

IP2010 Laparoscopic insertion of a non-active implant for gastro-oesophageal reflux disease

Testimony received before the company was aware of the patient survey. Some experiences may be duplicated in the patient survey responses.

Response 1:

Hello,

I used to have severe, chronic acid reflux, which affected my daily life very severely. I could feel the acid going up my oesophagus and as soon as I started to feel the burning sensation it caused, my nose started to run, and it would get to a point where I had to throw up.

Mostly it happened after eating. Any type of food could set me off and most of the time I would have to throw my dinner up. It was quite tough.

I started to notice in December 2022 that I had a cough that was bad, and not getting any better, and I was also vomiting three times a week.

I was really anxious about going out for dinner, knowing that I had a vigorous cough and that food would cause me to vomit, so I always ended up eating at home.

Thankfully, my employer was really understanding and if I had to leave a meeting to be sick, they were understanding. But being unwell, at work, in a public place, is really embarrassing.

It did affect my sleep. At bedtime, I would prop myself up with more pillows, so my head was above my body, to stop my throat burning. Even then I would wake up in the middle of the night with a massive burning sensation in my throat. I would sit up and wait up for it to pass.

People get standard heartburn now and then, but they don't understand the difference between severe and normal amounts of heartburn and the damage that having it every day, after every meal, can cause to your body.

In March I decided to go to the doctor, and I was put on Omeprazole medication to make the fluid in my stomach less acidic. I completed a month's course. As soon as I stopped taking it, the symptoms came back straight away.

Then the doctor referred me for an endoscopy in August 2023. The endoscopy showed that I had developed a condition called oesophagitis, which meant that the acid coming up my throat from my stomach had damaged my oesophagus. The doctor doubled the dose of the Omeprazole, and it was at that point that I started to get IBS symptoms from the medication itself.

I had a second endoscopy in October 2023 which showed that my oesophagus had healed well. But I was recommended to have a meeting to discuss which common surgeries the NHS offers, and it was then that the medical team started to talk about a new option called RefluxStop. I met with my surgeon, [REDACTED], who works at [REDACTED].

I had a camera down into my stomach in March 2024 which basically showed my swallowing was okay, so I was eligible for all surgical options.

RefluxStop was the one I wanted to go with because it is less invasive than the other options. RefluxStop is a small implant which is sewn into the top of the stomach, parallel to the oesophagus. The RefluxStop implant restores the natural function of a valve which opens and closes the stomach. The implant allows the valve to work as it should, and not let acid up into the oesophagus. It's a lifelong implant, so basically, once it's in place, you carry on as if it never happened.

I was really looking forward to not having to take medication anymore!"

I had the keyhole operation to implant RefluxStop on April 29, 2024 at [REDACTED]

Now, two months later, I have no reflux at all, and I am off medication. I was on a soft food diet for 8 weeks and I think that restricted diet meant my IBS was back straight after the operation. But I am now back to normal, and eating anything I want, and the IBS is getting better.

I am so grateful to [REDACTED] for my very quick referral and treatment on the NHS.

Response 2:

My reflux started off as a fairly minor problem which gradually got worse. Despite cutting out all spicy food, citrus fruits and alcohol, but it just wouldn't go away.

Over time, I became quite severely depressed. I lost a lot of weight and at nearly 6 foot tall, I weighed less than 11 stone. I survived on toast and potatoes. I couldn't go out because I felt too unwell to socialise, I couldn't go to the pub, out for a meal or for a coffee. The only people I saw were my close family, and I had to sit and watch them eating while I picked at my food. It affected them too. They were upset to see me like this.

Food is social, it affects all of your life. Suffering from chronic pain at every moment of every day affects your mind. Chronic acid reflux also affects your sleep, so you can't think or rationalise properly. After years of no sleep, no socialising and lots of pain, even the most well-adjusted people can want to do something drastic.

I was referred by my GP to [REDACTED] where I underwent an endoscopy. I was diagnosed with a hiatus hernia. The gastroenterologist in the hospital prescribed proton pump inhibitors (PPIs), to counteract the symptoms.

