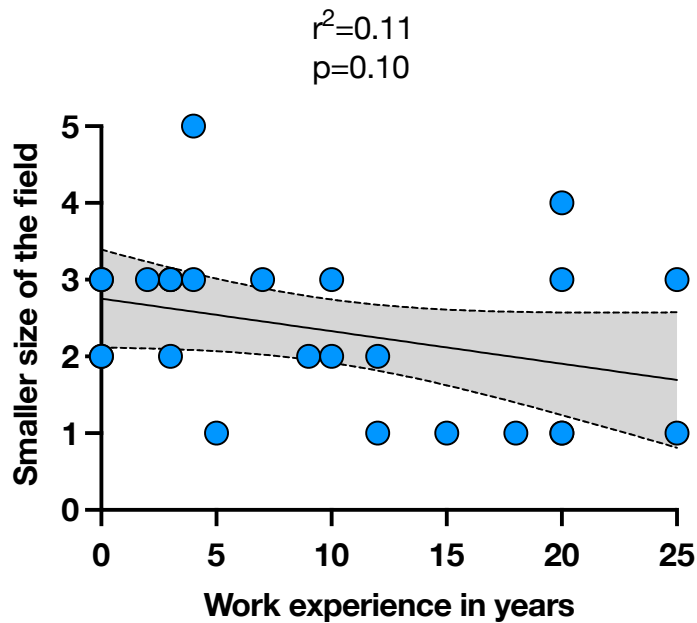


Figure 30. Linear regression diagram showing the relationship of work experience and size of the field; where $p=0.12$ (ns), $p=0.033$ (*), $p=0.002$ (**), $p<0,001$ (***) and r^2 = goodness of fit which evaluates the scatter of the data points around the fitted regression line

A trend towards a negative correlation was found between work experience of participants and the impression that 3D-HD endoscopy provides a smaller size of the field ($r^2=0.11$; $p=0.10$). More experienced participants disagreed about the reduced size of the field with 3D-HD endoscopy, whereas inexperienced participants did not agree or were neutral about it. Generally speaking, participants did not find the size of the field to be small with 3D-HD endoscopy.

Relationship between work experience of participants and handling of the camera

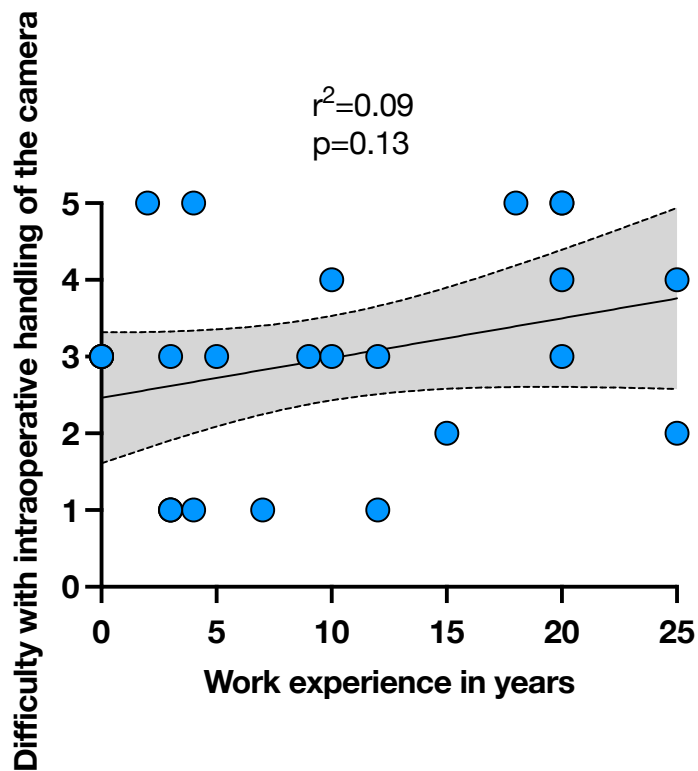


Figure 31. Linear regression diagram showing the relationship of work experience and handling of the camera; where $p=0.12$ (ns), $p=0.033$ (*), $p=0.002$ (**), $p<0,001$ (***) and $r^2=$ goodness of fit which evaluates the scatter of the data points around the fitted regression line

A trend towards a positive correlation was found between longer work experience of participants and difficulty with handling of the camera during dissection ($r^2=0.09$; $p=0.13$). More experienced participants felt trouble in movement of the camera during dissection, whereas inexperienced participants felt comfortable working with 3D-HD endoscopy.

Relationship between work experience of participants and dissection of all sinuses

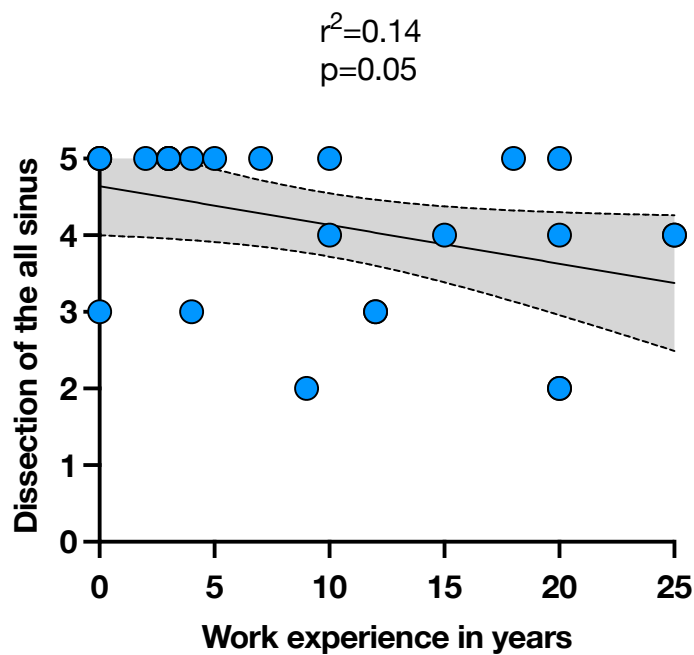


Figure 32. Linear regression diagram showing the relationship of work experience and dissection of all sinuses; where $p=0.12$ (ns), $p=0.033$ (*), $p=0.002$ (**), $p<0,001$ (***) and $r^2=$ goodness of fit which evaluates the scatter of the data points around the fitted regression line

A possible negative correlation as found between the longer work experience of participants and advantages of 3D-HD-endoscopy for the dissection of all sinuses ($r^2=0.14$; $p=0.05$). More experienced participants were almost neutral about advantages of 3D-HD endoscopy for the dissection of all sinuses, whereas inexperienced participants agreed that 3D-HD-endoscopy provided a benefit during dissection.

3.3.4 Imaging properties of 3D-HD in comparison to 2D-HD endoscopy system

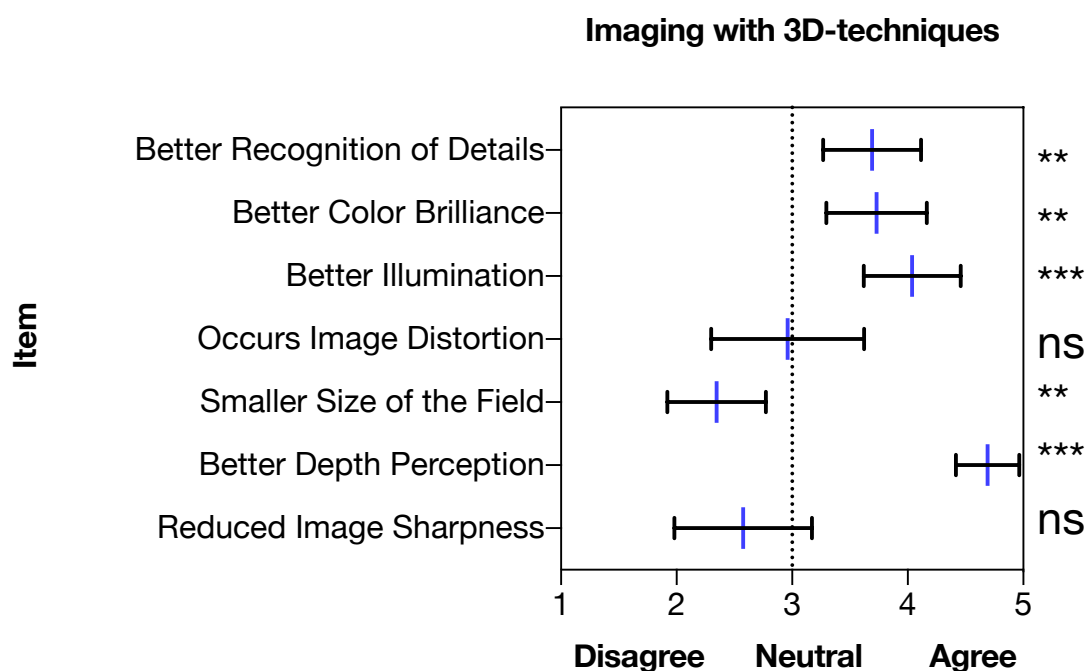


Figure 33. Results for imaging properties of all sinuses with 3D-HD endoscopy compared to 2D-HD endoscopy (n=26). Data are shown with mean and mean with 95% CI, $p > 0.05$ (ns: non-significant), $p \leq 0.01$ (**), $p \leq 0.001$ (***); one sample t-test with a hypothetical mean of 3.0 was used

In total 26 times ethmoid, maxillary, sphenoid and frontal sinus were evaluated. Regarding imaging properties of all sinuses (Fig 33), participants agreed on the fact that 3D-HD endoscope was superior to 2D-HD in headings of “better recognition of details” (mean 3.7; 95% CI [3.27, 4.11]), “better color brilliance” (mean 3.7; 95% CI [3.30, 4.17]), “better illumination” (mean 4.0; 95% CI [3.62, 4.46]) and “better depth perception” (mean 4.7; 95% CI [4.42, 4.97]).

Furthermore, statistical analysis revealed that in headings of better recognition of details ($p=0.002$), better color brilliance ($p=0.002$), better illumination ($p<0.001$) and better depth perception ($p<0.001$), the sample mean deviated significantly from the hypothetical mean of 3 towards 3D-HD technique. Participants concluded that during the surgery these features were better reflected in 3D-HD endoscopy than in 2D-HD endoscopy. In contrast the heading smaller size of the field ($p=0.004$) was significantly better in 2D-HD, which means that participants didn’t perceive smaller size of the field with 3D-HD endoscopy. There was no

significant difference in both techniques for headings as image distortion and reduced image sharpness.

3.3.5 Usability aspects of 3D-HD in comparison to 2D-HD endoscopy system

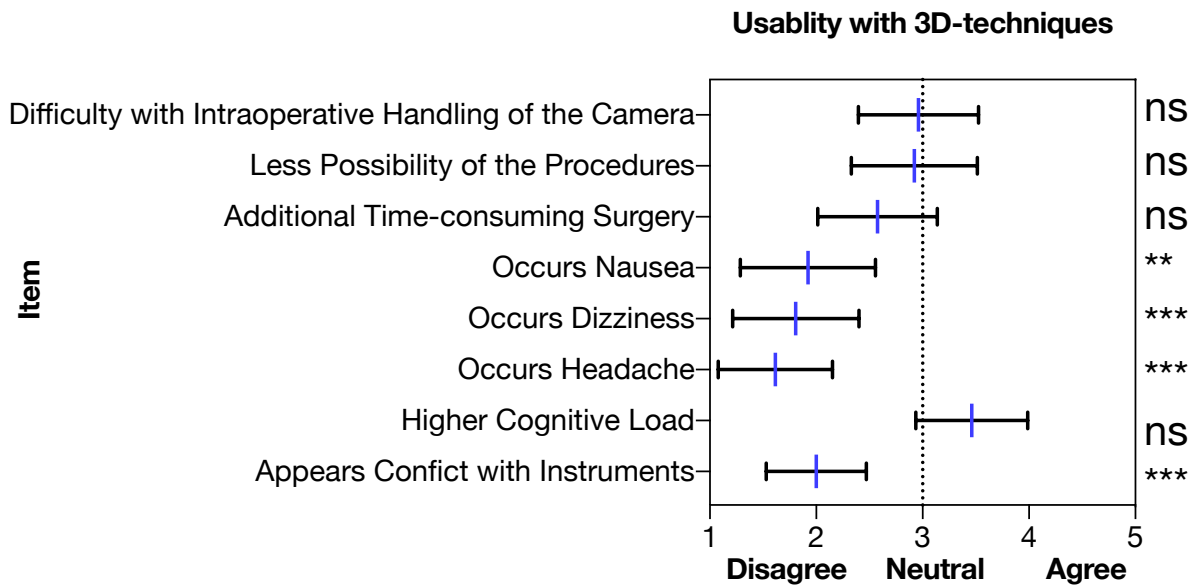


Figure 34. Results for usability properties of all sinuses with 3D-HD endoscopy compared to 2D-HD endoscopy (n=20). Data are shown with mean and mean with 95% CI, $p > 0.05$ (ns: non-significant), $p \leq 0.01$ (**), $p \leq 0.001$ (***); one sample t-test with a hypothetical mean of 3.0 was used

For usability aspects of all sinuses (Fig 34) participants concluded that 3D-HD technique showed better score to 2D-HD only in heading of “higher cognitive load” (mean 3.5; 95% CI [2.94, 3.99]). Participants felt difficulty to concentrate in dissection with the new 3D-HD technology due to limited experience. They were almost neutral to 2D-HD-techniques in headings of “difficulty with intraoperative handling of the camera” (mean 2.9; 95% CI [2.40, 3.53]), “less possibility of targeted procedures” (mean 2.9; 95% CI [2.33, 3.52]) and “additional time-consuming surgery” (mean 2.6; 95% CI [2.02, 3.14]). They didn’t have symptoms as “nausea” (mean 1.9; 95% CI [1.29, 2.56]), “dizziness” (mean 1.8; 95% CI [1.21, 2.40]), “headache” (mean 1.6; 95% CI [1.08, 2.15]) and disagreed upon the heading “appear conflict with instruments” (mean 2.0; 95% CI [1.53, 2.47]) with 3D-HD-technique.

