A Technique with Manipulator-Assisted Endoscope Guidance for Functional Endoscopic Sinus Surgery: Proof of Concept

Miloš Fischer, MD1,2, Christina Gröbner1, Andreas Dietz, MD, PhD1,2, Maximillian Krinninger, Dipl-Ing3, Tim C. Lüth, PhD3, and Gero Strauß, MD, PhD1,2

Abstract

Objective. The goal of this study was to examine the theoretical feasibility of a new manipulator system for endoscope guidance in functional endoscopic sinus surgery.

Study Design. The accuracy of endoscope positioning and time of endoscope movement with an endoscope manipulator system were determined with an artificial sinus model.

Setting. A laboratory trial was performed. The time for 60 repetitions of manual compared to manipulator-assisted endoscope movements directed at 3 different target positions was evaluated. In addition, the alignment of the position vector for each endoscope movement was examined.

Subjects and Methods. A zero-degree Hopkins II telescope with a camera was used to head for the target positions. First, the endoscope movements were done manually, and afterward the endoscope manipulator system was used for endoscope guidance. The alignment of the position vector of the endoscope was measured with a portable measuring arm.

Results. There was no statistical difference between the time for manual and manipulator-assisted endoscope movements for all target positions. The alignment of the position vector of the endoscope was statistically different at 2 target positions: anterior ethmoid left side and ostium of maxillary sinus left side. There was no statistical difference at all other positions.

Conclusion. The endoscope manipulator system has the potential to be integrated into the operating workflow without extending the time for endoscope guidance. The surgeon will be able to use both hands for the manipulation of the instruments. Less frequent endoscope movements and instrument changes may be expected after technical modification.

Keywords

functional endoscopic sinus surgery, endoscope guidance, manipulator assistance, bimanual manipulation

1Department of ORL-HNS, University Hospital Leipzig, Leipzig, Germany
2BMBF–Innovation Center Computer Assisted Surgery ICCAS, University of Leipzig, Leipzig, Germany
3Institute of Microtechnology and Medical Device Technology (MiMed), Technical University Munich, Munich, Germany

The results of this study were presented as a scientific session at the 2010 AAO-HNSF Annual Meeting & OTO EXPO; September 26-29, 2010; Boston, Massachusetts.

Corresponding Author:

Miloš Fischer, MD, Department of ORL-HNS, University Hospital Leipzig, Liebigstr. 10-14, 04103 Leipzig, Germany
Email: milos.fischer@medizin.uni-leipzig.de
(FreeHand Surgical plc, Guildford, UK) are not suitable for FESS. Therefore, most of these “stand-alone” systems require a lot of room being positioned close to the operating table with limited approach to the operating site. The goal of this study was to investigate the theoretical feasibility of a miniature manipulator system for endoscope guidance in FESS. We formulated 2 tasks for this study:

1. Comparison between manipulator-assisted endoscope guidance and standard approach in FESS
2. Description of surgical requirements for bimanual manipulation with manipulator-assisted endoscope guidance in FESS

**Methods**

**Test Model: Artificial Skull Model with Bony Paranasal Sinuses**

For the evaluation of the endoscope movement, an artificial skull model with a replaceable sinus module was used. This involved an anatomically identical sinus model of an actual patient on the basis of a computed tomography (CT) data record. The model was manufactured in a procedure by the use of pressure on a cast material, which can be formed and repeatedly reformed with high precision (Spectrum Z 510; 4D Concepts, Grossgerau, Germany). The inner layer, which represents mucosa, was made of colored silicone (Figure 1). It comprised the bony walls of the anterior and posterior ethmoid, the maxillary sinus, the sphenoid sinus, and other surgically relevant anatomical structures (mucosa of nasal septum, inferior and middle turbinate). Texture and feel were highly similar to real intraoperative impressions. An experienced ear, nose, and throat (ENT) surgeon performed FESS on this model and exposed the anterior ethmoid, the anterior wall of the sphenoid sinus, and the ostium of the maxillary sinus on both sides (Figure 2).

