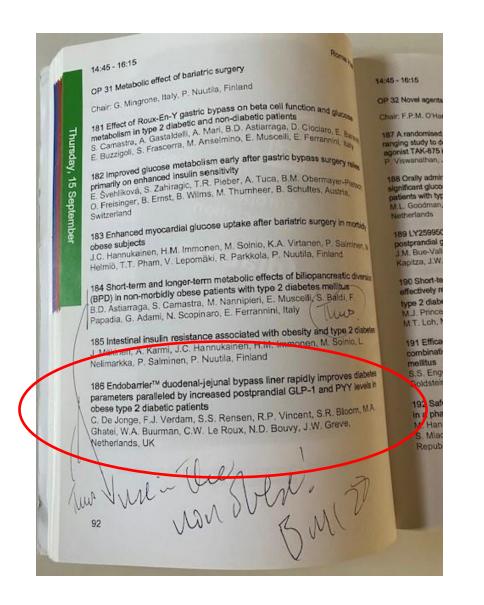
#### EASD Lisbon 2011







## EndobarrierTM duodenal-jejunal bypass liner rapidly improves diabetes parameters paralleled by increased postprandial GLP-1 and PYY levels in obese type 2 diabetic patients

Session: OP 31 Metabolic effect of bariatric surgery

Q Lisbon 2011

Roma Hall

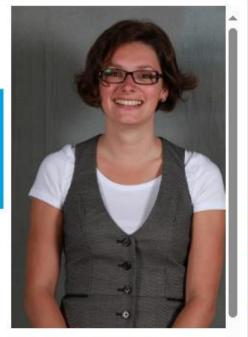
② 15. September 2011 16:00 - 16:15

440 views

EndoBarrier® Duodenal-Jejunal Bypass Liner rapidly improves diabetes parameters paralleled by increased postprandial GLP-1 and PYY levels in obese type 2 diabetic patients

Charlotte de Jonge

Department of Surgery, Maastricht University Medical Centre



Charlotte de Jonge

EndobarrierTM duodenal-jejunal bypass liner rapidly



Charlotte de Jonge

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de Jonge, et al.

EASD 2011

## Notes made by me during the EASD presentation by Charlotte de Jonge

love polide, here Gayronerber Regarts we Collaboratos 1? - ah statistin 11 + Lim Juy + Contine 3

## Notes made by me during the EASD presentation by Charlotte de Jonge

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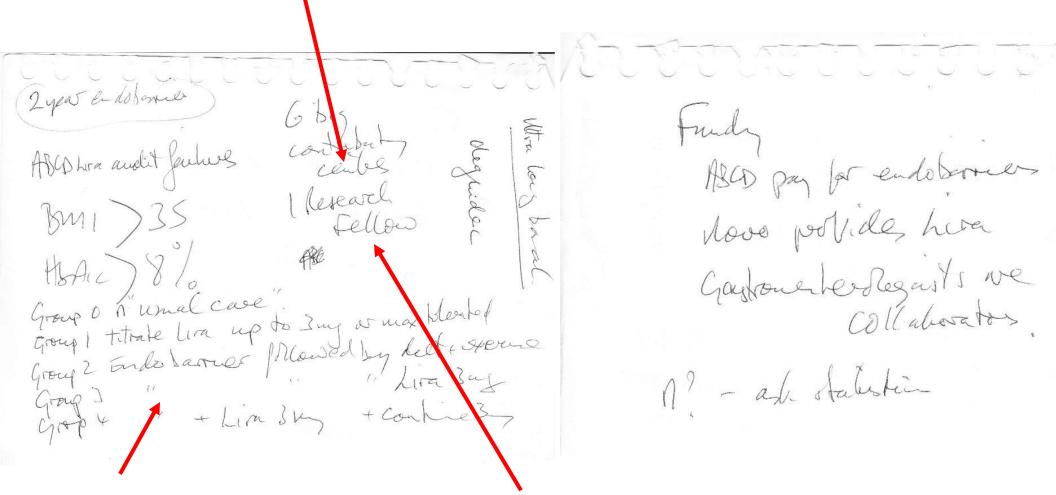
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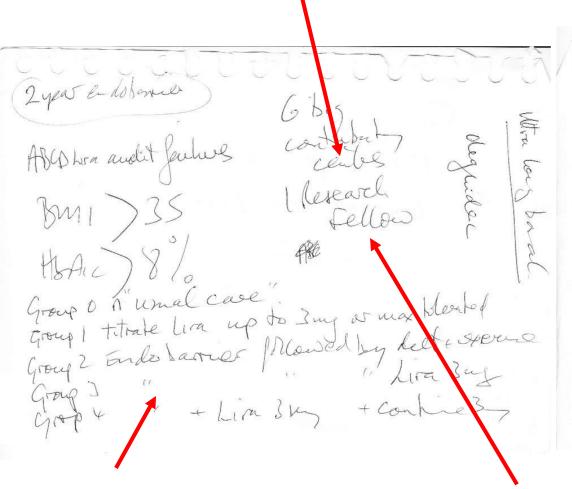
## the EASD presentation by le Jonge



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Piya Sen Gupta

## the EASD presentation by the Jonge



Became the REVISE-Diabesity study

Piya Sen Gupta

ASCO pay for endoberries.

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Collaboratos.

70 patients randomised to EndoBarrier plus continue liraglutide EndoBarrier plus stop liraglutide Higher dose liraglutide (1.8mg)

## the EASD presentation by de Jonge

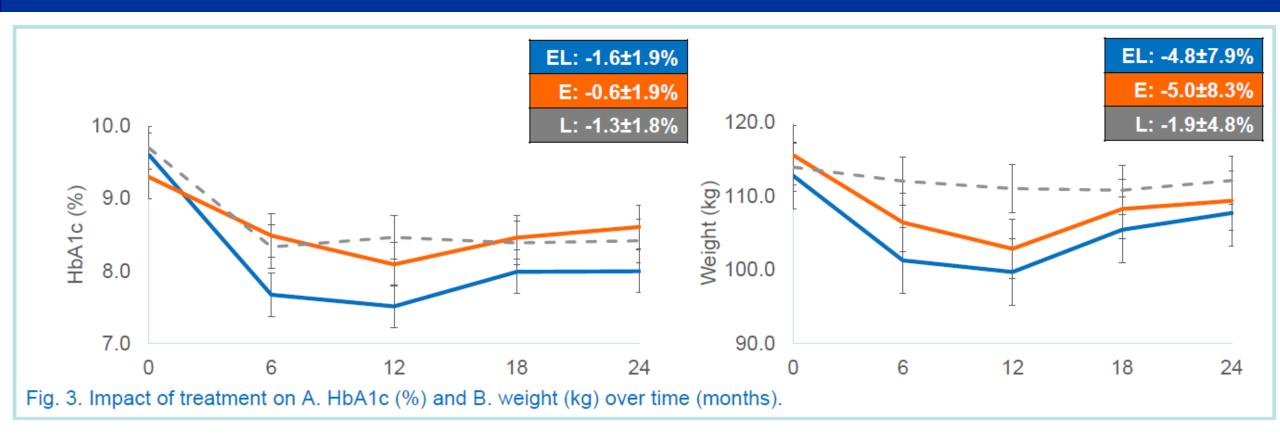
Became the REVISE-Diabesity study

Piya Sen Gupta

ABCD funded the study Gaykonerber Regasts we 70 patients randomised to EndoBarrier plus continue liraglutide EndoBarrier plus stop liraglutide

Higher dose liraglutide (1.8mg)

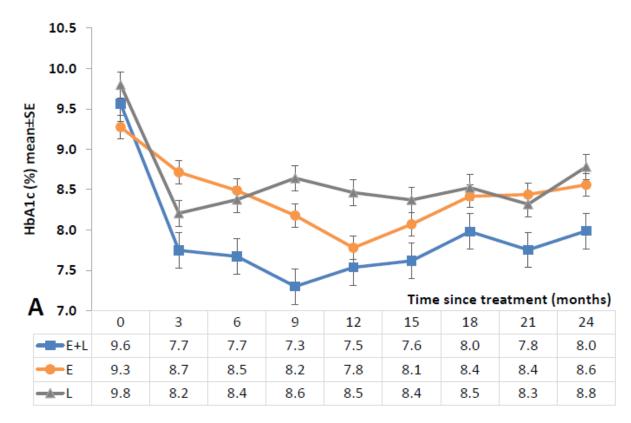
#### **REVISE-Diabesity Results**

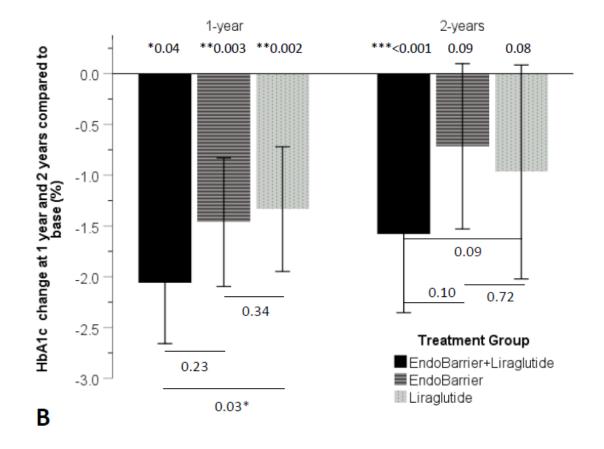


Presented at WCIT2D, New York, USA, 8 Apr 2019



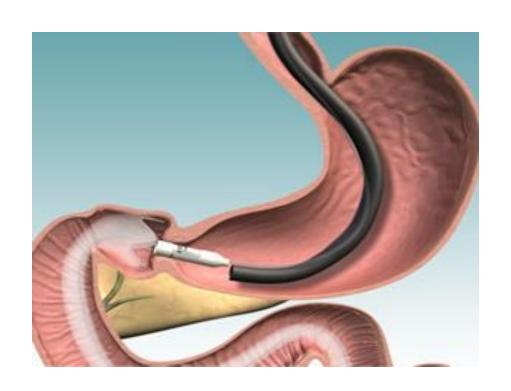
Fig. 3.3. Impact of treatment on A-B HbA1c (%) and on C-D body weight (kg) over time. Error bars indicate standard error.







