

# EndoBarrier treatment for longstanding type 2 diabetes and obesity: Outcomes two-years after EndoBarrier in 90 consecutively treated patients

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## BACKGROUND

EndoBarrier (also known as RESET<sup>®</sup>, Morpich Medical, Boston, USA), is a 60 cm endoscopically implanted, impermeable intestinal liner which reduces weight and improves glycaemic control during a year of treatment in patients with type 2 diabetes and obesity.



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

## AIMS and METHODS

We aimed to: i) assess the safety and efficacy of EndoBarrier in 90 consecutive patients with longstanding poorly controlled type 2 diabetes and obesity by monitoring outcomes in a registry; ii) assess maintenance of efficacy 24 months after EndoBarrier removal.

## RESULTS

**Table 1:** All 90 patients have completed two-years post EndoBarrier; 60/90 (66%) attended follow up. Baseline characteristics, n=60:

Parameter	N=60
Age (years)	51.2±8.3
Sex (% male)	47
Ethnicity (% white ethnicity)	50
BMI (kg/m <sup>2</sup> )	41.5±6.8
HbA1c (mmol/mol)	77.9±19.5
(%)	9.3±1.8
Diabetes duration (median (IQR) (years))	11.0 (6.0-18.5)
Taking insulin (%)	60

**Table 2:** Outcomes at explant of EndoBarrier; n=60

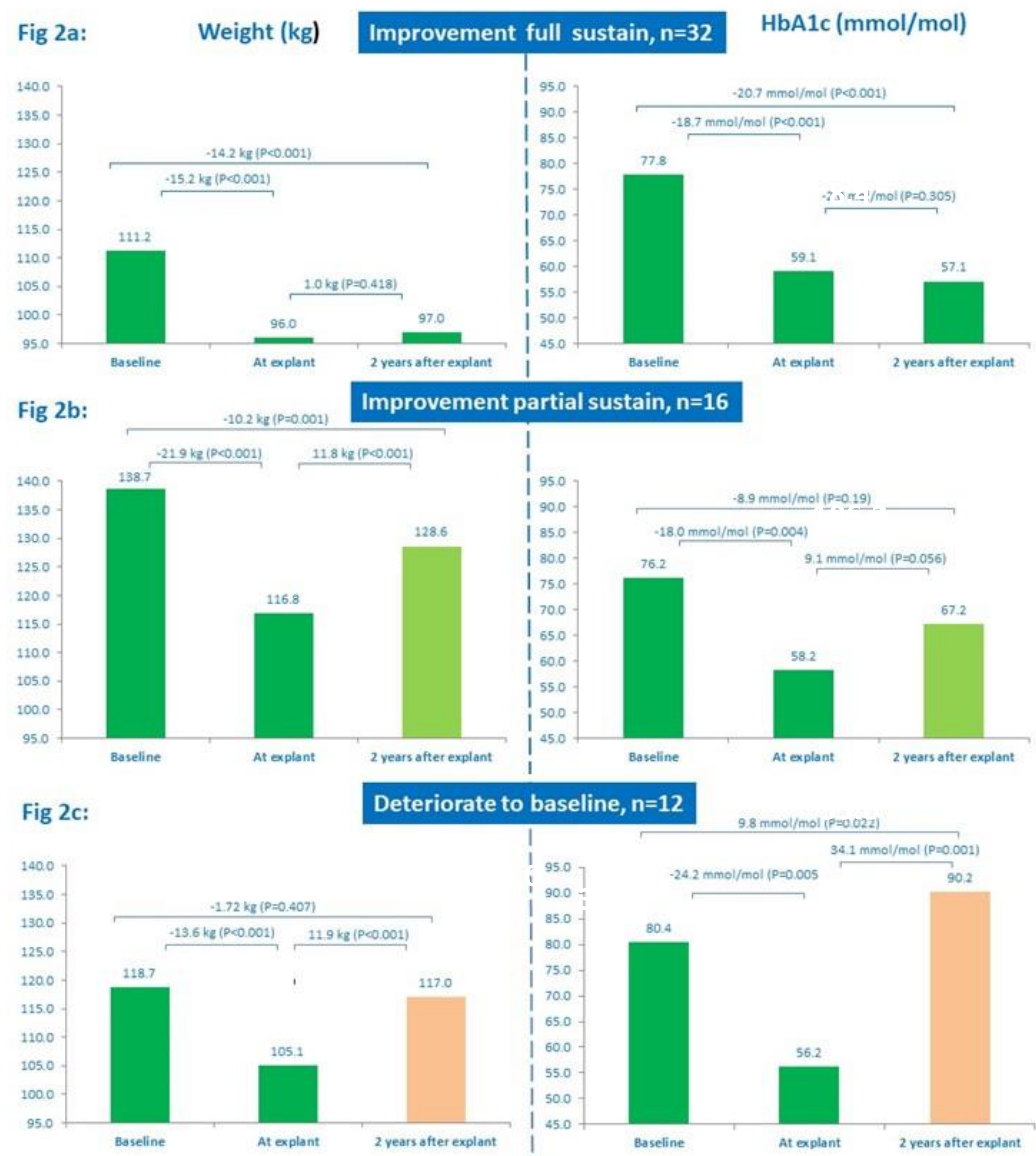
Parameter	Baseline	At explant	Difference	P-value
Weight (kg)	120.0±28.2	103.4±28.7	-16.7±8.4	<0.001
BMI (kg/m <sup>2</sup> )	41.5±6.8	35.5±7.2	-6.0±3.2	<0.001
HbA1c (mmol/mol)	77.9±19.5	58.3±13.5	-19.6±19.0	<0.001
HbA1c (%)	9.3±1.8	7.5±1.2	-1.8±1.7	<0.001
Systolic blood pressure (mmHg)	138.8±14.8	127.9±17.5	-10.9±19.8	<0.001
Cholesterol (mmol/L)	4.87±1.21	4.01±0.93	-0.85±0.92	<0.001
ALT (U/l)	31.1±17.5	19.3±10.3	-11.7±18.2	<0.001
Insulin daily dose* (n=36)	100(49-159)	37(0-64)	-63	<0.001