**Endoscope Manipulator System**

Manipulator-assisted endoscope guidance in FESS requires specifications that were considered when the endoscope manipulator system (EMS) was developed. Our technical partner, the MiMed Institute, Technical University Munich, Germany, developed that system. Compared to other surgical disciplines, the endoscope manipulator needs the following:

1. Close positioning to the operating site
2. Possibility for quick mounting and demounting
3. Easy integration into the surgical workflow
4. An optimum power-weight ratio
5. Possibility to switch to manual endoscope guidance anytime
6. Suitable handling

The components of the EMS were attached to the operating table by a fixation bar with adjustable articulations opposite to the surgeon’s position. The remote steering panel was also fixed to the operating table next to the surgeon’s position. The HD-endoscope camera was equipped with an adapter that fits into the collet of the manipulator device. The fitting design is similar to one of a buckle to guarantee a firm fixation but easy removal of the camera by the surgeon at any time. The remote steering panel and the manipulator device were connected with cables and also with the power switch. The manipulator device consisted of an L-shaped chassis with detergent-resistant
Fischer et al

lacquering and rounded edges, 2 parallel-switched 5-pivot gears with gimbal-mounted guide arms, and 1 linear module allowing movements in all 3 dimensions (x/y/z). The remote steering panel had 2 joysticks, one for linear endoscope movement (z-axis) and the other for pivoting and tilting (x/y-axis). Considering that the anterior skull base may be reached after 80 mm, movement in the linear direction was restricted to 50 mm. The angle for pivoting and tilting, which was assumed to be at the level of the nostril, was technically restricted to 5°. The control logic was based on a microcontroller (Figure 3). The materials used were from carbon fiber–strengthened plastic to give consideration to the lightweight construction. After connecting the camera with the manipulator device, the surgeon did an approximate alignment, and all articulations were fixed by tightening a single setscrew. With a torsional moment of 5 Nm, there was a holding force of 50 N. It takes about 2 minutes to mount and install the system. All connections and parts were designed so the camera cable, light cable, and an optional sterile packing would not interfere with the movements of the EMS. The precise alignment of the endoscope was done by using the 2 joysticks of the remote steering panel. Potentiometers collected the joystick signals, and the microcontroller processed the data, which resulted in signal generation and activation of the two 5-pivot gears with movements of the guide arms. Because of the close positioning of the steering panel to the surgeon’s position at the operating table, the surgeon can remote the EMS independently or as a 4-hand technique with an assistant. After its use, all components could easily be cleaned with disinfecting wipes.

Surgical Instruments

For the endoscopy, a zero-degree Hopkins II telescope (Ø 4 mm, length 18 cm; Karl Storz GmbH & Co KG, Tuttingen, Germany) and, for visualization, an HD-Endoscope Camera and HD-Videendoscopy Tower (Image1 H3, Three-Chip HD Camera-head, resolution 1920 × 1080 pixels, 23-inch Karl Storz HD Flat Screen, Karl Storz AIDA compact II system; Karl Storz GmbH & Co. KG) were used.

Three-Dimensional Coordinate Measurement

The alignment of the position vector of the endoscope and its movement were determined by a 3-dimensional coordinate measurement using the portable coordinate measurement device FAROArm Platinum (FARO Europe GmbH & Co KG, Kornthal-Münchingen, Germany; Figure 4). For value analysis, the software PolyWorks (InnovMetric Software, Inc, Québec, QC, Canada) was used.

Laboratory Trial Setup

The skull model was fixed to the operating room table, and an experienced ENT surgeon guided the endoscope manually. Three different target positions (anterior ethmoid, anterior wall of the sphenoid sinus, and ostium of the maxillary sinus) had been
chosen. For each target position, the surgeon guided the endoscope so the target position was in the center of the endoscopy monitor about 5 mm in front of the telescope. For each repetition, the endoscope had to be removed from the site, and each endoscope movement restarted at a starting position 10 mm in front of the nose. After 30 iterations, the EMS was installed and all the endoscope movements had been repeated with manipulator-assisted endoscope guidance. In addition, the 3-dimensional coordinates of each position vector for all endoscope movements were measured at the starting and target positions.

