

Endoscopic Duodenal-jejunal Bypass Liner treatment for Type 2 Diabetes and Obesity: A comparison of the outcomes with an implantation period of 6 months versus 12 months in a worldwide registry

Dr REJ Ryder<sup>1</sup>, Dr M Yadagiri<sup>1</sup>, Mr Harry Frydenberg<sup>2</sup>, Dr Sigal Fishman<sup>3</sup>, Dr James Byrne<sup>4</sup>, Mr Jacob Chisholm<sup>5</sup>, Dr John Mason<sup>6</sup>, Ms C de Jonge<sup>7</sup>, Prof JW Greve<sup>8</sup>, Dr P Sen Gupta<sup>1,9</sup>  
<sup>1</sup>City Hospital, Birmingham, UK, <sup>2</sup>Epworth Hospital, Richmond, Australia, <sup>3</sup>Sourasky Medical, Tel Aviv, Israel, <sup>4</sup>University Hospital Southampton NHS Foundation Trust, Southampton, UK, <sup>5</sup>Adelaide Bariatric Centre, Adelaide, Australia, <sup>6</sup>Trafford General Hospital, Manchester, UK, <sup>7</sup>Maastricht University Medical Center, Maastricht, Netherlands, <sup>8</sup>Zuyderland Medical Center, Heerlen, Netherlands, <sup>9</sup>Guy's and St Thomas' Hospitals, London, UK

AIMS and METHODS

Endoscopic Duodenal-Jejunal Bypass Liner (DJBL) (AKA EndoBarrier® or RESET®) is a 60cm impermeable sleeve which is endoscopically implanted into the first part of the small intestine for up to one-year. Uncertainty exists re risk:benefit of DJBL which has been used as treatment for obesity, both with and without diabetes. In view of this, during 2017, an independent, secure, online registry was established under the auspices of the Association of British Clinical Diabetologists, for the collection of safety and efficacy data worldwide.

RESULTS

As of October 2024, data had been entered on 1101 patients, of whom 261 (age 52.3±10.1 years, 53% male, 82% white ethnicity, HbA1c 71.1±19.3mmol/mol, weight 115.4±23.2kg, BMI 39.9±7.2kg/m2) had both 6 and 12 month data entered. See Tables 1 and 2 for further results re benefits and risks.

