



XXIX IFSO World Congress

1-4 September 2026 | Toronto, Canada

Dr. Luigi Flagiello, Italy



TORONTO 2026

**The Future of Obesity Management:
From Weight Loss to Health Gain**



ifso2026.org

Disclosure

None. No financial or commercial interest in Allurion or Eli Lilly.



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SEQUENTIAL SWALLOWABLE INTRAGASTRIC BALLOON (ALLURION) AND LOW-DOSE TIRZEPATIDE THERAPY

Major fat mass-driven weight loss with excellent tolerability

Prospective single-centre cohort · n = 79 · 12-month follow-up

Luigi Flagiello¹, Alessandro Romano¹, Rita Romano², Vincenza Motanaro², Angela Maisto²,
Roberto Cortese¹, Maria Rosaria Flagiello¹, Gianmattia Del Genio¹

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²Ruesch Clinic - minimally invasive bariatric division - Naples, Italy



Where we left off

What we showed

- Retrospective cohort, n = 52
- Allurion balloon + semaglutide ≤ 1.0 mg
- 8 months $\rightarrow$ 20.3 % TBWL
- Lean mass fraction 60.2 % $\rightarrow$ 68.2 %
- 100 % adherence to the GLP-1 regimen



Research Article

Metabolically Healthy Weight Loss: Synergistic Effects of the Swallowable Balloon and Low-Dose GLP-1 Therapy on Muscle Mass and GLP-1 Adherence: A Retrospective Study

Luigi Flagiello¹ MD, Romano Alessandro¹, Romano Rita², Maisto Angela³, Montanaro Vincenza³, Borrelli Sara³ and Gianmattia Del Genio⁴ MD, PHD, FACS

Three questions it could not answer

1 Was it real, or retrospective bias?

Data were collected after the fact, from a single centre, with no protocol fixed in advance.

2 Was the balloon effect still there at 12 months?

Follow-up stopped at 8 months, only 4 months after balloon removal.

3 Was lean mass truly preserved?

We reported percentages only. A percentage can rise while the absolute mass falls.



What changed — and why

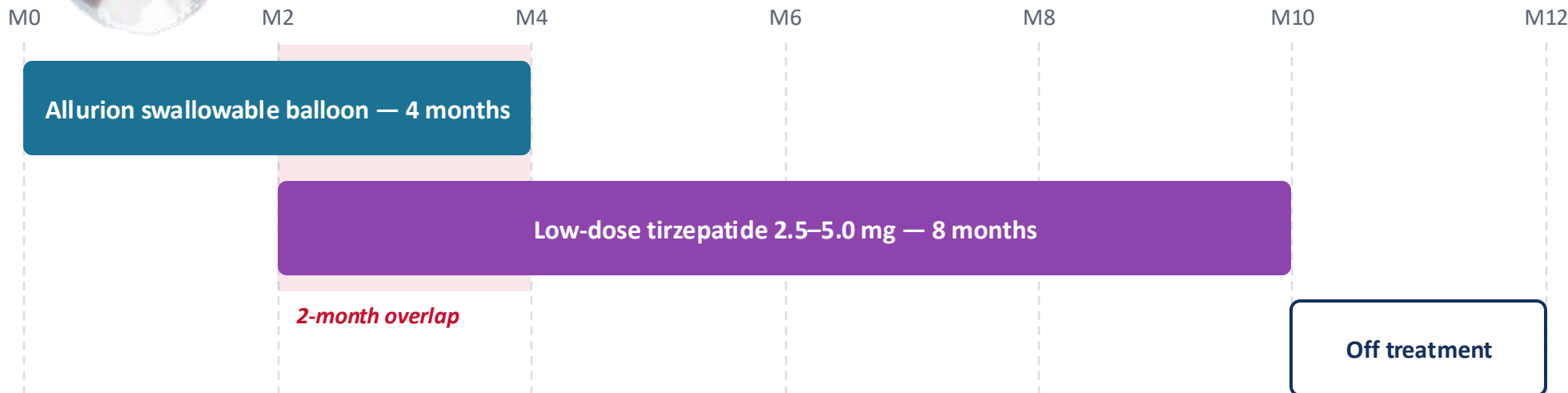
	IFSO 2025	IFSO 2026	Why it matters
Design	Retrospective	Prospective, protocol-driven	<i>Endpoints fixed before the first patient</i>
Patients	52	79	<i>Larger, consecutively enrolled</i>
Incretin	Semaglutide ≤ 1.0 mg	Tirzepatide 2.5–5.0 mg	<i>Dual GIP/GLP-1; greater fat-mass effect</i>
Duration	8 months	12 months	<i>Includes 2 months off all treatment</i>
Body comp.	Percentages only	Absolute kg + percentages	<i>A rising % can hide a falling mass</i>

