

Case Study

AngelChik device removal and revisional fundoplication: lessons from the past and thoughts for the Future.Hannah Chase¹, Sotiris Mastoridis², Nicholas D Maynard⁵Keywords:
GORD, reflux disease,
fundoplication, AngelChik.¹Medical Sciences Division, University of Oxford, UK.²Oxford University Hospitals NHS Foundation Trust.³Oxford University Hospitals NHS Foundation Trust, Oxford OesophagoGastric Centre, Churchill Hospital.

Key Learning Points**Mr Sotiris Mastoridis and Mr Nicholas Maynard**

The treatment of reflux is incremental, with surgery reserved for those with severe disease failing to respond to conservative and medical treatments. Nissen's Fundoplication is the current preferred approach and will achieve good outcomes in 85-90%, with patients tending to find the advantages to outweigh the common drawbacks which include an inability to belch, flatulence, and early satiety. Fundoplication is, however, not without the potential for significant complications – para-oesophageal herniation, re-operation for dysphagia, gastrointestinal perforation, to name a few. In a bid to improve outcomes and minimise morbidity, there are advocates of alternative laparoscopic approaches, of endoscopic procedures, and of the insertion of implantable devices for the augmentation of the lower oesophageal sphincter. Among the latter is the now largely obsolete AngelChik device. In the report below, the author draws on a recent case involving AngelChik failure and the need for revisional surgery. The report describes some of the shortcomings in the evaluation of surgical devices prior to widespread utilisation, and highlights progress being made in providing frameworks for the regulation and implementation of novel implantable devices. Finally, in light of the adoption of newer magnetic sphincter augmentation devices, a call is made for caution, and practitioners are reminded of the need for informing patients as fully as possible of the potential risks involved over and above 'tried-and-tested' conventional approaches. It is imperative, as per the recent recommendation from the Royal College of Surgeons of England, that the registration and regulation of all implantable devices be compulsory.

Introduction

Gastro-oesophageal reflux disease (GORD) is a common condition in developed countries with an increasing incidence in the UK, currently estimated at 5 per 1000 person-years¹. Risk factors for GORD include male gender, obesity, alcohol consumption, smoking and genetic predisposition. Surgical management is performed in chronic, severe cases of GORD, refractory to medical and conservative treatments.

Here, we describe a patient who underwent placement of an AngelChik Device (AD) 30 years ago for the treatment of refractory GORD. Used mainly in the 1980s, these silicone devices aimed at augmenting the lower oesophageal sphincter became largely obsolete, in part due to associated complications, but also because of the improving technical results associated with fundoplication procedures. The case described highlights another example of AD failure, and of the need for revisional surgical intervention. Following description of the case, we will discuss the increasing incidence of late complications of

AD and consider the pros and cons of a proactive 'recall' approach for individuals with such devices. Finally, we discuss the latest evidence for novel magnetic sphincter augmentation (MSA) devices, more recently gaining traction in the treatment of GORD. We emphasise that more stringent assessment, drawing on transparent international collaboration is needed in the evaluation and regulation of such medical devices when bringing them into clinical care.

Case Report**Case presentation**

A 54 year-old woman presented to the Oxford Oesophagogastric Centre with worsening dyspepsia, starting acutely three years previously, following an episode of severe vomiting. The retrosternal burning associated with her reflux would consistently wake her at night, and she suffered significant changes to her sense of taste.

This presentation was on a background of AD placement in August 1990 following many years of severe

reflux, regurgitation and persistent cough. This surgical intervention completely resolved her reflux symptoms. However, since surgery she had always had mild dysphagia manifested by only being able to swallow food with simultaneous liquid and having to limit portion size. She presumed these symptoms were expected and carefully managed them. She also reported being unable to vomit after the original surgery until the episode three years ago when her symptoms recurred.

A diagnosis of bronchiectasis was made at around the time of her first surgery in 1990, presumed to be due to recurrent gastric acid aspiration. Due to this she has always had some exercise intolerance but regularly swims and has managed her weight to minimise her respiratory pathology. She is on 750mg carbocysteine orally, 2 puffs Symbicort (budesonide and formoterol) and 2 puffs salbutamol, all twice daily as long-term management for bronchiectasis. Her only other regular medication 2mg estradiol once daily for hormone replacement therapy.