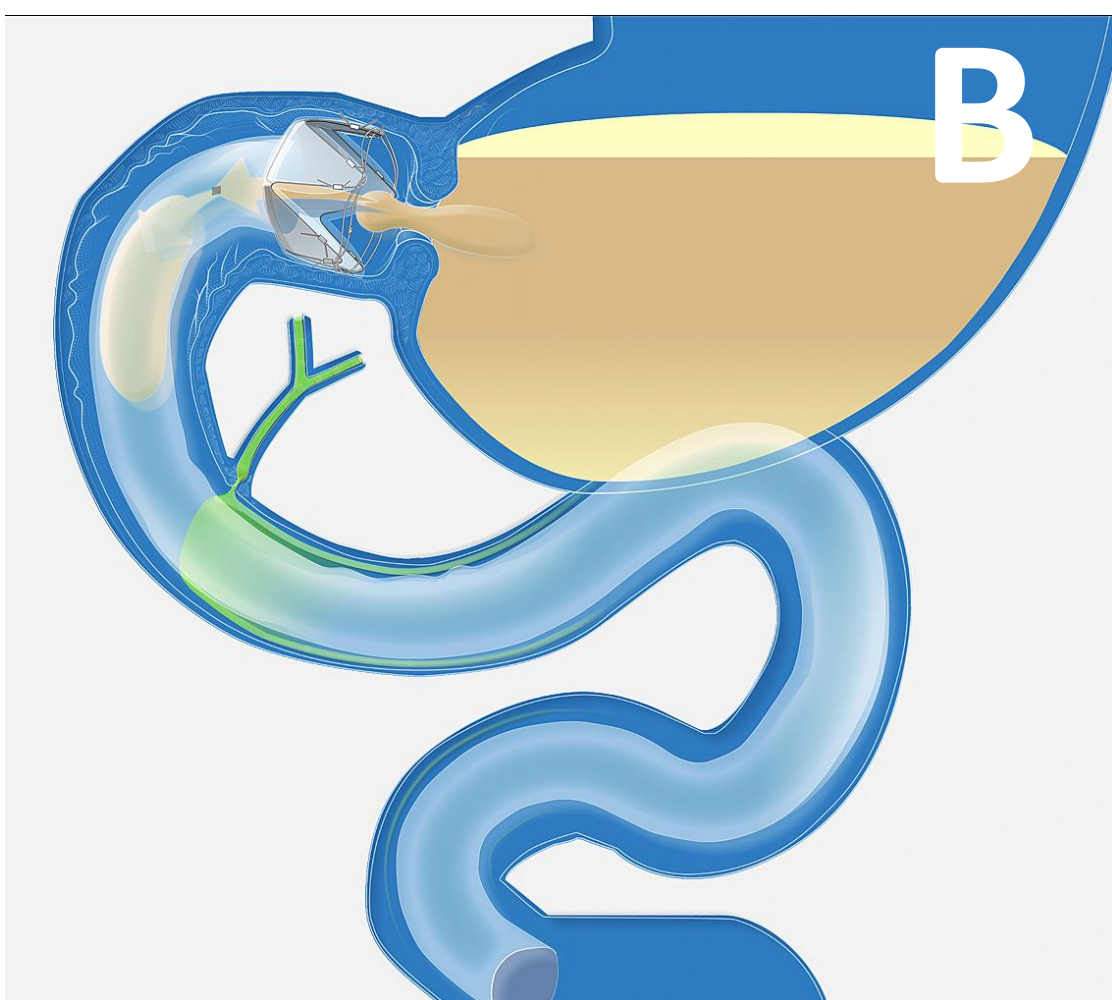
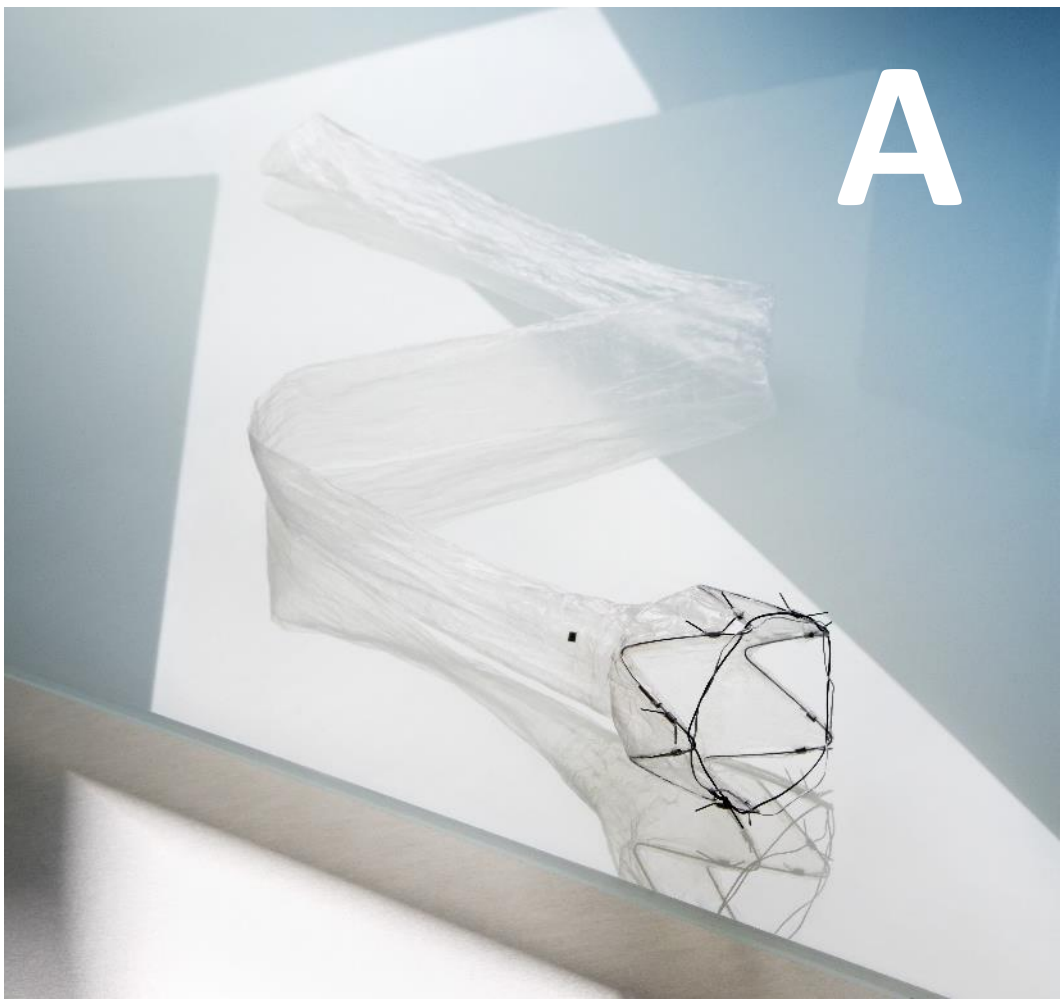


