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**Outcome after computer-assisted (robotic) Nissen fundoplication in children measured as pre- and postoperative acid reducing and asthma medications use.**

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Running title: Outcome after computer-assisted fundoplication in children

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## **Abstract**

**Purpose:** To report the clinical outcome of computer-assisted fundoplication (CAF) in children.

**Methods:** Since our center changed policy to using computer assisted surgery only, a prospectively studied cohort of 40 children underwent CAF, during the period from January 2006 through May 2013. The collected data include patient demographics and postoperative complications as well as medication, 24h pH measurements and DeMeester scores before and after surgery.

**Results:** In the studied group the median percentage of the duration of the 24h pH<4 decreased postoperatively from 11% (5–39) to 1% (0–12) ( $p<0.001$ ); the DeMeester score decreased from 40 (17–137) to 5 (1–42) ( $p<0.001$ ). All 40 patients required anti-reflux medication before the fundoplication. This number decreased significantly to 8 (20%) after the fundoplication ( $p<0.001$ ). Before the fundoplication 22 children (55%) were using asthma medication and 12 (30%) after the fundoplication ( $p=0.04$ ).

**Conclusions:** The CAF significantly reduced the acid reflux from the stomach to the esophagus and the use of anti-reflux as well as asthma medication during the median observation period of five years.

**Key words:** Gastro-esophageal reflux; children; fundoplication; laparoscopy; computer-assisted surgery; outcome; robotic;

## **Introduction**

Gastro esophageal reflux is common in infants and children and most of them will outgrow their symptoms by 12 to 18 months of age [1]. Gastro esophageal reflux disease (GERD) is pathological and can, if left untreated, result in complications such as reflux esophagitis, Barret esophagus and esophageal stricture. GERD may also be associated with pulmonary complications, apnea and failure to thrive. Medical treatment such as antacids and prokinetic medication is the first-line therapy and is successful in most patients. When this is insufficient, anti-reflux operations are considered. Previous studies have shown excellent results and low morbidity with fundoplication indicating that the operation should be performed early for children with GERD [2].

Laparoscopic fundoplication (LF) has now become the gold standard for surgical treatment of GERD in children and excellent symptomatic results have been shown [3 – 8]. More and more pediatric centers around the world are now using robotic assisted laparoscopy to perform a fundoplication. Since there is nothing robotic, i.e. automatic, about the system, we consider the term computer assisted laparoscopic surgery (CALs) more appropriate. Although the computer-assisted technique is similar to that of conventional laparoscopy there are considerable differences, e.g. the use of 3D vision in CALs but, on the other hand, the lack of tactile response. Various studies have reported excellent short term results and demonstrated the safety and feasibility of computer assisted fundoplication (CAF) [6-8] but so far long-term studies are scarce.

Computer-assisted laparoscopic surgery is now the preferred method when performing Nissen fundoplication in patients at our center for pediatric surgery. The purpose of this study is to disclose whether CAF leads to a decrease in the use of acid reduction and asthma medication in children over time.

## **Methods**

This is a prospective study of the first 40 fundoplications using the da Vinci® Surgical System operation robot from Intuitive Surgical® during the period January 2006 to May 2014 at the tertiary center of pediatric surgery.

The fundoplication was performed by the same team and the same method was used on all patients. The preoperative work-up was the same for all the patients: an endoscopy with esophageal biopsy, a 24 h pH measurement and, if the patient showed any signs of problems

with swallowing, an upper gastrointestinal X-ray series was carried out searching for anomalies, hiatus hernia, partial outlet obstruction or malrotation. Impedance measurements were not performed in any of the patients. For the 24 h pH measurements the BRAVO® (Medtronic, Shoreview, MN, USA) was used.

Follow-up included personal interviews after one, six and twelve months. The patients were scheduled for endoscopy and esophageal 24 h pH measurement one year after surgery. The patients and their guardians were questioned specifically about heartburn, regurgitation, retrosternal pain, dysphagia and vomiting as well as the use of anti-reflux and asthma medication. The outcome after at least one year was compared with each patient's preoperative situation, the endpoint of the study. Information on medication was collected from the pharmacy database throughout the study period.

### **Ethical considerations**

The intention to treat was the main analysis strategy and encompassed all the patients. The da Vinci® Surgical System was approved by the FDA in 2000 and by the Institutional Review Board at the University Hospital. Verbal, informed consent from all the children's guardians was obtained prior to surgery. The use of CALS instruments, when performing pediatric surgery, and performing scientific studies comparing CALS and controls was approved by the regional research ethics committee (D nr 2009/59 and D nr 2010/49).

### **Results**

The demographic data of the 40 included children are summarized in Table 1. Previous operative interventions for gastrostomy are summarized in Table 2. The gastrostomies were never taken down during the fundoplication operations. The postoperative complications included reoperation, wound infection and conversion to open surgery (Table 3).