To determine the significance of handling with 3D-HD endoscopy, we performed statistical analysis which revealed occurring of nausea ($p=0.002$), dizziness ($p<0.001$), or headache ($p<0.001$) and appeared conflict with instruments ($p<0.001$), sample mean was deviated significantly from the hypothetical mean of 3 towards 2D-HD technique. Participants concluded that during the surgery they didn't experience these features with 3D-HD endoscopy.

3.3.6 Advantages of 3D-HD-techniques

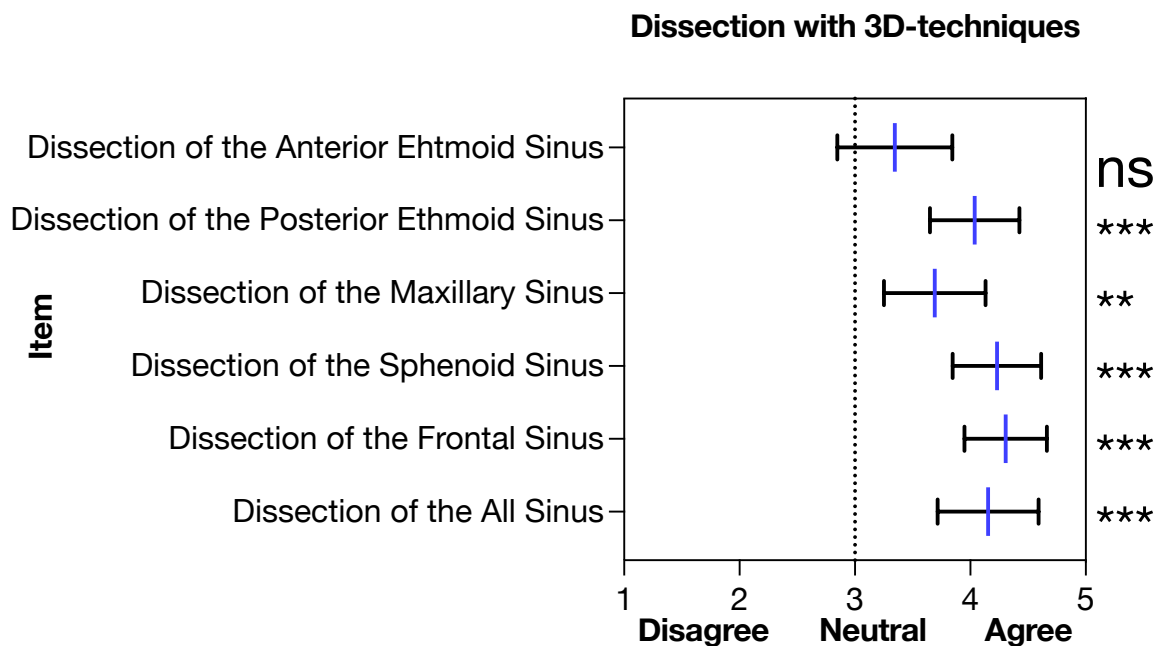


Figure 35. Results for dissections of all sinuses with 3D-HD endoscopy compared to 2D-HD endoscopy ($n=26$). Data are shown with mean and mean with 95% CI, $p>0.05$ (ns: non-significant), $p\leq 0.01$ (**), $p\leq 0.001$ (***); one sample t-test with a hypothetical mean of 3.0 was used

Descriptive analysis revealed that for dissection with 3D-HD-techniques, participants agreed on the fact that 3D-HD technique was superior to 2D-HD in headings of “dissection of the anterior ethmoid sinus” (mean 3.3; 95% CI [2.85, 3.84]), “dissection of the posterior ethmoid sinus” (mean 4.0; 95% CI [3.65, 4.43]), “dissection of the maxillary sinus” (mean 3.7; 95% CI [3.25, 4.13]), “dissection of the sphenoid sinus” (mean 4.2; 95% CI [3.85, 4.62]), “dissection of the frontal sinus” (mean 4.3; 95% CI [3.95, 4.67]) and “dissection of the all sinuses” (mean 4.2; 95% CI [3.72, 4.59]). Most of the less experienced participants were fascinated by the 3D-

HD-visualization and supposed to have better performance of dissection with 3D-HD endoscopy (Fig 35).

In dissection of the posterior ethmoid sinus ($p<0.001$), maxillary sinus ($p=0.003$), sphenoid sinus ($p<0.001$), frontal sinus ($p<0.001$) and all sinuses ($p<0.001$), statistical analysis presented the sample mean to be deviated significantly from the hypothetical mean of 3 towards 3D-HD technique. Participants agreed that during the surgery these features were better appreciated with 3D-HD endoscopy than with 2D-HD endoscopy.

3.4 Cadaver dissection course 2019 /Study on specimen 3D-HD vs 2D-4K

3.4.1 Use of different types of cameras by participants

Different types of camera used by participants

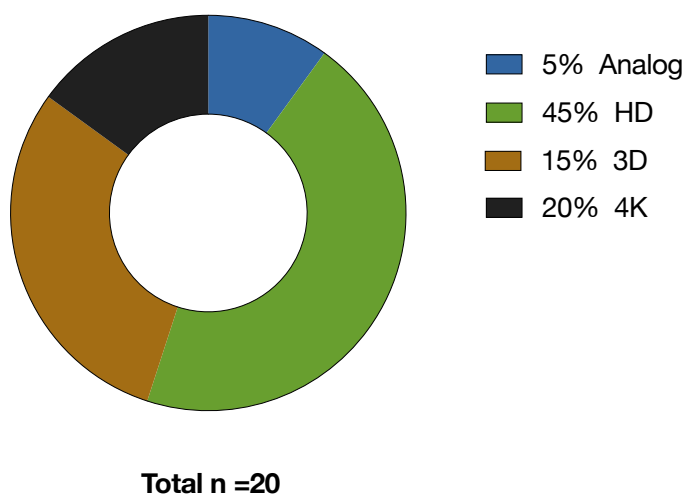


Figure 36. Different type of cameras used by participants in the form of a pie chart (total participants, n=20)

There were a total of 20 participants, whom we had asked regarding the type of cameras they were using in their daily practice for the sinus surgery. Total 9 of the participants were using HD (high definition) camera, 4 of them were already using 2D-4K camera, 3 of them were using 3D-HD camera and only one was using analog camera. There were 3 participants who were using 2 different types of cameras

3.4.2 Expectations of participants for the future imaging systems

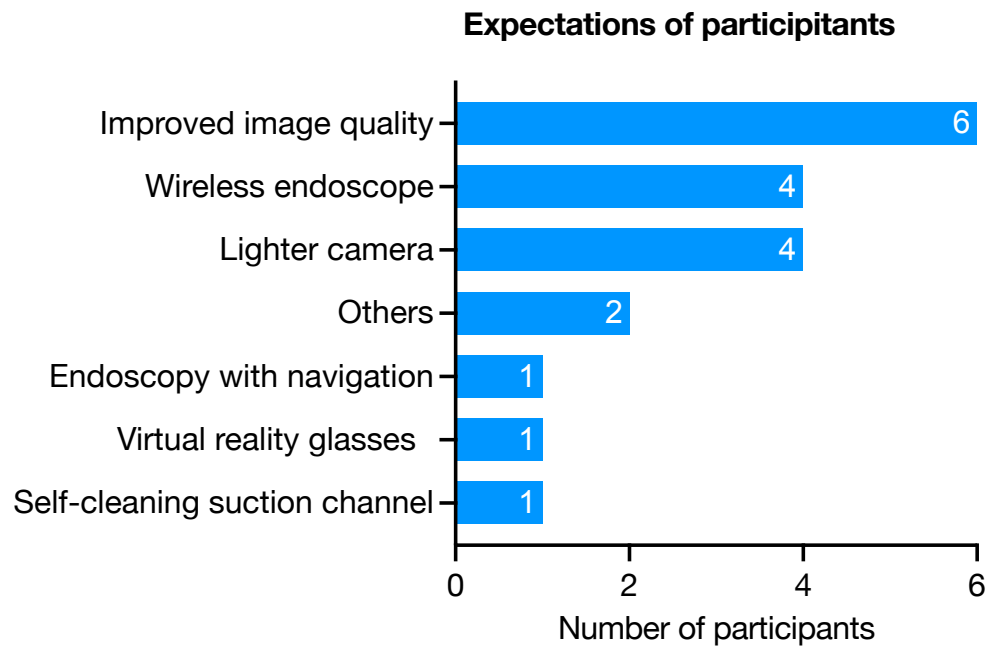


Figure 37. Representation of the expectations of the participants for the future imaging systems (total participants, n=26); the number in the bar diagram represents the number of participants with corresponding expectations

To all participants (n=26), we asked about their expectations about the advancement for future imaging system. 23% of them wishes about further improved image quality, as visualization is a best requirement for better surgery; 15% of them desiring about reduced weight of camera and wireless endoscope; and rest were individual wishes like endoscopy with navigation, virtual reality glasses and self-cleaning suction channel.

3.4.3 Time to locate and remove an object with 3D-HD- and 2D-4K-techniques

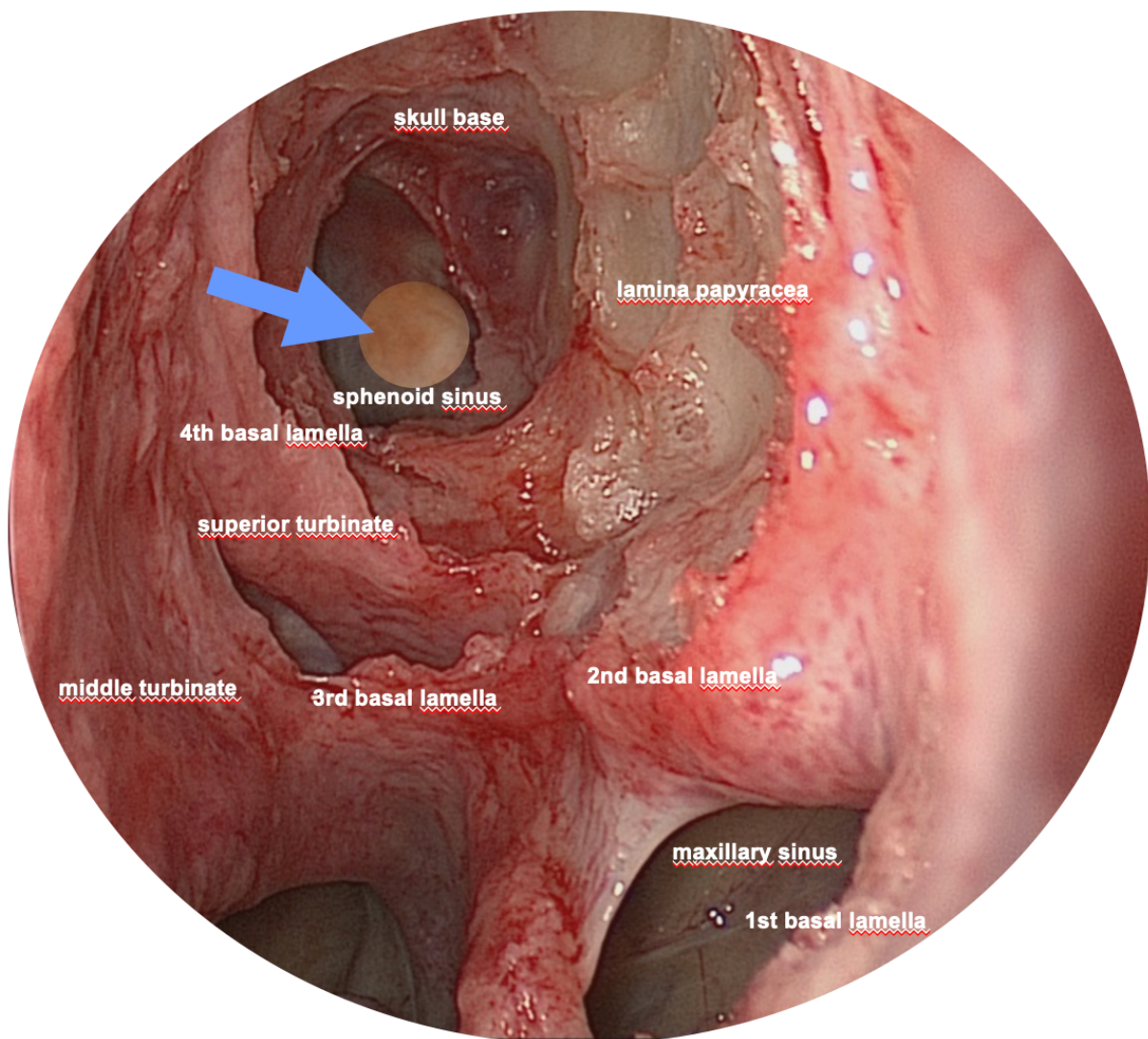


Figure 38. An object (a chickpea) located inside the sphenoid sinus (approximate location blue arrow). Participants were requested to place and remove it from the sphenoid sinus. Task completion time and imaging properties were evaluated

