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## Original article

# A histologic evaluation of the laparoscopic adjustable gastric band capsule by tissue sampling during sleeve gastrectomy performed at different time points after band removal

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**Abstract**

**Background:** Laparoscopic sleeve gastrectomy (SG) is gaining popularity as a revision option after failed laparoscopic adjustable gastric banding (LAGB). Data have shown that single stage revisions may be associated with a higher complication rate. A histologic basis for this observation has not been studied. The objective of this study was to document the histologic properties of the LAGB capsule across the gastric staple line after SG at various time points after LAGB removal.

**Methods:** Gastric sleeve specimens of all LAGB to SG revisions were identified from January to May 2013 and underwent histologic evaluation of the LAGB capsule. Single blinded pathologist interpretation was performed, with inflammation, fibrosis, neovascularization, foreign body (FB) reaction, and wall thickness assessed semi-quantitatively and scored from 0–3. Based on combined features, an attempt was made to predict the timing of revision surgery.

**Results:** The study identified 19 revisions performed for inadequate excess weight loss or weight regain. The mean age for revision was 44 (19–65). The minimum time to revision was 42 days, the longest 1,188 days. There were no surgical complications. Varying degrees of inflammation and fibrosis were common features at all times. Angiogenesis, neovascularization and FB reaction were prominent in revisions performed before 80 days. The gastric wall was thicker during early revision. The optimal time to perform revision was difficult to determine.

**Conclusions:** LAGB caused varying degrees of inflammatory and FB reaction that time did not fully resolve. The lower leak rates observed with delayed revisions do not appear to be attributable to gastric histology. (Surg Obes Relat Dis 2014;■:00–00.) Crown Copyright © 2014 Published by Elsevier Inc. on behalf of American Society for Metabolic and Bariatric Surgery. All rights reserved.

**Keywords:**

Obesity; Laparoscopic adjustable gastric band; Sleeve gastrectomy; Revision surgery; Histology

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The first use of the adjustable gastric band was reported in rabbits in the 1980s [1] and first used in humans for weight loss in 1986 [2]. It was subsequently rapidly taken up in Europe, Australia, and Latin America and later

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approved by the FDA for use in the United States in 2001 [3]. Longer-term reviews of the laparoscopic adjustable gastric band (LAGB) later showed mixed results [4]. A recent long-term review by O'Brien et al. [5] revealed that revisional procedures were performed for complications of the LAGB such as proximal enlargement (26%), erosion (3.4%), and port and tubing problems (21%). Band explanation occurred in 5.6%.

Despite the established widespread use of the band and perceptions that the band is reversible [6], there have been no histologic studies that demonstrate the effect of the band on the stomach in the literature. The only studies that have been published, examined “the fragments of fibroadipose tissue in close contact with the band” [7].

Laparoscopic sleeve gastrectomy (SG) has recently gained acceptance as a stand-alone primary bariatric procedure, despite its inception as the first step of a 2-stage bariatric procedure. It is also increasingly becoming an option for revisional surgery after failed or complicated LAGB [8–11].

At our institution, we have accumulated a significant cohort of patients who have been revised from a failed band to a sleeve gastrectomy [12]. This has provided us with an opportunity to utilize the SG technique in the revision of a failed LAGB, to obtain histologic data on the effect of the band on the gastric wall. We also sought information to determine the effects of staging a revision, by analyzing the histologic properties of the SG staple line with respect to the length of time since LAGB removal.

## Methods

This descriptive study is prospective in nature and before commencement, ethical approval from University of New South Wales was obtained. All patients received written and verbal information with regard to the consent process and the intended use of their gastric sleeve specimen. No formal selection process was implemented, as there was little likelihood of specimen selection bias. All LAGB to SG conversion surgeries from January to May 2013 in our bariatric unit contributed to our specimens. As a control specimen, a paragastric implant (PGI) to sleeve specimen was included for analysis, as the gastric sleeve staple line would essentially be across normal stomach. Another comparison was sent for staple line analysis in the form of a fundectomy specimen obtained during an immediate LAGB to RYGB revision.

