POST-GRADUATE EDUCATION

Gastric band implants

Slipping, Pouch Dilatation and Gastric Wall Perforation

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Part 2

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 obtained from two independent testing institutes, in which a technical comparison is made between materials used in the three types of gastric band currently on the market.

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In the case of the GB II, the original pouch volume was achieved after five minutes during each test carried out in the 1st series (Table 3a). These results were also repeated where a 2.5 mL adjustment was made (2nd series). There was no evidence of band dislocation with maximum trans-oesophageal filling, at 210 mL (3rd series) or with a maximum adjustment, of 5 mL. The maximum of 5 mm slippage was never exceeded during this process.

GB II: Pouch volume voiding into the residual stomach was not slowed down until the adjustment volume reached 5 ml

It was not until the 3rd series that delayed outlet occlusion was seen, with 5 mL adjustment. Here, there was evidence of a delay in the time it took the methylene blue to appear in the residual stomach. The adjustment had to rise to 5 mL before there was any slowing down in voiding of the pouch volume into the residual stomach.

The following figures were measured during trans-oesophageal filling of the SAGB band: during the first stage of the test series, with 4 mL of adjustment, it took five minutes for the full original pouch volume to be achieved. Slippage rates came to a maximum of 5 mm for 10° of band dislocation. There were no cases of occlusion. During the second test series, where the gastric band was adjusted with 5.5 mL, there were no cases of complete voiding of the pouch volume after five minutes. Where a 210 mL trans-oesophageal filling volume was used, the maximum 5-minute pouch volume figure was still 46 mL, with 32 mm of posterior slippage and 39° of band dislocation. There was no recorded methylene blue evidence in the residual stomach of total outlet occlusion and it required an 8 mL adjustment of the gastric band to obtain total occlusion. Where 150 mL and 210 mL trans-oesophageal filling volumes were used, the maximum 5-minute residual pouch volume figures were 135 and 207 mL, respectively. With 150 mL trans-oesophageal filling volume and 8 mL of band adjustment, band dislocation came to 41°. Here, occlusion was virtually total. There were still traces of methylene blue in evidence in the residual stomach. During the final stage of the test, slippage amounted to 46 mm and band dislocation to 48°, with total occlusion.

LAP band: with a 2.5 mL adjustment volume, the pouch volume was, on average, twice the original volume after 5 minutes.

As expected, the results measured during trans-oesophageal filling of the LAP band yielded figures similar to those achieved during the tests carried out on the SAGB band. With a 1.5 mL adjustment, the original pouch volume was achieved after five minutes. Slippage amounted to 3 mm and band dislocation to five or eight degrees. There was no evidence of occlusion. During the second stage in the tests, using a volume of 2.5 mL for adjustment, the pouch volume after five minutes was, on average, twice the original figure. Slippage of the posterior wall of the stomach came to 7, 12 and 31 mm, with 18, 19 and 35 degrees of band dislocation. There was no methylene blue evidence whatsoever, in any of the tests, which means that there were no cases of outlet occlusion. The third series, with 6 mL of adjustment and with trans-oesophageal filling volumes of 150 and 210 mL, resulted in outlet occlusion in both cases, with negative methylene blue evidence in the residual stomach. In these two cases, band dislocation amounted to 44° and 47° and slippage to 44 mm and 45 mm, respectively. With trans-oesophageal filling no higher than 75 mL, residual pouch volume after five minutes amounted to 53 mm, 2.5 times higher.

A complication rate of between 6% and 13% of cases requiring further surgery is not acceptable

Posterior stomach wall slippage is an Achilles heel for gastric band surgery.

In the investigation reported here, relevant post-operative parameters, following gastric band implantation – such as pouch volume, band dislocation and slippage – were compared with one another, using the model. Reports in the Literature show pouch dilatation in four to six percent of cases and posterior wall slippage in five to 19% of cases. Here, band dislocation needs to be viewed as a function of slippage. The complication rate for cases requiring further surgery came to between six and 13% [1, 2, 4-7, 10-12, 14, 17, 18, 20]. Posterior stomach wall slippage is an 'Achilles heel' for gastric band surgery [17]. To date, reports in the Literature suggest a complication rate requiring corrective surgery of between six and 13%, which is unacceptable; this has led to the development of modern gastric band implants. The complication rate for gastric band implantation, arising from the materials used, is quoted in the Literature at between 0.5% and 2% [2, 4-7, 10, 12, 18, 20]. Due to the wrong choice of sterilisation procedure in the case of the *GastroBelt I*, there were materials-related problems with this device between April and August 1998 [20]. The GB II device investigated in this paper is a further technical development based on the *GastroBelt I*, one that exhibits completely new materials properties. It differs fundamentally from the LAP and SAGB bands and has been in use since June 1999, in modified form.

