Robotic-Assisted Nissen Fundoplication
with the Senhance® Surgical System:
Technical Aspects and Early Results

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ABSTRACT

Introduction: Robotic-assisted surgery continues to evolve. Technical advantages are reported for intracorporeal suturing, a technique with a long learning curve in conventional laparoscopy. The success of laparoscopic fundoplication relies on precise suturing at the hiatus and of the fundal wrap. Therefore, robotic assistance can be a useful tool for this particular procedure. In March 2017, the Senhance® Surgical System (Transenterix, Inc., Morrisville, North Carolina) was introduced into robotic-assisted procedures at the St. Marien-Krankenhaus, Siegen, Germany.

Materials and Methods: Between March 2017 and July 2019, we performed 36 surgeries of the upper GI tract with the Senhance® Surgical System. Eighteen patients underwent the classic Nissen fundoplication and are the subject of this study. All patients gave informed consent for robotic assistance with prospective data acquisition and analysis.

Results: Seven male and 11 female patients were included in the study. The median age of the cohort was 58.5 years (range 30–81 years) and the median body mass index (BMI) was 30.4 kg/m² (range 22.7–40.1 kg/m²). The median total operative time was 95.5 minutes (range 68–194 minutes) and, despite the small sample size, we observed a significant learning curve throughout the study period (p<0.05). Before the introduction of the Senhance® Ultrasonic energy device, conversion to laparoscopic fundoplication was necessary in two patients. We performed one re-do laparoscopy on the day of surgery due to pain without any significant intraoperative findings and one laparoscopic revision to Toupet fundoplication after seven months due to dysphagia.

Conclusion: This first report of robotic-assisted Nissen fundoplication with the Senhance® Surgical System demonstrates technical feasibility. After successful introduction of the Senhance® Ultrasonic, our conversion rate to standard laparoscopic surgery was significantly reduced.
standard after the first case series was published in 1991. In the 2000s, the introduction of robotic surgery has added another tool to minimally-invasive anti-reflux surgery. Robot-assisted hiatal hernia repair has shown some advantages compared to laparoscopic hernia repair that include shorter hospital stay and lower complication rates.

We started using the Senhance Surgical System in March 2017. After we gained experience with the robotic transabdominal preperitoneal hernia repair (rTAPP), we extended our practice to surgical interventions of the upper gastrointestinal tract, with special focus on the surgical treatment of gastroesophageal reflux disease (GERD). Here we describe our first experience with the Nissen fundoplication in our first 18 patients utilizing the Senhance Surgical System.

**MATERIALS AND METHODS**

Since 2015, we have evaluated patients with GERD in a multidisciplinary setting, which involves the expertise of gastroenterologists, nutritionists, and surgeons to decide on the optimal treatment plan. From a surgical standpoint, we recommend for patients with no hiatal hernia or a small hiatal hernia (<3 cm) the implantation of an anti-reflux stimulation system (EndoStim, EndoStim Inc., Dallas, Texas). Patients with a hiatal hernia >3 cm are recommended to undergo classic Nissen fundoplication. In patients with a very large hiatal hernia combined with an intra-thoracic stomach, we prefer a closure of the hiatal hernia in the form of a cardia—hiatopexy in combination with a fundo—and gastropexy after repositioning the stomach into the abdominal cavity.

With the Senhance Surgical System, we introduced robotic-assisted surgery into the surgical management of GERD at our institution. Between March 2017 and July 2019, we performed 36 surgeries of the upper GI tract with the Senhance Surgical System. Fourteen patients underwent implantation of the EndoStim device and four patients underwent gastropexy (cardiofundohiatopexy) without fundoplication. Eighteen patients underwent the classic Nissen fundoplication and are the subject of this study.

**Team training**

Our team included four surgeons and two nurses. Prior to performing the first robotic Nissen fundoplication, we participated in cadaver labs and supervised mentored cases in addition to practice sessions in robot manipulation and docking. We then gained our first experience in inguinal hernia repairs before the first anti-reflux procedure was undertaken. By now, our combined experience includes approximately 400 general surgical procedures.