Gastric sleeve specimens obtained, were immediately fixed in 10% neutral buffered formalin. All cases were dissected and sampled for histologic analysis using uniform methods by a single operator. In all cases, except for the PGI specimen, the band capsule was easily identified macroscopically. Two representative sections of stomach were taken from the region underlying the location of the gastric band. These were examined histologically with

hematoxylin and eosin (H&E) staining and Masson's Trichrome stain. One section from each stomach was examined by immunohistochemistry. Immunohistochemistry was performed on formalin fixed paraffin embedded tissue sectioned at 4  $\mu$ m onto positively charged slides (Superfrost plus, Menzel-Glaser, Germany) using mouse monoclonal antibodies to collagen III (clone HWD1.1, Biogenex, CA USA, dilution 1 in 25) and to CD 31 (clone JC70 A, Dako CA USA, dilution 1 in 80). All slides were processed with an automated staining system - the Leica BondIII autostainer (Leica Biosystems, Mount Waverley, Victoria, Australia) used according to manufacturer's protocol and with the manufacturer's retrieval solutions. For collagen III enzyme based antigen retrieval was employed for 10 minutes using the manufacturers enzyme pretreatment kit (Cat: VBS Part no: AR 9551). For CD31 heat induced epitope retrieval was performed for 30 minutes in the manufacturer's acidic retrieval solution ER1 (Cat: VBS Part no: AR9961).

Slides were interpreted by a single pathologist (S.V.), blinded to all other data including the timing of surgery. The degree of chronic inflammation, acute inflammation, old fibrosis, recent fibrosis (assessed by H&E and collagen III IHC), neovascularization (assessed by H&E and CD31 immunohistochemistry), foreign body reaction, and wall thickness were all assessed semiquantitatively and scored from 0–3+. Based on combined features the pathologist also attempted to estimate whether the surgery was immediate or delayed.

## Results

Table 1 represents the results obtained after single pathologist interpretation. A semiquantitative grading score was recorded for all parameters tabulated, and a blinded prediction of old or recent revision surgery was made. After this, the table was then modified to reflect time to revision, revision type, and a total numerical score to enable identification of trends with respect to revision time.

During the study time, 3 surgeons working within our bariatric unit performed 19 revisions. The mean age for revision was 44 years, and all patients had revision for inadequate excess weight loss or weight regain. Women comprised the majority of patients with 15 undergoing revision as opposed to 4 males. The youngest patient to undergo revision was 19 and the oldest was 65. No postoperative complications were encountered.

The minimum time from removal of LAGB to subsequent SG was 42 days, with the exception of the LAGB-RYGB that was performed immediately as an open procedure. The longest time to revision was just over 3 years. As expected, the PGI to SG revision acted as an appropriate control specimen, as no inflammation (acute or chronic), vascularization, angiogenesis (CD31) nor foreign body reaction was recorded at the gastric sleeve staple line.

Table 1  
Pathologist interpretation and revision information

Case no.	Chronic inflamm	Old fibrosis	Acute inflamm	Recent fibrosis	Collagen 3	Neovasc	CD31	FB reaction	Wall thick	Predict	Total	Days to revision	Revision type
19	1+	1+	1+	1+	1+	1+	1+	1+	1+	NP	9	0	B-BY (OPEN)
6	2+ E	2+	1+	1+	1+	3+	3+	1+	2+	O	16	42	B-SG
5	3+ E	3+	min	1+	min	2+	2+	0	2+	O	13	49	B-SG
3	0	min	0	0	0	1+	1+	0	0	R	2	67	B-SG
15	1+	2+	0	1+	1+	2+	2+	2+	2+	O	13	74	B-SG
16	2+ E	2+	1+	1+	min	2+	2+	2+	2+	O	14	77	B-SG
2	3+ E	3+	0	1+	2+	1+	2+	2+	2+	O	16	81	B-SG
11	0	1+	min	1+	min	3+	1+	0	1+	R	7	81	B-SG
7	2+	min	0	0	0	1+	1+	0	0	R	4	83	B-SG
14	1+	2+	0	1+	1+	1+	2+	2+	0	?O	10	95	B-SG
1	0	1+	1+	1+	1+	1+	2+	0	min	R	7	105	B-SG
8	0	min	min	1+	min	1+	1+	0	0	R	4	112	B-SG
18	0	1+	0	1+	min/1+	1+	1+	0	1+	R	6	116	B-SG
12	min	2+	0	1+	min	1+	1+	1+	1+	O	7	120	B-SG
13	1+	1+	1+	1+	0	2+	2+	0	1+	NP	9	168	B-SG
4	1+	2+	1+	1+	min	2+	2+	0	2+	NP	11	336	B-SG
10	2+	2+	0	1+	min	min	1+	2+	2+	O	10	506	B-SG
9	0	0	0	min	0	min	min	0	0	NP	0	1173	PGI-SG
17	1+	2+	0	1+	1+	1+	1+	2+	1+	NP	10	1188	B-SG