The medication just didn't make any difference. The dosage steadily increased but my condition worsened – the pain started to feel unbearable. I had constant throat pain. My chest felt tight, like an elastic band was constricting it.

he consultant in the hospital saw me again and offered me an operation called fundoplication. I did some research, and frankly the procedure sounded barbaric. I didn't fancy the after-effects. The surgeon said I won't be able to belch, or vomit, if something upset my stomach.

He explained that during the procedure, the oesophagus is wrapped around the stomach. That sounded medieval, like something I wanted to avoid, if I am honest. So, I said no, I didn't want to have that operation. After that my condition started really getting to me, severely impacting my mental health. I didn't want to eat anything at all. Eating made the symptoms worse. I followed my doctor's advice to the letter, but nothing helped. My sleep was affected because when I lay down at night, the acid would come into my mouth.

I was recommended to raise the end of bed by 6 inches, which I did. I even researched on forums of people who have GORD about low acid diets.

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I had already cut out all the so-called trigger foods: fruit juices, citrus, tomatoes, wine, black tea.

I only drank water, and ginger tea – the latter helped me slightly.

I have never been a heavy drinker, but now I cut out alcohol completely. My diet was so bland, I avoided so many things to keep symptoms down, my wife had to eat differently to me. mainly ate bread, potatoes, and lean meat. I think probably the diet helped a little.

I was on PPIs for some years, and I was on the maximum dose that the GP was allowed to give me. I realised that no medication going to help, and diet didn't make a sufficient difference. I got onto my laptop, started going on patient forums a lot, and was surprised to see the massive proportion of the population of England and the rest of the western world who suffer from this. What I read worried me more: untreated acid reflux can cause oesophageal changes that can lead to cancer. I knew I needed to do something.

I started to research other types of operation. That's when I came across an operation called Linx and one called RefluxStop.

The problem with Linx is that I was told by my consultant that the muscles in my digestive tract weren't working properly, so I wouldn't be able to have that procedure.

This left RefluxStop. This is a procedure which doesn't require patients to have good motility. Afterwards, there were no patients reporting issues with burping or vomiting as with Fundoplication. I saw that there were positive reviews from patients who live abroad who had RefluxStop, which reassured me.

Luckily, when I was researching it, at the end of 2021, the operation was just about to come to the U.K. and was to be offered by a surgeon called [REDACTED] who works privately for a company called RefluxUK.

I went to see [REDACTED] and he said, I may be able to help you. He confirmed that I had weak motility, but that RefluxStop is an operation that has been cleared for use in the U.K. that is suitable for me. I felt I had nothing to lose by this stage. I found the money to have this operation privately because I felt I had no other choice.

I had my RefluxStop operation on 3rd March 2022 at the [REDACTED]

I got there early in the morning, they did the usual tests: temperature, pulse, etc. [REDACTED] came in to have a chat. I was prepped up and just before midday I was taken down to the theatre. I woke up about 2 hours later. My wife was there. We had a chat. Mr Boyle came to see me. The nurse came in, gave me water, I drank it, and that seemed fine.

At about 6pm, they brought in a soft food meal, it was chicken, potatoes, and carrots, all finely shredded. I was quite surprised that they were letting me eat. I was hungry; I hadn't had anything to eat all day. So, I tucked in, though I was wary, after reading what they were going to do, I thought: shouldn't I be on fluids?

But the weird thing was I had no acid. Fabulous. I was a bit sore from the operation, I'd some very small incisions in my abdomen. There are 5 small cuts, around the tummy, each of which were about 1.5cm long.

I stayed in overnight as I didn't live locally and had a long journey to get home, so the next morning, [REDACTED] came to see me. I was quite surprised when he said, I don't want to hear you're pureeing your food, try to get on to a normal diet straight away.

So I had my first proper meal at home for lunch when I got home.

It was chicken, mashed potatoes, and I think I had peas. I was back on a normal diet! It felt fantastic. I had no problem with swallowing, there was no pain at all in my throat or chest. It was a great feeling!

My wife cooks dhal, so within a week I was eating Asian food again – or anything else I fancied. I had rotis, anything I wanted, with no unwanted side effects.

It's been over 2 years now since the operation. I forget I've had the operation to be honest. My quality of life has been brilliant. Food wise I can eat anything I want without thinking about.

I am a big fan of a curry so I am really enjoying spicy food again. I have cut down on alcohol because of my age, but I do like a glass of wine so I back to making the most of nights out with friends again, going for coffees and enjoying all the social occasions I missed so much.

