

Biomarkers in Diabetes: EndoBarrier® in obese subjects with type 2 diabetes: Short- and midterm effects on glucose metabolism

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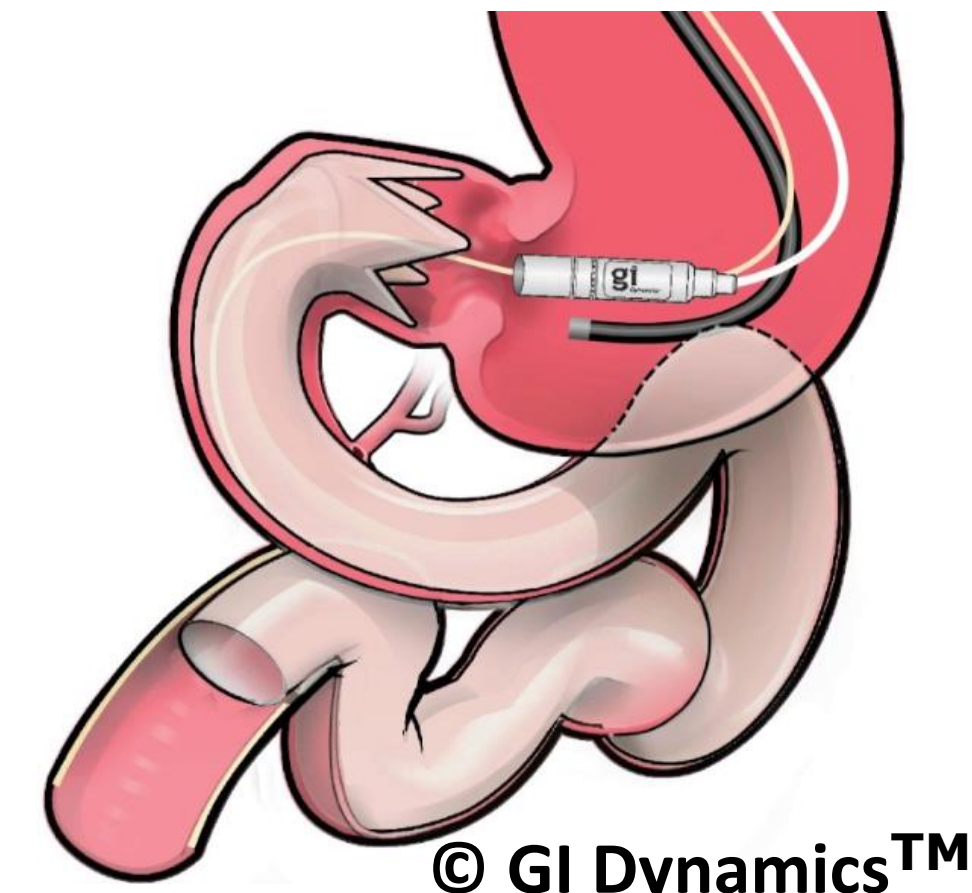
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EndoBarrier®

• Endobarrier® – a 60cm duodeno-jejunal bypass liner – which is endoscopically implanted, provides a physical barrier between intestinal mucosa and chyme. Previous studies have shown a reduction in body weight after implantation of this reversible device, but effects on insulin sensitivity and beta-cell function have not been adequately studied in people with diabetes mellitus.



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Study Design

• A monocentric, prospective pilot study on 10 subjects with manifest type 2 diabetes mellitus (HbA1c >48mmol/mol) and obesity was performed to investigate the impact of EndoBarrier® on insulin resistance, beta-cell function, body composition and microbiome composition. Subjects with pre-existing cardiovascular disease, indications for NSAID therapy or steroid therapy were excluded from study participation.

Interventions

• The EndoBarrier® device was implanted under general anesthesia and left in situ for 9 months.

Visits/Investigations

4 Trial visits

Implantation

Removal

Follow-up

Baseline

4 Weeks

9 Months

15 Months

- Mixed meal tolerance test
- Botnia Clamp
- DXA body composition scan
- Lactulose/Mannitol test (Intestinal permeability)
- Gut-microbiom-analyses
- Food frequency questionnaire
- Biopsies (Corpus, Duodenum)

Results

	Baseline mean ± SD	4 Weeks mean ± SD	9 Months mean ± SD	P-Value ¹	p-Value ²
Body weight (kg)	121,2 ± 18,5	116,3 ± 18,2	115,7 ± 22,5	<0,001	0,016
Fat mass (kg)	58,1 ± 12,0	55,0 ± 12,5	53,3 ± 16,1	0,001	0,014
BMI (kg/m²)	42,9 ± 4,7	41,2 ± 4,8	40,2 ± 6,1	<0,001	0,018
HbA1c (mmol/mol)	61 ± 10	56 ± 9	55 ± 12	0,016	0,139
Waist circumference (cm)	128 ± 12	125 ± 11	124 ± 13	0,014	0,008
Waist to hip ratio	1,00 ± 0,07	1,00 ± 0,06	1,00 ± 0,07	0,516	0,828
Blood pressure systolic (mmHg)	143 ± 16	129 ± 24	125 ± 21	0,059	0,007
Blood pressure diastolic (mmHg)	94 ± 10	85 ± 15	79 ± 16	0,107	0,021
GIR (mg/kg/min)	0,50 ± 1,02	0,86 ± 0,99	0,81 ± 1,28	<0,001	0,034
AUCcpep (ng/mL)	8,10 ± 3,01	7,27 ± 3,76	5,81 ± 2,09	0,440	0,046

p-Value¹: Comparison Baseline vs. 4 Weeks; p-Value²: Comparison Baseline vs. 9 Months

Conclusions

Significant reduction in body weight, body fat mass, BMI and waist circumference after 4 weeks and 9 months, respectively, were observed. Insulin sensitivity significantly improved already after 4 weeks and the beneficial effect sustained until removal after 9 months. Data on microbiome composition, gut permeability and biopsy material are currently being analysed.

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