**Measurement**

The time for all endoscope movements was documented. The duration of endoscope movement from the starting position toward the target position was measured with a stopwatch. The 3-dimensional coordinates were measured at the starting position and the target position for each endoscope movement. A software tool calculated the value of each position vector. Thus, for the duration and the position vector, a mean value, a standard error of mean, and a minimum and maximum value (range) were calculated. Considering the mean values and using an unpaired $t$ test, we tested whether there was a significant difference between the manual endoscope guidance and the manipulator-assisted endoscope guidance. The significance level was $\alpha = 0.05$. If the $P$ value had been $\leq \alpha$, it could be stated with a probability of error of 0.05 that the mean values of both groups were significantly different. Because all measurements were undertaken on a phantom and thus without any patient contact, no statement from the institutional ethics committee was required.

**Results**

**Time of Manual and Manipulator-Assisted Endoscope Movement**

The time results of the manual and manipulator-assisted endoscope movement are shown in Table 1. After applying the unpaired $t$ test, we found that the $P$ value was $\geq 0.05$ for all tested target positions. With $P \geq \alpha$, there was no evidence that the mean time of endoscope movement differed significantly in the manual and manipulator-assisted groups.

**Position Vector of Manual and Manipulator-Assisted Endoscope Movement**

The results of the position vectors of the manual and manipulator-assisted endoscope movement are shown in Table 2. After applying the unpaired $t$ test, we found that the $P$ value was $\geq 0.05$ for 4 of 6 target positions. With $P \leq \alpha$, it became evident that the mean position vector of endoscope movement differed significantly in the manual and manipulator-assisted groups for the target positions of the anterior ethmoid and ostium of the maxillary sinus, both on the left side.

**Discussion**

Manipulator systems are not new to surgery. They have been developed to provide a high precision for limited surgical workspace.7 With the help of telesmanipulators, the direct interaction between surgeon and surgical instrument is separated, resulting in higher accuracy by reducing manual tremor or possible scaling of the instrument movement. Telemanipulators such as the daVinci System (Intuitive Surgical, Inc) have been used for ENT surgical procedures, but they are not applicable for FESS, requiring a lot of space, a long setup procedure, and also high economic expenses.8,9 Nevertheless, there is a positive impact by bimanual manipulation on the procedure time, which emphasizes the potential for endoscope guidance in FESS.5 With the use of manipulators, surgical procedures demanding assistance can be converted to “solo-surgical” procedures, or they may improve surgical performance by optimizing endoscopic characteristics such as picture alignment and stabilization.10 Compared to other endoscope manipulator systems such as AESOP (Intuitive Surgical, Inc), EndoAssist (Armstrong Healthcare), or Freehand (FreeHand Surgical plc), the examined endoscope manipulator system is suitable for FESS because of the small volume, the
ergonomic design, and the easy and quick mounting to the operating room table. The L-shaped chassis is adapted to an opened human hand, which allows an unrestricted view to the operating site at any time. The mounting and the installation of the system, which take only about 2 minutes, are done by fixation with MAQUET (Wayne, New Jersey) operating room table components. This allows an ubiquitous application of the system without any other structural or technical requirements in the operating room. The tightening with a single setscrew easily allows the system to be swung close to the operating site. The approximate alignment can be done by the surgeon with 2 hands in a single work step. The design of the connection between the camera head and manipulator device allows an easy and fast disconnection in case of dysfunction or demand for manual endoscope guidance, which is obligatory for patient safety.

**Interpretations of the Presented Results**

The significant difference in the position vector of manipulator-assisted endoscope guidance compared to manual endoscope guidance at 2 target positions (anterior ethmoid and ostium of the maxillary sinus, both on the left side) can be explained by a deficient trajectory of the endoscope alignment on the left side. Because of the left-sided fixation of the manipulator device, there was an insufficient view with the straightforward telescope, which was needed to display the target in the center of the endoscope monitor. Moreover, there was no further approximate alignment possible because of the constructional limitation of the fixation bar. The main point was a misinterpretation of the engineers, who assumed that the position of the manipulator device would be changed depending on the side of surgery. Prior to the design and construction of the manipulator system, a surgical workspace requirements analysis was performed. The linear trajectory should allow not more than 80 mm, and the plane of tilting and pivoting was defined as 60 by 40 mm. The standard functional area of a zero-degree telescope is a cone-like space of 35 mm length with an open angle of 70°. Considering that the pivot point is located close to the nostril, the mechanical angle for pivoting was calculated as 4° and for tilting as 5°. So, for security reasons, the dimension of endoscope movement was technically restricted. However, more viewing angles are provided because of the modification of the pivot point by linear endoscope movement with the manipulator. Additional improvements would be the use of angled optics or a modified fixation of the manipulator device coming from the upper end of the operating room table. After consultation with the technical