The operation has been a total success, so I would wholeheartedly advise that NICE recommends RefluxStop for use on the NHS.

Response 3:

About 20 years ago, I started to develop problems with reflux. I had the feeling of burning in my chest after every meal and at night. So I did the usual things like changing my diet – I cut out high starch foods like croissants and biscuits and this helped a little but didn't resolve the problem.

I went to my GP who prescribed Omeprazole, a proton pump inhibitor drug. This helped and the reflux seemed to be reasonably under control, but still occasionally it would play up quite badly. It was a very unpleasant feeling, a burning feeling in my lower chest and sometimes I regurgitated my food.

About six years ago, I felt that the heartburn was getting worse. I was becoming very worried about the constant pain of heartburn, and as the sensation of acid was worse when I lay down to sleep at night, the condition was severely affecting my ability to sleep and, consequently, I was tired all the time and that affected my performance at work. I had an ultrasound examination which showed that I'd developed an ulcer in my oesophagus and Barrett's oesophagus was diagnosed.

Barrett's is a condition where some of the cells in the oesophagus grow abnormally and is caused by reflux. It can increase your risk of developing cancer.

I knew I had to do something different and look for a surgical solution. At that time, I knew that the NHS is not keen on performing reflux surgery, I decided to go private to speed things up.

I saw a number of specialists, including a [REDACTED] England, who wanted to perform a procedure called a Fundoplication, or stomach wrap surgery.

I was not keen to do this, as I knew that some people who have had this surgery are left with an impaired ability to swallow, particularly if before surgery, they have been shown to have a condition called dysmotility, which means the normal contractions of the stomach to push their food down to the stomach are not working as well as they should, which is due to the damage from the reflux.

I felt more comfortable with having another type of surgery known as Linx, but another test revealed this wouldn't be suitable either, as, like fundoplication, it's not suitable for people who have poor contractions of the oesophagus. It was then suggested I have a less invasive option, called an anterior partial

fundoplication, but I wasn't keen on this either. It seemed that all the surgical options available at that time had significant risks of long-term side effects.

I started looking online for other solutions and I found RefluxUK, a specialist clinic based in the south of England, with an excellent website and detailed description of the procedures in place for reflux. One of the procedures they offer is RefluxStop which at that time was quite new in the UK.

As a vet, I found this procedure especially interesting. I am knowledgeable about human anatomy and the mechanical design struck more than just one chord. It seemed to address various shortcomings of the other procedures mentioned, which appear to rely very much on scar tissue keeping the lower oesophagus aperture closed. RefluxStop is essentially a small medical implant made of medical grade silicone, which is incorporated in the top of the stomach in a fashion that, by light pressure, it helps the closure of the lower oesophagus but still lets food through into the stomach via the flexibility of the silicone material.

Even though the RefluxStop surgery only has a history of about 6 years compared to about 15 years for Linx, and 30 years for laparoscopic fundoplication, I felt most confident that RefluxStop would work for me.

The consultation I had with [REDACTED] was excellent; factual, professional, and, due to the test findings, he recommended the anterior wrap procedure (partial fundoplication) or the RefluxStop procedure. At the time, Mr Boyle had done 17 such procedures, 15 without any problems, and the other 2 were without complications after an initial recovery period. I proceeded with [REDACTED] for the RefluxStop procedure which I had on May 3, 2023.

Immediately after the keyhole surgery I was able to eat fairly normally, though I limited myself to small meals taken in small bites, chewed thoroughly every two hours or so, with liquid. All went well and has stayed well. On the very odd occasion I felt some food accumulating upwards from the now narrower hole in my diaphragm, but that could easily be resolved with drinking fluids. Since the procedure, the amounts I can eat are somewhat less, which is no problem.

As a result, even more so than I already did, I focus on very healthy eating. Initially there was pain, likely associated with the two incisions on the left side (there are 5 small incisions in total), which made any use of the muscles in that area painful, so it was a bit sore when I sneezed, laughed, or got up from lying down, but all that resolved gradually, and I came off painkillers after a short time. The 2 left side incisions still feel a bit thickened but are healed.

