

One year adjustable intragastric balloon: safety and efficacy of the Spatz3 adjustable balloons

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ABSTRACT

Background: The Spatz3 Adjustable balloon system is approved for 1 year implantation and allows multiple changes in the balloon volume during the course of implantation. Other intragastric balloons are currently approved for 6 months and their balloon volumes cannot be adjusted after implantation.

Aim: To determine the efficacy and safety of the Spatz3 adjustable balloon system.

Methods: Seventy seven consecutive patients (66 females and 11 males) in two medical centers were implanted with the Spatz3 adjustable balloon device and were followed prospectively. The patients' mean BMI was 37.2; the mean weight was 108.7 kg; the mean age was 41 (16-68); the mean balloon volume was 469 ml (450-500 ml). Adjustments were made for intolerance or weight loss plateau.

Results: The mean weight loss at 1 year was 17.2 kg with 15.9 % weight loss and 42.9 % Excess Weight Loss (%EWL). Eighteen patients underwent balloon volume adjustments: three downward adjustments of 100 -150 cc which alleviated early intolerance; 15 upward adjustments (mean 320 ml; range 200-500) at a mean 4.1 months (range 2-5 months) yielded additional mean wt loss of 8.2 kg (range 0-25 kg) after the adjustment. Three balloons were removed before the 1 year completion date due to intolerance and three others were removed for other reasons (pregnancy, gall bladder surgery, and alcoholism). There was one episode of gastric ulceration which required endoscopic therapy and balloon removal. There were no deflations or perforations.

Conclusions: The Spatz3 adjustable balloon is a safe and effective treatment for weight loss. The adjustability function can yield greater weight loss for those who show weight loss plateau and can mitigate intolerance.

Keywords: Obesity; Weight loss; Intragastric balloons; Adjustable gastric balloon; Weight loss plateau; intolerance

Introduction

Intragastric balloons (IGBs) have been successfully used to achieve weight loss in the past 30 years. Previously published results revealed an average weight loss of 12–15 kg over 6 months with an excellent safety profile [1–16]. The Spatz Adjustable balloon was introduced in 2010 as the first IGB approved for 1 year implantation while featuring an adjustability function that afforded balloon volume changes as needed. It was approved in May 2010 in all 27 countries of the EU for patients with BMI > 27 that failed previous attempts at weight loss (certificate number 10 0384 QS/NB). The adjustability

function was developed to address the issues related to other standard 6 months IGBs; 1) reduced efficacy after 2 to 3 months from implantation [3,16], and 2) significant nausea, vomiting, and discomfort in the early implantation period, necessitating balloon extraction in 4–7% of patients [1, 2]. Two studies have reported results showing that the Spatz adjustable balloon can result in weight losses of 21.6 kg (45.7 % Excess Weight Loss, EWL) and 24.4 kg (48.8% EWL) respectively [17, 18]. In 2012, the Spatz3 adjustable balloon was approved for 1 year implantation with the same features as the original Spatz balloon, but with a softer and smaller profile catheter. We report our experiences with the Spatz3 adjustable balloon in the Czech Republic and the UK.

Patients and methods

The Spatz3 ABS (Spatz3 Adjustable Balloon System, Spatz FGIA, Inc. NY, USA) was implanted at the University Hospital, Ostrava, Czech Republic and at the Trafford General Hospital, Manchester, UK. Seventy seven consecutive patients were selected according to National Institutes of Health criteria and guidelines for obesity surgery [19] and were independently evaluated by members of staff: gastroenterologists, dieticians, and psychologists. Previous esophageal or gastric surgery, bowel strictures or history of bowel obstruction, inability to comply with frequent follow up, use of anticoagulants or anti-platelet medications, inability to tolerate endoscopic procedures or multiple episodes of vomiting were among the grounds for exclusion. No patients were excluded from implantation. The implantations were performed under the approval of the Ethics Committee and informed consent was obtained from all patients. The records of relevant co-morbidities, medications or family history were not available for review. Indications for Spatz ABS implantation included one of the following: (1) temporary weight loss treatment in patients with body mass index (BMI) in the range of bariatric surgery (>35) who refused surgery or were at high risk for surgery, (2) temporary weight loss treatment for patients with no indications for surgery (BMI 29-35). All patients underwent endoscopy using conscious sedation (Midazolam 5-10 mg and Fentanyl 50-100 mcg).

Balloons were inflated with normal saline with the addition of 5 ml of undiluted methylene blue. Patients were recovered for 45 minutes and discharged the same day on pantoprazole 40 mg BID, ondansetron 4 mg BID, and a progressive clear liquid diet for 3-5 days. After the fifth postoperative day, the patients began a progressive solid 1,000 kcal diet. Monthly follow up was offered to all patients after implantation. Patients who were intolerant to the balloon could be adjusted downward by 100-150 ml, and those who did not lose weight, or whose weight loss reached a plateau could be adjusted upward by a volume of 250-500 ml at the discretion of the endoscopist. After 12 months of placement, the balloon was deflated by grasping the valve with a snare, and attaching an extension tube through which suction was applied, or via needle puncture. The device was removed endoscopically under conscious sedation using a grasping forceps or a polypectomy snare.

Endpoints

The primary endpoints of the study were successful implantation, adjustment and extraction of the Spatz device, without bowel obstruction, perforation, ulceration or hemorrhage. Secondary endpoints were a > 10% weight loss; additional weight loss following adjustment; and salvage patients following adjustment for intolerance. The final overall results were calculated based on all patients that were implanted with the balloon, including those that completed treatments as well as those that did not complete 12 months for various reasons. Those patient dropout results were calculated based on weight at 12 months.