### DJBL – Implantable Duodenal-Jejunal Bypass Liner The Worldwide Experience



Dr Bob Ryder

**ABCD Midlands Regional Meeting 2025** 

1, October 2025





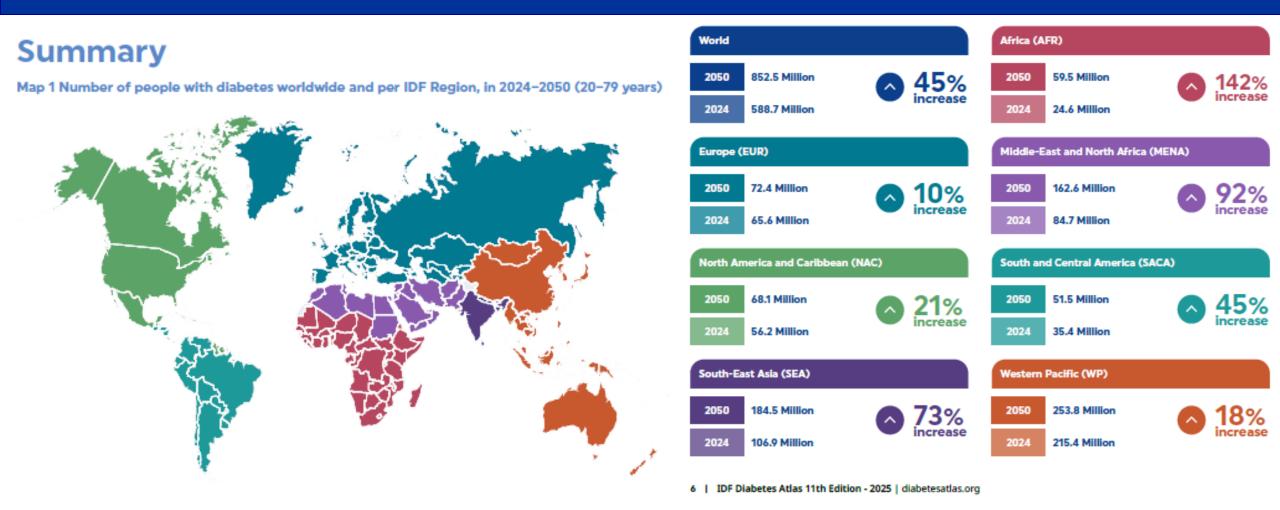
#### Disclosures

 Dr Bob Ryder has received speaker fees, and/or consultancy fees and/or educational sponsorships from Abbott, Astra Zeneca, Besins, BioQuest, Morphic Medical and Novo Nordisk





#### There is a worldwide pandemic of diabetes and obesity



### RESET® DJBL – Implantable Duodenal-Jejunal Bypass Liner



Patients reported on in the data presented here received the DJBL device branded as EndoBarrier<sup>®</sup>. To reflect the rebranding of the company to **Morphic Medical**<sup>®</sup> and the rebranding of the device to **RESET**<sup>®</sup>, this presentation will use the new brand name throughout.





#### **RESET® – Implantable Duodenal-Jejunal Bypass Liner**



- 60 cm impermeable sleeve
- Minimally invasive



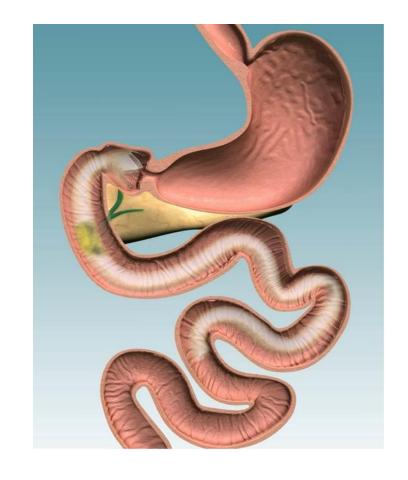


#### **RESET® – Implantable Duodenal-Jejunal Bypass Liner**



Fluoropolymer Nitinol wall Anchor

- 60 cm impermeable sleeve
- Minimally invasive







#### **RESET® – Implantable Duodenal-Jejunal Bypass Liner**



gastric bypass surgery

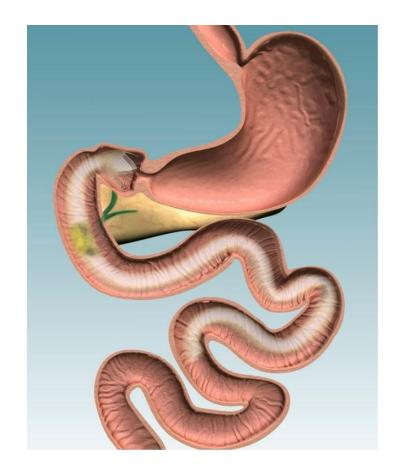


• 60 cm impermeable sleeve

**Anchor** 

Minimally invasive

wall

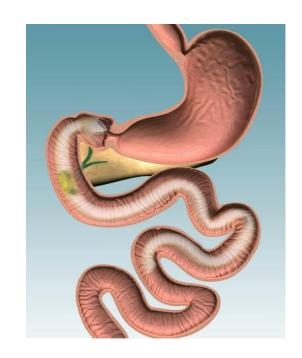






#### First NHS RESET® Service for Refractory Diabesity

- We implanted RESET® into 62 patients with sub optimally controlled diabesity
- Of these 43/62 (69%) attended for review 3 years after RESET® removal



### 43 NHS patients attended follow up 3 years after RESET® removal – baseline characteristics

	Parameter	N=43
	Age (years)	51.6±7.6
	Sex (% male)	55.8
	Ethnicity (% Europid)	55.8
$\rightarrow$	BMI (kg/m <sup>2</sup> )	41.7±7.3
<u> </u>	HbA1c (mmol/mol)	76.3±19.2
	(%)	9.1±1.8
$\rightarrow$	*Diabetes duration (years)	14.6 (8 -21)
$\rightarrow$	Taking insulin (%)	62.8

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NHS Trust
Where
EVERYONE
Morters

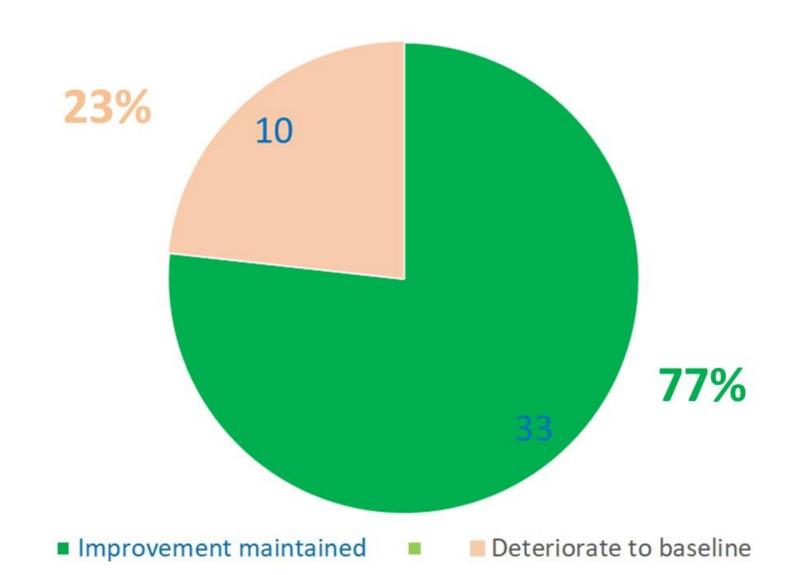
#### Outcomes at explant of RESET®, n=43

	Parameter	Baseline	EB Explant	Difference	P-value
$\rightarrow$	Weight (kg)	123.3±30.0	105.9±30.8	-17.4±9.1	<0.001
	BMI (kg/m <sup>2</sup> )	41.7±7.3	35.6±7.7	-6.2±3.5	<0.001
	HbA1c (%)	9.1±1.8	7.2±1.0	-1.9±1.8	<0.001
	HbA1c (mmol/mol)	76.3±19.2	55.7±11.1	-20.6±19.6	<0.001
	Systolic blood pressure (mmHg)	138.7±14.4	125.4±14.7	-13.3±16.2	<0.001
	Cholesterol (mmol/L)	4.6±1.0	3.7±0.7	0.8±0.8	<0.001
	ALT (U/I)	30.8±17.2	19.3±11.2	-11.5±18.3	<0.001
	Insulin daily dose* (n=30)	114(54-180)	20(0-65)	-94	<0.001