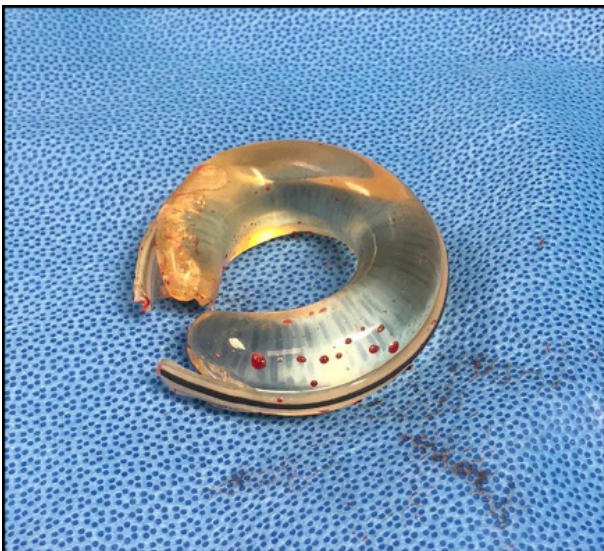
She is a farmer and lives independently at home with her husband. She has never smoked or taken illicit drugs and is a mild social drinker. There is no significant family history of disease and she has no allergies.

Investigations

Initial symptomatic medical management with 20mg esomeprazole once daily and 300mg ranitidine twice daily proved ineffective. Although the patient described a 30% improvement in her reflux symptoms, she was intolerant of the medication, describing symptoms of fatigue when taking them. Though ranitidine was substituted with cimetidine, there was little improvement to these reported side-effects.

Upon referral to the Oesophagogastric team, an initial barium swallow (28 months prior to surgery) showed moderate dysmotility in the mid and distal oesophagus but no significant hold-up at the gastro-oesophageal junction (GOJ) and no hiatus hernia. This was followed by gastroscopy, which corroborated an absence of a hiatal hernia and diagnosed oesophageal candidiasis. Although most commonly associated with HIV, oesophageal candidiasis has a prevalence of approximately 1.6% in patients not infected with HIV, with reflux oesophagitis being a risk factor². This was treated successfully with fluconazole and a repeat gastroscopy one year later was grossly normal. Biopsies taken showed reflux oesophagitis and moderate gastritis.

A computed tomography (CT) scan of the thorax



and abdomen was undertaken at around the same time as the repeat gastroscopy, 16 months prior to the surgery. The AD was visualised around the proximal stomach rather than GOJ, in an abnormal position under the left hemidiaphragm. Other investigations undertaken were oesophageal physiology studies including pH-testing and manometry, whereupon pathological reflux was diagnosed. Following extensive discussion of the results of the investigations, and of the benefits and risks of operative intervention, the patient elected to proceed to surgery.

Surgical intervention

The planned operation involved laparoscopic removal of the AD and revision Nissen fundoplication.

The abdomen was relatively hostile, with dense adhesions due to prior surgery requiring meticulous adhesiolysis. Despite these adhesions the operation was completed laparoscopically. Upon open insertion of the epigastric trocar, it was noted that the tip of the left lobe of the liver, which was firmly adherent to the anterior abdominal wall, had sustained mild iatrogenic injury. No bleeding but minimal bile leakage was observed, which soon ceased and, on inspection at the end of the procedure, remained dry. A Robinson's drain was left at the site of the bile leak. The AD was located anteromedial to the hiatus, was heavily fibrosed, and adherent to the stomach and diaphragm. Following careful adhesiolysis and dissection using an endoscopic energy device, the AD was successfully removed - as seen in Figure 1.

Finally, revisional Nissen fundoplication was performed. Oesophageal mobilisation too proved technically challenging, with dense adhesions around the left lobe of the liver, hiatus, and stomach. The diaphragmatic crura were re-approximated by placement of three interrupted sutures anteriorly, and a 360° fundoplication was carried out via a retro-oesophageal window.