E = eosinophils prominent; R = recent; O = old; NP = not predictable; B = laparoscopic Roux-en-Y gastric bypass; SG = sleeve gastrectomy; BY = Roux-en-Y gastric bypass; PGI = paragastric implant

Gastric wall thickness was also unchanged. The other comparison fundectomy specimen from the LAGB to RYGB revision showed low-grade levels of inflammation, neovascularization, and foreign body (FB) reaction, with all parameters scoring +1 by pathologist interpretation.

One of the most obvious trends was the presence of neovascularization as determined by morphology and CD31 immunohistochemistry. These scored highly (+2 to +3) in revisions up to 80 days. After 80 days, neovascularization tended to be less significant. Parallel trends were seen with chronic inflammation and old fibrosis, likewise with acute inflammation and recent fibrosis. Not surprisingly, FB granulomatous reaction featured prominently in early revisions up to 80 days, and eosinophils identified in early revision specimens were a reliable marker of foreign injurious agents—namely the silicone elastomer LAGB and became less prominent with time.

The collagen III assay, representing immature collagen, was not helpful. We expected this assay to mirror acute inflammation and recent fibrosis, as immature collagen is laid down early in the healing processes. Almost all the specimens recorded a minimum or +1 result and no correlation was identified with revision times. Wall thickness appeared to be most significant between 0–80 days and after 336 days, but was noted to be thinnest at a revision period between 80–336 days.

From Table 1, the most recent revision procedures had the highest cumulative total scores. This appears to be due to the presence of chronic inflammation and old fibrosis, as well as neovascularization and CD31

immunohistochemistry. Revision predictability was rather haphazard, with the majority of revisions before 80 days thought to be old, and revisions between 80–116 days thought to be recent. Several of the older revisions were unable to be predicted, as was the immediate fundectomy specimen from the RYGB.

Fig. 1 and Fig. 2 represent histologic sections demonstrating features semiquantitatively assessed and scored by a blinded pathologist.

## Discussion

The popularity of SG as a revisional procedure for LAGB is increasing. Our descriptive study, although somewhat limited by sample size, sheds some light on the histologic activity at the SG staple line at various points in time after removal of the band. We show here that morphologic changes to the LAGB capsule exist for at least 3 years after removal, and it is likely that these changes are irreversible.

Revisional surgery is undoubtedly more technically challenging compared with primary surgery [13]. Adhesions, unclear anatomy, less pliable tissues, and fibrosis related to the previous operation require a careful compromise between patient safety and an efficacious operation. These technical difficulties are partly reflected by longer operative times in revisional surgery [10]. Gagniere et al. [14] noted in 2011 that undergoing first line gastric banding increases the risk of complication after secondary SG. Their finding was that the only independent risk factor for staple line disruption was first line gastric banding. Although