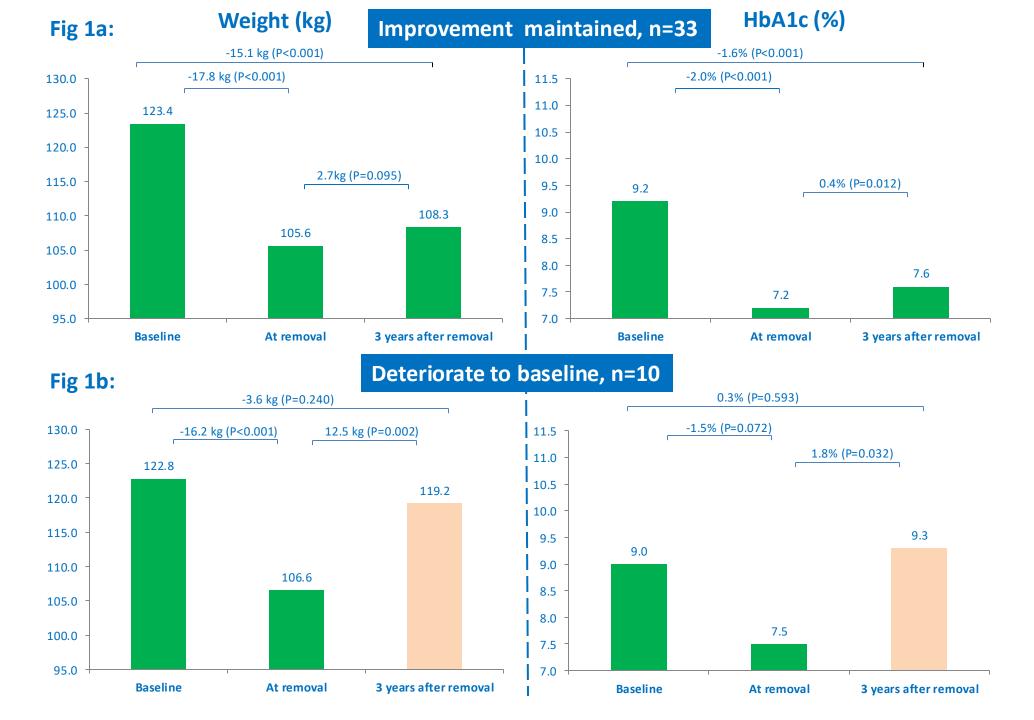
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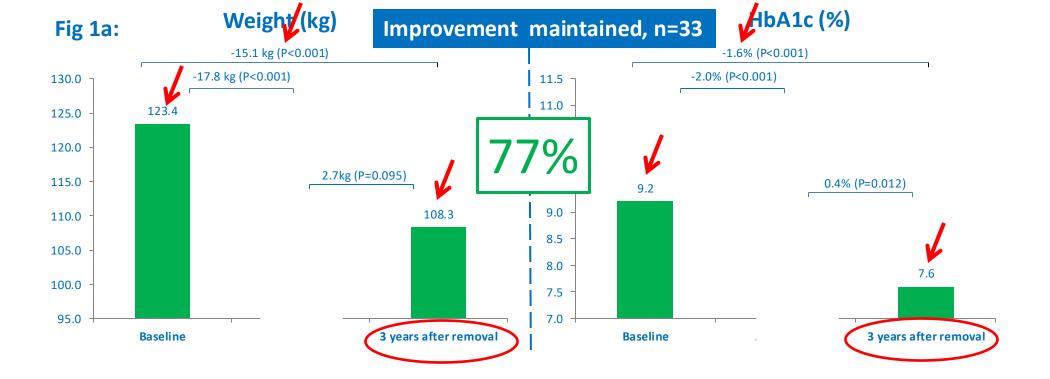


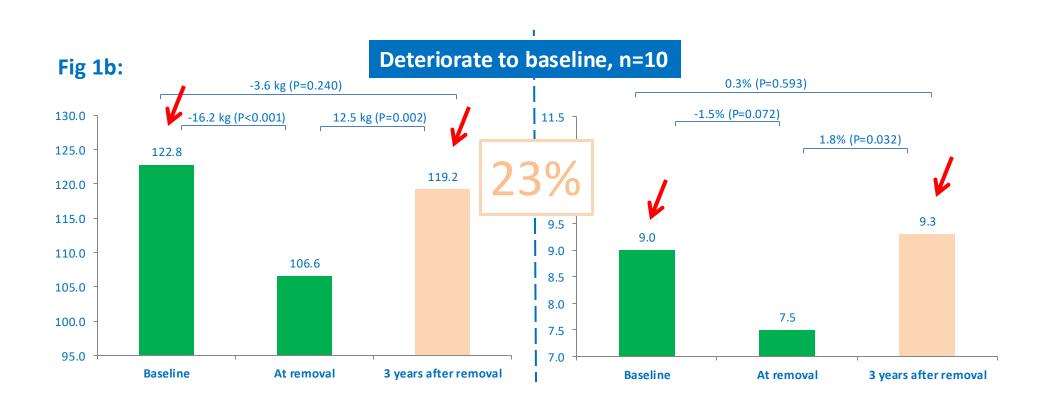
### 33/43 (77%) maintained most of the improvement 10/43 (23%) reverted to baseline three years post explant



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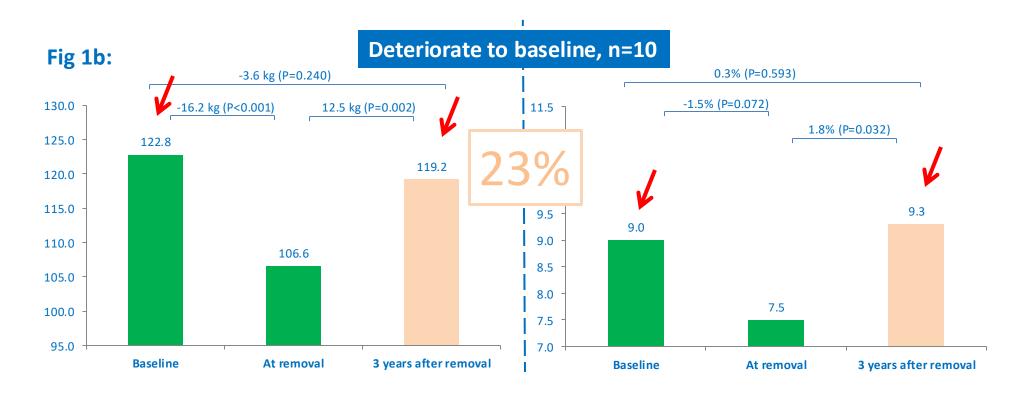






# Those who deteriorated to baseline reported to us many problems in their lives and 9/10 (90%) had

depression and/or bereavement and/or major health problems/disability.



### 62 NHS service patients – impact of RESET® Early removal

- 10/62 (16%) patients
- 4 x gastrointestinal haemorrhage
- 2 x liver abscess
- 1 x other abscess
- 3 x gastrointestinal symptoms
- all made a full recovery and most derived considerable benefit despite the early removal
- In some patients these problems were related to non compliance with advice given



### 62 NHS service patients – impact of RESET® Early removal

- 10/62 (16%) patients
- 4 x gastrointestinal haemorrhage
- 2 x liver abscess
- 1 x other abscess
- 3 x gastrointestinal symptoms
- all made a full recovery and most derived considerable benefit despite the early removal
- In some patients these problems were related to non compliance with advice given – could have been averted by compliance\*



### 62 NHS service patients – impact of RESET® Examples of avoidable early removal

- One GI bleed could have been averted: the patient reverted to normal food during 2nd week after insertion instead of recommended pureed food
- A second GI bleed could have been averted: the patient stopped taking recommended proton pump inhibitor after 10 weeks
  - Nevertheless, he lost 9.6 kg, HbA1c fell from 12.1% to 6.5% and his insulin requirement fell from 140 to 30 units daily
- Early removal at 10 months could have been averted in a patient swallowed a piece of steak without sufficient chewing
  - She lost 23.6 kg during 10 months with EndoBarrier
- Diagnosis of liver abscess not recognised in ITU being treated as pneumonia (the liver abscess complication was not known at that time).
  - He lost 18.4 kg during 7 months before Endobarrier removal





**Before** 

- Pre-RESET®
- HbA1c = 70 mmol/mol (8.6%)
- Wt = 82.9 kg
- BMI =  $33.6 \text{ kg/m}^2$
- ALT = 86 U/L (Fatty liver)
- Obese BMI