Results

From January 2012 to June 2013, 77 consecutive patients (66 female, 11 male) underwent Spatz3 ABS placement with demographics displayed in Table 1. The mean age was 41, with a mean weight of 108.7 kg, and a mean excess weight of 42.9 kg and a mean BMI of 37.2.

Table 1

	Mean	Range
Age	41	16-68
Weight	108.7 kg	70-177 kg
Excess Weight	42.9 kg	15-84 kg
BMI	37.2	29.3-50

Seventy patients completed the 12 month implantation period and seven patients underwent early removal. The causes of early removal were pregnancy, gall bladder surgery, alcoholism, GERD, early intolerance and intermittent intolerance (both refusing downward adjustment) and one bleeding gastric ulcer. These are displayed in Table 2.

Table 2

Time of Removal	Reason for Early Removal
6 months	Pregnancy
6 months	Gall bladder surgery
10 months	Alcoholism
2 months	Intolerance due to GERD (Refused downward adjustment)
3 ½ weeks	Early intolerance (Refused downward adjustment)
6 ½ months	Intermittent intolerance (Refused downward adjustment)
5 months	Gastric ulcer

The mean weight loss was 17.2 kg, with a mean % weight loss of 15.9% and a mean % excess weight loss of 40.1%. A > 10% weight loss was obtained in 80.3% of our patients.

Weight loss results of the implanted patients are displayed in Table 3.

Table 3

Mean Weight Loss (Range)	17.2 kg (0- 47.3 kg)
Mean % Weight Loss	15.9 % Weight Loss
Mean % Excess Weight Loss	40.1 % EWL

Adjustments

Downward adjustments

Six patients were intolerant to the balloon beyond 1 week. Three of them agreed to volume adjustment and were able to complete the 12 month treatment period. The other three patients refused downward adjustment and the balloons were extracted prematurely at 3 ½ weeks, 2 months and 6 ½ months, respectively (Table 2). The mean of additional weight loss after downward adjustment was 12.7 kg (Table 4).

Upward adjustments

Fifteen patients underwent upward adjustments as weight loss reached a plateau. All adjustments were successful and resulted in a further mean weight loss of 8.2 kg. The extra weight loss that resulted after adjustment ranged from zero to 25 kg (0, 1, 3.2, 4, 4, 5, 5.9, 6, 7, 8, 11, 12, 13, 18, 25 kg).

TABLE 4

DOWNWARD ADJUSTMENT	Patients	Time (range)	Volume (range)	Additional Wt loss post adjustment (kg)
	3	3.7 weeks (2-6)	133 ml (100-150)	12.7 kg (12.5-12.8)
UPWARD ADJUSTMENT	Patients	Time (range)	Volume (range)	Additional Wt loss post adjustment (kg)
	15	4.1 months (2-11)	320 ml (200-500)	8.2 kg (0-25)

Complications

Complications included intolerance in six patients, of which three agreed to downward adjustment resulting in alleviation of intolerance – the other three patients had their balloons removed and remained asymptomatic post extraction. During one adjustment procedure the valve disconnected requiring a balloon replacement – the patient continued with the new balloon to the end of the 12 month implantation period. There was one gastric ulceration at 5 months which required endoscopic therapy for bleeding and balloon removal. The patient was discharged post extraction of the balloon on pantoprazole 40 mg BID and remained asymptomatic with confirmed healing of the ulcer on subsequent endoscopy. There were no deflations or perforations.

Discussion

Having previous experience with the original Spatz Adjustable balloon from 2010 to 2011 in over 180 procedures in our two institutions, it is our opinion that the original Spatz had a lengthier and more complicated implantation and extraction procedures, whereas the procedures for Spatz3 are less complicated with fewer steps. The weight loss results are comparable with respect to %EWL (45% and 48% in Spatz and 40.7% EWL in Spatz3). The complication rate reported with the original Spatz was 4.1% with a deflation rate of 4% which has diminished with Spatz3- (1.3% complication rate and no deflations) [17,18]. We can conclude that the Spatz3 balloon is easier to use and has the same efficacy with a very low side effect profile. We report our experience with the Spatz3 ABS in 77 consecutive patients. In the present experience, other than intolerance in six patients and one bleeding gastric ulcer requiring endotherapy and balloon removal, there were no other complications. Three of the 6 intolerant patients agreed to downward adjustments which alleviated their symptoms. The additional mean weight loss of 12.7 kg is similar to the previously reported 13.2 kg lost after downward adjustment [18].

Our experience with upward adjustments confirms earlier reports of added weight loss after adjustment. We report a mean additional weight loss after upward adjustment of 8.2 kg which is similar to the 9.4 kg reported in the previous Spatz publication [18]. Adjustment was an effective tool for our intolerant patients as well as for our patients with weight loss plateau who were willing to undergo an extra procedure. In the Czech Republic, all of our patients except one underwent upward adjustment whereas in the UK only 12% of our patients opted for upward adjustment. We believe this is as a result of the long distance travel for our UK patients from all over the UK to the UK center in Manchester.

Based on our experience, the Spatz3 Adjustable Balloon System is an effective procedure for weight reduction, without mortality, and very limited morbidity.

Disclosure: Dr Jeffrey Brooks is the CEO of Spatz FGIA Inc which is the manufacturer of the Spatz balloon. Dr Evgen Machytka and Dr John Mason have no conflict of interest to report.

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