The pre- and postoperative findings in the study group i.e. vomiting, measured duration in per cent of 24h pH<4 and the DeMeester score decreased significantly after the fundoplication (Table 4). Before the fundoplication, all 40 patients in the study group required acid reduction medication and this number decreased significantly to 8 (20%) after the fundoplication ( $p<0.001$ ). Of the 40 patients, 2 (5%) were restarted on anti-reflux medication within 1 year after CAF. Before the fundoplication 22 (55%) children in the CAF group used asthma medication and 12 (30%) after the fundoplication ( $p=0.04$ ).

## Discussion

This study demonstrates that the CAF significantly reduced the acid reflux from the stomach to the esophagus and the use of anti-reflux medication. The use of asthma medication also decreased significantly after the CAF.

There are retrospective studies of medical management and laparoscopic Nissen funduplications [9] that show good results. To our knowledge there are no reports on the influence of a CAF on the postoperative use of anti-reflux, antacid or asthma medication compared with that used preoperatively. There are also, to our knowledge, no reports where patients have been followed up with postoperative pH measurements or endoscopies.

Reports comparing computer-assisted Nissen fundoplication with laparoscopic Nissen fundoplication [6, 7] found that there were no significant differences in postoperative complication rates, postoperative analgesic requirements or lengths of hospital stay between the groups. Short-term clinical results with respect to gastroesophageal reflux symptoms were comparable in both groups after 14 months of follow-up [6]. The authors concluded that CAF is a safe and feasible alternative to conventional laparoscopic fundoplication. This further supports the findings in our report of a good symptomatic relief and significant reduction in the use of anti-reflux medication. Since there were no significant differences observed in outcomes measured between CAF groups and laparoscopy operated groups [6] it has been concluded that there are no clear benefits from using robotics in Nissen fundoplication particularly in view of the high cost of the computer-assisted devices.

The cost of the computer device is indeed higher at least at the outset of its use [10] and throughout the five-year instalment plan period for the instruments. The cost decreases with time, as more operative interventions are performed each year and the operating time is reduced. When introducing new technology the cost is an important issue. In a report [10] the cost for CAF was higher than that for conventional laparoscopic surgery. The difference was mainly due to the cost for the initial investment in the new CAF instruments as compared with the conventional laparoscopic surgical instruments that were already included in the cost for the operating theatre. Now when the first five years from the start of using the CAF have elapsed, the CAF instruments are included in the cost for the operating theatre. Thus the difference in cost between CAF and the conventional laparoscopic instruments has dropped and is no longer significant.

The goals of an antireflux operation are to relieve reflux symptoms, avoid or decrease GERD-related complications and hospitalization and reduce or halt the use of antireflux medications. A previous study, a multi-institutional review of 7467 patients, has shown that antireflux procedures are successful in relieving reflux symptoms in children and reported good to excellent resolution of symptoms in 95% of neurologically healthy children and 85% resolution in neurologically impaired children after fundoplication [2]. However, these subjective outcomes were not clearly defined and there were no objective outcome measures in this study as in the study reported here. Furthermore, follow-up was based on a questionnaire filled out by each of the participating institutions rather than on objective evaluation of the patient and directly collected information from their guardians as in this present report. For these reasons, the methods and results of that study can be questioned and are not comparable with the results reported here. On the other hand, the results of the present study are largely based on information from the parents of the neurologically handicapped children, who are unable to express themselves, and represent the vast majority of our patients.

In spite of the fact that the children studied were included prospectively, our study has several limitations. The operative interventions were performed during a period of 7.5 years. There is a wide spectrum of the children's age and weight and the group of children is very heterogeneous when it comes to diagnosis. Although the majority in our group is neurologically impaired this diagnosis comprises several different diagnoses influencing the children's situation which is well known. Thus, the data presented here are not comparable with data from a discharge abstract database which is based on the International Classification of Diseases or Current Procedural Terminology coding of each diagnosis and procedure which are not independently validated.

Due to the prospective nature of collecting data in this study, we were able to determine the exact indications for the fundoplication which was not the case in retrospective reports [9]. None of the patients with underlying neurological or cardiac anomalies had antireflux surgery performed based on the perceived risk of developing GERD as had been the case in retrospective studies [9].

Few studies have documented objective outcome and end points following fundoplication in children including health survey scores, and overall satisfaction with anti-reflux therapy [11].

Such end points following fundoplication are difficult to reproduce in neurologically impaired children where one has to rely on information from their guardians only. Also, technical details of the fundoplication such as the length of wrap, crural approximation, or division of the brevis vessels or the presence and the fate of a gastrostomy were readily available. This is not always the case in older retrospective studies [9]. In the cohort of patients reported here the gastrostomy was never taken down during the CAF, an experience of gastrostomy preservation shared by other authors [12].