#### Outcomes at explant of RESET®, n=43

	Parameter	Baseline	EB Explant	Difference	P-value
$\rightarrow$	Weight (kg)	123.3±30.0	105.9±30.8	-17.4±9.1	<0.001
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	HbA1c (%)	9.1±1.8	7.2±1.0	-1.9±1.8	<0.001
	HbA1c (mmol/mol)	76.3±19.2	55.7±11.1	-20.6±19.6	<0.001
	Systolic blood pressure (mmHg)	138.7±14.4	125.4±14.7	-13.3±16.2	<0.001
	Cholesterol (mmol/L)	4.6±1.0	3.7±0.7	0.8±0.8	<0.001
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#### REVISE- Diabesity: Liver fat pre- and post-MR images



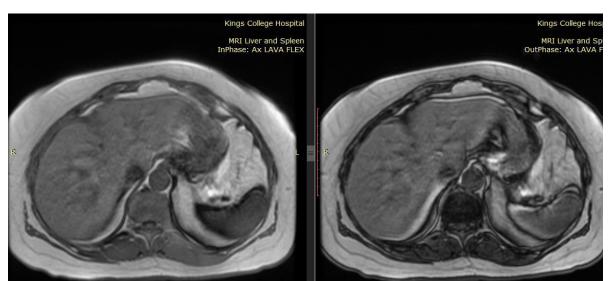
Baseline

In-Phase

College Hospital
Liver and Spleen
AX LAVA-Flex (BH)

Cout of phase
Rit Liver and
OutPhase: AX LAVA-Flex

4-months post-RESET®





#### REVISE- Diabesity: Liver fat pre- and post-MR images

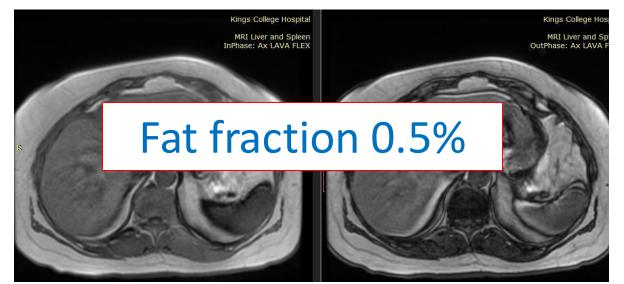


Baseline

In-Phase
Liver and Spleen
Liver and Spleen
Available: Ax Lava-Flex (BH)

Fat fraction 22.4%

4-months post-RESET®





### MRI analysis: mean fat fraction (n8) (Impact of four months RESET® treatment)



• Hepatic fat:  $14.9 \pm 9.4\%$  to  $2.9 \pm 4.5\%$ , p=0.003

• Pancreatic fat:  $6.9 \pm 8.5\%$  to  $1.3 \pm 8.9\%$ , p=0.02

- Reduction in hepatic fat leads to improvement in hepatic insulin sensitivity
- Reduction in pancreatic fat is associated with improved insulin secretion



**Before** 

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- HbA1c = 70 mmol/mol (8.6%)
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- Obese BMI



12 months

- 12 months RESET®
- HbA1c = 51 mmol/mol (6.8%)
- Wt = 62.2 kg
  - =Wt loss 20.7 kg (45.6 lbs)
- $BMI = 24.8 \text{ kg/m}^2$
- ALT = 18 U/L (normal)
- **Normal BMI**







- Pre-RESET®
- HbA1c = 70 mmol/mol (8.6%)
- Wt = 82.9 kg
- BMI =  $33.6 \text{ kg/m}^2$
- ALT = 86 U/L (Fatty liver)
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  - =Wt loss 20.7 kg (45.6 lbs)
- BMI =  $24.8 \text{ kg/m}^2$
- ALT = 18 U/L (normal)
- Normal BMI



4 years

- 4 years after RESET®
- HbA1c = 43 mmol/mol (6.5%)
- Wt = 55.8 kg
- BMI = 22 kg/ $m^2$
- ALT = 10 U/L
- Improvement sustained

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- HbA1c 128 mmol/mol (13.9%)
- Weight = 102 kg
- BMI =  $39.3 \text{ kg/m}^2$  (Obese BMI)
- Insulin 260 units





# Outcomes at explant of RESET®, n=43

Parameter	Baseline	EB Explant	Difference	P-value
Weight (kg)	123.3±30.0	105.9±30.8	-17.4±9.1	<0.001
BMI (kg/m <sup>2</sup> )	41.7±7.3	35.6±7.7	-6.2±3.5	< 0.001
HbA1c (%)	9.1±1.8	7.2±1.0	-1.9±1.8	<0.001
HbA1c (mmol/mol)	76.3±19.2	55.7±11.1	-20.6±19.6	<0.001
Systolic blood pressure (mmHg)	138.7±14.4	125.4±14.7	-13.3±16.2	<0.001
Cholesterol (mmol/L)	4.6±1.0	3.7±0.7	0.8±0.8	<0.001
ALT (U/I)	30.8±17.2	19.3±11.2	-11.5±18.3	<0.001
Insulin daily dose* (n=30)	114(54-180)	20(0-65)	<b>-</b> 94	<0.001

Sandwell and West Birmingham Hospitals NHS Trust





- HbA1c 128 mmol/mol (13.9%)
- Weight = 102 kg
- BMI =  $39.3 \text{ kg/m}^2$  (Obese BMI)
- Insulin 260 units







**NHS** service patient



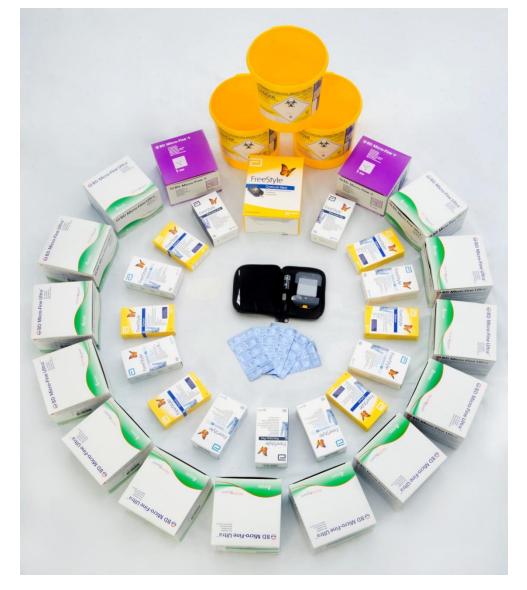
- HbA1c 128 mmol/mol (13.9%)
- Weight = 102 kg
- BMI = 39.3 kg/m<sup>2</sup> (Obese BMI)
- Insulin 260 units

- HbA1c 49 mmol/mol (6.6%)
- Weight 64.2 kg=Weight loss 37.8 kg (83.3 lbs)
- BMI 24.46 kg/m<sup>2</sup> (Normal BMI)
- Insulin no longer required

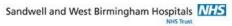








- 1,095 blood glucose tests/year (\$+++)
- 1,460 pen needles/year (\$+++)
- 1,095 lancing devices/year (\$+++)
- 3 sharps bins for sharps disposal/year (\$+++)









- Weight = 102 kg
- BMI = 39.3 kg/m<sup>2</sup> (Obese BMI)
- Insulin 260 units



• HbA1c 49 mmol/mol (6.6%)

- Weight 64.2 kg=Weight loss 37.8 kg (83.3 lbs)
  - BMI 24.46 kg/m<sup>2</sup> (Normal BMI)
- Insulin no longer required



- HbA1c 59 mmol/mol (7.5%)
- Weight 67.6 kg
- BMI 25.7 kg/m<sup>2</sup>
- Remains off Insulin:
- 474 insulin pens avoided since RESET® removed



- HbA1c 128 mmol/mol (13.9%)
- Weight = 102 kg
- BMI = 39.3 kg/m<sup>2</sup> (Obese BMI)
- Insulin 260 units



- HbA1c 49 mmol/mol (6.6%)
- Weight 64.2 kg=Weight loss 37.8 kg (83.3lbs)
- BMI 24.46 kg/m² (Normal BMI)
- Insulin no longer required



At 4 years after RESET® she continued to remain off

- insulin i.e.948 insulin
  - pens saved!

474 insulin pens avoided since Endobarrier removed

# **Summary and Conclusion**

- Our data demonstrate RESET® as highly effective in patients with refractory diabesity, with maintenance of significant improvement three years after RESET® removal in 77%
- Patients reported considerable improvements in wellbeing, energy, fitness, exercise ability; 10/27 (37%) insulin-treated patients discontinued insulin
- Of the 10 patients (23%) whose weight and glycaemic control deteriorated to baseline after removal of RESET®, 9/10 had depression and/or bereavement and/or major health problems/disability
- There were high patient satisfaction levels and an acceptable safety profile
- These data are supportive of risk:benefit being strongly towards benefit
  and they support the continuance of RESET® as an important treatment
  option for refractory diabesity
- As endoscopy units are ubiquitous, our service could be readily disseminated.