**Robot setup**

Details of the Senhance Surgical System have been published previously. For the robotic-assisted Nissen fundoplication, we used three of the four robotic arms. Two robotic arms were placed on the patient’s left side and one on the right. After using a 0-degree scope in the first cases, we changed to a 30-degree scope, which was placed through an upper midline 10 mm port and held by the arm positioned at the patient’s lower left side. The port placement was similar to standard laparoscopy. A 5 mm or 10 mm port was placed in the right upper quadrant for a grasper, which was controlled by the robotic arm on the patient’s upper right side. An additional 10 mm port was placed in the left upper quadrant for the monopolar hook cautery or the Senhance Ultrasonic, which was controlled by the robotic arm on the patient’s upper left side (Fig. 1).

The 3D camera is controlled by the surgeon with eye-tracking technology which is unique to the Senhance system (Fig. 2). We had one robotic-trained surgeon at the operating table.

**Figure 1. Robotic arm and port positioning for robotic-assisted Nissen fundoplication.**

**Figure 2. Surgeon operating the Senhance console.**
In our standardized procedure, we start with the preparation of the “pars flaccida” close to the right diaphragmatic crus, and dissection is carried out across the oesophagus to the left crus of the diaphragm. Great care is taken to avoid injuries to the vagal trunk. If a hiatal hernia is present, mobilization of the lower 5 cm of the oesophagus into the abdominal cavity is performed. Where necessary, a posterior hiatalplasty with one to three stitches with non-absorbable polyester (Ethibond, Johnson & Johnson) are placed. Finally, the Nissen wrap is positioned behind the GEJ and secured ventrally with three non-absorbable 2-0 polyester stitches (Ethibond, Johnson & Johnson) (Fig. 3). Insertion of a bougie transorally confirms the creation of a “floppy” Nissen wrap, and the procedure is terminated after ensuring haemostasis.

Patients were routinely hospitalized for four to five nights. On postoperative day four, a gastrografin swallow study was performed to document a proper anti-reflux plasty at the GEJ. All patients were clinically re-evaluated in the outpatient setting within four weeks after surgery.

Informed consent

Informed consent was obtained from all individual participants included in the study. All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. All patients were offered inclusion in the registry study TRUST (TransEnterix European Registry for robotic-assisted surgical procedures in urology, abdominal surgery, thoracic surgery and gynaecology) and clinical data were collected prospectively. Approval for the TRUST study (2017-463-F-S) had been granted by the ethics committee of the St. Marien-Krankenhaus Siegen (Ethics committee of the Chamber of physicians Muenster, Germany).

Data analysis

Charts and clinical data were reviewed and analysed in cooperation with Duke University Department of Surgery. Adverse events were documented intra- and postoperatively until postoperative day 30. Complications were defined following the Clavien-Dindo classification. Statistical analyses were performed using Microsoft Excel® (Microsoft Cooperation, Redmond, Washington). The median and range were used for skewed data.

RESULTS

Between April 2017 and July 2019, 18 patients underwent Nissen fundoplication with the Senhance® Surgical System. In this study, we included seven male and 11 female patients. The median age of the cohort was 58.5 years (range 30–81 years) and the median body mass index (BMI) was 30.4 kg/m² (range 22.7–40.1 kg/m²). Twelve patients had a hiatal hernia >3cm. Six patients had a large hiatal hernia with the majority of the stomach being intrathoracic. Seven patients had prior abdominal surgery. Extensive lysis of adhesions from prior surgery or chronicity of the hiatal hernia was required in eight patients. All patient characteristics, including past medical history, are summarized in Table I.

The docking time (time from diagnostic laparoscopy to start of the procedure at the console) took a median of seven minutes (range 4–14 minutes). The median time on the robotic console for all cases that were completed robotically was 74 minutes (range 52–172 minutes), and the median total operative time was 95.5 minutes (range 68–194 minutes). All operative times are summarized in Figure 4a–c. Even though this is a small case series, we observed a significant learning curve in the total operative time throughout the study period (p<0.05). Three of the first four cases lasted longer than 150 minutes, which highlights this learning curve.

