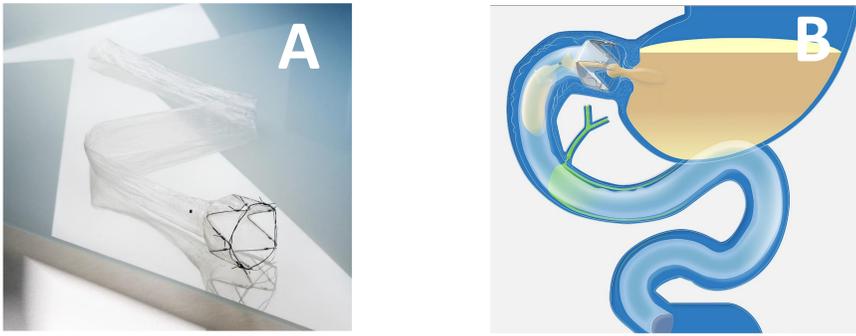


# UK FIRST NHS ENDOBARRIER SERVICE FOR ADVANCED TYPE 2 DIABETES AND OBESITY: OUTCOMES IN ALL PATIENTS 6 MONTHS AFTER DEVICE EXPLANT

REJ Ryder<sup>1</sup>, M Yadagiri<sup>1</sup>, SP Irwin<sup>1</sup>, W Burbridge<sup>1</sup>, T Bashir<sup>2</sup>, MC Wyres<sup>1</sup>, ML Cull<sup>1</sup>, JP Bleasdale<sup>3</sup>, RA Allden<sup>4</sup>, EN Fogden<sup>4</sup>, M Anderson<sup>4</sup> and P Sen Gupta<sup>5</sup>  
 Departments of <sup>1</sup>Diabetes, <sup>2</sup>Dietetics, <sup>3</sup>Anaesthetics, <sup>4</sup>Gastroenterology, City Hospital, Birmingham, UK, <sup>5</sup>Guy's and St Thomas' Hospitals, London, UK

## BACKGROUND

EndoBarrier (GI Dynamics, 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 the device.

## AIMS and METHODS

We aimed to: i) establish an NHS service to offer EndoBarrier treatment to patients with advanced diabetes; ii) to assess its safety and efficacy by monitoring outcomes in a registry; iii) to assess maintenance of efficacy 6-months after removal.

## RESULTS

**Table 1:** All 62 patients have completed 6 months post EndoBarrier; 50/62 (81%) attended follow up. Baseline characteristics, n=50:

| Parameter                                | N=50             |
|--|------------------|
| Age (years)                              | 52.2±7.0         |
| Sex (% male)                             | 56               |
| Ethnicity (% Europid)                    | 58               |
| BMI (kg/m <sup>2</sup> )                 | 42.0±7.9         |
| HbA1c (mmol/mol)                         | 81.3±22.3        |
| HbA1c (%)                                | 9.6±2.0          |
| Diabetes duration (median (IQR) (years)) | 13.0 (7.5-20.25) |
| Taking insulin (%)                       | 62               |

**Table 2:** Outcomes at explant of EndoBarrier; n=50

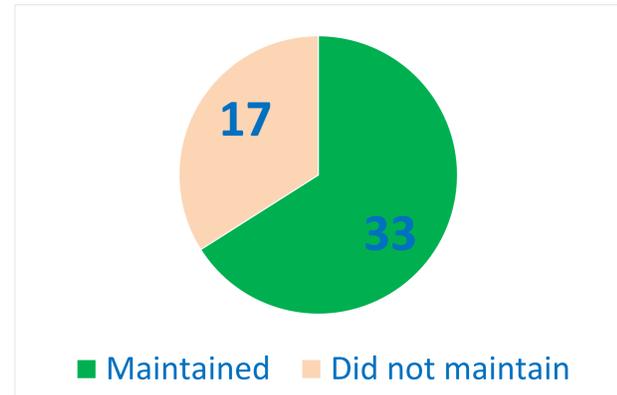
| Parameter                      | Baseline    | At explant | Difference | P-value |
|--------------------------------|-------------|------------|------------|---------|
| Weight (kg)                    | 123.4±30.1  | 107.3±30.4 | -16.1±9.0  | <0.001  |
| BMI (kg/m <sup>2</sup> )       | 41.9±7.4    | 36.2±7.6   | -5.7±3.2   | <0.001  |
| HbA1c (mmol/mol)               | 81.3±22.3   | 56.9±12.4  | -24.4±20.1 | <0.001  |
| HbA1c (%)                      | 9.6±2.0     | 7.4±1.1    | -2.2±1.9   | <0.001  |
| Systolic blood pressure (mmHg) | 139.9±14.9  | 125.6±14.2 | 14.3±16.9  | <0.001  |
| Cholesterol (mmol/L)           | 4.7±1.4     | 3.8±0.9    | -0.90±1.18 | <0.001  |
| ALT (U/l)                      | 30.4±18.7   | 19.6±11.8  | -10.8±19.5 | <0.001  |
| Insulin daily dose* (n=31)     | 104(54-146) | 30(0-65)   | -60        | <0.001  |