In this study the indications for administration of anti-reflux medication were reviewed and well known. This differs from reports where the indications for administration of anti-reflux medication were not reviewed and not known [9]. Previous studies [13, 14] have shown that anti-reflux medication may be over-prescribed in children. Anti-reflux medication was prescribed without adequate workup and documented GERD. In adult studies, up to 80% of patients were still receiving antireflux medication following Nissen fundoplication [15]. However, other adult studies have shown that only 25% of patients receiving acid suppression medication after Nissen fundoplication had abnormal pH study results [16, 17]. Similar reports are still not available in children. In our study two out of eight children that started to use anti-reflux medication after the fundoplication had normal pH studies postoperatively.

In our study we know why and who started the patients on anti-reflux medication and we know that such medication was actually discontinued following the fundoplication. It has been our practice to wean patients off all anti-reflux medication starting one week after the operation and to be finished two weeks later. On the other hand, we do not know how compliant patients were in using the anti-reflux medication. Our pharmacy database presents dispensed medication, but we cannot be sure that the patients were using what was prescribed.

Overall, the findings of this study demonstrated that the CAF significantly reduced the acid gastro esophageal reflux and the use of anti-reflux medication during the median observation period of five years. Also the decrease in the use of asthma medications was significant after the CAF. The conclusion that can be derived from our data is that the use of CALS for fundoplication achieves good results. The evidence of advantages compared to conventional laparoscopic fundoplication remain to be confirmed.



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**Competing interests:**

When performing this work, there were no external influences or conflicts of interests.

All authors have completed the Unified Competing Interest form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) (available on request from the corresponding author).

All authors declare:

- (1) No financial support for the submitted work from anyone other than their employer;
- (2) No financial relationships with commercial entities that might have an interest in the submitted work;
- (3) No spouses, partners, or children with relationships with commercial entities that might have an interest in the submitted work;
- (4) No non-financial interests that may be relevant to the submitted work.

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**Table 1**

The table summarizes the demographic data of the children included in the studied group of 40 children undergoing computer assisted fundoplication.

	Children N
Number of children (girls/boys)	40 (10/30)
Age in years, median (range)	6 (1 – 15)
Weight in kilograms, median (range)	19 (6 – 78)
The children's diagnosis:	
- GERD only	4
- Syndrome*	8
- Neurologically impaired	23
- Gastrointestinal malformation**	2
- Respiratory insufficiency	3

\*Turner, Cornelia de Lange, Catch 22, Chiari syndrome and Mb Down

\*\*Esophageal atresia in one child

**Table 2**

The existence of a gastrostomy in 40 reported children undergoing computer assisted fundoplication. The gastrostomies were never taken down during the operative interventions.

Gastrostomy	Children
	N
No gastrostomy	12
VAG* pre op	22
VAG post op	1
VAG per op	2
PEG** pre op	3
Sum	40

\*Video-assisted gastrostomy

\*\*Percutaneous endoscopic gastrostomy

**Table 3**

The number of postoperative complications in the 40 children undergoing computer assisted fundoplication.

Complications:	N
Converted to open surgery*	1
Re-do fundoplication**	4 ***
Incarcerated hernia in cicatrices in umbilicus	1
Minor wound infection, treated with antibiotics	2
Mortality, unrelated to the fundoplication (after)	4 (3, 9, 16, 17 months)

\*Due to a perforation of the esophagus during the computer assisted operation, and due to technique problems when performing laparoscopy.

\*\*Due to hiatus herniation in one child, and due to re-hiatus herniation in one child and recurrence of gastro esophageal reflux in two children operated on with the computer assisted technique.

\*\*\* In three children after: 11 months, after 19 months and in the third child: twice after 6 and 14 months respectively.

**Table 4**

The outcome after computer assisted fundoplication in 40 children

Findings in	preoperative	postoperative	p-value
<b>The study group, after follow-up for median years (range)</b>		1 (0.5 – 2) years	
<b>Symptoms</b>			
- Vomiting in	40	1	
<b>Esophageal pH measurements:</b>			
24 h pH < 4, median (range) %	11 (5 – 39)*	1 (0 – 12)**	<0.001***
DeMeester score, median (range)	40 (17 – 137)	5 (1 – 42)	<0.001***
<b>Use of medicines: after median years (range)</b>		5 (1 – 8) years	
Proton pump inhibitors	40/40	8/40	< 0.001****
Asthma medication	22/40	12/40	0.041****

\*In 9 children preoperative esophageal pH measurements have not been performed. Re-dos were necessary in three children.

\*\* Due to very good clinical relief of symptoms any further pH measurements were not considered necessary in nine children and six children are waiting for the pH measurement. Four children later died unrelated to the fundoplication.

\*\*\*Mann-Whitney U test, two tailed.

\*\*\*\*Fisher's Exact Test, two tailed