Post-operative course

Early post-operative recovery was uneventful. At 48 hours, bile-coloured discharge from the epigastric port-site was observed. A wound manager was placed over the port-site to contain the leakage and monitor contents. There was also concurrent well demarcated pigmented skin change over the central abdomen, initially periumbilical and then spreading diffusely over the entire abdomen. Blood tests were reassuring, including liver function and clotting parameters. An urgent CT confirmed port-site

Figure 1: The AngelChik Device after removal. The radiopaque tape was found broken open.

infection, but no evidence of ongoing intra-abdominal bile leak, liver bleed, or drainable collection.

Three times daily intravenous co-amoxiclav was commenced. The patient was monitored carefully with a low threshold for repeat CT-scanning or further intervention. An endoscopic retrograde cholangio-pancreatography (ERCP) was booked, in order for stent placement to facilitate anatomical drainage and minimise bile leak. Over the next 3 days, the epigastric wound manager continued to collect 200-300ml bile daily, whereas the intra-abdominal drain produced only minimal serosanguinous fluid.

The patient's pain was well controlled with opioid and non-steroidal anti-inflammatory medication. She mobilised multiple times a day around the ward and received daily dalteparin injections for venous thromboembolism prophylaxis. Nevertheless, on the fifth post-operative day she became acutely short of breath, and CT-pulmonary angiogram demonstrated a right anterobasal pulmonary embolus (PE) in addition to consolidation in the left lower lobe with a small effusion. Treatment dose of dalteparin (15000units) was initiated and co-amoxiclav re-started.

The diagnosis and management of the PE postponed the planned ERCP, and over the following 24 hours a significantly reduced volume of bile (20ml) was noted in the wound bag. 10 days post-surgery the leak had completely resolved and her respiratory symptoms had improved. She was discharged on post-operative day 10 following a normal liver ultrasound identifying no free fluid, biliary dilatation, or biloma.

At a 4-week outpatient follow-up appointment the patient's reflux had resolved completely, and she was tolerating a soft diet very easily. The consistency of her diet was to be gradually increased from this point.

Discussion

AngelChik device complications

An AD is a C-shaped silicone ring placed around the gastroesophageal junction and secured by radiopaque Dacron tape. They were first introduced in 1979³ and it is estimated more than 25,000 devices were implanted worldwide⁴. They were almost entirely abandoned by 1990 after a randomised controlled trial (RCT) comparing AD and Nissen fundoplication highlighted the significant morbidity associated with an AD⁵. Another report, with longer duration of follow-up of 12 years in 65 individuals receiving an AD reported a device removal rate of 15%, with a further 18% experiencing device migration. Dysphagia was the most common complication and persistent

severe dysphagia occurred in 17% of cases, half of which underwent device removal while the remaining patients required medical management or endoscopic dilation⁶. Higher rates of dysphagia and prosthesis removal - up to 24% - have also been reported in the literature⁴.

A comprehensive search of case reports since the year 2000 highlights the growing incidence of late complications of ADs, and is summarised in Table 1. Complications directly related to the AD included migration, erosion, dysphagia, fistula formation and worsening reflux. There are also 6 reported cases of gastro-oesophageal adenocarcinoma in patients with an AD (Table 2), possibly a consequence of failure to alleviate reflux in these patients.

The patient presented here described persistent dysphagia since AD insertion, and explained that they assumed this to be an expected side-effect of the device. For this reason, she managed symptoms conservatively by diet modification without seeking medical advice. Her symptoms are consistent with those reported in other case reports in the literature, with several surveyed patients describing persistent dysphagia or reflux following AD insertion, which they held to be a 'normal' complication that they would have to endure^{7,8}.

Given the accumulating reports of late complications in a decreasing pool of patients that still have the device in situ, it ought to be considered whether these patients should be recalled for a discussion regarding elective AD removal. This is particularly relevant given the apparent lack of awareness of patients of expected outcomes and possible side-effects following AD insertion. It is evident that patients in this cohort tend to tolerate symptoms for a prolonged period before seeking medical advice, something which puts them at greater risk of suffering from consequences of these complications - discomfort, oesophagitis, and dysphagia among others. While symptom profiling, patient selection, and appropriate counselling are key prerequisites, it might be appropriate that patients with an AD in place be offered referral to specialist oesophagogastric units in order to be informed of known device related concerns. Striking a balance between the inappropriate generation of anxiety amongst this patient group, with the need to relay any information needed for informed decision-making to be possible from the patient's perspective is, of course, challenging.