We converted two cases to standard laparoscopy in the period of using the monopolar hook cautery, which is a smooth and fast transition with the Senhance® system. One patient had very dense adhesions of the hernia sac in the mediastinum, which required an advanced energy device for safe dissection. However, the Senhance® Ultrasonic was not available at that time and, therefore, the decision was made to convert to standard laparoscopy. In the second case, we encountered some bleeding from the short gastric vessels and converted to standard laparoscopy for the same reason and to achieve appropriate haemostasis. This patient underwent re-do laparoscopy on the day of surgery to evaluate pain out of proportion, but that operation revealed no significant findings. Further recovery of both patients was uneventful. Therefore, we observed one IIIb complication according to the Clavien-Dindo classification, although there is some debate in the literature about whether negative re-explorations should be classified as such.23 We also had one readmission approximately seven months after surgery for prolonged dysphagia. Endoscopic dilatation of the gastroesophageal junction did not improve the symptoms and, therefore, the patient underwent laparoscopic conversion from Nissen to Toupet fundoplication for sufficient symptom relief.

Figure 3: Robotic-assisted suturing of the Nissen wrap.
A group from Belgium reported the first case series of laparoscopic Nissen fundoplications in 1991. Eight years later, the first robotic-assisted Nissen fundoplication was performed with the Mona robot. Over the last decade, the da Vinci system has dominated robotic-assisted upper GI-surgery. However, due to high costs and a long learning curve, robotic-assisted surgery remains a rather exotic technique in this field. Owen et al. reported that only 2.8% out of 12,000 cases between 2008 and 2012 were performed robotically in the United States. The Senhance Surgical System has unique innovations that aim to overcome the reported disadvantages of robotic surgery. With haptic feedback and controllers that mimic laparoscopic instruments, the transition for surgeons with experience in laparoscopy is effortless. The independent arms make the docking fast and efficient and the reusable instruments reduce operation costs. Furthermore, the Senhance system allows the use of standard trocars used for regular laparoscopy in 3mm, 5mm, and 10mm sizes. Case series with the Senhance Surgical System have been published in a variety of gynaecologic procedures, colorectal surgery, cholecystectomy, and inguinal hernia repair with good outcomes.

This study was designed to evaluate the feasibility and safety of the Senhance Surgical System in anti-reflux surgery with special focus on the Nissen fundoplication. Our group had already gained experience in a variety of surgical procedures with the Senhance system and, therefore, we were able to easily adapt the platform to a new procedure. Our experience with the robot was also reflected by the median docking time of seven minutes that did not show a significant learning curve. However, even though this is a small case series, we experienced a learning curve in the overall operative time, which decreased significantly throughout the study period. This learning curve is mainly explained by two points that changed our practice: (1) changing the scope from a 0-degree to a 30-degree version in combination with moving the trocar placement 2–3cm closer to the operative area which allowed for increased range of motion of the working arm. (2) Changing the scope to a 30-degree view that allowed for a better view of the stomach and diaphragm.

**Table**

<table>
<thead>
<tr>
<th>Characteristics of all included patients who underwent robotic-assisted Nissen fundoplication (N=18)</th>
<th>N (%) or median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>58.5 (30–81)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>11 (61.1%)</td>
</tr>
<tr>
<td>Male</td>
<td>7 (38.9%)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>30.4 (22.7–40.1)</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
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<tr>
<td>Intrathoracic stomach</td>
<td>6 (33.3%)</td>
</tr>
<tr>
<td>GERD + hiatal hernia</td>
<td>12 (66.7%)</td>
</tr>
<tr>
<td>Extend of adhesiolysis</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>10 (55.6%)</td>
</tr>
<tr>
<td>Extensive</td>
<td>8 (44.4%)</td>
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<tr>
<td>Past surgical history</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>11 (61.1%)</td>
</tr>
<tr>
<td>Positive</td>
<td>7 (38.9%)</td>
</tr>
<tr>
<td>Past medical history</td>
<td></td>
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<tr>
<td>Negative or non-significant</td>
<td>4 (22.2%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>7 (38.9%)</td>
</tr>
<tr>
<td>CAD</td>
<td>2 (11.1%)</td>
</tr>
<tr>
<td>COPD/Asthma</td>
<td>4 (22.2%)</td>
</tr>
<tr>
<td>Smoker</td>
<td>2 (11.1%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>2 (11.1%)</td>
</tr>
<tr>
<td>Hypothyroidism</td>
<td>3 (16.7%)</td>
</tr>
<tr>
<td>Other comorbidities</td>
<td>4 (22.2%)</td>
</tr>
</tbody>
</table>