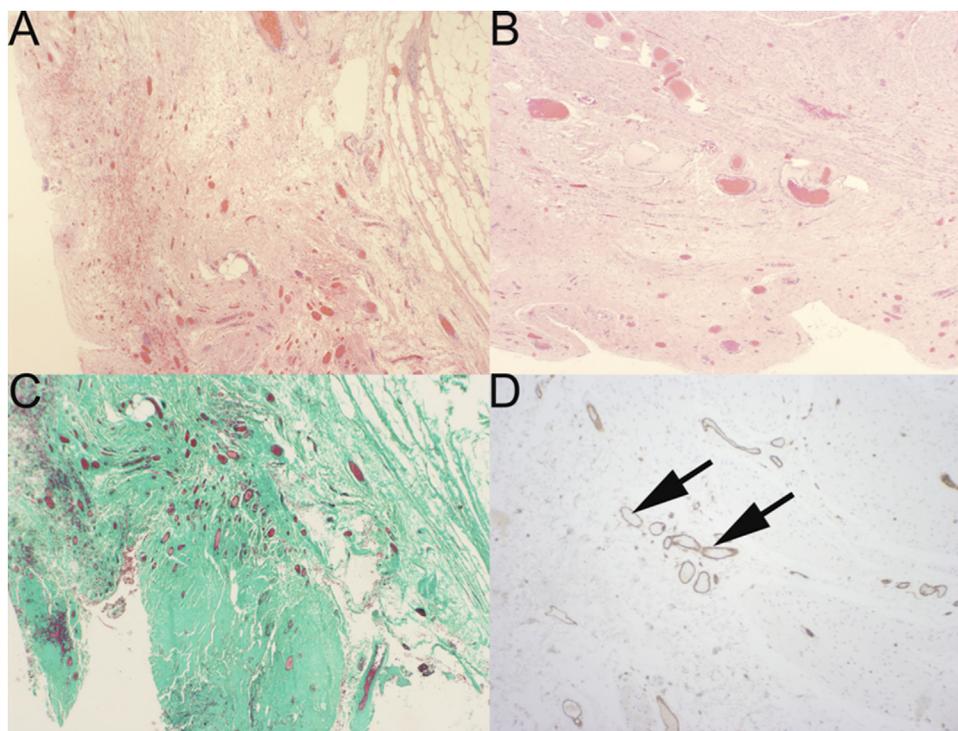


Fig. 1. Representative sections from sleeve gastrectomy showing established fibrosis. (A,B) Fibrous tissue at serosal surface (H&E). (C) Established fibrosis at serosal surface, collagen staining green with Masson's Trichrome stain. (D) CD31 immunohistochemistry highlighting moderate neovascularization (arrows). Original magnifications (A,C) 100 ×, (B,D) 200 ×.

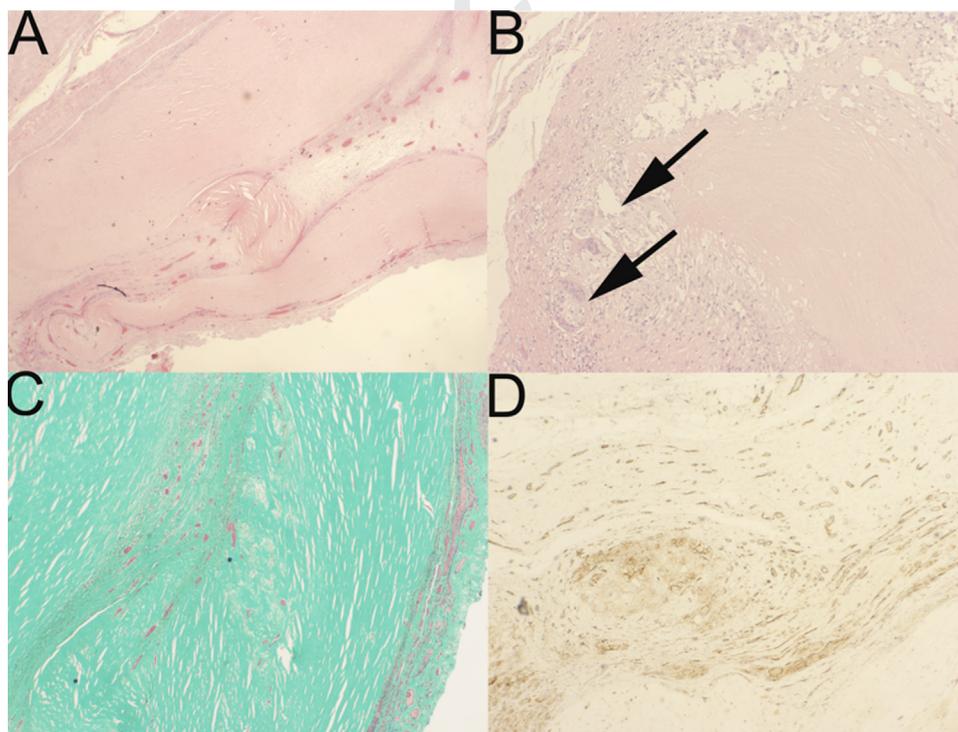


Fig. 2. Representative sections from sleeve gastrectomy showing established hyalinized fibrosis and foreign body reaction. (A) Dense hyalinized fibrosis (H&E). (B) Foreign body type giant cells (arrows) presumably as a response to the band (H&E). (C) The dense hyalinized fibrosis stains green with Masson's Trichrome stain. (D) Prominent neovascularization highlighted with CD31 immunohistochemistry. Original magnifications (A) 100 ×, (B–D) 200 ×.

studies by Gagniere et al. [14] and Alqahtani et al. [15] have shown minimal complications at single stage revision, the majority of the literature has demonstrated higher complications rates for both bleeding and leak in single stage revisions compared to 2-stage revision [6,8,9,11,16].