Furthermore, as this case highlights, elective surgery to remove the device with or without an additional corrective procedure for reflux is not without risks. Procedure related acute complications are well documented, with instances of iatrogenic liver injury such as in this report

| Author (Year) of report | Complication | Years since AD device implant | Management |
|--|--|-------------------------------|---|
| Plaiser and Lange (2000) ⁹ | Migration | 17 | Laparoscopic removal followed by medical control of reflux. No complications. |
| Florez et al. (2003) ¹⁰ | Oesophageal mechanical obstruction and partial erosion | 21 | Endoscopic removal |
| Carbonell and Maher (2006) ¹¹ | Erosion through the gastroesophageal junction | 25 | Endoscopic removal with laparoscopic guidance |
| Zavareh and Dubbins (2009) ¹² | Migration to pelvis | 20 | Not causing signs so monitoring |
| Jalil et al. (2011) ¹³ | Severe reflux | 25 | Laparoscopic removal and immediate Nissen's fundoplication |
| Sloane and Gupta (2013) ¹⁴ | Migration to abnormal position causing acquired stenosis | 15 | Laparoscopic removal and immediate Nissen's fundoplication |
| Pence et al. (2015) ¹⁵ | Gastroesophageal fistula | 17 | Watchful waiting |
| Masuda and Mittal (2018) ⁷ | Worsening dysphagia and reflux | 37 | Laparoscopic removal and Roux en Y gastric bypass |
| Arazi et al. (2020) ¹⁶ | Progressive dysphagia to end stage oesophageal disease | 30 | Surgical removal and jejunostomy feeding tube placement |

Table 1: Case reports since 2000 of late complications directly caused by the AngelChik Device

| Author (Year) of report | Complication | Years since AD device implant | Management |
|-------------------------------------|----------------|-------------------------------|--|
| Jenkins et al. (2005) ¹⁷ | Adenocarcinoma | 25 | |
| Mercer et al. (2007) ⁸ | Adenocarcinoma | Case 1 – 12 | Palliative chemotherapy |
| | | Case 2 – 17 | Surgical resection (Ivor-Lewis oesophagectomy) |
| | | Case 3 – 12 | Surgical resection (gastro-oesophagectomy) |
| Shetty et al. (2010) ¹⁸ | Adenocarcinoma | Case 1 – 19 | Surgical resection (cardio-oesophagectomy) |
| | | Case 2 – 27 | Surgical resection (cardio-oesophagectomy) |

Table 2: Case reports of oesophageal malignancy in patients with an AngelChik Device in situ.

not being without precedent¹⁹. A recent retrospective study found total 30-day complication rate was approximately 4.1% following primary anti-reflux laparoscopic surgery, but significantly increased to 23.4% following secondary, revisional anti-reflux surgery²⁰. Total 30-day mortality rate was very low (0.1%), but the patient numbers (n = 77) in the revisional surgery group were insufficient to establish whether a secondary surgery increased the mortality risk. The probability of complications will vary depending on patient comorbidities and general health status, which is another reason it is important to assess all patients on an individual basis.

The current mainstay of surgical treatment for GORD is laparoscopic fundoplication. The procedure has an approximately 90% success rate at controlling symptoms, but a third have recurrent reflux when tested by pH monitoring²¹. As in all medical and scientific fields, it is important to have innovation in surgical techniques in order to improve outcomes further. However, it is important that lessons are learned from the AD experience, as well as that from other surgical devices such as gastric bands, urogynaecological meshes and Poly Implant Prothèse (PIP) implants.