Same protocol backbone, same centre, same operator — the sequence itself was not changed.



PROTOCOL · N = 79

One sequence, twelve months



79

adults enrolled

121.7 kg

mean baseline weight

40.9

mean baseline BMI

45.9 kg

mean baseline fat mass

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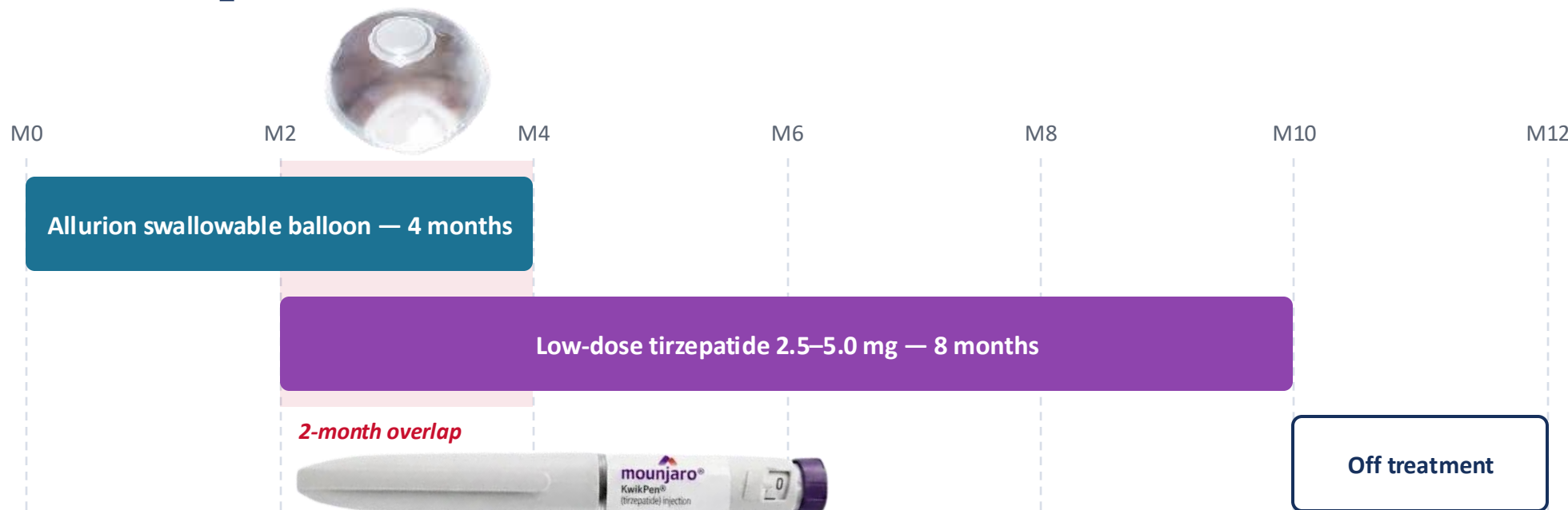