Sandwich, modulus or compound engineering at the expense of elasticity

Slippage of the posterior wall of the stomach came to 7, 12 and 31 mm, with 18, 19 and 35 degrees of band dislocation. There was no methylene blue evidence whatsoever, in any of the tests, which For the GB II, the degree of elasticity/stretch selected was up to 4 times higher than that found in the SAGB band and about twice as high as that found in the LAP band. The poorer elasticity characteristics in the SAGB band can be ascribed to the raw material and to the manner in which this is processed. The SAGB band is manufactured in the form of a compound material. There is also a transparent silicone sheath surrounding the LAP band, allowing adjustments to be made. Sandwich, modulus or even compound engineering is achieved at the expense of the modulus of elasticity. The better stretch and elasticity properties in the GB II can be put down to a mean hardness hardness of 75.6 and 72.3, respectively, in the LAP and SAGB bands, compared with 54.3 in the GB II. As Table 2 shows, hardness in the selected material, in both the SAGB and LAP bands, is, on average, 33% higher than it is in the GB II. The excellent elasticity and stretch properties in the GB II neutralise contractile forces at work in the stomach and the device adapts to gastric flexing movements. In this respect, pressure-induced ulceration is also avoided efficiently – particularly once the gastric band has been adjusted, in the manner described by Forsell *et al.* [5, 6, 13]. According to Ablaßmeier *et al.* [1], it is completely unclear what the long-term effects might be as pressure is applied to the wall of the stomach by the silicone band. There is an increasing incidence of penetration, as a long-term complication associated with banding, with reports coming in at an increasing rate, associated with both SAGB and LAP bands, of acute bleeds [19] and multiple intestinal lesions [3]. Elasticity in the GB II is so high that the risk of loop avulsion can be virtually ruled out (Fig. 8). Animal tests carried out previously, involving the *GastroBelt*, have shown that after no more than four days, there was already evidence that tissue was growing into all of the securing loops, even those not sutured into position.

Fig. 7: Evidence of autofixation in the GastroBelt.

Table 3a: Trans-oesophageal filling: GastroBelt II

Test series	Trans-oesophageal filling vol (ΔV([mL]	Adjustment [mL]	Pouch vol. after 10s [mL]	Pouch vol. after 5 mins [mL]	Slippage [mm]	Band dislocation [□°]	Occlusion	Methylen blue evidence [Stomach residue]
I	75	1,5	20	20	0	0	no	yes
	150	1,5	25	20	0	0	no	yes
	210	1,5	38	20	3	0	no	yes
II	75	2,5	25	20	3	0	no	yes
	150	2,5	38	20	5	0	no	yes
	210	2,5	53	20	5	0	no	yes
III	75	5	65	30	3	0	no	yes
	150	5	140	75	5	0	no	yes
	210	5	195	135	5	0	no	yes

Table 3b: Trans-oesophageal filling: SAGB

Test series	Trans-oesophageal filling vol (ΔV([mL]	Adjustment [mL]	Pouch vol. after 10s [mL]	Pouch vol. after 5 mins [mL]	Slippage [mm]	Band dislocation [□°]	Occlusion	Methylen blue evidence
I	75	3	20	20	0	0	no	yes
	150	3	24	20	3	5	no	yes
	210	3	29	20	5	10	no	yes
II	75	5,5	45	34	8	23	no	yes
	150	5,5	89	38	15	31	no	yes
	210	5,5	110	46	32	39	no	yes
III	75	8	68	59	23	35	no	yes
	150	8	141	135	33	41	yes	no
	210	8	210	207	46	48	yes	no