### Table 1. Time of the Manual and Manipulator-Assisted Endoscope Movement

<table>
<thead>
<tr>
<th></th>
<th>Manual Right</th>
<th>EMS Right</th>
<th>Manual Left</th>
<th>EMS Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior ethmoid</td>
<td>Mean (range)</td>
<td>2.48 (1.92-2.91)</td>
<td>2.18 (1.86-2.43)</td>
<td>2.72 (2.24-3.20)</td>
</tr>
<tr>
<td></td>
<td>Standard error of mean</td>
<td>0.17</td>
<td>0.10</td>
<td>0.14</td>
</tr>
<tr>
<td></td>
<td><em>P = .17</em></td>
<td><em>P = .64</em></td>
<td><em>P = .01</em></td>
<td><em>P = .01</em></td>
</tr>
<tr>
<td>Anterior wall of sphenoid sinus</td>
<td>Mean (range)</td>
<td>3.73 (3.25-4.15)</td>
<td>4.19 (3.09-7.24)</td>
<td>3.47 (3.23-3.70)</td>
</tr>
<tr>
<td></td>
<td>Standard error of mean</td>
<td>0.13</td>
<td>0.70</td>
<td>0.07</td>
</tr>
<tr>
<td></td>
<td><em>P = .54</em></td>
<td><em>P = .39</em></td>
<td><em>P = .27</em></td>
<td><em>P = .34</em></td>
</tr>
<tr>
<td>Ostium of maxillary sinus</td>
<td>Mean (range)</td>
<td>3.78 (3.43-4.09)</td>
<td>3.56 (2.18-6.88)</td>
<td>3.56 (3.03-3.87)</td>
</tr>
<tr>
<td></td>
<td>Standard error of mean</td>
<td>0.11</td>
<td>0.81</td>
<td>0.14</td>
</tr>
<tr>
<td></td>
<td><em>P = .79</em></td>
<td><em>P = .34</em></td>
<td><em>P = .19</em></td>
<td><em>P = .07</em></td>
</tr>
</tbody>
</table>

Abbreviation: EMS, endoscope manipulator system.

### Table 2. Position Vector of the Manual and Manipulator-Assisted Endoscope Movement

<table>
<thead>
<tr>
<th></th>
<th>Manual Right</th>
<th>EMS Right</th>
<th>Manual Left</th>
<th>EMS Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior ethmoid</td>
<td>Mean (range)</td>
<td>23.51 (23.35-23.65)</td>
<td>23.65 (23.52-23.83)</td>
<td>23.51 (23.30-23.62)</td>
</tr>
<tr>
<td></td>
<td>Standard error of mean</td>
<td>0.05</td>
<td>0.05</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td><em>P = .11</em></td>
<td><em>P = .001</em></td>
<td><em>P = .01</em></td>
<td><em>P = .01</em></td>
</tr>
<tr>
<td></td>
<td>Standard error of mean</td>
<td>0.03</td>
<td>0.01</td>
<td>0.06</td>
</tr>
<tr>
<td></td>
<td><em>P = .51</em></td>
<td><em>P = .17</em></td>
<td><em>P = .01</em></td>
<td><em>P = .01</em></td>
</tr>
<tr>
<td>Ostium of maxillary sinus</td>
<td>Mean (range)</td>
<td>23.08 (22.99-23.24)</td>
<td>23.27 (22.90-23.62)</td>
<td>23.37 (23.25-23.55)</td>
</tr>
<tr>
<td></td>
<td>Standard error of mean</td>
<td>0.04</td>
<td>0.11</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td><em>P = .19</em></td>
<td><em>P = .01</em></td>
<td><em>P = .19</em></td>
<td><em>P = .01</em></td>
</tr>
</tbody>
</table>