An endoscopic surgical task was designed putting an object (here a chickpea) inside the sphenoid sinus in a specimen. This technique provided an easy model of the operating setting in comparison to a simple box trainer or in an anatomical model. Participants were instructed and trained about the 3D-HD- and 2D-4K-system and were explained about their task before the starting of the procedure. We had provided chickpeas to the participants and their task was to place the chickpea inside the sphenoid sinus on ipsilateral side with 3D-HD technique and on the contralateral side with 2D-4K technique in the cadaver. Side selection was done randomly, but each participant must have used both the techniques so that the comparison between 3D-HD und 2D-4K was possible.

The time taken to locate and remove the object was recorded; and after the completion of procedure, a questionnaire was set up asking participants' perception on the use of 2D-4K techniques in endoscopic sinus surgery. Easiness of 2D-4K techniques were compared with the 3D-HD technique using a Likert scale.

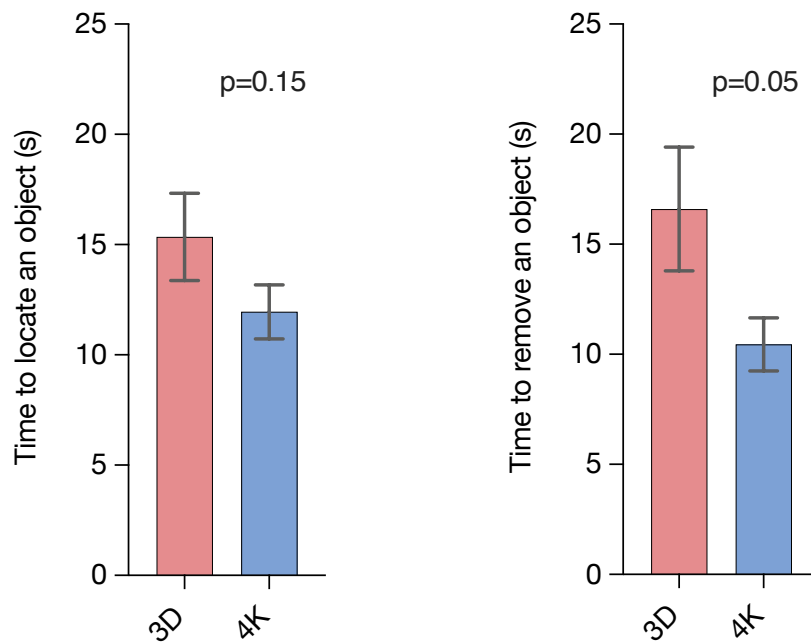


Figure 39. Results of time to locate and remove an object (a chickpea) using 3D-HD- and 2D-4K-techniques presented with mean±SEM (Left graph: n=20 for both 3D-HD & 2D-4K; right graph: n=20 for both 3D-HD & 2D-4K); two-tailed student's t-test was used, both tests were non-significant

In total 20 participants who were requested to place an object (a chickpea) in sphenoid sinus, reported the time taken to locate an object in sphenoid sinus using 3D-HD-techniques (15.4±2.0) was longer than 2D-4K-techniques (12.0±1.2). However, it was not significant (p=0.15) statistically. Hence, there was no significant difference between the use of 3D-HD und 2D-4K in time required to accomplish the task.

Similarly, time taken to remove an object in sphenoid sinus using 3D-HD-techniques (16.6±2.8) was longer than 2D-4K-techniques (10.5±1.2). However, it was only borderline significant (p=0.05). Hence, there was a trend towards a difference between the use of 3D-HD

and 2D-4K in time required removing the object. Overall, in both instances there is an apparent trend towards faster task completion with 2D-4K compared to 3D-HD endoscopy.

3.4.4 Total task completion time with 3D-HD- and 2D-4K-techniques in comparison to routinely practicing other endoscopy-techniques

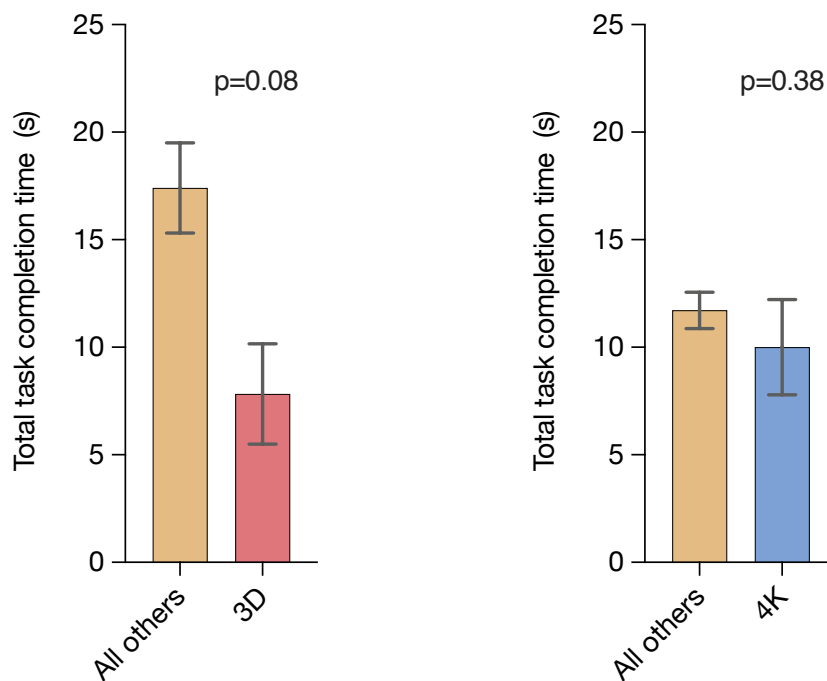


Figure 40. Results of total task completion time (time to locate and remove an object) using 3D-HD- and 2D-4K-endoscopy in comparison to routinely practicing endoscopy presented with mean±SEM (Left graph: n=17 for all others, n=3 for 3D-HD; right graph: n=14 for all others, n=6 for 2D-4K); two tailed student's t-test was used, both tests were statistically not significant

The total 20 participants who were requested to take part in task completion procedure, one side with 3D-HD-techniques and other side with 2D-4K-techniques. And we evaluated the total task completion time with respect to the mode of endoscopy they were regularly using throughout the year. Users already using 3D-HD endoscopy camera (7.8 ± 2.3) were trending towards being faster ($p=0.08$) in task completion with 3D-HD endoscopy than users using other (analog, HD, 2D-4K) endoscopy cameras (17.4 ± 2.1) in their regular practice.

Similarly, users already using 2D-4K endoscopy camera (10.0 ± 2.2) were not faster in task completion with 2D-4K endoscopy than users using other (analog, HD, 3D-HD) endoscopy cameras (11.7 ± 0.8) in their routine use, this finding was not significant ($p=0.38$).

3.4.5 Imaging properties of 2D-4K in comparison to 3D-HD

The subjective perception of imaging after the dissection has been explained in the following paragraphs. We have designed a graph which is similar to forest plot where 3 points on the x-axis indicates 3D-HD is equivalent to 2D-4K on the questionnaire. All features were assessed on a 5-point Likert scale where 1 indicates 3D-HD is superior to 2D-4K and 5 indicates 2D-4K is highly superior to the 3D-HD system.

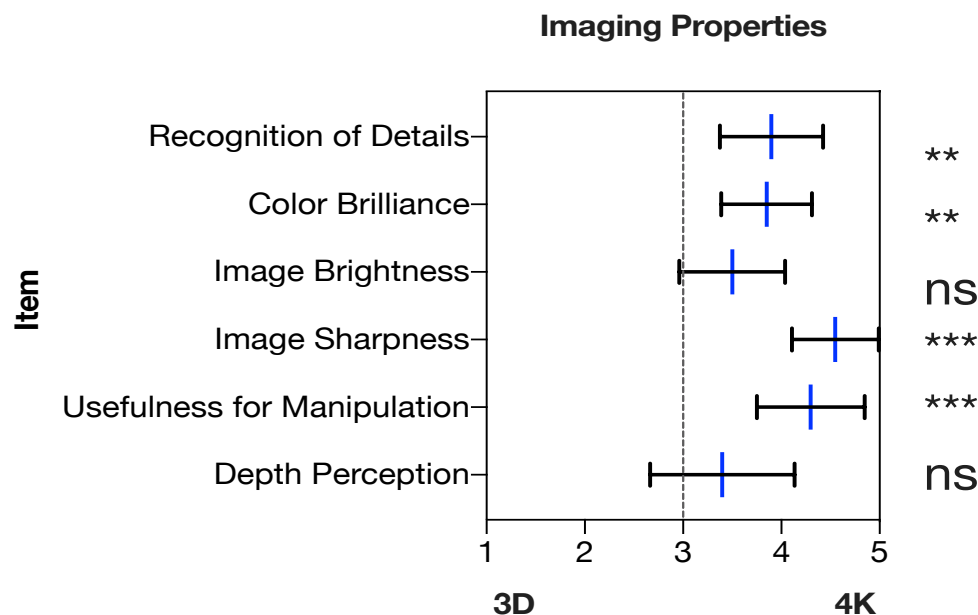


Figure 41. Results for imaging of all sinuses with 2D-4K endoscopy compared to 3D-HD endoscopy ($n=20$). Data are shown with mean and mean with 95% CI, $p>0.05$ (ns: non-significant), $p\leq 0.01$ (**), $p\leq 0.001$ (***); one sample t-test with a hypothetical mean of 3.0 was used

The results of the questionnaire regarding imaging properties of 3D-HD- and 2D-4K-endoscopy systems by all participants participated in the study has been summarized in Fig 41.

As we descriptively analyzed the imaging aspects of all studied sinuses (Fig 42), the results yielded the superiority of 2D-4K over 3D-HD in all features including “recognition of details” (mean 3.9; 95% CI [3.38, 4.31]), “color brilliance” (mean 3.9; 95% CI [3.39, 4.31]), “image brightness” (mean 3.5; 95% CI [2.96, 4.04]), “image sharpness” (mean 4.6; 95% CI [4.11,

4.99]), “usefulness of manipulation” (mean 4.3; 95% CI [3.75, 4.85]) and “depth perception” (mean 3.4; 95% CI [2.67, 4.14]). This could be explained by the fact that the high resolution of 2D-4K system reflected to improve visualization of the paranasal sinuses.

Additionally, we performed the statistical test to check the significance between 2D-4K- and 3D-HD- endoscopy systems. The results revealed that in headings of recognition of details (p=0.002), color brilliance (p=0.001), image sharpness (p<0.001) and usefulness for manipulation (p<0.001), sample mean deviated significantly from the hypothetical mean of 3 towards 3D-HD technique. Participants concluded that during the procedure, these features were better reflected in 2D-4K endoscopy than in 3D-HD endoscopy. However, image brightness (p=0.07) and depth reception (p=0.27) were not significantly better in 2D-4K. Overall, the imaging qualities of the 2D-4K technique evaluated were significantly superior over 3D-HD technique.