Several papers have been published examining gastric histopathologies in patients undergoing SG and changes in gastric morphology and histopathology after sleeve gastrectomy in diet-induced rats. These have not specifically addressed the staple line after failed LAGB and only provide information on the appearances and incidental pathology of the gastric sleeve specimen and gastric tube after SG [17,18]. A single other publication has examined the perigastric band tissue upon removal of the LAGB, with the specific intent of determining a histologic cause for LAGB erosions [7]. Lattuada et al. [7] noted that the band induces a fibrosclerotic response that is postulated to offer protection to the gastric wall from the band, within a background of mild acute and chronic inflammation, features that we now show to persist many years after LAGB removal.

Neovascularization and angiogenesis represented by CD31 immunohistochemistry featured prominently in the early revision procedures and is consistent with the pathologic processes of early wound healing. After removal of the LAGB, the process of tissue remodeling and healing commences almost immediately. A transition between acute and chronic inflammation, and old and new fibrosis, however, could not be easily identified. There is significant overlap within our samples with both acute and chronic inflammation as well as old and new fibrosis coexisting at any point in time after removal of the band.

While the cellular component of acute inflammation is identified from a collection of inflammatory cells containing a predominance of neutrophils; its acellular component (recent fibrosis) demonstrates loose connective tissue and immature fibroblastic tissue that does not show hyalinization. In contrast, the cellular component of chronic inflammation is a collection of inflammatory cells such as lymphocytes, plasma cells, and histiocytes amidst granulation tissue. The acellular component of this process is chiefly represented by old fibrosis in the form of hyalinized collagen.

All of these phenomena can occur simultaneously in long standing inflammatory or reactive processes. While we anticipated the predominance of a particular process correlating with time, what we in fact found was a varying combination of both inflammatory processes. Other histologic features, such as FB reaction, the presence of collagen III, and variability in wall thickness, showed no discrete correlation with time. In most cases (except for the control PGI revision), there was a varying degree of both acute and chronic inflammation in each specimen. Acute inflammation and recent fibrosis were present at a low level at all revision times, with chronic inflammation and old fibrosis featuring

prominently in the revisions up until approximately 80 days. This inflammation and fibrosis may have contributed to the increased wall thickness of early revision specimens.

While some weak correlations regarding time from band removal have been identified, there were none that provided definitive guidance as to whether or not revision surgery should be performed as an immediate or staged procedure. What we have identified, is that acute inflammation and recent fibrosis appear to feature at low levels regardless of time to revision, and also that chronic inflammation, old fibrosis, neovascularization, CD31 immunohistochemistry, and foreign body reaction feature prominently in revisions up to around 80 days. Wall thickness was also increased at revision times up to 80 days, and this may be due in part to the presence of fibrotic scar tissue related to the LAGB capsule.

Our study has nevertheless provided some insight into possible processes underlying staple line failure in revision surgery. Inflammation both acute and chronic is present at all revision times, and wall thickness at early revision may account for staple line ischemia. Shortly after LAGB removal, there is increased neovascularization and angiogenesis, but our only immediate revision specimen has demonstrated low levels of vascularity perhaps suggesting that the presence of nonangiogenic tissue and a thicker gastric wall at immediate revision may compound staple line ischemia accounting for a higher complication rate.

An important factor in the clinical outcomes of revisional surgery not examined in our study is the technical aspect of the surgery, which includes tissue trauma related to retraction and stapling across a plicated fundus. Good surgical technique and an awareness of these issues should minimize the effect of operative technique on staple line failure.

While it is difficult to form any strong conclusions about immediate versus delayed revisions from the above results, it is clear from the results tabulated, and figures demonstrated above, that gastric tissue after removal of the LAGB is unlikely to ever recover. Our findings dispel any notions that the LAGB is a simple and easily reversible procedure without any lasting effects on the stomach.

## Conclusions

This study has provided an insight into the histologic happenings across the LAGB capsule at the SG staple line in staged revisions. Our results show that the LAGB changes to the gastric wall are unlikely to convincingly resolve with time and tissues may never fully recover after LAGB surgery. We have been able to identify histologic trends that correlate weakly with revision times—an aspect of revisional surgery that has not been documented in the literature to date. Further research in this field comparing larger sample sizes in 2 separate cohorts—immediate versus

delayed LAGB to SG conversions—may resolve the ongoing argument regarding the optimal time for revision.

## Disclosures

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