\*10 of the 31 (32.3%) patients discontinued insulin

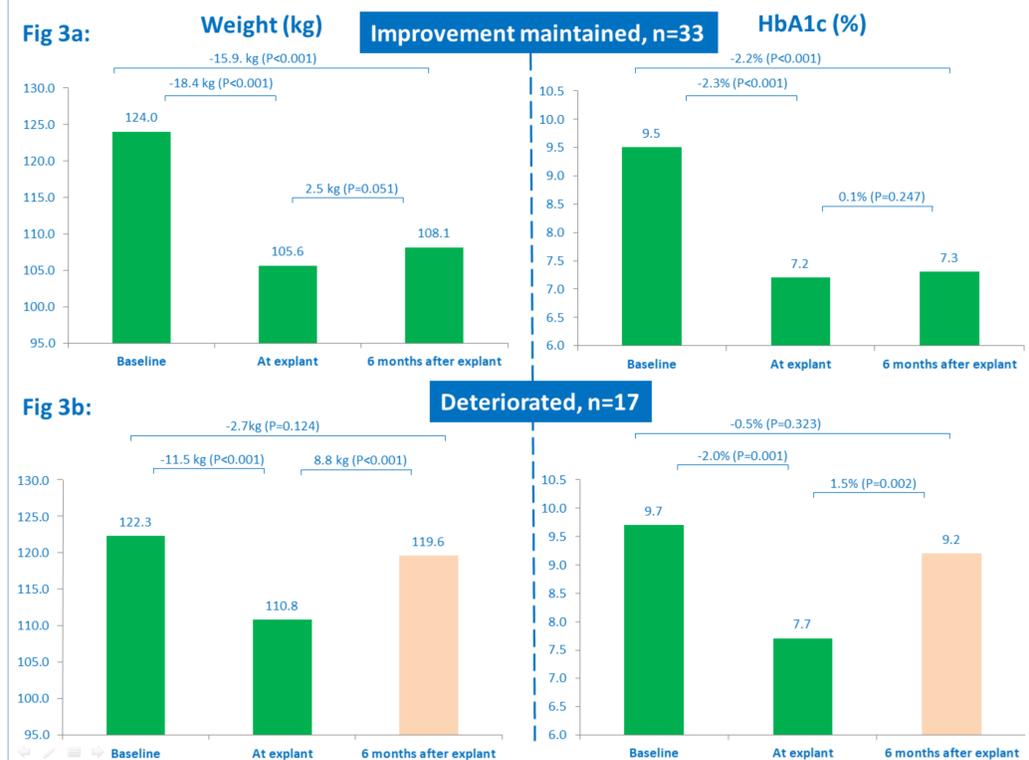
**Early removal of EndoBarrier:** 10/62 (16.1%) patients had early EndoBarrier-removal: 4 GI bleed, 2 liver abscess, 1 other abscess and 3 GI symptoms. All 10 had full recovery after removal and most experienced benefit despite the setback. All other patients achieved a full year of EndoBarrier treatment.

6-months after the removal of EndoBarrier, 33/50 (66.0%) had maintained the improvement (Figure 3a).

**Figure 2:** 33/50 (66.0%) of the patients had maintained the treatment effect at 6 months post explant



**Figure 3:** The weight and HbA1c at baseline, at explant and 6-months after explant in the 33/50 (66.0%) who maintained the improvement (Figure 3a) and 17/50 (34.0%) who deteriorated (Figure 3b).



**Table 3:** The patients who went on to deteriorate (Figure 3b) had had less fall in weight and HbA1c during the period of EndoBarrier treatment than those who maintained (Figure 3a):

|                     | Weight loss during EndoBarrier treatment | Fall in HbA1c during EndoBarrier treatment |
|---------------------|--|--|
| Maintained (n=33)   | 18.4 kg                                  | 2.3%                                       |
| Deteriorated (n=17) | 11.5 kg                                  | 2.0%                                       |

Of the 17 whose weight and/or HbA1c deteriorated (Figure 3b), 9/17 (53%) had **depression** or **bereavement**.

## 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. The improvement was sustained 6-months after removal in 66%. Patients with early removal because of serious adverse events made a full recovery and derived considerable benefit despite the setback. These data are supportive of risk:benefit being strongly towards benefit and they support the continuance of EndoBarrier as an important treatment option for refractory diabetes. As endoscopy units are ubiquitous, our service could be readily disseminated.