

Gastric band implants

Slipping, Pouch Dilatation and Gastric Wall Perforation

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Surgical implantation of a gastric band to deal with adiposity is increasingly commonplace and is being performed at an ever-growing number of hospitals. The laparoscopic technique used in connection with this technique is particularly demanding. The main post-operative complications that may, possibly, be associated with this procedure are slippage of the posterior gastric wall, pouch dilatation, gastric band penetration and port problems, along with the usual technical problems. The resultant corrective surgery rate lies at between six and 13 per cent. Using a gastric motility model that we designed, we were able to simulate complications, such as pouch formation, band dislocation and band slippage. In this CHAZ paper, the authors present results from two independent testing institutes, featuring a technical comparison of the materials used in the three types of gastric band currently on the market.

At present, there are three different types of gastric band in use (Figs. 1a - 1c). Within the past few months, a further band, developed in France, has come onto the market. There are known technical complications associated with all these bands. Table I shows the incidence of complications reported by various working groups. In this paper, the authors will be looking into the ways in which the different geometrical patterns and the differing mechanical-physical characteristics affect pouch volume, band dislocation and slipping, using a gastric motility model (pig stomach). They will also be looking into the ways in which laboratory testing was carried out. In order to produce an objective basis for discussion, three gastric bands (the SAGB, the LAP band and the *Gastrobelt II*) were put through a number of mechanical testing processes carried out at two independent testing institutes (Aachen *Fachhochschule* and ENDOLAB, Munich), where variables that were tested included elasticity patterns and visco-elastic deformation (Shore hardness).

The following investigations were carried out on the gastric motility model:

- stretch in the main body of different types of gastric band when closed;
- Pouch formation associated with the three types of gastric band (GB II, LAP band, SAGB) with different trans-oesophageal filling volumes and under differing adjustment conditions;
- band dislocation for the three types of gastric band with different trans-oesophageal filling volumes and under differing adjustment conditions;
- slip stretch for the three types of band with different trans-oesophageal filling volumes.



Figs. 1a-1c: a) GASTROBELT II; b) LAP band (Inamed) c) Swedish Adjustable Gastric Band (SAGB, Obtech)

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Table I: Overview of the incidence of complications, ND = no data

Authors	Year	Band type	Patients	Technical complications %	Slipping/ pouch dilatation n[%]	Erosion/ Perforation n[%]
Heukrodt	1998	LAP band	130	2,3	5,4	0
Weiner	1998	LAP band	146	ND	5,4	1,4
Stieger	1998	LAP band	130	ND	6,9	0
Kunath	1998	LAP band	224	0,9	8	0,9
Belachew	1998	LAP band	350	ND	13,1	ND
Pier	1999	LAP band	150	1,3	12,7	0
Pier	1999	GB I	220	2,3	0,5	0
Forsell	1999	SAGB	326	1,8	0,6	4,6
Miller	1999	SAGB	158	2,3	1,3	0,6
Klaiber	2000	SAGB	103	1,9	0	0
Thevissen	2001	GB II	25	4	0	0
Hesse	2001	SAGB	41	2,4	3	0
Hesse	2001	LAP band	79	1,3	15,1	1,3

Various types of testing apparatus were used. The mechanical tests were carried out at two independent testing institutes. In order to illustrate pouch formation, band dislocation and slippage, *in vitro* tests were carried out, using the gastric motility model at different filling levels (test series 1-3). Each test series was carried out ten times. Mean values are shown in respect of the results that were obtained.

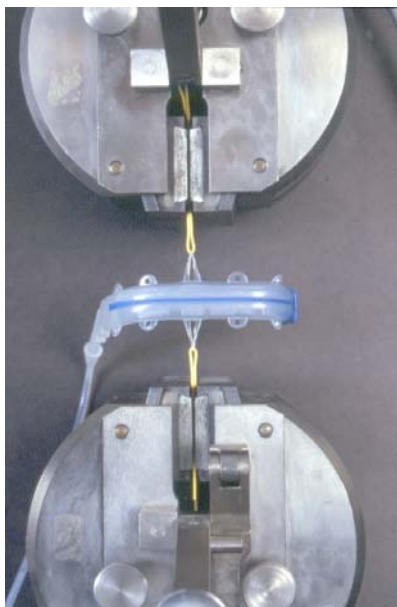


Fig. 2: Layout for tensile and stretch testing of retaining loops

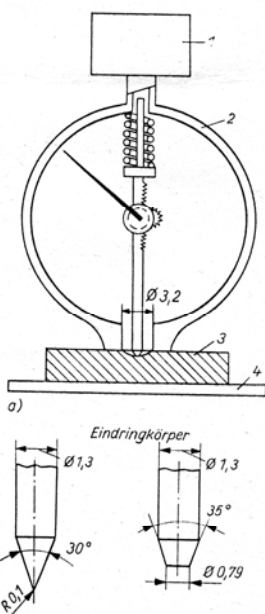


Fig. 3: Shore hardness testing a) instrumentation (1 - applied weight, 2 - casing, 3 - sample, 4 - test bench)