\*10 of the 36 (27.8%) patients discontinued insulin

**Early removal of EndoBarrier:** 13/90 (14%) patients had early EndoBarrier removal: five gastrointestinal haemorrhage, two liver abscess, one other abscess and five gastrointestinal symptoms. All made a full recovery after removal and most experienced benefit despite the adverse event. All other patients achieved a full year of EndoBarrier treatment.

Two years post-EndoBarrier 32/60 (53%) demonstrated fully-sustained improvement (which was defined as no significant difference between the weight and HbA1c at EndoBarrier removal and two years later – Figure 2a), 16/60 (27%) partially-sustained improvement (Figure 2b) and 12/60 (20%) reverted to baseline (Figure 2c).

**Figure 2:** The weight and HbA1c at baseline, at explant and two years after explant in the 32/30 (53%) who fully maintained (Fig 2a), and 16/60 (27%) who partially maintained the improvement (Fig 2b). Also, the 12/60 (20%) who deteriorated back to baseline (Fig 2c).



Of the 12/60 (20%) whose weight and/or HbA1c deteriorated (Figure 2c), 11/12 (92%) had **depression** and/or **bereavement** and/or **major health problem**.

## CONCLUSION

In patients with refractory diabetes, EndoBarrier resulted in considerable weight loss, improvement in glycaemic control, reduction in a marker of fatty liver (ALT) and reduction in the need for insulin. There continued to be significant improvement two-years after removal in 80%. Patients with early removal because of serious adverse events made a full recovery and most derived considerable benefit. These data support risk:benefit being strongly towards benefit, and they support EndoBarrier as a potential important treatment option for longstanding poorly controlled type 2 diabetes and obesity. As endoscopy units are ubiquitous, delivery of EndoBarrier treatment could be relatively straightforward. The benefits to the patients concerned are best appreciated from pictures and videos of them<sup>1</sup>.

## REFERENCE

1. See: <https://abcd.care/resource/birmingham-endoBarrier-treated-patients>