**Before** 

- Pre-RESET®
- HbA1c = 61 mmol/mol (7.7%)
- Wt = 86.6 kg
- BMI =  $35.1 \text{ kg/m}^2$
- Insulin 120 units daily
- Obstructive sleep apnoea requiring CPAP



12 months

- 12 months RESET®
- HbA1c = 43 mmol/mol (6.1%)
- Wt = 65.6 kg
  - Wt loss 21.0 kg (46.3 lbs)
- BMI =  $26.2 \text{ kg/m}^2$
- Insulin 12 units daily
- CPAP no longer required





**Before** 

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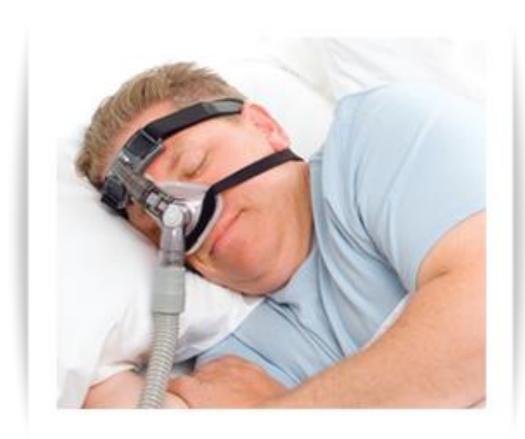


36 months

- 24 months after RESET®
- HbA1c = 53 mmol/mol (7.0%)
- Wt = 70.4 kg
- BMI =  $28.9 \text{ kg/m}^2$
- Insulin 16 units daily
- Remains off CPAP

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### **NICE**

Mild OSA: AHI<15 events/hr</li>

Moderate OSA: AHI 15-29 events/hr

Severe OSA : AHI ≥30 events/hr





### **NICE**

- Mild OSA: AHI<15 events/hr</li>
- Moderate OSA: AHI 15-29 events/hr
- Severe OSA : AHI ≥30 events/hr







80<sup>TH</sup> SCIENTIFIC SESSIONS

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Control/Tracking Number: 2020-A-3387-Diabetes

Activity: Abstract

Current Date/Time: 1/13/2020 6:11:10 AM

Endobarrier(EB) In Diabetes/Prediabetes With Obstructive Sleep Apnoea(OSA) Study- The Final Results

Author Block: MAHENDER YADAGIRI, FIONA Y. KINNEY, NATALIE ASHMAN, JESSICA ADAMS, MELANIE C. WYRES, EMMA S. SHARRATT, CHERYL GREENWOOD, MICHAEL H. LANG, JOHN BLEASDALE, EDWARD FOGDEN, MARK ANDERSON, CHRISTOPHER WALTON, MICHAEL A. GREENSTONE, ROBERT E. RYDER, Birmingham, United Kingdom, Hull, United Kingdom

### Abstract:

**Background/Aim:** EB, a 60cm endoscopically implanted proximal intestinal liner is implanted for up to one year and then removed. We aimed to assess the extent to which patients with type2 diabetes or pre-diabetes, obesity (BMI 30-45kg/m²) and moderate OSA requiring continuous positive airway pressure ventilation (CPAP) are able to discontinue CPAP following EB-related weight loss.

**Method:** We assessed Apnoea Hypopnoea Index (AHI), weight and HbA1c before and during EB treatment and following its removal in the 12 patients with moderate OSA requiring continuous positive airway pressure ventilation (CPAP) {75% female, 8/12 (66%) type 2 diabetes, 4/12 (34%) prediabetes, mean ± SD age 52.6±9.7 years, BMI 37.4±3.5 kg/m², median duration of OSA while on CPAP 9.0(7.0-15.0) months}.

Results: During the period of EB implantation, mean ± SD HbA1c fell by 1.26±0.7% from 7.9 ± 1.6 to 6.6 ± 0.9% (p=0.023), weight by 10.5±4.0 kg from 103.8± 14.1 to 93.3±13.7 kg (p<0.001) and AHI by 9.1±5.0 events/hour from 18.9±3.8 to 9.7±3.0 events/hour(p<0.001). Prior to EB, all patients had AHI in the National Institute for Health and Care Excellence (NICE) moderate OSA range (15-29.9 events/hour). During EB treatment the AHI of all 12 patients fell below 15 such that they no longer required CPAP according to NICE criteria. After EB removal, 10/12 (83%) patients attended follow up and at 12 months after removal, AHI remained below 15 in 5/10 (50%) patients but in the other 5 the AHI rose above 15 such that restarting CPAP was recommended. Two of these 5 patients, inspired by the desire to avoid CPAP, lost the regained weight and their AHI dropped below 15 again. Thus, 7/10 (70%) of patients were able to remain off CPAP 12 or more months after EB removal.

Conclusion: These results demonstrate major benefit of EB in moderate OSA, allowing patients to discontinue CPAP with maintenance of improvement at follow up in

70% and confirm previously demonstrated metabolic improvements in diabesity.

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After one year of RESET® treatment 12/12 (100%) patients with we sleep.

After one year of RESET® treatment able to discontinue CPAP

Method W.

OSA requiring continuous positive airway pressure ventilation (CPAP) {75% female, 8/12 (66%) type 2 diabetes, 4/12 (34%) prediabetes, mean ± SD age 52.6±9.7 years, BMI 37.4±3.5 kg/m<sup>2</sup>, median duration of OSA while on CPAP 9.0(7.0-15.0) months}.

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Sandwell and West Birmingham Hospitals WHS



Received: 2 May 2024 Accepted: 26 June 2024

DOI: 10.1111/cob.12694

### ORIGINAL RESEARCH



### Endoscopic duodenal-jejunal bypass liner treatment of moderate obstructive sleep apnoea—A pilot study

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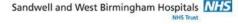
### Funding information

Association of British Clinical Diabetologists

### Summary

We aimed to assess the extent to which people with type 2 diabetes or pre-diabetes, obesity (BMI 30-45 kg/m<sup>2</sup>) and moderate obstructive sleep appose (OSA) requiring continuous positive airway pressure ventilation (CPAP) were able to discontinue CPAP following EndoBarrier-related weight loss. We assessed sleep and metabolic parameters before, during and after EndoBarrier in 12 participants with moderate OSA requiring CPAP (75% female, 8/12 [66%] type 2 diabetes, 4/12 [34%] prediabetes, mean ± SD age 52.6 ± 9.7 years, BMI 37.4 ± 3.5 kg/m<sup>2</sup>, median duration of OSA while on CPAP 9.0 [7.0-15.0] months). With EndoBarrier in-situ, mean ± SD Apnoea Hypopnoea Index (AHI) fell by 9.1 ± 5.0 events/h from 18.9 ± 3.8 to 9.7 ± 3.0 events/h (p < .001) with an associated reduction in symptoms of daytime sleepiness (mean Epworth Sleepiness Score) such that all the 12 participants no longer required CPAP according to National Institute for Health and Care Excellence criteria. After EndoBarrier removal, 10/12 (83%) patients attended follow-up and at

Yadagiri, M et al. Clinical Obesity. 2024;14:e12694 https://doi.org/10.1111/cob.12694





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Gastroenterology Department, Sandwell & West Birmingham NHS Trust, City Hospital, Birmingham, UK

<sup>&</sup>lt;sup>6</sup>Diabetes Department, Hull Royal Infirmary, Hull, UK

<sup>&</sup>lt;sup>7</sup>Respiratory Department, Castle Hill Hospital, Cottingham, UK



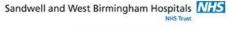


- Wt = 92.4 kg
- BMI =  $36 \text{ kg/m}^2$
- Insulin 147 units daily
- Creatinine 153 umol/L
- eGFR 30 mL/min/1.73m<sup>2</sup>



HbA1c = 50 mmol/mol (6.7 %)

- Wt = 73 kg
  - weight loss 19.4 kg (42.8 lbs)
- BMI =  $27.1 \text{ kg/m}^2$
- Insulin no longer required
- Creatinine 106 umol/L
- eGFR 46 mL/min/1.73m<sup>2</sup>









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HbA1c = 55 mmol/mol (6.7 %)

- Wt = 74.6 kg
- BMI =  $27.7 \text{ kg/m}^2$
- Remains off insulin
- Creatinine 116 umol/L
- eGFR 41 mL/min/1.73m<sup>2</sup>

Sandwell and West Birmingham Hospitals NHS





### Research Article

Volume 15 Issue 1 - July 2021 DOI: 10.19080/CRD0].2021.15.555902 Curr Res Diabetes Obes J Copyright © All rights are reserved by Bob Ryder

# Improvement in Renal Function in Participants in the First UK National Health Service (NHS) EndoBarrier Service for Uncontrolled Diabesity



Robert EJ Ryder<sup>1</sup>, Piya Sen Gupta<sup>1,2</sup>, Mahi Yadagiri<sup>1</sup>, Susan P Irwin<sup>1</sup>, Wyn Burbridge<sup>1</sup>, Tahira Bashir<sup>1</sup>, Rachael A Allden<sup>1</sup>, Melanie Wyres<sup>1</sup>, Melissa Cull<sup>1</sup>, John P Bleasdale<sup>1</sup>, Edward N Fogden<sup>1</sup>, Mark R Anderson<sup>1</sup> and Paul Cockwell<sup>3</sup>

<sup>1</sup>Sandwell & West Birmingham NHS Trust, City Hospital, Birmingham, England

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Submission: July 16, 2021; Published: July 30, 2021

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### Abstract

Aims: EndoBarrier, a 60cm proximal intestinal liner, endoscopically implanted for up to one-year, reduces weight and HbA1c. As the risk of progressive chronic kidney disease (CKD) is increased by high BMI, we assessed the impact of EndoBarrier on renal function.