3.4.6 Imaging of paranasal sinuses with the 3D-HD- and 2D-4K-endoscope during dissection

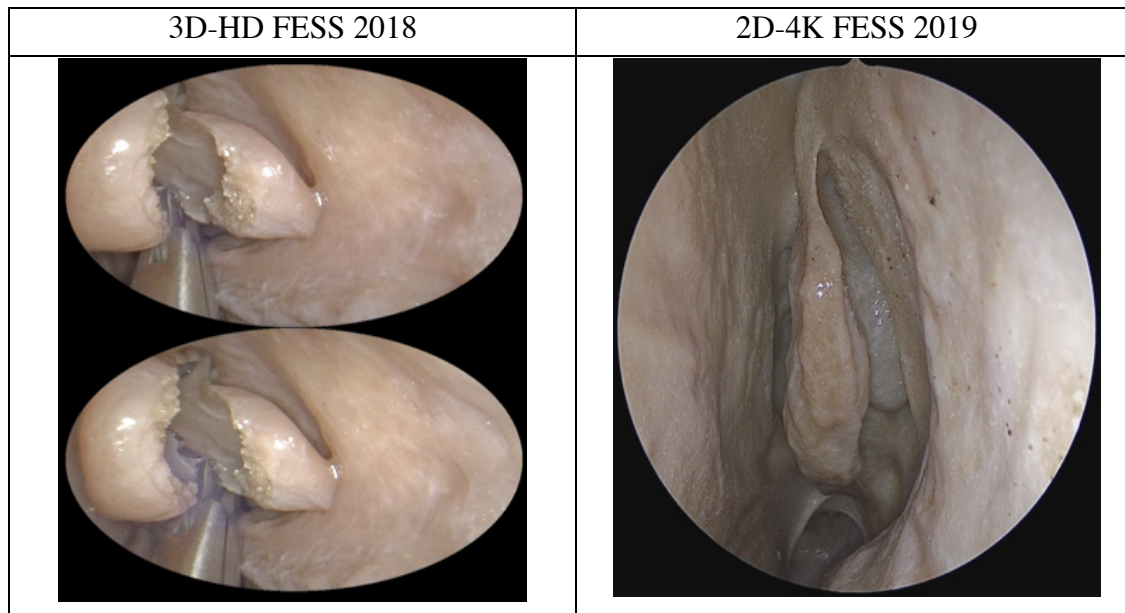


Figure 42. Images of different parts of the paranasal sinuses showing the comparison of 3D-HD- and 2D-4K endoscopy in cadavers

3D-HD images where anatomical understanding, depth perception were superior to 2D-4K

2D-4K images where color brilliance, image sharpness and overall image quality were superior to 3D-HD

4. Discussion

4.1 Socio-demographic profile of the patients

In order to compare the data collected from the present study with the results of other similar studies, we have compared the key characteristics from the patient's demographic profile with those from other studies.

The age distribution of patients from the present study basically corresponds to other studies that had performed surgeries with 3D-HD-endoscopy, both in the range (12-69 years) and in the mean value (41.8 years) (67-73). Albrecht T. et. al. for example reported the mean age to be 46.3 ± 16.7 years in a three-dimensional study among patients undergoing FESS evaluation (67). The reports are in congruence with the present study.

While assessing the gender distribution, the present study contains fewer women than men (almost 1: 2). In congruence to the present study, a 3D-HD study has shown a similar gender ratio as reported by Tabae A et. al. (69). Contrasting results with the present study with reversed gender distribution was observed in a study published by Kari E. et. al. (70). These differences could be possibly explained by the small subset of patients taken for the study. On the other hand, it is a random selection as all patients were included sequentially in a cross-sectional manner within a period of time. Overall, both the age and gender distribution can be viewed as representative.

Preoperative endoscopic diagnosis belongs to the standard procedure in the paranasal sinus surgery. This permits both the examiner and the assistant to make a direct comparison with the previous records and thus helps to provide a better outcome of the procedure.

The present study has emphasized on the endoscopic findings in comparison to the 2D-HD and 3D-HD technology. The endoscopic findings shown here have emphasized on the fact that patients presenting with features of chronic rhinosinusitis often have nasal polyps, hyperplastic inferior nasal turbinate and/or septal deviation.

A prior radiological diagnosis is required for an optimal intraoperative anatomical orientation in order to avoid injuries to the bordering structures. Nowadays, the use of computer-aided

navigation systems appears to be not only reasonable, but also essential for complex interventions on the anterior and lateral skull base surgeries. To deliver quality health care service; high priority in such training should be emphasized (74).

The data described in the present study has demonstrated that all patients were operated with the support of computer-aided navigation systems with 3D-HD-reconstruction of the paranasal sinuses. Oeken J et. al has similarly described data with intra- and postoperative outcomes by use of a navigation system (75).

In the present study, the indication for surgical intervention was mostly chronic rhinosinusitis (CRS) with nasal polyps. Nasal polyps were further subdivided into two subgroups: ethmoidal polyposis and aspirin-induced nasal polyposis. In one patient there was an additional sphenoid sinus fungal ball. The histopathology analysis revealed in 45 % of the surgically treated patients eosinophilia (>200 eosinophils per x40 objective-visual field). The exception of such study is a laboratory based experimental study showing comparison of various fields of view (76). Other studies have indications comparable to the present study (67, 68).

In the present study, the methodology intends to compare the two sides of nasal cavity among performed operations. In every case, the procedure was made uniform while comparing the two sides of nasal cavity and air sinuses. The requirements for a standard operating procedure were basically fulfilled. A proper documentation of the findings was done.

However, some published literatures concerning 3D-HD endoscopy techniques have similar sample size (69, 77). Many published studies have compared the sinuses on a case and control basis rather than on a single patient basis (67, 72). In contrast to the present study, some studies have published literature with significantly higher number of cases (68, 71). Barkhoudarian G et. al. has published a paper on 160 operations of 3-dimesnsional endoscopy in transsphenoidal surgery over a period of 18 months (45). While comparing the current study with published literatures, there are varieties of categories including prospective clinical studies (67, 70) or retrospective studies (69, 71, 72). A study similar to the present study published by Tomazic PV et al included a total of 80 patients where 70 ethmoid, 70 maxillary, 60 sphenoid and 61 frontal sinuses were evaluated (68).

Limited sample size of 20 patients could be a major limitation of the present study. As the study is a part of dissertation, only limited patients have been enrolled in this representative

study. However, the good methodology of the present study with paired samples of 2D-HD-3D-HD-model comparison could yield an informative value. Considering this as a pilot study, if a future study could be carried out with adequate sample size, a crucial and practice changing knowledge might be obtained.

4.2 Evaluation of methodology and data collection

Tomazic PV et al published a prospective randomized multicentric study in 2020 evaluating 80 patients with chronic rhinosinusitis with or without polyps comparing the 2D-HD endoscopy to 3D-HD technology in functional endoscopic sinus surgery (FESS) (68). They concluded that the 3D-HD endoscope had improved depth perception and better recognition of anatomic details but inferior overall picture quality. However, 2D-HD techniques delivered a better outcome in terms of feasibility for routine endoscopic approaches.

The study design of the present study also concerns the total operative time between the 2D-HD- and 3D-HD-endoscopy techniques and analysis of the operative field by surgeon's perception.

With regard to such comparative 3D-HD-studies, two fundamentally different methodologies have been identified in the literature. Some researchers prefer the inter-individual comparison, which means that one group is operated with the 3D-HD-technique and the other control group with the 2D-HD-technique; in order to compare two diverse groups with one another (67, 69-71). An alternative is the intra-individual comparison, where the difference within an individual is obtained. Such interrelation of the data within an individual may result in two essential advantages: firstly, better statements about imaging can be obtained with a smaller number of patients; and secondly, the large inter-individual anatomical variance of the paranasal air sinuses or socio-demographic variables can be avoided. For these reasons, the present study was carried out comparing the two sides of paranasal sinus in intra-individual basis. Literature search revealed several other studies which have chosen similar method, both in clinical and laboratory setups (77, 78). A possible disadvantage of such intra-individual comparison could be the fact that only patients with bilateral surgical indications could be included in the study for ethical consideration. Additionally, the socio-demographic variables and operative data studied here were obtained exclusively by one surgeon in order to minimize various confounding biases. Such advantages of the present study lead to standardization and thus to

improved comparison of various variables and therefore has a robust methodological advantage.

A partially double-blind method was used in the present study. Before the start of surgery, neither the patient nor the surgeon knew the type of the technique used for intervention. From this fact, a high level of validity of the data is expected to be derived.

The present work uses the 5-point Likert scale to measure the imaging and usability properties which are generally difficult to evaluate. Certain subjective perception like recognition of details or comfort feelings of the surgeon like nausea or headache after the surgery could provide some confounding bias. Such method of data collection using a questionnaire based on 5-point Likert scale was easy to use and had also proven it better in numerous other 3D-HD related studies (67, 79, 80). We also have incorporated this Likert scale method in our experimental laboratory-based study with 3D-HD- and 2D-4K-endoscopy techniques.

In the following Table 5 provide an overview of three-dimensional studies that were in used in different parts of the body.

Table 5: Comparative studies showing the comparison of 2D-HD-, 3D-HD- and 2D-4K- endoscopy including number of participants, type of study, measures done, and results obtained.

Author, Years	Participants	Study type	Measures	Results
2D-HD vs 3D-HD patients				
Tabaee et al. 2009 (69) Clinical	13 patients 2 surgeons	Retrospective, comparative, matched study; 2D-HD vs 3D-HD; resection of endoscopic pituitary surgery	Safety, possibility, depth, perioperative variables	Improved depth perception with 3D-HD; no differences in operative time, hospital stay, resection & complication rate
Kari et al. 2012 (70) Clinical	58 patients (32 in 2D-HD group 26 in 3D-HD group)	Prospective randomized comparison study; 2D-HD vs 3D-HD; endoscopic pituitary surgery	Stereoscopic vision, peri-and postoperative factors	Improved depth perception with 3D-HD; no change in operative time, hospital stay, endocrine, readmission
Barkhoudarian et al. 2013 (71) Clinical	160 patients (95 in 2D-HD group 65 in 3D-HD group)	Retrospective, comparison study; 2D-HD vs 3D-HD; 3D-HD in transsphenoidal surgery	Operative time, CSF leak, hospitalization days, readmission	3D-HD-endoscope surgically more efficient & shorter learning curve
Albrecht et al. 2016 (67) Clinical	46 patients, 4 surgeons	Prospective randomized comparison study; 2D-HD vs 3D- SD vs 3D-HD	Operative time, depth perception, sharpness & brightness of image, comfort	Shorter operative time with 3D-HD; depth perception: 3D-HD>3D-SD>2D-HD; brightness: 3D-HD >2D-HD>3D-SD
Sørensen et al. 2016 (58) Clinical	340 articles screened 31 RCT included	Metanalysis, randomized controlled trials; 2D-HD vs 3D-HD laparoscopy	Operative time number of errors	Improved surgical speed & reduction in errors with 3D-HD laparoscopy
Molinari et al. 2020 (79) Clinical	34 patients	Comparison study; 2D-HD vs 3D-HD endoscopic ear surgery	Surgical approach, type, operative time, outcomes, complications, subjective feelings	Longer operative time with 3D-HD; superior depth perception, improved view of anatomy & pathology with 3D-HD

Van Gompel et al. 2014 (76) Laboratory + clinical	5 patients	Prospective comparison study; 2D-HD vs 3D-HD	Field of view	Reduction of field of view with 3D-HD both in Lab & in patients
Inoue et al. 2013 (77) Laboratory + clinical	16 patients 43 examinees (16 novices 21 beginners 6 experts)	Comparison study; 2D-HD vs 3D-HD; neuroendoscopic surgery	Time, total path length, subjective feelings	Improved perception & task performance with 3D-HD; shortening the learning curve with 3D-HD
Zaidi et al. 2016 (81) Laboratory + clinical	26 articles (14 clinical 5 environmental 5 cadaveric 2 expert opinions)	Metanalysis 3D-HD-endoscopy for ventral skull base pathology	Depth perception, spatial orientation, anatomical structures	3D-HD provides improved surgical dexterity with better depth perception
2D-HD vs 3D-HD labor				
Fraser et al. 2009 (82) Laboratory	33 neurosurgeons and otolaryngologists	Randomized comparison study; 2D-HD vs 3D-HD; two runs of task-based simulator paradigm using 2D-HD and/or 3D-HD	Speed, efficiency and error rate	Increase in efficacy & speed with 3D-HD; 75% preferred 3D-HD; 87.5% said the 3D-HD helped
Shah et al. 2011 (78) Laboratory	8 patients, 15 surgeons (6 novices, 9 experts)	Comparison study; 2D-HD vs 3D-HD; 5 standardized tasks: incision, ring transfer, nerve hook, distance estimation	Errors, time, distance estimation, preference	No difference in error rate; novices superior at hook transfer; distance estimation precise with 3D-HD; novices preferred the 3D-HD
Kawanishi et.al 2013 (83) Laboratory	30 novices	Comparison study; 2D-HD vs 3D-HD; Group A: Task 1- 3D-HD to 2D-HD, Task 2- 2D-HD to 3D-HD & Group B: vice-versa	Performance accuracy, speed	Better accuracy & speed; lower inaccuracy rate & performance time when 3D-HD included