The IDEAL-D framework for evaluation of surgical devices

Evaluation of surgical devices is complex and can be problematic for multiple reasons^{22,23}. Developers often present relatively poor-quality evidence for devices which often undergo repeated modifications. Furthermore, there are difficulties in generalizing the evidence obtained in a specific setting with specific expertise and there is normally a 'learning curve' effect whereby outcomes improve with experience. Finally, there are difficulties in defining the correct scope of the evaluation such as reliability, safety, ease of use, market demand, cost-effectiveness and rare or late complications.

However, guidance is now available for evaluating innovative surgical devices in the IDEAL-D framework to promote evidence-based practice²⁴. This framework expands on the IDEAL approach previously developed to lay out the studies and evidence required during the development of new surgical procedures. 'IDEAL' is an acronym for the stages of development namely Idea (Stage 1), Development (Stage 2a), Exploration (Stage 2b), Assessment (Stage 3) and Long-term follow up (Stage 4). There is progression from a first-in-human case report to large RCTs to the initiation of a disease based registry or database²⁵. A Delphi process modification of this framework was used to make it applicable to surgical devices (IDEAL-D). It still involves a safe and structured progression from innovation to large-scale RCTs. Notable differences are:

- The addition of stage 0, requiring publication or registration of preclinical data
- A more flexible approach to stage 2, with potential fusion of 2a and 2b
- A need for registries from an earlier stage (Stage 1)
- Tightening of regulation to govern surgical

innovations is supported by the Royal College of Surgeons of England²⁶. One aspect that would particularly enhance safety of new surgical devices urgently would be the creation of international registries to maximise data on new devices systematically with greater regulation prior to widespread device insertion.

Magnetic sphincter augmentation

With these considerations in mind, we turn to a recently introduced medical device aimed at the management of GORD - magnetic sphincter augmentation (MSA). This consists of an expandable chain of magnetic titanium beads designed to enhance contraction of the lower oesophageal sphincter²⁷. The theory of its mechanism of action and the attraction of its simplicity is similar to that of the AD. Since introduction in 2008 thousands have been inserted in the United States²⁸. The Food and Drug Administration approved the device in 2012, but in the UK the National Institute of Clinical Excellence only endorses it under 'special arrangements for clinical governance, consent and audit or research' due to 'limited evidence of safety and efficacy'²⁹.

A recent systematic review by Kirkham et al.³⁰ evaluating the evidence of the device shows a concerning lack of unbiased evidence in the literature with no long-term safety demonstrated. Only one RCT has been carried out and this compared the surgery to medical management rather than fundoplication. In addition, there was no information to assess the risk of bias. In all 39 studies included, 9.15% of patients had undergone device removal within the specified follow-up periods, which varied from 4 weeks to 5 years. 12 studies were funded by the device manufacturer and 24 stated conflict of interest. The evaluation of the device in the last 11 years is not consistent with the IDEAL-D framework. The review concluded there was a lack of robust evidence to support its effectiveness or long-term safety. This is concerning for both this particular device and other current and future surgical innovations. It emphasises the need for increased regulation.

Conclusion

The case reported here is a further example of a late complication associated with an AngelChik

device requiring revisional surgical intervention. There are likely to be patients who have an AD in situ with no adverse side effects where the risks and morbidity of a second surgery outweigh the potential benefits. However, there is increasing incidence of late complications and a low rate of self-reporting of morbidities among those with ADs. Consultation with patients who still have the prosthesis in place, to review their current clinical status and to check for unidentified prosthesis migration or erosion, would be a sensible approach to reduce avoidable morbidity going forward. Importantly it would allow patients to make an informed decision regarding any further intervention.

Looking to the future, the AD device demonstrates why a thorough and systematic method for introducing new surgical interventions is required and the IDEAL-D

framework is now recommended to increase evidence-base of new technologies. It is a matter of concern that recent innovations appear to not be following these frameworks, and in some cases to exhibit a lack of standardised reporting in long-term safety and efficacy data. This needs to be addressed urgently in the case of MSAs as current published literature does not allow long-term safety or efficacy to be adequately established. This lack of standardisation places clinicians and patients at potential risk, and needs to be addressed for future innovations by International collaboration and regulation.

Conflicts of interest

None.

Funding

None.

Consent

The patient has consented to the publication of this case study.

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