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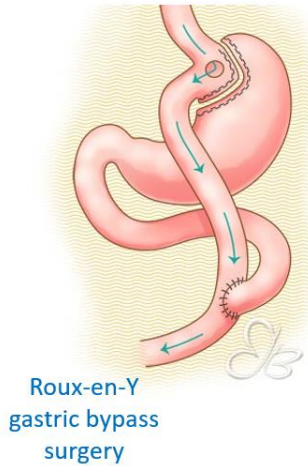
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# AN INNOVATIVE APPROACH TO IMPROVING SAFETY VS EFFICACY OF ENDOSCOPIC DUODENAL JEJUNAL BYPASS LINER (DJBL) TREATMENT FOR TYPE 2 DIABETES AND OBESITY

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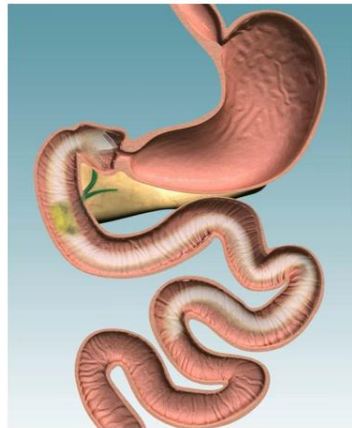


# Background

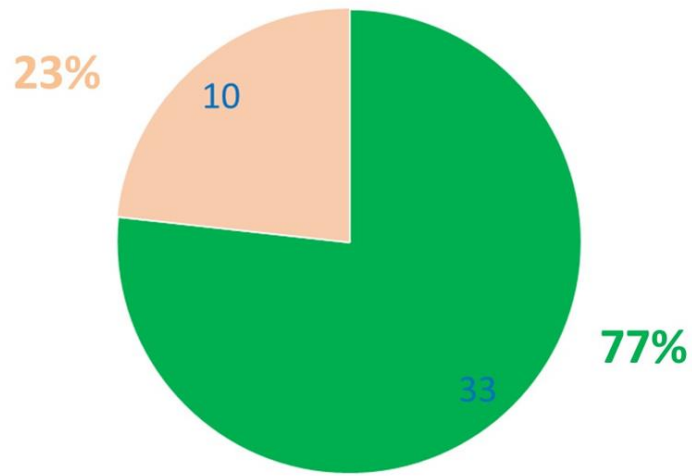


Fluoropolymer wall Nitinol Anchor

- 60 cm impermeable sleeve
- Minimally invasive



33/43 (77%) maintained most of the improvement  
 10/43 (23%) reverted to baseline **three years post explant**<sup>1</sup>



■ Improvement maintained ■ Deteriorate to baseline



## Meta-Analysis: published in Diabetes Care<sup>2</sup> (Type II Diabetes + Obesity Studies)

Endpoint	Change	# Studies	# Patients
<b>HbA1c</b>			
Change at explant*	↓ 1.3%	14	388
<b>Weight</b>			
Total body weight change	↓ 18.9%	10	301

\*Example: HbA1c 8.5% → 7.2% = 1.3% point reduction

1. Ryder REJ, et al. Br J Diabetes 2022;22:82-8

2. Jirapinyo P, et al. Diabetes Care 2018;41(5):1106-1115.

Most SAEs @ 9 to 12. Hypothesis: Can  implant time to 9 month can decrease complications, keeping efficacy?

- Data in the ABCD worldwide DJBL registry to compare HbA1c and weight at 9- vs 12-month implantation.
- 1298 patients, 37 centres in 12 countries had data in the registry. **Of these 258 had both 9- and 12-month data.**

Parameter	n	Baseline	9-months	12-months	Difference 9-months vs baseline	Difference 12-months vs baseline	P-value baseline vs 9-months	P-value baseline vs 12-months	P-value difference 9- vs 12-months
Weight (kg)	228	113.8±22.5	101.6±22.0	100.7±23.0	-12.2±8.1	-13.1±8.6	<0.001	<0.001	0.005
All HbA1c (%)	197	8.8±2.0	7.3±1.4	7.3±1.3	-1.5±1.7	-1.5±1.7	<0.001	<0.001	0.571
HbA1c ≥ 7%	170	9.3±1.8	7.5±1.3	7.5±1.2	-1.7±1.7	-1.7±1.8	<0.001	<0.001	0.639
HbA1c ≥ 8%	132	9.8±1.7	7.7±1.4	7.7±1.3	-2.0±1.8	-2.1±1.8	<0.001	<0.001	0.447
HbA1c ≥ 9%	82	10.6±1.7	7.9±1.6	7.8±1.5	-2.6±2.0	-2.8±1.9	<0.001	<0.001	0.203
HbA1c ≥ 10%	48	11.4±1.7	8.4±1.8	8.1±1.5	-3.1±2.3	-3.3±2.0	<0.001	<0.001	0.091
HbA1c ≥ 11%	26	12.4±1.9	8.6±2.0	8.5±1.8	-3.8±2.7	-3.8±2.5	<0.001	<0.001	0.857

**No difference in WL and glucose control between 9 and 12 mo**

- Full registry: 60/1298 (4.6%) SAEs
- **22/60 (36.7%) SAEs** would have been **avoided by 9 removal @9mo** (12 liver abscess, 8 GI bleeding, cholecystitis, 1 surgical removal of displaced liner).
- **12/18 (66.6%) liver abscess** would have been avoided by removal of DJBL at 9-months.

Serious Adverse Event	All	Before 9-months	After 9-months
Early removal because of GI bleed (removal: by endoscopy = 30/31; by laparoscopy = 1/31)	31	26	5
Liver abscess (early removal = 12/15; found at time of routine explant = 3/15)	15	6	9
Early removal because of pancreatitis or cholecystitis	4	3	1
GI bleed after prolonged implant (1/3 = 18 months; 2/3 = 13 months)	3	0	3
Liver abscess after prolonged implant (1/2 = nearly 2 years; 1/2 = 16 months)	3	0	3
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	1	0
Early removal - gastric perforation – surgical removal as part of successful Roux-en-Y procedure	1	1	0
Surgical removal required as liner was displaced	1	0	1
<b>Total</b>	<b>60</b>	<b>38</b>	<b>22</b>

\*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

**Conclusion: REMOVAL @ 9 mo x 12mo, KEEPS DJBL SAFER, KEEPING ITS EFFICACY**