Marcus et al. 2014 (84) Laboratory	10 surgeons (novices)	Randomized comparison study; 2D-HD vs 3D-HD & HD vs SD	Time, accuracy, workload perception, subjective impression	Time to task completion & depth perception superior with 3D-HD; probe placement accuracy & image quality superior with HD; novices preferred the 3D-HD & HD
Ogino-Nishimura et al. 2015 (85) Laboratory	5 specimens, 73 surgeons (63 otolaryngologists, 10 neurosurgeons)	Retrospective comparison study; 2D-HD vs 3D-HD; 3D-HD ESS, 3D-HD EPS, 2D-HD ESS	Operative time, bleeding, efficacy, subjective feelings	Time & bleeding not inferior with 3D-HD; improved anatomical understanding of the posterior structures of the sinuses & skull base with 3D-HD
Rampinelli et al. 2017 (86) Laboratory	68 surgeons (50 novices, 18 experts)	Randomized comparison study; 2D-HD vs 3D-HD; 2 tasks: grasping & dissection	Time, subjective feelings	Execution time & effectiveness of surgical maneuvers superior with 3D-HD; novices preferred 3D-HD
Ten Dam et al. 2020 (87) Laboratory	2 specimens, 30 novices	Randomized comparison study; 2D-HD vs 3D-HD	Efficiency, distance, velocity, accuracy, subjective feelings	Imaging properties superior with 3D-HD; efficiency & accuracy not significantly better with 3D-HD
3D-HD vs 2D-4K				
Rigante et al. 2017 (80) Clinical	22 patients	Analysis of pros and cons of 2D-4K in skull base surgery (2D-4K vs 2D-HD & 3D-HD)	Operative time, follow-up days, hospitalization days, physical strain	Recognition of anatomical & pathological structures superior with 2D-4K, operative time & physical strain same with 2D-HD & 3D-HD
Uozumi et al. 2020 (72) Clinical	86 patients	Retrospective comparison study; 2D-SD vs 3D-HD vs 2D-4K	Operative time, surgical accuracy	3D-HD beneficial for intranasal phase, 2D-4K beneficial for intradural phase; operative time &

				accuracy: 3D-HD> 2D-4K> 2D- SD
Khanna et al. 2018 (88) Laboratory	49 articles	Metanalysis, Articles related to endoscopic sinus surgery (ESS)	Speed, safety, outcome	Reduced operative time & hospital stay with new techniques; 2D-4K UHD improved visualization
Abdelrahmen et al. 2018 (89) Laboratory	24 novices	Comparison study; 2D-HD vs 3D-HD vs 2D-4K; laparoscopic surgery	Time, errors, repetitions number, side effects	Improved accuracy with 2D-4K, Improved performance with 3D-HD & 2D-4K than 2D-HD

4.3 Results

The following discussion is based upon comparison of results obtained from the present study with existing literature. It intends to compare the aspects of operative time, imaging and usability properties in regard to 2D-HD- and 3D-HD-endoscopy techniques.

4.3.1 Time of surgery with 2D-HD- and 3D-HD techniques

Table 6: Comparative studies of 2D-HD- and 3D-HD-endoscopy (OT: operative time, ns: not significant)

	Tabee et al 2009 (69)		Kari et al 2012 (70)		Barkhoudarian et al 2013 (71)		Albrecht et al 2016 (67)		Uozumi et al 2020 (72)		Molinari et al 2020 (79)		Sørensen et al. 2016 (58)		Present study	
	Transsphenoidal surgery						FESS		Endonasal skull base surgery		Ear		Laparoscopy		FESS	
	2D-HD	3D-HD	2D-HD	3D-HD	2D-HD	3D-HD	2D-HD	3D-HD	2D-SD	3D-HD	2D-HD	3D-HD	2D-HD	3D-HD	2D-HD	3D-HD
OT (min)	143.5	142.6	162.6	146.4	157.6	149.4	3D-HD shorter time ns		34.4	27.1	85.0	99.0 ns	71 % reported reduced performance time with 3D-HD		33.1	37.9 ns

When compared to the existing literature, the total time of surgery with the 3D-HD-endoscopy technique was found to be longer than with the 2D-HD-endoscopy. In contrast the present study has shown that the operative time did not differ significantly between the two-techniques. This could be partially explained because of the limited number of samples included. It could also be reasoned as the changing of the endoscopes with the 3D-HD endoscopy system needs to be plugged in at the support whereas in 2D-HD-endoscope the surgeon can easily change angled scopes own self. Another recognized disadvantage with the 3D-HD technique is that the surgeon needs to wear a 3D-glass during the surgery continuously. Additionally, there are chances of fogging of lenses easily and thus the user needs to clean the lenses regularly which can prolong the total time of surgery. One general comment for this can be made as the surgeon is less familiar with such new commercially available 3D-HD-endoscopy system, such problems of adaptation may occur. While for the 2D-HD-endoscopy system it is being used since many years.

For paranasal sinus surgery there are paucity of published literatures concerning the effectiveness of 3D-HD techniques in functional endoscopic sinus surgery (FESS) and

comparing their utility and clinical value to traditionally used 2D-HD techniques. Albrecht T et al published a paper in 2016 which was prospective, a randomized, controlled clinical study involving 46 patients with polypoid chronic rhinosinusitis who underwent FESS (67). The primary objective was to evaluate the three-dimensional visualization during FESS. The FESS procedure was carried out by four surgeons with three different types of endoscopes: 2D-HD, 3D-SD and 3D-HD. The total operative time between all three endoscope groups in cases that received bilateral infundibulotomy, ethmoidectomy and maxillary antrostomy was recorded and evaluated. And there were no significant differences in the total operative time between 3D-SD and 3D-HD (studied group) in comparison with the 2D-HD (control group). However, an inclination towards a shorter operative time in the 3D-HD group was observed. This shorter total time of surgery with 3D-HD than with the 2D-HD technique in this quoted study contrasts to the present study. This could be explained by their inter-individual evaluation in contrast to our intra-individual evaluation, and less is known regarding the severity of diseases in the study published by Albrecht T et al. They compared the operative time of 8 bilateral total sinus surgeries with 3D-HD and 5 bilateral total sinus surgery with 2D-HD and concluded that the total operative time (surgical procedure including set up) was shorter with 3D-HD techniques. The present study however described 20 bilateral total sinus surgery on the ipsilateral side with 2D-HD-technique and the contralateral side with 3D-HD technique. This could have resulted in longer time of surgery with 3D-HD technique. Such shorter operative time with 3D-HD technique was also supported by Uozumi et al. in their article published in the year 2020; where they concluded that the operative time for the nasal phase with the 3D-HD endoscopy was significantly shorter than that of the 2D-SD endoscopy (72). Also, there was no difference in operative time of the sphenoidal phase between the 2D-SD and 3D-HD systems. They operated a total of 12 patients with 2D-SD techniques and 14 patients with 3D-HD and made an inter-individual comparison. We could less compare this study with the present study because of varying techniques they used for surgery of pituitary adenomas. Overall, they have demonstrated significant clinical benefits of 3D-HD system over 2D-SD system during endoscopic endonasal surgery.

Similarly, Tabaee et al, Kari et al and Barkhoudarian et al performed comparison of 2D-HD- and 3D-HD-neuroendoscopy for trans-sphenoidal surgery and calculated the total average operative time (69-71). They concluded that the total operative time was shorter with 3D-HD endoscope but there were no significant differences between both the techniques. The reason

behind the shorter operative time in these studies with 3D-HD endoscope in trans-sphenoidal surgery could be because of the proper view of deeper structures with improvement in recognizing the carotid and optic protuberances in the lateral sphenoid sinus with the 3D-HD endoscope. They recommended 3D-HD endoscopy technique as a beneficial alternative to the 2D-HD endoscopy for the trans-nasal anterior skull base surgery. And the surgeon can really perform faster with the 3D-HD technique faster. In contrast to the trans-sphenoidal study, where critical structures are located in deeper anatomy, the present study concerning paranasal sinuses; the anterior ethmoid sinus and maxillary sinus which are not that deep anatomically. They could be operated in a faster manner with a 2D-HD endoscopy technique.

Several other investigations with 3D-HD surgery in other parts of the body have been reported about positive outcomes in terms of shorter operative time; mostly from 3D-HD laparoscopy and urology related studies (58, 90, 91). These surgeries are more frequently performed than paranasal sinus surgeries. Also, advancement of technologies in these disciplines and their consistent use for decades has added extra value to it. In contrast to neuro-endoscopy, laparoscopy and cystoscopy related studies, a study concerning 3D-HD endoscopic surgery in the ear canal published by Molinari et al, compared the 3D-HD to 2D-HD endoscopy technologies. Their results have demonstrated longer operative time with 3D-HD group which was less statistically significant when compared to the 2D-HD group (79). This study is in congruence with results from the present study with longer operative time with 3D-HD technique. The reason for this could be because of paucity of studies with larger sample size regarding endoscopic ear surgery and endoscopic sinus surgery. Also, there are less advancement in these technologies of these areas in comparison to other frequently operated parts of the body.

With regard to the FESS surgery in the present study, it can be summarized that surgery with 3D-HD-endoscopy does not necessarily shorten the procedure than with the 2D-HD-endoscopy technique. A significant difference between the two techniques was therefore not demonstrated in statistical analysis. Moreover, we would like to emphasize that, a limited sample size could have provided a less representative data set.

4.3.2 Imaging properties

Imaging poses an immense role in the evaluation of paranasal sinus surgery. After the development of two-dimensional (2D-HD) endoscopes, these endoscopic techniques have set a milestone in the visualization of the surgical field of paranasal sinuses and anterior skull base surgery. Many studies have shown superiority of endoscopic techniques to microscopic techniques (92, 93). Also, during anterior skull base surgery, various outcomes of endoscopic techniques have proven significant compared to microscopic techniques (94). The microscopic technique provides a three-dimensional image, but it lacks visibility and maneuverability at different angles. Also, the 2D-HD endoscopic techniques have less ability of providing three-dimensional image (67). The latest technology of 3D-HD endoscope is thus supposed to overcome this inability of the 2D-HD endoscopes with better visualization of the surgical field.

The present study tested the hypothesis that 3D-HD endoscopy technique shows superior imaging features in comparison to the 2D-HD endoscopy during functional endoscopic sinus surgery (FESS). It is possibly the first study in individual patients comparing intra-individual 2D-HD and 3D-HD endoscopy views. A single surgeon operated all patients with the 2D-HD- and 3D-HD-endoscopes devised from KARL STORZ® focusing on imaging of all four paranasal sinuses. Immediately after each the surgery the surgeon had filled up the forms containing questions regarding the imaging properties.

As the present study had predicted, the 3D effect was better in 3D-HD endoscopy system. While comparing other properties of imaging in headings as recognition of details, anatomical understanding and depth perception were superior with 3D-HD endoscopy than in 2D-HD endoscopy technique. Among all sinuses, the recognition of details in maxillary sinus was perceived slightly better with 2D-HD endoscopy. This could be explained by the fact that maxillary sinus has smooth anatomical structure and lacks bulging structures for example carotid prominences or optic nerve in sphenoid sinus. Additionally, frontal sinus and sphenoid sinus showed the better score in depth reception, meaning that surgeon had better visualization of optic nerve and carotid artery, which provides additional advantages during endoscopic sinus surgery or skull base surgery. In contrast, 3D-HD endoscopy showed slightly distorted image and it used to get easily fogged in its lenses. Headings as color brilliance, illumination and size of the field were superior in 2D-HD technique than in 3D-HD endoscopy technique.

There are limited published articles in English literature which have compared the 2D-HD endoscopy technique to 3D-HD endoscopy in a clinical setup. Majority of the studies have focused on the non-clinical feasibility of 3D-HD endoscopy and have thus operated in experimental settings. A pilot study was performed by Manes et al (73) in the year 2011 to evaluate the usefulness of 3D-HD endoscopy for paranasal and skull base surgery. After performing a surgery among 7 patients, they concluded that the 3D-HD endoscopic system provides improved depth of perception and reduced complications. In 2016, Albrecht et al. (67) compared the 2D-HD to 3D-SD and 3D-HD and analyzed various approaches. They concluded that 3D-HD had offered a significantly better depth perception and 2D-HD presented significantly better image brightness. Also, image sharpness was almost same in both the techniques. Uozumi et al. (72) in the year 2020 concluded the usefulness of 3D-HD due to its better depth perception in the nasal phase and they suggested the use of 3D-HD when normal anatomical structures were badly damaged and are difficult to see with 2D-HD endoscope. Barkhoudarian et al. (71) made an analysis of neurosurgical case series among 160 patients who underwent endoscopic parasellar surgeries with the 3D-SD and 2D-HD endoscopy system and concluded the superior subjective application of 3D endoscope during pituitary adenoma resection. They recommended it to be a convenient alternative to the 2D endoscope for transnasal anterior skull base surgery. Like in the present study, all these studies agreed regarding the better recognition of details and depth perception with 3D-HD endoscopy. According to Van Gompel et al. (76), who compared the field of view between 2D-HD and 3D-HD endoscopy; 3D-HD endoscopy technique showed 55% loss of field view. They first performed an experiment in a laboratory setting and later on confirmed their result by performing surgeries in 5 patients. The result from the present study also agreed upon this study with reduced size of field with 3D-HD endoscopy.

