SUPPLEMENTARY APPENDIX.

Table 1. Eligibility criteria

1. **Inclusion criteria**

To be eligible for participation in this study, subjects must conform to the following inclusion criteria:

1. Age between 18-65 years;
2. Class I or class II obesity (i.e. BMI between 30 to 40 kg/m²);
3. Must be able to comply with all study requirements for the duration of the study as outlined in the protocol. This includes complying with the visit schedule as well as study-specific procedures such as: clinical assessment, endoscopy, radiography, as well as laboratory investigations;
4. Must be able to understand and be willing to provide written informed consent;
5. Must live within 75 km of the treatment site;
6. Had followed the bariatric multidisciplinary work-up (blood analyses, dietician, psychologist and doctor appointments).

2. **Exclusion criteria**

Subjects meeting any of the following exclusionary criteria cannot be enrolled in the study:

1. Achalasia and any other esophageal motility disorders;
2. Severe esophagitis;
3. Gastro-duodenal ulcer;
4. Heart disease: unstable angina, myocardial infarction within the past year, or heart disease classified within the New York Heart Association's Class III or IV functional capacity;
5. Hypertension: uncontrolled hypertension during last 3 months;
6. Diabetes: uncontrolled diabetes (on insulin therapy or oral therapy with Hba1c > 10%);
7. TBWL >5% over the last 6 months;
8. Severe renal, hepatic, pulmonary disease or cancer;
9. GI stenosis or obstruction;
10. Pregnancy, breastfeeding or willing to become pregnant in the coming 18 months;
11. Previous bariatric surgery, balloon removal or other endoscopic obesity-related therapy in less than 6 months from inclusion;
12. Anticoagulant therapy;
13. Impending gastric surgery 60 days post intervention;
14. Currently participating in an other study

Table 2. Short Form 36 (SF36) Results

Parameter	**Baseline**		**6m**		**12m**	**18m**
Group	Procedure	Control	Procedure	Control	Procedure	Control
N	46	17	35	20	25	10
SF36 - PCS (Physical Component Score)	*46.3*	*42.2*	52.8	45.1	56.1	48.2
95% CI	*[43.6-48.9]*	*[37.7-46.8]*	*[50.2-55.4]*	*[39.7-50.5]*	*[52.9-59.2]*	*[40.2-56.3]*
Difference between groups	4.0		7.7		7.8	
95% CI	[-1.1-9.2]		[1.8-13.6]		[-0.6-16.2]	
p-value	0.121		0.012		0.065	
Evolution from baseline (points)	-	-	6.8	3.7	10.3	7.6
95% CI	-	-	[3.6-9.9]	[0-7.3]	[6.8-13.7]	[3.4-11.7]
p-value	-	-	<0.001	0.051	<0.001	0.003
SF36 - PCS (Mental Component Score)	38.0	41.1	45.8	39.2	41.9	42.1
95% CI	[34.92-41.07]	[34.39-47.76]	[42.6-48.9]	[32.9-45.4]	*[36.4-47.3]*	*[33.5-50.7]*
Difference between groups	-3.1		6.6		0.2	
95% CI	[-9.4-3.3]		[-0.3-13.5]		[-9.6-10.0]	
p-value	0.333		0.059		0.961	
Evolution from baseline (points)	-	-	7.8	0.5	3.1	2.4
95% CI	-	-	[4.0-11.6]	[-2.5-3.4]	[-2.6-8.8]	[-8.2-3.4]
p-value	-	-	<0.001	0.738	0.272	0.374

Table 3. Drinking satiety test

Parameter	**Baseline**		**6m**		**12m**	**18m**
Group	Procedure	Control	Procedure	Control	Procedure	Control
N	43	19	35	18	17	6
Satiety V (ml), mean	440.5	374.2	233.1	346.7	208.3	215.0
95% CI	[387.3-493.6]	[287.7-460.8]	[200.0-266.3]	[253.8-439.6]	[175.0-241.7]	[83.8-346.2]
Difference between groups	66.3		-113.5		-	-
p-value	0.174		0.024		-	-
Reduction from baseline (%)	-	-	40.8%	2.5%	49.9%	33.8%
95% CI	-	-	[31.1-50.6]	[-17.6-22.5]	[40.5-62.8]	[14.1-53.5]
p-value	-	-	<0.001	0.277	<0.001	0.009
Satiety E (kCal), mean	661.7	561.3	351.4	520.0	301.5	322.5
95% CI	[582.1-7414]	[431.5-691.1]	[301.5-401.3]	[380.6-659.4]	[253.4-349.5]	[125.7-519.3]
Difference between groups	100.4		-168.6		-	-
p-value	0.169		0.026		-	-
Reduction from baseline (%)	-	-	40.7%	2.5%	51.6%	33.8%
95% CI	-	-	[30.9-50.4]	[-17.6-22.5]	[40.5-62.8]	[14.1-53.5]
p-value	-	-	<0.001	0.277	<0.001	0.009
Satiety t (min), mean	15.2	12.5	7.8	11.4	6.8	7.2
95% CI	[13.4-17.1]	[9.6-15.4]	[6.7-8.9]	[8.5-14.4]	[5.7-7.9]	[2.8-11.5]
Difference between groups	2.7		-3.6		-	-
p-value	0.111		0.026		-	-
Reduction from baseline (%)	-	-	42.5%	3.3%	51.4%	34.8%
95% CI	-	-	[33.4-51.5]	[-16.7-23.3]	[39.8-62.9]	[16.8.8-52.8]
p-value	-	-	<0.001	0.210	<0.001	0.005

Changes in the Protocol:

- Protocol v1 – 17 july 2017
- Protocol v2 – 7 june 2018: v2 was created to:

  Summary of changes:

  - Change of coordinating investigator (Prof. Barthet, Marseilles, France handed over the coordinating investigatorship as it was uncertain if the EC would give approval for this protocol).
  - Add an additional center (Gemelli, Roma, Italy).

Statistics

To avoid a sham intervention that is ethically questionable, subjects will not be blinded to their assigned study arm. Randomization is to be done only after patients have been confirmed eligible for the study. Although subjects who have provided written informed consent and completed their pre-enrollment screening will be considered enrolled in the study, subjects who do not meet the eligibility criteria will not be randomized and are to be categorized as screen failures on the screening log. Randomization will be stratified by clinical center. Patients will be randomized to receive either the Endomina procedure or not (control group) with a 2:1 allocation ratio (Endomina : Control). The randomization schedule will be generated using the permuted block method with varying block sizes (block sizes will be known only to the generator of the randomization schedule). The randomization schedule will be administered locally via sealed envelopes. Each envelope will be clearly labeled with stratum information (i.e., center) and a sequential number indicating the order in which the envelopes are to be used within each clinical center. Randomization will be done after the signature of the inform consent.
If a randomization envelope has been opened in error, i.e., before the subject has been confirmed eligible for study treatment and is found not eligible, the envelope must be discarded.

All the statistical analysis has been done by Mr. Assan Njimi, statistician of Université Libre de Bruxelles (ULB), Hôpital Erasme.