Abbreviation: EMS, endoscope manipulator system.
developer, the fixation was switched to the cranial position, and the manipulator device was turned through 180°. This would not only allow symmetrical endoscope alignment on both sides of the patient but also prevent collisions between instruments and the manipulator that we recognized from prior assembly. With the modified device, the surgeon’s hands and instruments are situated below the manipulator device (Figure 5). Further instrument collisions were not expected, so we did not perform a separate investigation of instrument movements. Studies introducing 4-hand techniques in FESS or in transnasal skull base surgery have already been described, so we know that in narrow anatomical regions (eg, the frontal recess), manipulations with multiple instruments are more difficult.

Following the technical modification, we performed another test surgery with the skull model, which showed no more restrictions in the endoscope alignment.

Because there were no significant mean time differences for the manual and manipulator-assisted endoscope movement, we assume that the endoscope manipulator system will not result in prolongation of the procedure time. Rather, there is potential to reduce the procedure time because bimanual manipulation will be possible, which will result in fewer interruptions of the surgical workflow caused by instrument changes. Other advantages of manipulator-assisted endoscope guidance would be an increase in endoscopic picture alignment and stabilization by eliminating human tremor or the reduced need for endoscope cleaning due to less frequent endoscope contaminations.

The joystick-based remote steering allows the surgeon to serve as a supervisor over the surgical task of “endoscope guidance.” This “master-and-slave” principle provides a lower level of automation but has a high impact on patient safety.11 Remote steering by the surgeon himself or herself as well as by an assistant may have a positive impact on the procedure time. In a previous study, we showed that most surgical interruptions in FESS are caused by instrument changes between the suction and cutting instrument.4 This fact can be completely neglected by manipulator-assisted endoscope guidance. To increase the level of automation, an automatic navigation-based tracking of the endoscope movement would be a possible solution.
This preliminary technical modification was not part of this study.

Limitations of the Study
The system was evaluated with an artificial model of the nose and paranasal sinuses. Of course, this model cannot meet all the possible anatomical variations that may influence the functionality of such a system. In addition, there was no possible intraoperative complication such as bleeding. Nevertheless, we think that preclinical evaluation of medical device technology with artificial models is an innovative solution to recognize potential misfunction without harming patients.

The study investigated the positioning of the manipulator-guided endoscope movement without evaluating active instrument manipulation, although we did assess the instrument manipulation while the target positions in the skull model were prepared. We did not recognize increased collisions between the telescope and active instruments, but there were limitations due to the backhand holding of instruments dissecting in the left maxillary sinus. This fact also resulted in modification of the fixation and positioning of the endoscope manipulator system (Figure 5).

Conclusion
In summary, the investigated endoscope manipulator system meets the minimum technical requirements for a promising integration into the surgical workflow not only for FESS but also for transnasal skull base surgery. Nevertheless, further clinical investigation will be necessary.

Acknowledgment
We thank Phacon GmbH, Leipzig, Germany, which provided the skull model and gave support with coordinate measurements.

Author Contributions
Miloš Fischer, main author of study report, manuscript, data analysis and interpretation, final approval of the version to be published; Christina Gröbner, data acquisition, final approval of the version to be published; Andreas Dietz, substantial contributions to analysis and interpretation of data, final approval of the version to be published; Maximillian Krinninger, substantial contribution in the development of the endoscope manipulator system, final approval of the version to be published; Tim C. Lüth, initial conception of the endoscope manipulator system, critical revision of the article, final approval of the version to be published; Gero Strauß, initial conception of the study concerning the clinical problem, substantial contribution in the conception and design of the study, data interpretation, critical revision of the article, final approval of the version to be published.

Disclosures
Competing interests: None.
Sponsorships: Karl Storz GmbH & Co KG provided surgical systems and technical support.
Funding source: BMBF DFG (GZ: DI 1404/2-1, 1404/3-1) funded research activity of the EMS.

References