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- HbA1c 109 mmol/mol (12.1%)
- Weight 136.9 kg
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## WHO Definition of Diabetes Mellitus

'Diabetes mellitus is a state of **chronic hyperglycaemia** which may result from many environmental and genetic factors, often acting jointly'

WHO Expert Committee on Diabetes Mellitus 1980



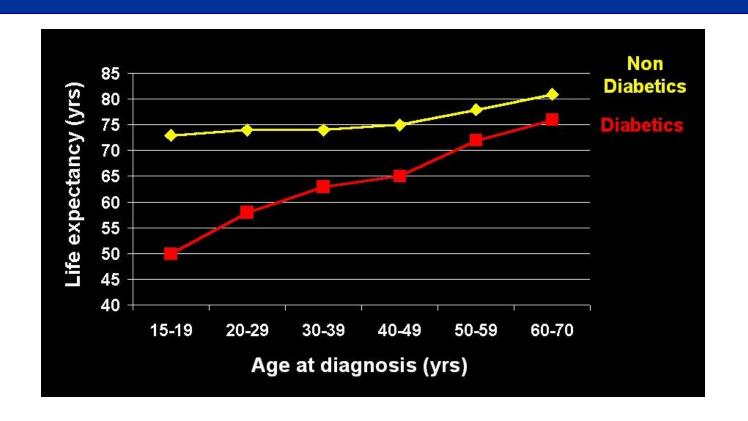
## Re-definition of diabetes

'Diabetes is a state of premature cardiovascular death which is associated with chronic hyperglycaemia and may also be associated with blindness and renal failure'

Miles Fisher, British Diabetes Association, Dublin, 1996

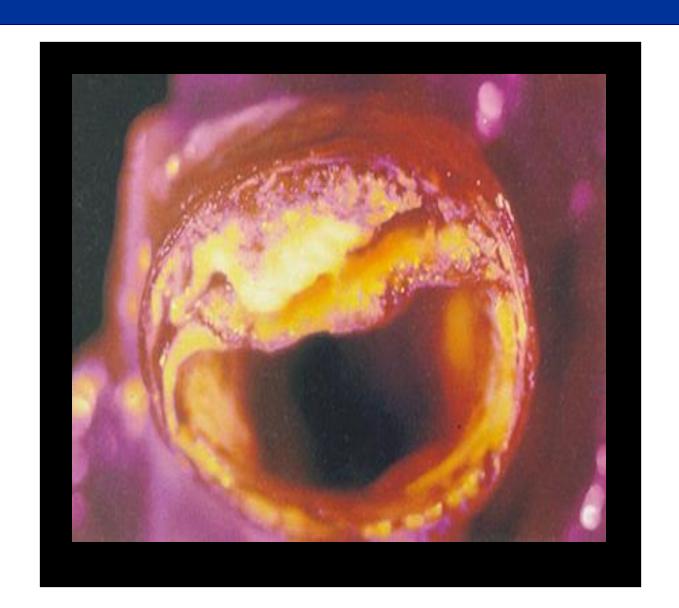


## **Life Expectancy and Diabetes**



'Adults with diabetes have an annual mortality of about 5.4%, double the rate for non-diabetic adults. Life expectancy is decreased by 5–10 years.'

# **Diabetes and Macrovascular Disease**



# Outcomes at explant of RESET®, n=43

	Parameter	Baseline	EB Explant	Difference	P-value
	Weight (kg)	123.3±30.0	105.9±30.8	-17.4±9.1	<0.001
	BMI (kg/m <sup>2</sup> )	41.7±7.3	35.6±7.7	-6.2±3.5	< 0.001
_	HbA1c (%)	9.1±1.8	7.2±1.0	-1.9±1.8	<0.001
	HbA1c (mmol/mol)	76.3±19.2	55.7±11.1	-20.6±19.6	<0.001
$\rightarrow$	Systolic blood pressure (mmHg)	138.7±14.4	125.4±14.7	-13.3±16.2	<0.001
$\rightarrow$	Cholesterol (mmol/L)	4.6±1.0	3.7±0.7	0.8±0.8	<0.001
	ALT (U/I)	30.8±17.2	19.3±11.2	-11.5±18.3	<0.001
	Insulin daily dose* (n=30)	114(54-180)	20(0-65)	-94	<0.001

Sandwell and West Birmingham Hospitals



# Impact of big weight loss in diabesity

- Decreased liver fat
- Decreased pancreatic fat



# Impact of big weight loss in diabesity

- Decreased liver fat
- Decreased pancreatic fat
- ?Decreased fat in the arteries of the heart
- ?Decreased fat in the arteries to the brain



# The United Kingdom's first NHS Endobarrier service for advanced diabesity: 1-year outcomes for all 62 treated patients

**RESET®** 

ROBERT EJ RYDER, SUSAN P IRWIN, WYN BURBRIDGE, HARDEEP GANDHI, TAHIRA BASHIR, RACHAEL A ALLDEN, MORDEL WILSON, MELANIE WYRES, MELISSA CULL, MAHI YADAGIRI, JOHN P BLEASDALE, EDWARD N FOGDEN, MARK R ANDERSON, PIYA SEN GUPTA

### Abstract

Aims: EndoBarrier is a 60 cm proximal intestinal liner, endoscopically implanted for up to 1 year, designed to mimic the bypass aspect of Roux-en-Y gastric bypass surgery. We aimed to assess its safety and efficacy in patients with advanced diabesity.

Methods: Since October 2014 we have implanted 62 Endo-Barriers in our NHS service. By November 2018 all were explanted. Outcomes were monitored in a registry.

Results: In 61 of the 62 patients (98.4%) (age  $51.4\pm7.2$  years, 54.1% male, 57.4% Europid, diabetes duration 12.0 (8.0–19.5) years, 57.4% insulin-treated, BMI  $41.9\pm7.4$  kg/m²) with implant and explant data, mean $\pm$ SD HbA $_{1c}$  fell by  $23.7\pm21.4$  mmol/mol from  $80.2\pm22.5$  to  $56.5\pm11.5$  mmol/mol (p<0.001), weight fell by  $15.9\pm8.5$  kg from  $122.6\pm27.9$  to  $106.7\pm28.9$  kg (p<0.001), systolic blood pressure from  $138.5\pm15.0$  to  $125.8\pm14.6$  mmHg (p<0.001), shelpstered from  $4.7\pm4.4$  to  $3.0\pm0.0$  mmol/l/ (p  $\pm0.001$ ) and

device removal and most derived benefit despite early removal.

Conclusion: EndoBarrier was highly effective in this setting in patients with advanced diabetes and obesity. Given the high cardiovascular and microvascular risk of these patients, benefits might outweigh risks. As an endoscopic procedure it is relatively simple and non-invasive. Early removal rates require monitoring and there needs to be increased focus on preventing complications but, on balance, EndoBarrier deserves further investigation as a potential treatment for wider use.

Br J Diabetes 2019;19:110-117

**Key words:** EndoBarrier, duodenal–jejunal bypass liner, DJBL, obesity, type 2 diabetes, diabesity, bariatric surgery

### Introduction

Daskaraund and rationala

### ORIGINAL RESEARCH

**Table 4** EndoBarrier impact on 10-year CV risk as assessed by the UKPDS risk engine

	Before EndoBarrier	At EndoBarrier removal	p-value	Absolute risk reduction	Cases saved (out of 100)	Numbers needed to treat
CHD	15.8 <u>+</u> 11.8	9.0 <u>+</u> 6.0	<0.001	-6.8 <u>+</u> 7.6	6.8	14.7
Fatal CHD	11.4 <u>+</u> 10.1	5.6 <u>+</u> 4.7	<0.001	-5.7 <u>+</u> 6.7	5.7	17.5
Stoke	5.90 <u>+</u> 4.71	4.84 <u>+</u> 3.70	<0.001	-1.06 <u>+</u> 1.50	1.06	94.3
Fatal stroke	0.94 <u>+</u> 0.89	0.61 <u>+</u> 0.52	<0.001	-0.33 <u>+</u> 0.54	0.33	303.0

### Interpretation:

According to UKPDS risk engine about 8 patients out of 100 will not have a coronary heart disease or stroke event over the next 10 years because of EndoBarrier treatment about 6 lives will be saved

### ORIGINAL RESEARCH

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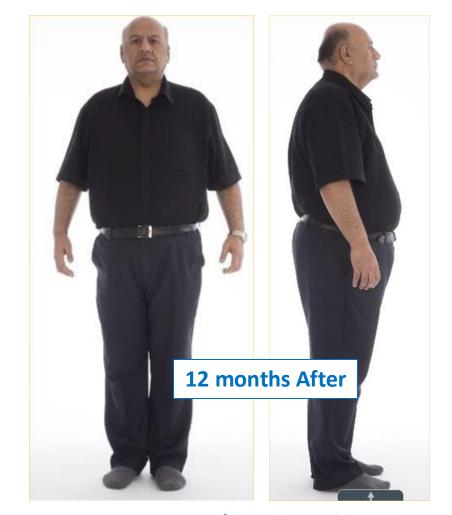