Table 3c: Trans-oesophageal filling: LAP band

Test series	Trans-oesophageal filling vol (ΔV([mL]	Adjustment [mL]	Pouch vol. after 10s [mL]	Pouch vol. after 5 mins [mL]	Slippage [mm]	Band dislocation [□°]	Occlusion	Methylen blue evidence [Stomach residue]
I	75	1,5	20	20	0	0	no	yes
	150	1,5	30	20	3	5	no	yes
	210	1,5	38	20	3	8	no	yes
II	75	2,5	48	32	7	18	no	yes
	150	2,5	92	40	12	29	no	yes
	210	2,5	104	44	31	35	no	yes
III	75	6	65	53	21	37	no	yes
	150	6	143	139	36	44	yes	no
	210	6	210	205	45	47	yes	no

As a result, the GB II was fastened to all the ten retaining loops arranged in a circular pattern in the gastric motility test. Gastric contractile forces were simulated by manual flexing of the stomach. In each test series, ten different adjustment settings were used. The results are shown in Tables 3a - 3c.

<u>After five minutes, all three types of band had regained their original 20 mL pouch volume</u>

For the **first series of tests**, a 1.5 mL adjustment was selected for the GB II, 3 mL for the SAGB band and 1.5 mL for the LAP band. This is equivalent to a comparable reduction in outlet diameter of 23%, 26% and 22%, respectively, in the GB II, SAGB and LAP bands. When pouch volumes were checked, it was found that the original 20 mL had been restored in all three gastric band implants after five minutes, irrespective of trans-oesophageal filling volume. After ten seconds, with 75 mL of trans-oesophageal filling, a 20 mL pouch volume was re-established in all three cases for the gastric band implants. However, this figure altered with a 150 mL trans-oesophageal filling volume. In the case of the SAGB band, a residual pouch volume of 24 mL was observed where a 3 mL adjustment had been made, due to the larger outlet diameter at the outset. This contrasted with findings in respect of the other two bands. Where a 1.5 mL adjustment was made in each case, with a 150 mL trans-oesophageal volume, the residual pouch volume amounted to 25 mL in the case of the GB II and to 30 mL for the LAP band. The best pouch volume figure came from the SAGB band, which managed 29 mL after ten seconds, for a trans-oesophageal filling volume of 210 mL. Under the same conditions, the residual pouch volume for the LAP and GB II bands still came to 38 mL. The reason why the SAGB exhibited better cut-off in the first series of tests was that the outlet geometry with 3 mL of adjustment yielded a cross-sectional area of 421 mm². The figures achieved with the LAP and GB II bands were 338 and 250 mm², respectively. With reference to band dislocation, the *GastroBelt* turned in a better performance, due to the circular pattern adopted for securing the device in position. There were no cases of dislocation associated with this band. The maximum dislocation figures recorded for the SAGB and LAP bands were ten and eight degrees, respectively. In the SABG and LAP bands, dislocation is due to deficient dorsal fixation. The maximum extent of slippage recorded with the GB II was 3 mm, the same as that for the LAP band. The corresponding figure for the SAGB band was 5 mm. It was not until the next set of tests that the inadequacy inherent in the technique used to secure the device to the posterior wall of the stomach really made an impact, in terms of slippage, on the part of the SAGB and LAP bands.

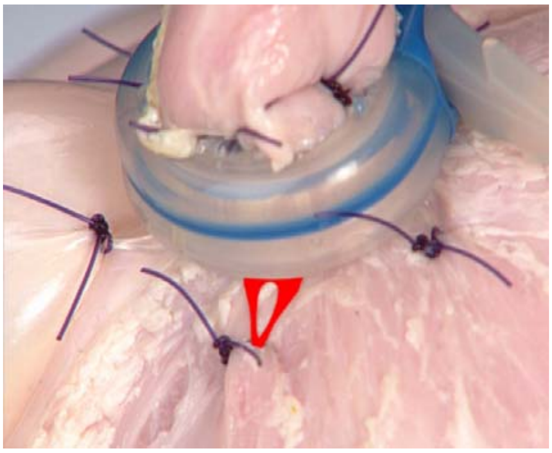


Fig. 8: Neutralisation of contractile forces by means of elasticated loops fitted to the GastroBelt II

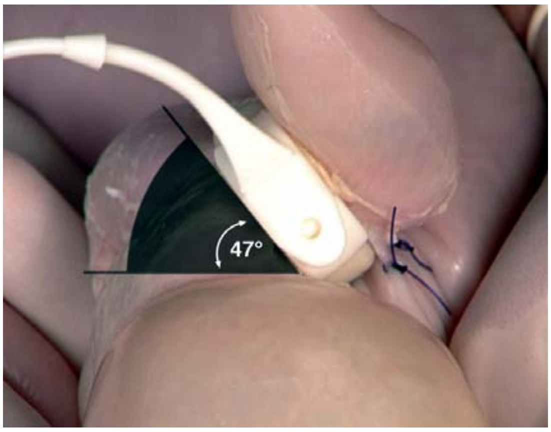


Fig. 9: Illustration of LAP band dislocation in the absence of retaining loops.