Studies addressing other body parts like the study published by Molinari et al. (79) compared the 3D-HD to 2D-HD technology in endoscopic ear surgery (EES). They concluded that the 3D-HD endoscopy system offered better views of both anatomy and pathology of the middle ear, with improved depth perception. Komaei et al. (95) reviewed 10 similar papers and studied the advantages and disadvantages of 3D-HD and 2D-HD laparoscopic cholecystectomy. They concluded that the 3D-HD laparoscopic system showed better depth perception than the 2D-HD system.

4.3.3 Usability properties

In the present study, before starting the surgery with 3D-HD endoscopy technique, both the surgeon and assistant were well instructed and trained about the 3D-HD endoscopy system in order to avoid relevant bias of 2D-HD endoscopy system, which they have been using since many years. As described in the heading of imaging properties above; after each surgery surgeon used to fill up relevant form containing the questionnaire regarding its usability properties. With regard to the usability properties, 3D-HD technique was found superior to 2D-HD only in the heading of weight of endoscope. This advantage of 3D-HD endoscopy system can be justified by the low weight of the new 3D-HD endoscope (TIPCAM 0° 30° 45°= 295g); whereas 2D-HD endoscopes have heavier weight (camera head HD weight= 270 g + endoscope weight 0°=68g, 30°=72g, 45°=72g). There are some documented disadvantages of 3D-HD endoscope as well. For example, because of its single piece consisting of scope and camera, surgeon either must turn the endoscope upward or laterally during angled endoscopy which might rotate the entire image, or he must change the positioning of the scope digitally. Other known disadvantages of 3D-HD endoscopy technique are the intraoperative handling of the camera. As the surgeon needed to wear polarizing glasses constantly, changing of the scopes was frequent, and a longer time for preoperative preparation and easy fogging of the lens were also experienced. This was because of the blood splash in the tip of the endoscope, which made an additional effort of cleaning in between surgery. In the present study, the surgeon did not experience any asthenopic symptoms like nausea, headache and dizziness because of 3D-HD visualization system. This could be related to the shorter duration of surgery and small surgical field of the paranasal sinuses.

There are again limited papers published till date which have compared the usability aspects of 2D-HD- and 3D-HD-endoscopy. Al Kadah B et al. (96) in 2012 operated 30 patients with paranasal and skull base pathologies using 3D-HD endoscopes. They recognized that the operative handling of the 3D-HD endoscopes in regard to design and weight of endoscopes was easy to use for surgeons. But as they did not compare the 3D-HD endoscopy with 2D-HD endoscopy, and they also did not remark any lens cleaning effort secondary to fogging in lens during the surgery. Barkhoudarian et al. (71) also agreed about the lighter weight of 3D-HD endoscope and they mentioned blurring of image as there was blood splash on the camera lens, as a major drawback of the 3D-HD system. In such case, use of anti-fogging solution and repeated cleaning of the tip of the endoscope has been suggested, so that the tip of the endoscope is kept clear and defogged (79).

In contrast to the present study, a small number of surgeons in some studies had noticed symptoms like headache, dizziness, eye strain and fatigue because of the worse illumination and image resolution when they used 3D-HD camera system during laparoscopic surgery (97, 98). The contrasting results for such finding could again be because of the limited sample size or prolonged laparoscopic surgery. In congruence to the present study, there were other studies which showed no physical side effects among surgeons using 3D-HD imaging during laparoscopic surgery or endoscopic pituitary surgery (70, 99). So, we can conclude that these asthenopic symptoms may occur depending upon the time of the surgery and visualization of surgical field in different parts of the body.

4.3.4 Imaging and usability of 3D-HD in specimens

In the present study, we had demonstrated both the 3D-HD and 2D-HD endoscopic images to the participants before the surgery. They were permitted to simulate with the 3D-HD techniques to build up self-confidence about the new 3D-HD endoscopy system and to overcome the drawbacks of previously used 2D-HD endoscopy system. They were able to visualize and dissect the paranasal sinuses of the cadaver, in a similar fashion of one side with 2D-HD technique and the contralateral side with 3D-HD technique. At the end of procedure, each participant was requested to fill up questionnaires regarding imaging, usability and easiness of dissection with the 3D-HD technique. The questionnaires also included the work experience of participants and the number of surgeries performed so far performed, where positive correlation between them was determined.

For imaging properties, all participants reported the 3D-HD technique superior than the 2D-HD in entire aspects. They especially perceived better depth of perception with 3D-HD technique in comparison to 2D-HD technique. They disagreed upon the concerns of image distortion, smaller size of the field and reduced image sharpness with 3D-HD endoscopy. Such superiority of 3D-HD endoscopy in all imaging aspects might be described by the fact that the participants felt overwhelmed by stereoscopic vision of new 3D-HD techniques and moreover there was no bloody surgical field in the cadaver in contrast to patients' surgical field.

For usability properties, participants agreed upon the superiority of 3D-HD to 2D-HD technique in all features expect higher cognitive load with 3D-HD technique. This could be explained by the fact that they needed additional concentration during dissection with new

technology of 3D-HD endoscopy. Participants did not feel any symptoms like nausea, dizziness and headache after the procedure.

For dissection of all paranasal sinuses, participants accepted upon the superiority of 3D-HD over 2D-HD technique in all sinuses. In particular they found better visualization of posterior portions of nasal cavity as posterior ethmoid, sphenoid and frontal sinus and they felt comfortable during dissection of these parts.

Ogino-Nishimura et al. (85) in 2015 published a paper regarding the efficacy of three-dimensional endoscopy in endonasal surgery. They studied the usefulness of 3D-HD endoscopes on five cadavers and concluded the better depth perception of the posterior structures of the paranasal sinuses and skull base with 3D-HD technique. They also commented regarding the operative time and bleeding amount to be almost the same as with 2D-HD endoscope. They also made a questionnaire on 73 surgeons regarding impressions of 3D-HD endoscopy and concluded the better anatomical understanding of 3D-HD endoscopy. There were additionally low perioperative complications with 3D-HD endoscopy. This fact has also been confirmed by the present study. But in contrast to the present study, participants felt eye fatigue at the beginning of the procedure. However, after some time their eye adapted to the 3D-HD field of vision and this factor did not disturb the performance of the surgery.

Zaidi et al. (81) in 2016 reviewed 5 papers, which primarily studied the use of 3D-HD endoscopy to evaluate the efficacy of cadaveric dissection of the ventral skull base surgery. Among them 3 papers compared the 3D-HD and 2D-HD endoscopy systems and concluded that the 3D-HD system had detailed anatomical understanding, better depth perception and three-dimensional orientation. In 2020, Ten Dam et al. (87) analyzed various other approaches in 2 specimens by 30 novices and assessed the effect of three-dimensional visualization on performance in endoscopic sinus surgery. They concluded that imaging features of the 3D-HD endoscope were significantly better than 2D-HD. However, the surgical efficacy and precision showed no significant differences between the two systems. Participants with less experience in this study were not able to perform endoscopic surgery efficiently with 3D-HD endoscopy system. Their primary tasks were identification of anatomical landmarks or grasping and retrieving the objects. They also did not evaluate the subjective discomfort feelings of the participants after the surgery.

Shah et al (78) concluded in their study conducted in a box trainer model regarding the improvement of depth perception and task performance with 3D-HD endoscopy; and they also found out that novices preferred to use this 3D-HD technique for endoscopic surgery. Benefits of 3D-HD visualization in comparison to 2D-HD visualization in endoscopic endonasal surgery for novices were also strengthened by Kawanishi et al (83) in their study in dry laboratory model. In a new study published by Rampinelli et al (86), the results showed that novices preferred 3D-HD endoscopy more often than experienced users and 3D-HD endoscopy had more advantages regarding execution time and accuracy of surgical maneuvers. The outcomes of these three papers are in congruence with our result of superiority of 3D-HD endoscopy by most of non-experienced participants.

According to Markus et al. (84), who studied the comparative effectiveness of 3D-HD versus 2D-HD and HD versus SD during neuro-endoscopy. They evaluated the task completion time, accuracy and perceived task workload in 10 novice surgeons and concluded the superiority of 3D-HD and HD over 2D-HD and SD. Inoue et al. (77) similarly compared the usefulness of 3D-HD endoscopy with 2D-HD endoscopy in neuro-endoscopic surgeries, where 43 examinees (novices, beginners and experts) performed pituitary surgery among 16 patients using both the techniques. They concluded that 3D-HD endoscopes showed better depth perception and task performance and generally shortens the learning curve of young residents in the field of neurosurgery. Both in laparoscopic and neuro-surgery, 3D-HD endoscopy showed less time to task accomplishment in a laboratory setting. It is uncertain, to which degree this results from laparoscopic and neurosurgery can relate in endoscopic sinus surgery because the outcomes of the operating action and usefulness of 2D-HD & 3D-HD is associated with the surgical field properties and surgical technique.

Overall, summary of studies have concluded the superiority of 3D-HD endoscopy surgery as a substitute to the conventional 2D-HD endoscopic sinus surgery.

4.3.5 Imaging and usability of 2D-4K technique in specimens

2D-4K ultra-high definition (UHD) endoscopy was released for the first time in 2015 and is used for laryngoscopy in ENT discipline. It provides a great enhancement in terms of high resolution of the surgical field with excellent image qualities. Its advanced properties like lighter weight, standard eyepiece (where any camera can connect) and easy angulation by rotating the visualization system of the sinus- and skull base surgery are fascinating. This 2D-

4K UHD system does not need an advanced learning curve as it is a 2D-HD system and has no properties of 3D-HD visualization system of the surgical field.

In the present study, the time to keep and time to remove an object (here chickpea) in the sphenoid sinus with 2D-4K-technique was shorter than with 3D-HD-techniques by most of inexperienced participants. However, it was not statistically significant in both the cases. For imaging properties, participants experienced that the 2D-4K technique was significantly better in all aspects as compared to the 3D-HD endoscope except in headings of depth perception and image brightness. No studies were found in the existing literature comparing the 3D-HD and 2D-4K vision systems. The present study has however revealed some interesting advantages of the 2D-4K system despite its 2D-HD imaging system.

Rigante et al. (80) in 2017 published an article regarding the preliminary surgical experience in skull base surgery with 2D-4K-endoscope and analyzed the advantages and disadvantages of 2D-4K system. They operated total 22 patients with pituitary adenomas and evaluated various approaches like imaging, operative time, physical strain, follow-up days and hospitalization days. They concluded that visualization and surgical field with 2D-4K techniques provided better recognition of anatomical and pathological details which lead to higher safety and efficiency of the surgery. Operative time, ergonomics and weight of endoscope was also similar to 2D-HD and 3D-HD systems. They revealed that the visual filter system of 2D-4K-endoscope could help to distinguish the normal and pathological tissue, which could not be related to the present study. Further experience and studies are necessary to validate this filter system. A retrospective comparative study between the 3D-HD and 2D-HD 2D-4K to recognize their features in details and their advantages was published by Uozumi et al. (72). They operated 86 patients with pituitary adenomas with different techniques: 2D-SD, 3D-HD and 2D-HD 2D-4K. They concluded that because of the better depth perception 3D-HD was useful for nasal phase of surgery and because of its better image quality 2D-HD 2D-4K was useful for the intradural phase of surgery. In contrast to the present study, they also compared the task completion time between 3D-HD vs 2D-SD, 2D-4K vs 2D-SD. Overall, they found superiority of 3D-HD and 2D-4K over 2D-SD for endoscopic sinus surgery. Like their recommendations on proper selection of various endoscopic techniques, our results also confirmed the depth perception and image sharpness not being significantly superior in 2D-4K system in comparison to 3D-HD system.

Khanna et al. (88) reviewed 49 articles related to progress in instrumentation in the operating room for endoscopic sinus surgery and recommended the ENT-surgeons about recent advancements of instrumentations in the field of visualization and optics and benefits of these advances. They concluded that the advancement of 2D-4K UHD viewing system improved the quality and range of visual information and had increased safety and better outcome of sinus related surgery.

According to Abdelrahmen et al. (89), who compared the performance of 24 novices in 2D-HD vs 3D-HD vs 2D-4K vision system in laparoscopic peg transfer and intra-corporeal suturing tasks using a box trainer; favorable findings was obtained for 2D-4K vision system. They evaluated the task completion time, number of errors and number of repetitions. They concluded that 2D-4K vision system had better accuracy in complex tasks, and 2D-4K and 3D-HD showed better performance and precision in comparison to the 2D-HD vision system. In the present study, we have not measured the number of errors or number of repetitions but the superior image quality of 2D-4K endoscope was coordinated with 2D-4K laparoscopes.