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- Weight 136.9 kg
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- HbA1c 58 mmol/mol (7.5%)
- Weight 115.0 kg=Weight loss 21.9 kg (48.3 lbs)
- BMI 37.6 kg/m<sup>2</sup>



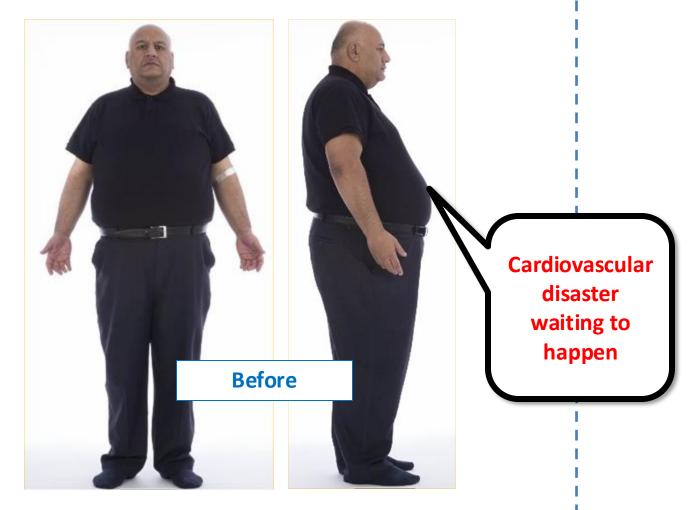


# "You can get another person in there"

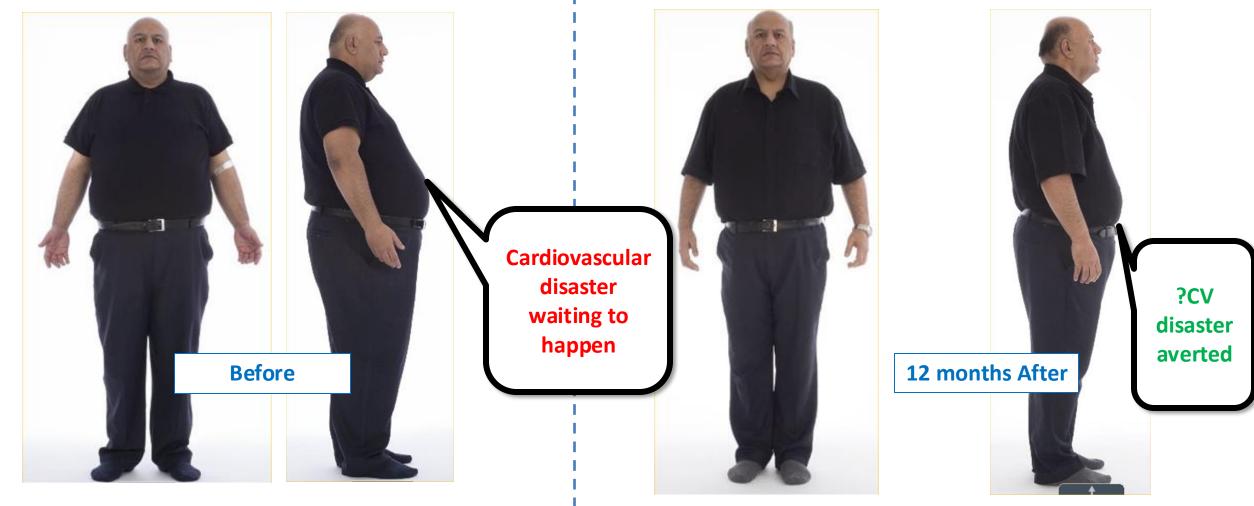


BBC news item 11 May 2016: <a href="https://youtu.be/xRcnMBOdb58">https://youtu.be/xRcnMBOdb58</a>

Search YouTube with terms "ABCD" and "Endobarrier"



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# EndoBarrier / RESET® worldwide registry

- Over 3000 EndoBarriers implanted worldwide in recent years
- In view of uncertainty about risks versus benefits of EndoBarrier, during 2017, an independent, secure, online registry was established under the auspices of the Association of British Clinical Diabetologists (ABCD), for the collection of EndoBarrier safety and efficacy data from patients worldwide
- As of March 2023, data had been submitted on 1022 patients from 34 centres in 10 countries: Australia, Austria, Brazil, Czech Republic, England, Germany, Israel, Netherlands, Scotland and Slovenia
- This registry is currently being updated to reflect the device name change to RESET® and the Company name change to Morphic Medical







Endoscopic Duodenal-Jejunal Bypass Liner Treatment for Type 2 Diabetes and Obesity: Glycemic and Cardiovascular Disease Risk Factor Improvements in 1.022 Patients Treated Worldwide

Diabetes Care 2023;46:e89-e91 | https://doi.org/10.2337/dc22-1952

Lynne Munro,4 Harry Frydenberg,4 Julian P. Teare, 5 Aruchuna Ruban, 5 Sigal Fishman, Erwin Santo, 6 Rainer Stengel,7 Charlotte De Jonge,8,9,10 Jan W. Greve, 11,12 Ricardo V. Cohen, 13 Cristina M. Aboud, 13 Gerald J. Holtmann, 14 Graeme Rich, 15 Jess J. McMaster, 14 Tadej Battelino, 16,17 Primoz Kotnik, 17 James P. Byrne, 18 John C. Mason, 19 Justin Bessell, 20 Jeanine Bascomb, 21 Lillian Kow, 21 Janes Collins, 22 Jacob Chisholm, 22 Peter N. Pferschy, 23 Harald Sourij, 23 Melissa L. Cull, Melanie C. Wyres, 1 Russell Drummond,24 Barbara McGowan,<sup>25</sup> Stephanie A. Amiel,26 Mahi Yadaairi.1 Piya Sen Gupta, 1,25 Jens Aberle, 27 and Jochen Seufert<sup>2</sup>

Robert E.J. Ryder, 1 Katharina Laubner, 2 Marek Benes, 3 Martin Haluzik, 3

There is a worldwide pandemic of type 2 diabetes (T2D) and obesity (1). In clinical practice, many patients with obesity have poor glycemic management despite diet and lifestyle advice and maximal medications (2–4). In this situation, Roux-en-Y gastric bypass is highly effective, and increased use of bariatric surgery has been recommended (2). Nevertheless, it is an invasive and irreversible surgical procedure. EndoBarrier (GI Dynamics, Boston, MA), also known as duodenal-jejunal bypass liner, is a 60-cm impermeable fluoropolymer sleeve that is implanted

endoscopically into the upper part of the small intestine (2–4), left in place for up to 1 year, and then removed endoscopically. The duodenal-jejunal bypass liner was developed to mimic the proposed small-bowel mechanisms of Roux-en-Y gastric bypass (2–4) while being less invasive. In Europe in 2017, approval for use (certificate of Conformité Européenne, or CE mark) of EndoBarrier was not renewed for reasons that are not entirely clear (3,4). As over 3,000 patients have been treated with EndoBarrier worldwide, during 2017, an independent, secure, online registry was established by the Association of British Clinical Diabetologists (ABCD) for the collection of safety and efficacy data of EndoBarriertreated patients worldwide.

By October 2022, data had been entered on 1,022 EndoBarrier-treated patients (mean ± SD age 51.3 ± 11.4 years, 52.5% male, 84.9% with diabetes, mean ± SD BMI 41.1 ± 8.7 kg/m<sup>2</sup>) from 34 centers in 10 countries. For those with both baseline and time-of-removal data, EndoBarrier treatment was associated with considerable reduction in weight, HbA<sub>1r</sub>, systolic

Outcomes on these 1022
 patients from the registry
 were published in Diabetes
 Care, April 2023

<sup>&</sup>lt;sup>1</sup>Diabetes and Endocrinology, Sandwell and West Birmingham Hospitals National Health Service Trust, Birmingham, U.K.

<sup>&</sup>lt;sup>2</sup>Division of Endocrinology and Diabetology, Department of Medicine II, University Hospital of Freiburg, Freiburg, Germany

<sup>&</sup>lt;sup>3</sup>Diabetes Centre, Institute for Clinical and Experimental Medicine, Praha, Czech Republic

<sup>&</sup>lt;sup>4</sup>Epworth Centre for Bariatric Surgery, Richmond, Australia

# Summary: 1022 RESET® treated patients

- Mean weight loss during the period of RESET® implantation was 13.3 kg with associated improvements in glycaemic control, blood pressure and cholesterol
- The higher the baseline HbA1c the greater the fall in HbA1c with a mean fall of 3.2% (34.9 mmol/mol) with those with a baseline HbA1c ≥ 10% (86 mmol/mol).
- The rate of serious adverse events was 4.2% with the majority of these (2.3%) being gastrointestinal bleeds
- The rate of early removal for hepatic abscess (1.1%) was noticeably less than that the 3.5% rate found in the US pivotal trial
- All patients with a serious adverse event made a full recovery and most experienced considerable benefit from the treatment despite the adverse event.