I very much support RefluxStop coming on to the NHS as soon as possible as it is suitable for a much wider cohort of patients than the current standard of care and it has transformed my life.

Response 4:

Hi, I understand NICE are collecting data on the RefluxStop implant from Implantica. I had this surgery privately at [REDACTED] hospital in September 2022, surgeon was [REDACTED]. I've been asked to provide some feedback from my own experience. I had GERD for over twenty years, at first the condition was managed by lifestyle changes. As the disease progressed there was notable regurgitation especially when sleeping which eventually necessitated sleeping in an upright position. I also appeared to develop symptoms of laryngopharyngeal reflux. In Sept 2019 I was placed on 2-week cancer pathway investigation after drastic weight loss, although I was at this time struggling to eat enough calories to maintain body mass due to symptoms. Endoscopy and CT scan were unremarkable, and I was referred to a GI surgeon at [REDACTED] hospital who agreed surgery was needed but that I would need to first go on a 3-month course of PPI's (I had previously been prescribed a lower dose which was ineffective). I was also told that surgery wait at that time may be several years.

In 2021 I had motility and pH impedance testing done privately in [REDACTED]. Results of pH impedance were inconclusive, but I was found to have very poor oesophageal motility, a hypotensive lower oesophageal resting pressure and a small hiatal hernia of 1.8cm. I also had a Restech test carried out from which my surgeon was able to diagnose oesophageal hypersensitivity, for which I was prescribed 10mg amitriptyline at night. I had a 48-hour bravo pH study in May 2022 which came back positive for acid reflux at which point my surgeon said he was happy to carry out surgery. I opted for the RefluxStop procedure.

I had surgery in Sept 2022, the first procedure of this type carried out by [REDACTED]. Surgery went well although my hiatal hernia was found to be considerably larger than previously suggested, and this was repaired at the same time. Recovery was unremarkable other than post-operative dysphagia which lasted for around 8 weeks. Regurgitation was eliminated from day one of surgery and I was for the first time in many years able to lay flat in bed at night. There were some very minor residual reflux events.

I am now approaching the two-year anniversary of surgery. Reflux events are almost non-existent now as is regurgitation. Other than residual LPR-type symptoms which are managed with a combination of fluoxetine (20mg every

other day) and 10mg amitriptyline (10mg), I now have very few problems from a reflux point of view. For me the RefluxStop implant and hiatal hernia repair have essentially returned quality of life not seen for many years. Diet has improved considerably, and I am now able to consume foods that were previously reflux triggers. The only downside to having surgery is that I have to be careful lifting heavy objects and on occasions I have possibly irritated tissue/scar tissue around internal sutures (subsides after a few days) although I understand this is common with all of the anti-reflux surgeries.

Response 5:

Good Afternoon

I want to support routine NHS take up of RefluxStop because it took three years of having to strongly emphasise the effects on my mental health of my reflux and associated digestive issues to get it on the NHS, as part of a small research project at [REDACTED]

My physical symptoms of reflux were awful. I was taking a high dose – 60mg of Lansoprazole - every day at one point, If I missed it, I couldn't keep food down at all, but the medication didn't stop my acid reflux. Most days even with the medication, if I ate a meal, I would bring most of it back up. The food was sitting in my pipe and wouldn't go down, causing major discomfort and social issues.

I went to my GP surgery in Hayes first. They referred me to [REDACTED], and from there, eventually I heard about a new procedure called RefluxStop, being offered to selective patients with severe, chronic reflux, at [REDACTED].

I had already been offered an operation called a fundoplication, which involves wrapping part of the stomach partially or fully around the sphincter which stops stomach acid coming up into your throat, but this operation is not usually offered to people with swallowing problems or issues with digesting food, as the procedure can tighten the food pipe, and make these symptoms worse.

I read up about RefluxStop, and it sounded potentially better than the standard treatment for someone like me with problems pushing food down to the stomach. I decided to go for it and I had the procedure in October last year. Since then I haven't looked back – I am now absolutely cured of my acid reflux and swallowing problems.

I am so grateful to my consultant Mr Ahmed and all his team at [REDACTED] [REDACTED] for their amazing treatment and support.

I believe this is a wonderful opportunity to help hundreds of thousands of people who may be in the same situation that I was or even worse.

Make it happen