<u>In the case of the GB II, there was no dislocation whereas, in the LAP and SAGB bands, it exceeded 30%</u>

The **second series of tests** was characterised by adjustment volumes of 2.5 mL, 5.5 mL and 2.5 mL, respectively, in the GB II, SAGB and LAP bands. At these figures, comparable levels of outlet diameter reduction were achieved, amounting to 44%, 48% and 45%,

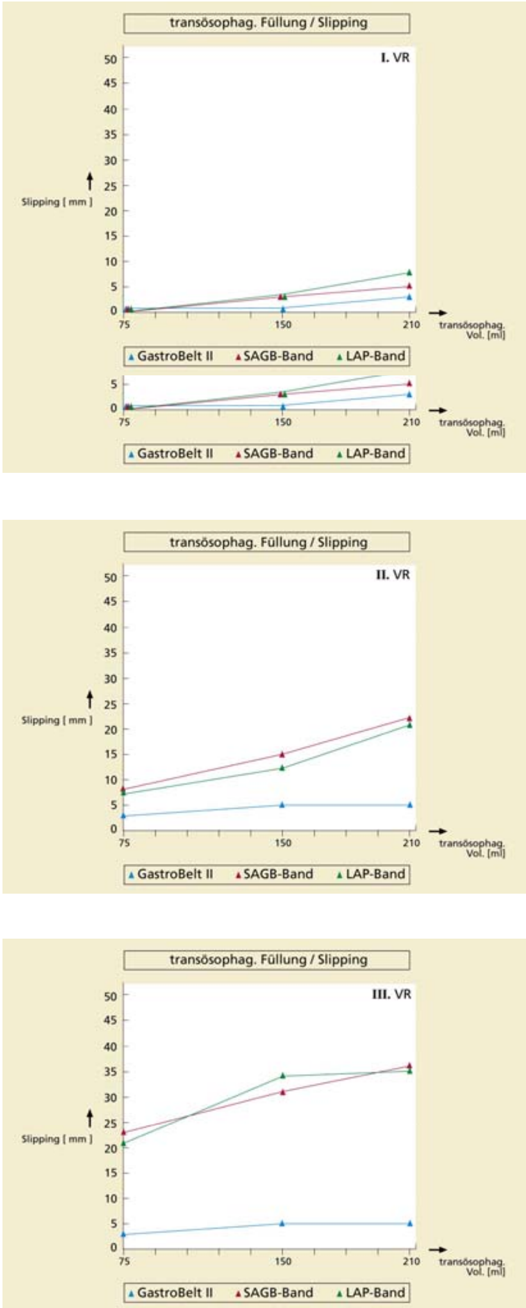
The high stretch capacity of the *GastroBelt* cancels out contractile forces in the stomach.

respectively, in the GB II, SAGB and LAP bands. Pouch volumes were measured after two different intervals, giving a constant 20 mL volume for the GB II after five minutes. On this occasion, neither the SAGB nor the LAP band managed to achieve the original 20 mL pouch volume. In the case of the SAGB band, the residue amounted to 46 mL. The corresponding figure for the LAP band was 44 mL. The GB II also achieved the best residual pouch volume results after ten seconds, with a residual 53 mL for a 210 mL trans-oesophageal filling volume. At this same filling volume, the corresponding residue figures for the SAGB and LAP bands came to 110 mL and 104 mL, respectively.

Under these test conditions, there was no band dislocation associated with the GB II, which turned in a 0° figure. The maximum degree of dislocation in the SAGB band, at 210 mL filling volume, came to 39°; the figure for the LAP band at the same volume came to 35°. At the maximum trans-oesophageal filling volume of 210 mL, slippage amounted to no more than 5 mm, whereas the results achieved with the LAP and SAGB bands came to almost identical figures of 31 and 32 mm, respectively. It was the inadequate arrangements for dorsal fixation of the two gastric bands (SAGB and LAP), with no retaining loops, that led to this considerably greater degree of slippage, relatively speaking.