## IMPROVING SAFETY VS EFFICACY OF DUODENAL JEJUNAL BYPASS LINER TREATMENT FOR TYPE 2 DIABETES AND OBESITY



#### **R.E.J. RYDER** on behalf of:

R.E.J. Ryder<sup>1</sup>, R. Drummond<sup>2</sup>, B. McGowan<sup>3</sup>, S Amiel<sup>4</sup>, R. Lopez-Gonzalez<sup>5</sup>, J. Pujol<sup>5</sup>, H. Frydenberg<sup>6</sup>, J. Stein<sup>7</sup>, T. Battelino<sup>8</sup>, S. Fishman<sup>9</sup>, C. de Jonge<sup>10</sup>, J. Greve<sup>11</sup>, R. Cohen<sup>10</sup>, P. M. Yadagiri<sup>1</sup>, Sen Gupta<sup>11,1</sup>

EASD 2025, Vienna

15–19 September 2025

<sup>1</sup>City Hospital, Birmingham, UK, <sup>2</sup>Glasgow Royal Infirmary, Glasgow, UK, <sup>3</sup>Guy's and St Thomas' Hospitals, London, UK, <sup>4</sup>Kings College Hospital NHS Foundation Trust, London, UK, <sup>5</sup>Consorsi Sanitari Integral, Barcelona, Spain, <sup>6</sup>Epworth Centre for Bariatric Surgery, Richmond, Australia, <sup>7</sup>Frankfurt-Sachsenhausen, Frankfurt, Germany, <sup>8</sup>University Medical Center Ljubljana, Ljubljana, Slovenia, <sup>9</sup>Tel Aviv Sourasky Medical, Tel Aviv, Israel, <sup>10</sup>Maastricht University Medical Center, General Surgery, Netherlands, <sup>11</sup>Zuyderland MC, Heerlen, Netherlands, <sup>12</sup>Oswaldo Cruz Hospital, Sao Paulo, Brazil.



## **EndoBarrier Worldwide Registry**

- Many of the of the serious adverse events associated with EndoBarrier occur during the last three months of treatment
- Reducing the period of implantation to 9-months may reduce the complication rate
- We aimed to assess safety and efficacy for 9-months vs 12months implantation using data in the registry



## **EndoBarrier Worldwide Registry**

- As of June 2025, data had been entered on 1298 EndoBarrier treated patients\*
- Of whom 258 had both 9- and 12-month data entered\*\*



<sup>\*</sup>From 37 centres in 12 countries

<sup>\*\*</sup>From 19 centres in 9 countries: Australia, Brazil, Germany, Israel, Netherlands, Scotland, Slovenia, Spain and England)

## Baseline demographics of the 258 patients

Parameter	n=258
Age (years)	49.5±13.3
Sex (% male)	46.5
Ethnicity (% white)	83
BMI (kg/m²)	39.6±6.9



# Impact of EndoBarrier on weight and HbA1c Little difference 9-months vs 12-months

Parameter	n	Baseline	9-months		The second secon	12-months	baseline vs	baseline vs	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



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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

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HbA1		oide	sq pi	1100	mO	nths	5!	<0.001	0.447
HbA1c	<b>a</b> /	, 1010	ed by	to 9		-2.8±1.9	<0.001	<0.001	0.203
HbA1c ≥ 1				8.1±1.5	-3.1±2.3	-3.3±2.0	<0.001	<0.001	0.091
HbA1c ≥ 11	20	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

- In the full registry, 60/1298 (4.6%) experienced serious adverse events (SAE)
- All patients with SAE made a full recovery, and most experienced benefits despite the SAE
- 22/60 (36.7%) SAE would have been avoided by removal at 9-months (12 liver abscess, 8 GI bleed, one cholecystitis, one surgical removal required as liner was displaced)
- It was particularly noteworthy that 12/18 (66.6%) liver abscess SAEs would have been avoided by removal 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
Total	60	38	22

<sup>\*</sup>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



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
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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
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## **Summary and Conclusion**

- The data confirms the effectiveness of EndoBarrier at reducing weight and HbA1c
- The higher the baseline HbA1c the greater the fall with a mean fall of 3.8% or more when baseline HbA1c ≥ 11%.
- Reducing the implantation period from 12-months to 9-months resulted in:
  - Little significant difference in weight loss or in the improvement in HbA1c
  - 36.7% reduction in SAE
  - It was particularly noteworthy that 66.6% liver abscess SAE would have been avoided by removal at 9months
- These data support a change in the recommended implantation period for EndoBarrier from 12-months to 9-months



## **Summary and Conclusion**

Since this abstract was submitted, the The data confirms the effectiveness of EndoBarrier at re-Duodenal Jejunal Bypass Liner has regained its The higher the baseline HbA1c the great CE Mark and has been relaunched with the baseline HbA1c ≥ 11%. name RESET® and it now has a recommended Reducing implantation time of 9 months prantation period for EndoBarrier The from









- HbA1c 109 mmol/mol (12.1%)
- Weight 136.9 kg
- BMI 43.2 kg/m<sup>2</sup>

#### 9 months

- HbA1c 40 mmol/mol (5.8%)
- Weight 113.8 kg (Wt loss 23.1kg)
- BMI 35.9 kg/m<sup>2</sup>

- HbA1c 58 mmol/mol (7.5%)
- Weight 115.0 kg (Wt loss 21.9kg)
- BMI 36.3 kg/m<sup>2</sup>





- HbA1c = 70 mmol/mol (8.6%)
- Wt = 82.9 kg
- BMI =  $33.6 \text{ kg/m}^2$
- ALT = 86 U/L (Fatty liver)
- Obese BMI

#### 9 months

- HbA1c = 60 mmol/mol (7.6%)
- Wt = 65.6 kg (Wt loss 17.3 kg)
- BMI =  $26.6 \text{ kg/m}^2$
- ALT = 20 U/L (normal)

- HbA1c = 51 mmol/mol (6.8%)
- Wt = 62.2 kg (Wt loss 20.7 kg)
- BMI =  $24.8 \text{ kg/m}^2$
- ALT = 18 U/L (normal)
- Normal BMI



- HbA1c = 61 mmol/mol (7.7%)
- Wt = 86.6 kg
- BMI =  $35.1 \text{ kg/m}^2$
- Insulin 120 units daily
- Obstructive sleep apnoea requiring CPAP



CPAP – continuous positive airway pressure ventilation



- HbA1c = 61 mmol/mol (7.7%)
- Wt = 86.6 kg
- BMI =  $35.1 \text{ kg/m}^2$
- Insulin 120 units daily
- Obstructive sleep apnoea requiring
   CPAP

- HbA1c = 57 mmol/mol (7.4%)
- Wt = 72.5 kg (Wt loss 14.1 kg)
- BMI =  $29.4 \text{ kg/m}^2$
- Insulin 45 units daily
- CPAP no longer required



12 months

- HbA1c = 43 mmol/mol (6.1%)
- Wt = 65.6 kg (Wt loss 21.0 kg)
- BMI =  $26.2 \text{ kg/m}^2$
- Insulin 12 units daily
- CPAP no longer required





- HbA1c = 69 mmol/mol (8.5 %)
- Wt = 92.4 kg
- BMI =  $36 \text{ kg/m}^2$
- Insulin 147 units daily
- Creatinine 153 umol/L
- eGFR 30 mL/min/1.73m<sup>2</sup>

#### 9 months

- HbA1c = 51 mmol/mol (6.8 %)
- Wt = 80 kg (Wt loss 12.4 kg)
- BMI =  $31.2 \text{ kg/m}^2$
- Insulin 26 units daily
- Creatinine 114 umol/L
- eGFR 42 mL/min/1.73m<sup>2</sup>

- HbA1c = 50 mmol/mol (6.7 %)
- Wt = 73 kg (**Wt loss 19.4 kg**)
- BMI =  $27.1 \text{ kg/m}^2$
- Insulin no longer required
- Creatinine 106 umol/L
- eGFR 46 mL/min/1.73m<sup>2</sup>





- HbA1c 128 mmol/mol (13.9%)
- Weight = 102 kg
- BMI = 39.3 kg/m<sup>2</sup> (Morbid obese BMI) •
- Insulin 260 units

#### 9 months

- HbA1c 45 mmol/mol (6.3%)
- Weight = 76.8 kg (Wt loss 25.2 kg)
- BMI =  $29.6 \text{ kg/m}^2$
- Insulin 12 units

- HbA1c 49 mmol/mol (6.6%)
- Weight = 64.2 kg (Wt loss 37.8 kg)
- BMI =  $24.46 \text{ kg/m}^2$  (Normal BMI)
- Insulin no longer required



- At 11.2 months, presented with right flank pain radiating to the back and vomiting. USS revealed liver abscess. Required intravenous antibiotics and urgent EndoBarrier removal
- This serious situation would have been avoided by removal at 9months

- HbA1c = 85 mmol/mol (9.9%)
- Wt =113.0 kg
- BMI =  $44.7 \text{ kg/m}^2$

#### 9 months

- HbA1c = 51 mmol/mol (6.8%)
- Wt = 103.6 kg (Wt loss 9.4 kg)
- BMI =  $40.9 \text{ kg/m}^2$

#### At explant (11.2 months)

- HbA1c = 51 mmol/mol (6.8%)
- Wt = 99.2 kg (Wt loss 13.8 kg)
- BMI =  $39.2 \text{ kg/m}^2$