Whether the 2D-4K system really improves the depth perception in endoscopic sinus system is truly a question of interest for future research. A multi-center study involving multiple number of cases could elucidate the proper scenario.

4.4 Comparison of results between patients and specimens

After the analysis of our results and discussion with other studies, we presented a table showing the “pros” and “cons” of 3D-HD in patients and a specimen and 2D-4K in a specimen.

Table 7: Pros and cons of 2D-HD vs 3D-HD vs 2D-4K

CLINICAL STUDIES		
	3D-HD in patients (1 surgeon: 20 patients)	
	PROS/Advantages	CONS/Disadvantages
Study design	Prospective study to compare 2D-HD vs 3D-HD technology in FESS from surgeon’s perception	Surgical outcomes or postoperative complications of patients unknown
Total time of surgery	No advantages	Longer time for surgery
Imaging properties	Better recognition of details/ anatomical understanding, depth perception, orientation, 3D effect	Inferior color brilliance and brightness; fogging
Usability properties	Lighter weight of endoscopes; no asthenic symptoms	Extra lens cleaning effort; asthenic symptoms may occur if operation take longer time
	Stereoscopic visualization with three-dimensional perception of surgical field; better movement of instrumentation during surgery; useful for dissection of critical structures or vessels (increases patient safety)	People with one eye cannot see 3D-HD image and some people just cannot focus 3D-HD image; Necessity of wearing 3D glasses; changing of the scopes in support system (surgeon cannot change angled scopes own self); for upward and sideward view whole endoscope must be turned because scope and camera are a single piece in 3D-HD-endoscope

LABORATORY STUDIES		
	3D-HD in a specimen (1 specimen: 26 participants)	
	PROS	CONS
Study design	Subjective feelings of participants measured, inexperienced surgeons significantly profit from the 3D-HD FESS compared to more expert surgeons	Objective qualities (surgical efficiency and accuracy) unknown
Imaging properties	Better recognition of details/ anatomical understanding, depth perception, color brilliance, illumination	False sense of confidence of inexperienced participants
Usability properties	Easier intraoperative handling of the camera (programmable camera head button), better possibility of the task completion, no asthenic symptoms	Higher cognitive load, non-expert participants felt more confident with the 3D-HD in a specimen which might not match with real patients
Dissection	Better dissection of all paranasal sinuses	Problematic in patients because of bleeding during surgery
Learning curve	Shortens the learning curve for novice surgeons; useful for teaching/training purposes for residents, medical students and nurses	Difficulty in transferability from the laboratory setting into the clinical setting
	2D-4K in a specimen (1 specimen: 20 participants)	
	PROS	CONS
Study design	Subjective feelings of participants measured	Objective qualities (surgical efficiency and accuracy) unknown
	Shorter time to locate and remove an object by most of inexperienced participants
Imaging properties	Better recognition of details, color brilliance, image sharpness; high resolution of surgical field; excellent image quality	Depth reception only relatively superior
Usability properties	18 cm, Ø 4 mm, 90 g lightweight; angulation via rotating wheel (better ergonomics); standard eyepiece connects to any camera	Need of correct chromatic configuration setting (especially red wave length) in bloody surgical field, never a substitute for surgical knowledge and experience

4.5 Conclusion and implications for future research

While answering the questions of the objectives of the present study, a blur conclusion emerges with regard to the individual points. On one hand, with the development of 4-mm HD 3D-HD endoscope, attention to the application of 3D-HD to FESS has lately increased in general practice. We found that among both in patients and specimen, when working inside the posterior ethmoid-, sphenoid- and frontal sinus, the improved spatial orientation provided by the 3D-HD system was helpful. From this we can draw a conclusion that 3D-HD endoscopy is valuable for activities that demand a high degree of depth perception and at places where most critical vessels are located.

On the other hand, our questionnaires for clinical and laboratory study were not identical. This might have resulted in some contradicting results. For example, size of the field was inferior when compared to the 3D technique among patient. In contrast the participants disagreed about reduced size of the field in the specimen with the same technique. Similarly, time taken for preoperative preparation was longer with 3D-HD in patients whereas participants disagreed about additional time-consuming surgery with 3D-HD. Furthermore, one experienced surgeon operated 20 patients in a clinical setting, whereas there were participants (26 participants in 3D-HD study and 20 participants in 2D-4K study), who were both experienced and inexperienced, who took part in different tasks in a laboratory setting. Because of this we could not make a direct correlation between our study in clinical and laboratory setting. Also, the present study did not study about the surgical outcomes of patients and perioperative complications, which may be the limitation of the present study.

From this, three dominant questions can be derived to which further investigations are necessary in the future of nasal endoscopy technique.

First, is the superiority of 3D-HD endoscopy really beneficial for patients concerning the surgical outcome and perioperative complications? As Khanna et al. (88) already said, new equipment is certainly not a replacement for surgical experience and skill. Hence, how can we balance the higher cost of new instrumentation with improvement of outcome?

Secondly, there is a one medical dictum that, “if you cannot see, you cannot operate” and fogging is a big challenge in the 3D-HD endoscopy. Fogging may be possibly tackled in the future by using different hemostatic agents to reduce the bleeding. This has been confirmed by Khosla AJ. (100), who used cleaning of the tips of the endoscopes frequently and using anti-fogging solution. With the development of Endomat Select (Clearvision Lens Cleaning System) from Karl Storz GmbH, which consist of a single roller pump for the irrigation and

suction of fluids during operation this might be achievable. This Clearvision system flushes the tip of the endoscope regularly and provides a clear vision for the surgeon. A specific focus should be given in future on whether the use of Clearvision system reduces the lens cleaning effort and the total time duration of surgery.

Thirdly, rather than a pure use of either 2D-HD endoscopy system or 3D-HD endoscopy system, a modular system where 3D-HD endoscopy combined with 2D-HD 2D-4K monitor system could provide a better outcome in endoscopic sinus surgery. Adding the improved depth perception of 3D-HD into 2D-4K system should be an ideal solution in the future. A large scale, multicenter study comparing clinical outcomes and operative times with 3D-HD 2D-4K endoscopy is needed in future.

5. References

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6. Appendix

6.1 3D-HD vs 2D-HD in patients

Questionnaire to evaluate imaging and usability

3D-HD Endoscopy compared to 2D-HD Endoscopy in Functional Endoscopic Sinus Surgery
Case Report Form

Location:

Date:

Patient Number:

Patient Name:

Patient Purname:

Sex:

Date of birth:

Age:

Name of procedure:

2D-HD-Endoscopy side:
time:

3D-HD-Endoscopy side:
time:

Reference: 2D-HD Endoscope = 3 points

Rate on a scale of 1-5 (1 = much worse, 2 = worse, 3 = equal, 4 = better, 5 = much better)

	Ethmoid Sinus	Maxillary Sinus	Sphenoid Sinus	Frontal Sinus
Imaging				
Recognition of Details / Anatomical Understanding				
Color Brilliance				
Illumination				
Image Distortion				
Size of Field				
Depth Perception				
Fogging				
3D effect				
Usability				
Intraoperative Handling of the Camera / Efficiency of Surgical Movements				
Ergonomics / Changing of Endoscopes				
Weight of Endoscopes / Camera				
Nausea				
Dizziness				
Headache				
Positioning of Endoscope (angled View)				
Time for preoperative Preparation				
Conflict with Instruments				
Lens cleaning Effort				
Time for Preparation 2D-HD				
Time for Preparation 3D-HD				

Signature surgeon:



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Fragebogen / Studienprotokoll

Vergleich von 3D-HD FESS mit 2D-HD-FESS (FESS=Functional Endoscopic Sinus Surgery)

Klinik:

Datum:

Patient Nummer:

Nachname:

Vorname:

Geschlecht:

Geburtsdatum:

Alter:

Bezeichnung der Operation:

2D-HD FESS Seite:

Dauer:

3D-HD FESS Seite:

Dauer:

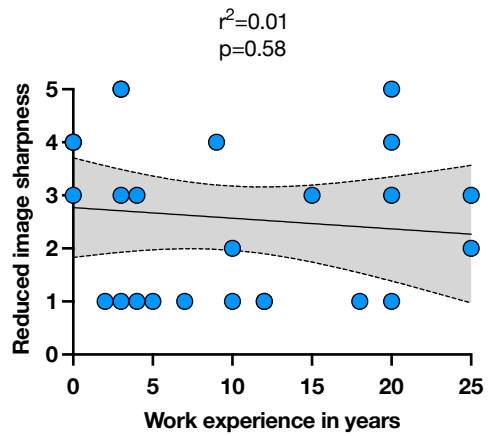
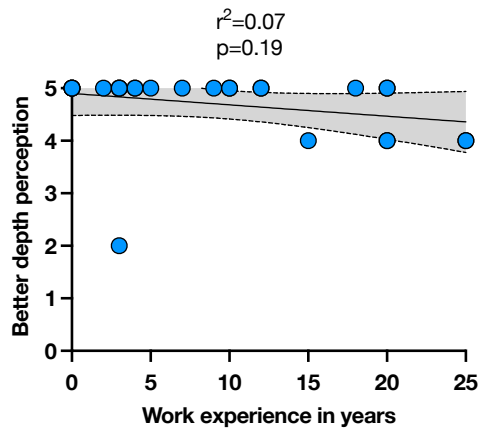
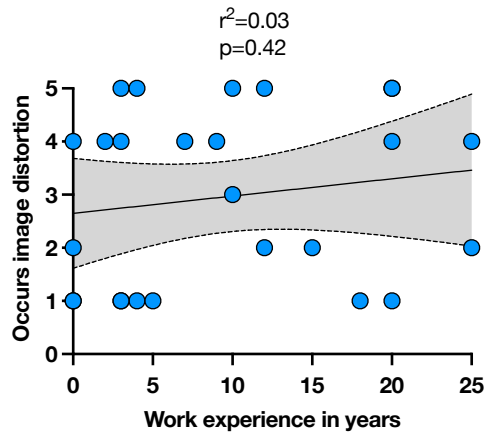
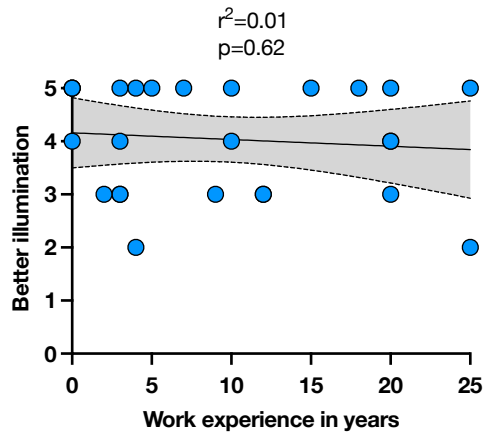
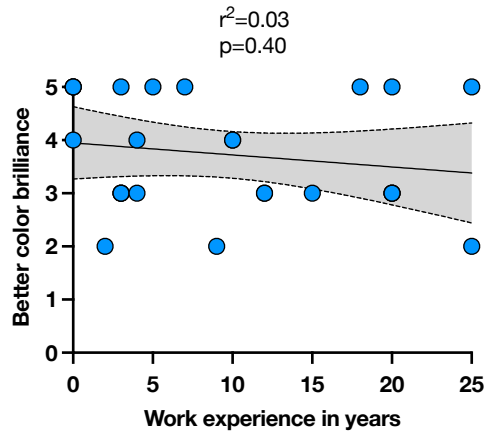
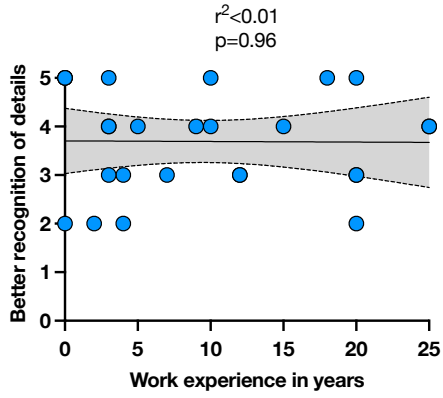
6.2 3D-HD vs 2D-HD Study in a specimen

Questionnaire to evaluate imaging and usability

Reference: 2D-HD Endoscope = 3 points

Rate on a scale of 1-5 (1=strongly disagree, 2=disagree, 3=neutral, 4=agree, 5=strongly agree)