Fig. 1A. Photograph of DJBL with anchor mechanism in foreground and tubing posteriorly; 1B shows the device implanted in the proximal intestine with ingested food (yellow) passing within it.

CONCLUSION

This international data from the Worldwide DJBL Registry suggests that most of the benefits of DJBL occur by 6 months and many of the SAE occur after 6 months. Therefore, there may be situations where removal at 6 months could improve the risk:benefit ratio.

Table 1. Impact of Endoscopic Duodenal-jejunal Bypass Liner (DJBL) on weight and HbA1c. Whilst there is significant further fall in weight and HbA1c between 6 months and 12 months, most of the improvement has occurred by 6 months. The higher the initial HbA1c, the greater the reduction. Data from 261 patients from 13 centres in 6 countries (Australia, Austria, Brazil, Israel, Netherlands, and United Kingdom) from the Worldwide DJBL Registry.

Parameter	N	Baseline	6 months	12 months	Difference 6 months vs baseline	Difference 12 months vs baseline	P-value baseline vs 6 months	P-value baseline vs 12 months	P-value difference 6 vs 12 months
Weight (kg)	261	115.4±23.2	105.2±21.8	103.2±22.6	-10.2±7.4	-12.2±8.8	<0.001	<0.001	<0.001
All HbA1c (%)	180	8.7±1.8	7.5±1.5	7.3±1.2	-1.2±1.6	-1.4±1.6	<0.001	<0.001	0.007
HbA1c ≥ 7%	157	9.0±1.6	7.7±1.4	7.4±1.1	-1.4±1.5	-1.6±1.5	<0.001	<0.001	0.001
HbA1c ≥ 8%	108	9.7±1.5	8.0±1.4	7.6±1.2	-1.7±1.6	-2.1±1.6	<0.001	<0.001	<0.001
HbA1c ≥ 9%	64	10.6±1.3	8.3±1.7	7.8±1.4	-2.3±1.7	-2.8±1.6	<0.001	<0.001	0.001
HbA1c ≥ 10%	38	11.4±1.0	8.7±1.7	8.0±1.5	-2.7±1.8	-3.3±1.6	<0.001	<0.001	0.001

Table 2. In the full registry, 46/1101 (4.2%) experienced serious adverse events (SAE). 20/46 (43.5%) SAE would have been avoided by removal at 6 months (11 liver abscess, 6 GI bleed, one cholecystitis, one pancreatitis, one abdominal abscess). It was particularly noteworthy that 11/13(85%) liver abscess SAE would have been avoided by removal at 6 months.

Serious Adverse Event	All	Before 6-months	After 6-months
Early removal because of GI bleed	26	20	6
Liver abscess (early removal = 9/12; found at time of routine explant = 3/12)	11	2	9
Liver abscess after prolonged implant (1/2 = nearly 2 years; 1/2 = 16 months)	2	0	2
Early removal because of pancreatitis	2	1	1
Early removal because of cholecystitis	2	1	1
Early removal because of liner obstruction - surgical removal required*	1	1	0
Abdominal abscess due to small perforation of bowel in relation to DJBL	1	0	1
Early removal - gastric perforation – surgical removal as part of successful Roux-en-Y procedure	1	1	0
Total	46	26	20

\*Extraction hood came off during removal and EndoBarrier became stuck in the oesophagus requiring removal through a small incision in the side of the neck