Traction was applied at a constant advance rate of 0.5 mm per sec. The trial was halted prior to failure of the implant. Before measurements were actually taken, one load cycle was carried out per series, for conditioning purposes. In addition, the main body of each of the gastric bands was checked every time, to investigate traction-stretch behaviour (Fig. 2).

Shore hardness: the contact surface on the sclerometer must be pressed down smoothly until full contact is made

The Shore test is used to measure hardness in elastomers and rubberised elastic polymers. The type of impact body that is used will determine whether the Shore A, C or D test is used [16]. Where the Shore method is used to determine hardness, the contact surface on the sclerometer must be pressed down smoothly onto the test specimen until full contact is made. (Fig. 3). In the tests reported here, Shore hardness A was determined ten times on each of three test specimens and the results were then compared. Once this had been done, a mean value was calculated for each test specimen and this was then added to Table 2. In addition, the LAP band was placed inside a silicone sleeve. The sleeve was removed so that the hardness of the main body could be determined.

The gastric motility model is used to simulate the physiological effects of dietary intake by patients fitted with implanted gastric bands. In accordance with the instructions, sets of tests were carried out to determine pouch volume, band dislocation and slippage after intervals of ten seconds and five minutes. All the tests were carried out with differing degrees of adjustment. Since adjustment delays pouch voiding, two intervals were used as observation periods for pouch volume measurements.

Table 2: Mean Shore hardness figures from 10 series of tests, measured on 3 different specimens of material

	GB II [Shore A]	LAP band [Shore A]	SAGB [Shore A]
Sample I	55	76	71
Sample II	54	75	74
Sample III	54	76	72
Mean	54,3	75,6	72,3

The material used in the GastroBelt is more than one third softer than the SAGB and LAP bands.

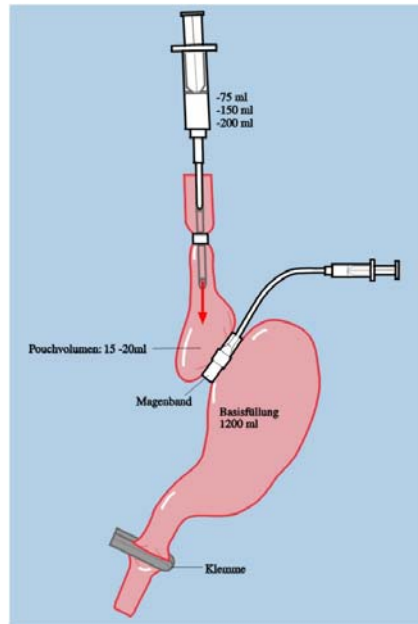


Fig. 4 Gastric motility model. Trans-oesophageal test apparatus.

A mere increase in the trans-oesophageal volume was enough to generate clear test results. Here, a 'stomach flexing and contraction' simulation that was carried out additionally played a less prominent role and this was, therefore, dropped subsequently. The test apparatus consisted of a fresh, intact stomach from a 75 kg domestic pig, with 20 cm stumps of the oesophagus and duodenum left *in situ*, as illustrated in Fig. 4.

Implant slippage, pouch formation and dislocation were investigated at various volumes

In order to ensure that trans-oesophageal filling took place, the duodenal stump was clamped off tightly. A Charrière 20 drain was pushed through the oesophagus, up to the vicinity of the cardio-gastric junction and the surrounding area was then clamped off tightly. The three gastric bands were then moved into position, using the prescribed surgical technique, with pouch volumes of between 15 and 20 mL. The baseline filled volume of the stomach amounted to 1200 mL. The intra-oesophageal route was then used to increase the volume by ΔV_2 (75, 150, 210 mL) and varying degrees of adjustment were then applied in order to investigate posterior stomach wall slippage, pouch formation and implant dislocation. The findings were documented. Recording of pouch formation took place after intervals of ten seconds and five minutes. With the SAGB and LAP bands, fixation was achieved by using the anterior wall of the stomach to formed a sleeve overlapping