**Figure 4.** a: Docking time of all robotic-assisted Nissen fundoplications (n=18). b: Console time of robotic-assisted Nissen fundoplications (n=16). Cases that were converted to standard laparoscopy were excluded from this analysis. c: Total operative time of all robotic-assisted Nissen fundoplications (n=18).
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arms and (2) the introduction of the Senhance® Ultrasonic, which replaced the hook cautery in the right robotic arm and allowed for safer dissection and better haemostasis in technically challenging cases with dense adhesions. Prior to the Senhance® Ultrasonic being available, we had to convert two cases to standard laparoscopy to use an advanced energy device. Using this platform, conversion to standard laparoscopy was seamless, without the need to adjust port position. In our study, we had one negative re-exploration, which was the only complication in the early postoperative period. This study is, however, underpowered to make any comparisons to standard laparoscopy or robotic surgery that are reported in the literature. In regards to the learning curve of robotic surgery, there has been a wide range of numbers reported in the literature depending on the type of procedure. Pernar and colleagues summarized the experience of 26 different case series and reported 19-128 cases for colorectal, 8-95 for forget/bariatric, 20-48 for biliary, and 10-80 for solid organ surgery as the case numbers needed to achieve a plateau in performance.\(^{27}\) In our experience, the learning curve with the Senhance® Surgical System is considerably shorter given its similarity to standard laparoscopy that most robotic surgeons have mastered. In a small series of the Fundamentals of Laparoscopic Surgery (FLS) manual skills assessment, surgeons and trainees were also able to quickly adapt to the new system.\(^{28}\)

Currently, robotic-assisted fundoplication has been unable to supersede conventional laparoscopic fundoplication as the surgical gold standard. A meta-analysis by Markar, summarizing six randomized trials of 226 patients, revealed no significant differences between robotic or laparoscopic fundoplications in terms of operative complications, hospital stay, or postoperative dysphagia. Laparoscopic intervention had shorter operating times, and the robotic-assisted procedures added additional costs of up to 1.806€.\(^{29}\) Therefore, the Senhance® Surgical System could be a bridge between these two technologies.

We acknowledge the limitations of our study that come with the small sample size and the short follow up. Therefore, we are unable to compare postoperative outcomes and perioperative complications to reported data for standard laparoscopy and robotic surgery. Our learning curve and operative times could also be falsely low, given the large experience our team has already gained with the Senhance® Surgical System. Therefore, more case series are required to confirm the safety of this procedure and determine the efficiency compared to standard laparoscopy.

**CONCLUSION**

Robotic-assisted Nissen fundoplication with the Senhance® Surgical System is technically feasible and safe. Especially with the introduction of the Senhance® Ultrasonic energy device, large, technically challenging hiatal hernia repairs can be performed safely. Larger case series and randomised trials are needed to verify the value of this new robotic system for upper GI surgery.\(^{31}\)

**AUTHORS’ DISCLOSURES**

Dr. Willeke received research support and speaker’s honoraria from TransEnterix, Inc. Dr. Darwich served as a proctor for TransEnterix, Inc. Dr. Zani is a consultant for TransEnterix, Inc. Dr. Stephan is a consultant and proctor for TransEnterix, Inc.

All other authors have no conflicts of interest to disclose.

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