Under peak load conditions, SAGB and LAP bands exhibited substantial degrees of slippage.

In the **third series of tests**, volumes of 5, 8 and 6 mL were used, respectively, to adjust the GB II, SAGB and LAP bands, these figures equating with a comparable reduction in the outlet diameter of 82%, 83% and 82%, respectively. The gastric band implants were thus exposed to the maximum levels of stress during the final series of tests. For a 210 mL trans-oesophageal filling volume, the GB II still yielded a residual pouch volume of 135 mL after five minutes, compared with 207 mL for the SAGB band and 205 mL for the LAP band. Measured ten-second residual pouch volumes were still 195 mL for the GB II, compared with total outlet occlusion in the SAGB and LAP bands. When methylene blue was injected, none of the trans-oesophageal fluid passed into the stomach and it took five minutes for traces to find their way into the residual stomach. As a result of a combination of slippage and band dislocation, both the SAGB and the LAP bands were occluded. In the case of the GB II, slippage did not exceed 5 mm, even under the most severe stress conditions.

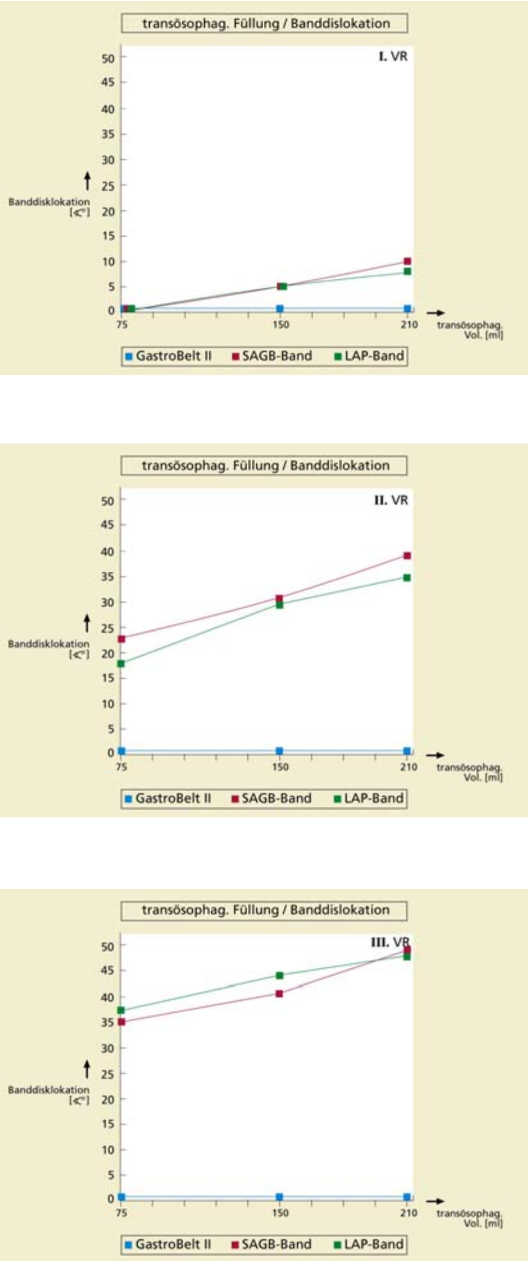


Figs. 10a-c: Slippage in all three gastric bands, shown as a function of trans-oesophageal filling. a) 1st series of tests; b) 2nd series of tests and c) 3rd series of tests.