the *in situ* gastric band and then securing it in position with three or four gastric-gastric monofil 1/0 interrupted sutures (Fig. 5a). The retaining loops arranged in a circle around the GB II were then attached to the stomach wall using 1/0 monofil seromuscular sutures (Fig 5b). In previous animal trials, it had been noted that, after no more than four days, 'auto-fixation' also led to insertion of non-sutured retaining loops on the GB II (Fig. 7). This justifies fixation of all retaining loops in the test apparatus. The second closure stage (CS) was selected in order to lock the *GastroBelt* into position (Fig. 5b). The different intra-oesophageal filling volumes (ΔV) came to 75, 150 and 210 mL. Resultant pouch volumes [mL] and slippage [mm] were documented. Band dislocation [Δ degrees] was measured. A check was also made for total occlusion of the outlet, due to a combination of slippage and band dislocation, using trans-oesophageal and gastric injection of methylene blue via an *in situ* Charrière 10 drain:

Total occlusion of the outlet:

no passage of methylene blue

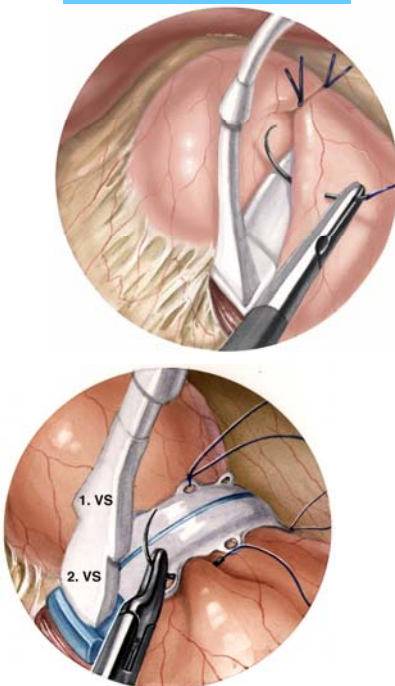
No occlusion of the outlet:

methylene blue passes

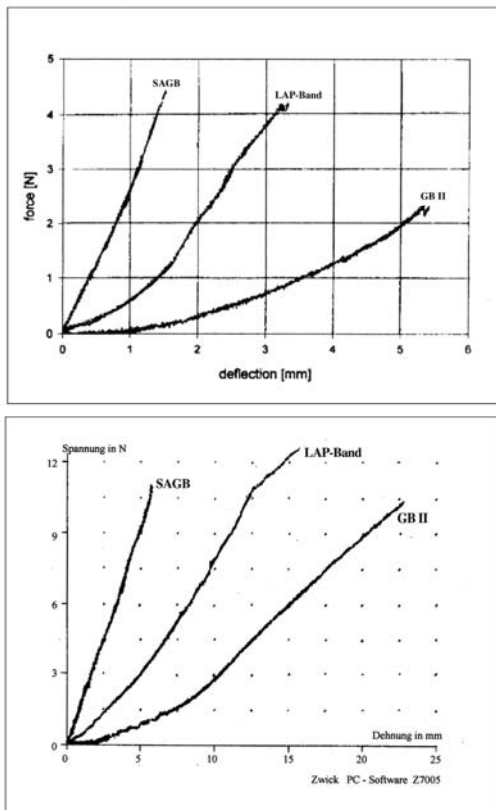
Testing shows that the GB II is two to four times safer in terms of avulsion of retaining loops

Traction-stretch graphs from two different testing institutes show that stretching, *i.e.* elasticity, induced in the GB II under tensile stress amounted to at least 400 % of that induced in the SAGB band and 200 % of that induced in the LAP band (Figs. 6a, b). This means that it is between two and four times safer in terms of retaining loop avulsion and of rupture of the sutures used to secure the device in position when contractile forces are applied. Results from investigations carried out by two independent institutes are both consistent and comparable.

Table 2 shows hardness and viscoelastic deformation. The material used in the GB II is 30% softer than that used in the LAP band and 33% softer than that used in the SAGB band. Compared with the SAGB and LAP bands, the GB II offers an average of a 36% improvement in elastic behaviour.



Figs. 5a and 5b: Anterior gastric sleeve fixation
b) Fixation using retaining loops



Figs. 6a and b: Laboratory:

- a) ENDOLAB, Munich: traction-stretch graph for three different types of gastric band implant.
 b) Aachen Fachhochschule: traction-stretch graph for three different types of gastric band implant.

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