1. How many years of professional experience as an ENT-Surgeon do you have?
2. How many endoscopic sinus surgeries have you performed so far?
3. Are the imaging qualities using the 3D-HD better than 2D-HD?
When using the 3D-HD camera than with 2D-HD:
 - better recognition of details/anatomical understanding
 - better color brilliance
 - better illumination
 - occurs image distortion
 - smaller size of field
 - better depth perception
 - reduced image sharpness
4. Are the usability aspects using the 3D-HD better than 2D-HD?
When using the 3D-HD camera..... than with 2D-HD:
 - intraoperative handling of the camera is more difficult
 - targeted surgery is less possible
 - procedures take more time
 - occurs nausea
 - occurs dizziness
 - occurs headache
 - higher cognitive load
 - appears conflict with other instruments
5. Which part of paranasal sinus surgery is particularly helpful to dissect by using 3D-HD? When using the 3D-HD camera, dissection of the following parts of the paranasal sinuses are specifically advantageous than 2D-HD:
 - anterior ethmoid sinus
 - posterior ethmoid sinus
 - maxillary sinus
 - sphenoid sinus
 - frontal sinus
 - all sinuses



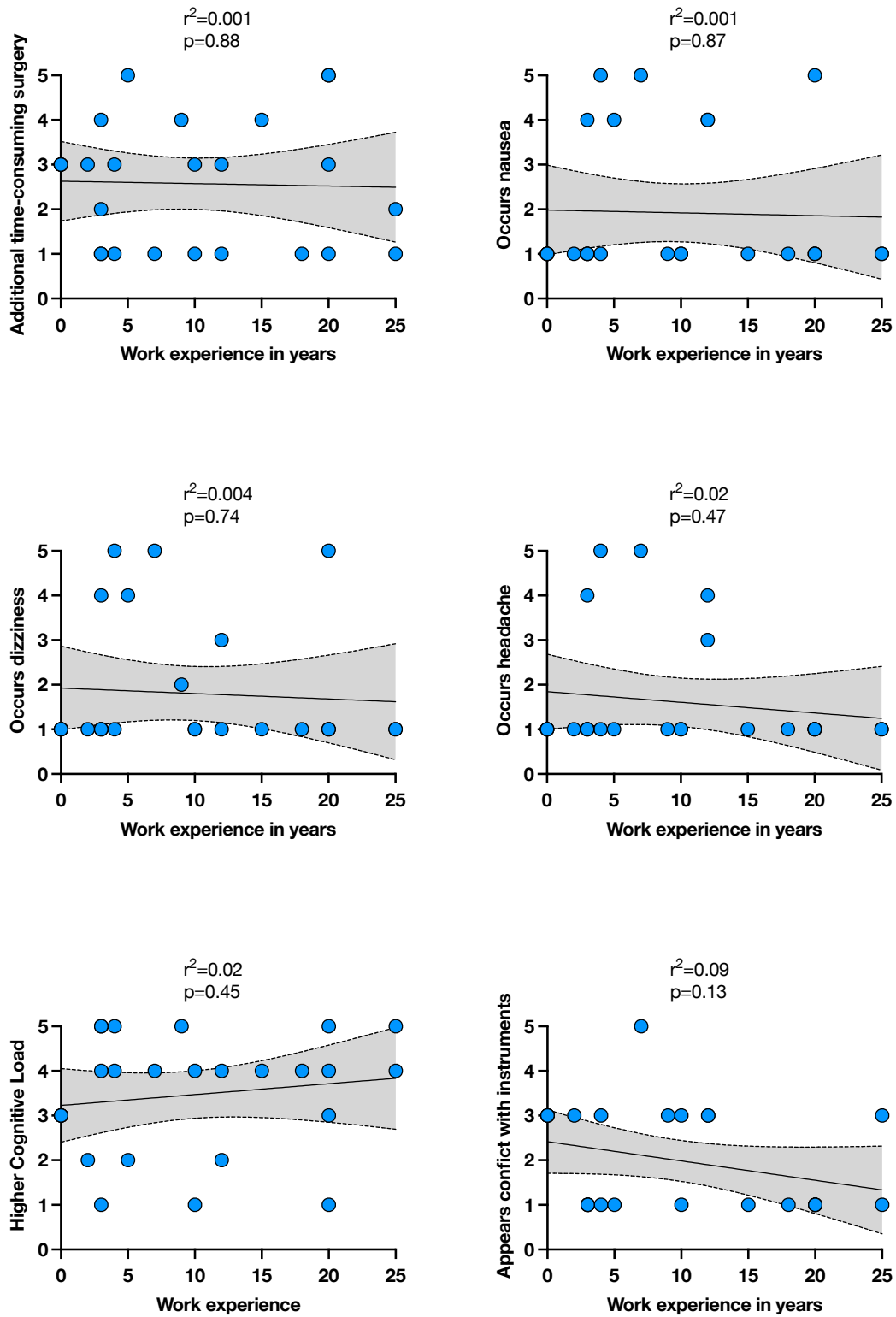


Figure 43: Linear regression diagram showing the relationship of work experience and imaging features (total participants, n=26); where $p=0.12$ (ns), $p=0.033$ (*), $p=0.002$ (**), $p<0,001$ (***) and r^2 = goodness of fit which evaluates the scatter of the data points around the fitted regression line.

6.3 3D-HD vs 2D-4K Study in a specimen

Questionnaire to evaluate imaging and usability

Rate on a scale of 1-5 (1 = 3D-HD, 3 = neutral, 5 = 2D-4K)

1. Which cameras do you use?
Analog, HD, 3D-HD, 2D-4K
2. What kind of features do you want from the future imaging systems?
3. How long does it take to place a chickpea with 3D-HD-techniques per side?
4. How long does it take to remove a chickpea with 3D-HD-techniques per side?
5. How long does it take to locate a chickpea with 2D-4K-techniques per side?
6. How long does it take to remove a chickpea with 2D-4K-techniques per side?
7. Which of the following properties are better in 2D-4K in comparison to 3D-HD?
 - recognition of details
 - color brilliance
 - image brightness
 - image sharpness
 - usefulness for manipulation
 - depth perception

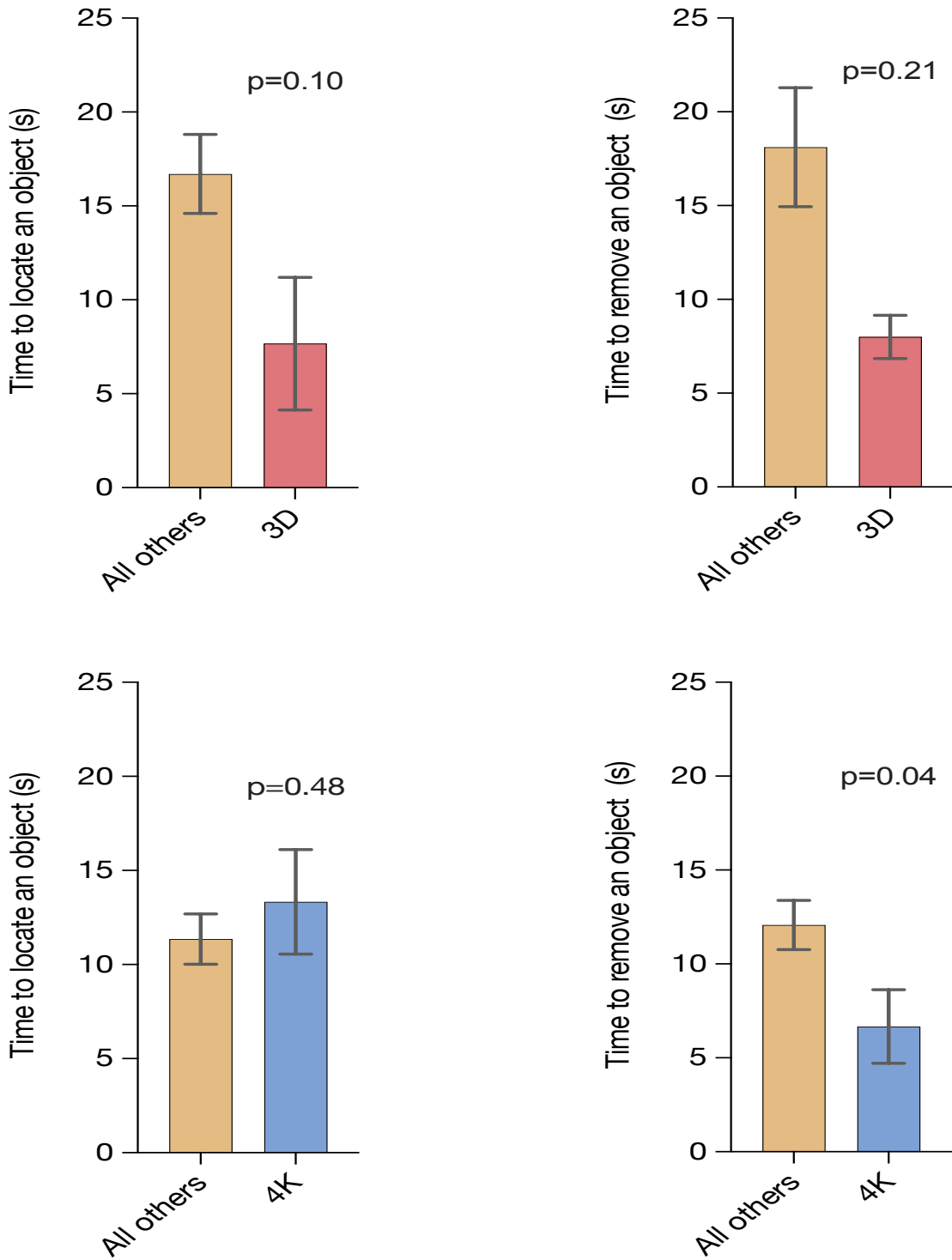


Figure 44: Results of time to locate and remove an object using 3D-HD- and 2D-4K-endoscopy in comparison to routinely practicing endoscopy presented with mean±SEM (upper graph: n=17 for all others, n=3 for 3D-HD; lower graph: n=14 for all others, n=4 for 2D-4K); two tailed student's t-test was used.

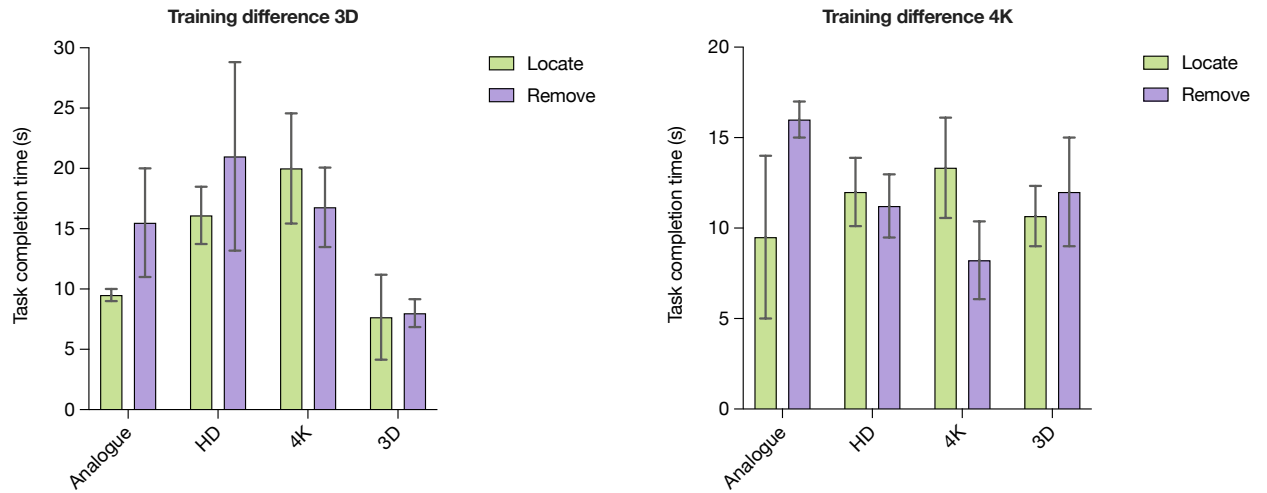


Figure 45: Results of time to locate and remove an object using 3D-HD- and 2D-4K- endoscopy in comparison to routinely practicing endoscopy presented with mean±SEM (n=2 for Analogue; n=9 for HD; n=6 for 2D-4K; n=3 for 3D-HD); multiple unpaired t-test was used.

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8. Affidavit

	LUDWIG- MAXIMILIANS- UNIVERSITÄT MÜNCHEN	Promotionsbüro Medizinische Fakultät		
Eidesstattliche Versicherung/ Declaration of an oath				

Dhital, Sagar

Surname, first name

I hereby declare, that the submitted thesis entitled

Comparison of Three-Dimensional Endoscopy with the standard Two-Dimensional Endoscopy in Functional Endoscopic Sinus Surgery (FESS)

is my own work. I have only used the sources indicated and have not made unauthorised use of services of a third party. Where the work of others has been quoted or reproduced, the source is always given.

I further declare that the submitted thesis or parts thereof have not been presented as part of an examination degree to any other university

Munich, 10.10.2022

Place, Date

Sagar Dhital

Signature doctoral candidate

9. Curriculum vitae