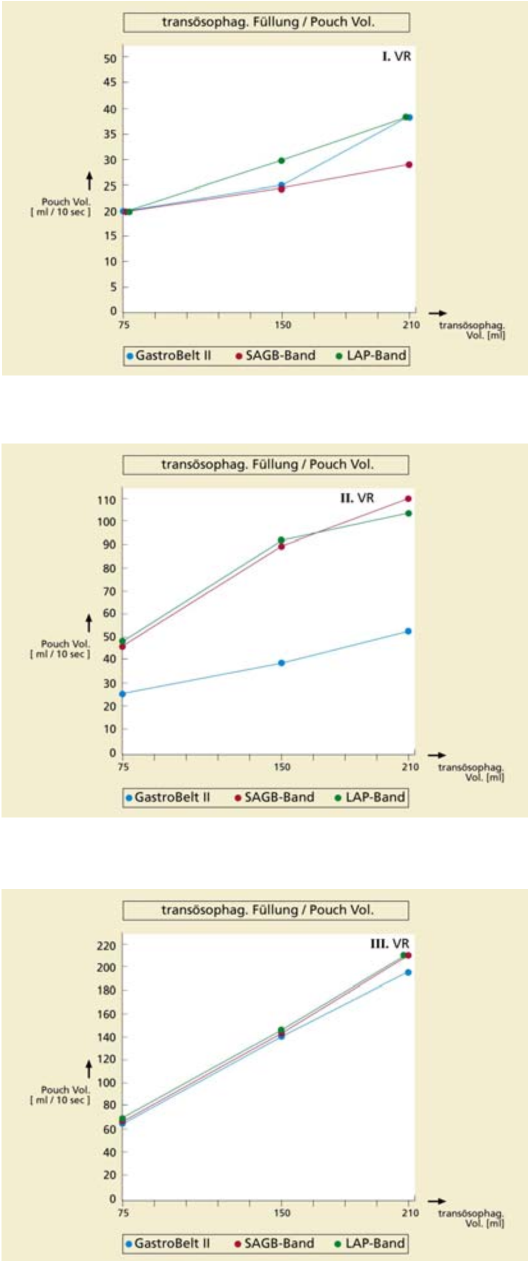
However, there was extensive slippage of both the SAGB and LAP bands here, amounting to 46 mm and 45 mm, respectively. The combined effect of this and of the ensuing band dislocation led to total occlusion with 210 mL of trans-oesophageal filling.

<u>Secure attachment of the gastric band in the case of the *GastroBelt*, thanks to the circular layout adopted for the retaining loops.</u>

The circular layout adopted for the retaining loops is an ingenious idea for preventing dislocation of the gastric band [17].



Figs. 11a-c: Band dislocation in all three gastric bands, shown as a function of trans-oesophageal filling. a) 1st series of tests; b) 2nd series of tests and c) 3rd series of tests.



Figs. 12a-c: Pouch volumes after ten second and after five minutes, at varying levels of trans-oesophageal filling. a) 1st series of tests; b) 2nd series of tests and c) 3rd series of tests.

In addition to the option of adopting direct fixation to the stomach, the retaining loops featured on the *GastroBelt* offer an advantage inasmuch as tissue in-growth (autofixation) starts in all ten of the loops arranged in a circle on either side of the device as early as 4 days after the procedure. This makes for secure fixation and prevents slippage of the gastric band, particularly in the dorsal region of the stomach. Given the enormous elasticity afforded by the circular pattern used for the retaining loops, contractile forces generated by flexing movements in the stomach are neutralised. In this way, the enormous stretch properties of the GB II are almost 4 times as efficient at preventing avulsion of the retaining sutures from the wall of the stomach where seromuscular fixation is carried out in the proper manner. Even under the most severe stress conditions, there were no cases of avulsion of the retaining loops from the wall of the stomach. Excellent deformation properties reduce the incidence of migration. According to FORSELL *et al.* [1, 5, 6, 13], adjustments to gastric band implants cause pressure ulcers, with the result that the implant migrates into the stomach. Where the seromuscular suturing technique is applied strictly, the risk of migration can be eliminated in the case of the GB II. Amongst our own patient cohort, there were no such cases whatsoever. The high degree of elasticity in the implant means that it can mould itself continuously to the shape of the stomach during contractile phases and this is particularly beneficial in preventing pressure ulcers from developing.

If corrective surgery is required following implantation of a GB II band, secured by means of retaining loops, the procedure will be a great deal more straightforward. The tissue lining that develops around the *GastroBelt* can be opened directly, without any risk, via the gastric band implant, since there are none of the components present on the anterior wall of the stomach, as there are in the cases of SAGB and LAP bands.

In contrast, preparation and identification of the correct layer in the case of implants, which are surrounded by a pouch formed from the anterior wall of the stomach, is far more difficult (Fig. 5a). Furthermore, there is the additional risk of perforation of the stomach wall, due to the preparation process. Usually, it is impossible to identify pouch sutures in conventional gastric band implants (SAGB and LAP bands), since these often attach themselves to the left hepatic lobe.

Bibliography

The reader is referred to Part 1.

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