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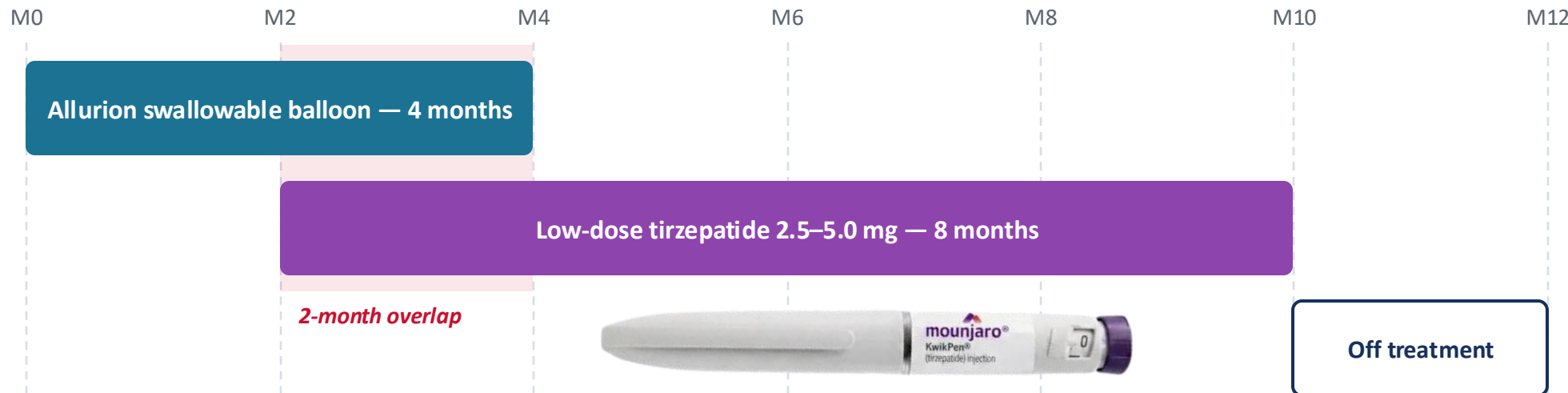


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PRIMARY OUTCOME

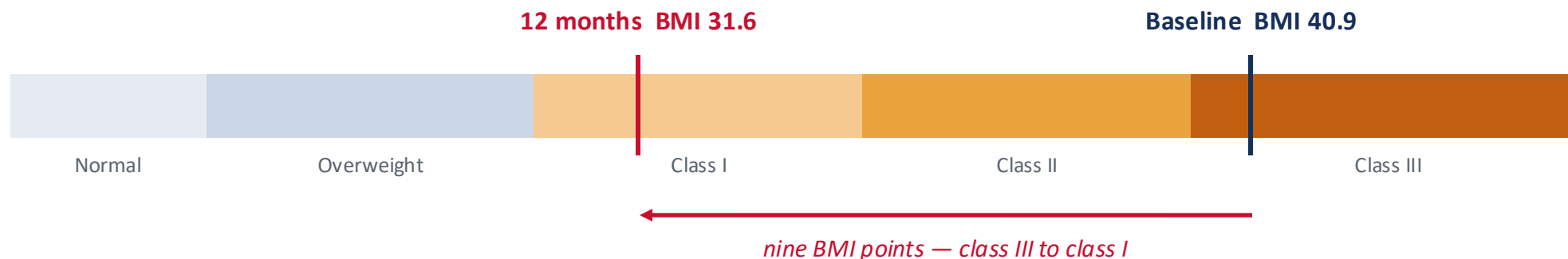
22.4 % total body weight loss at 12 months

22.44

% mean total body weight loss (± 6.36)

Measured at month 12 — two full months after the last dose of tirzepatide and eight months after the balloon was removed.

	Baseline	12 months	Change
Body weight	121.7 kg	94.3 kg	-27.3 kg
BMI	40.9	31.6	-9.3
Fat mass	45.9 kg	29.4 kg	-16.6 kg
Lean mass	74.6 kg	65.1 kg	-9.4 kg



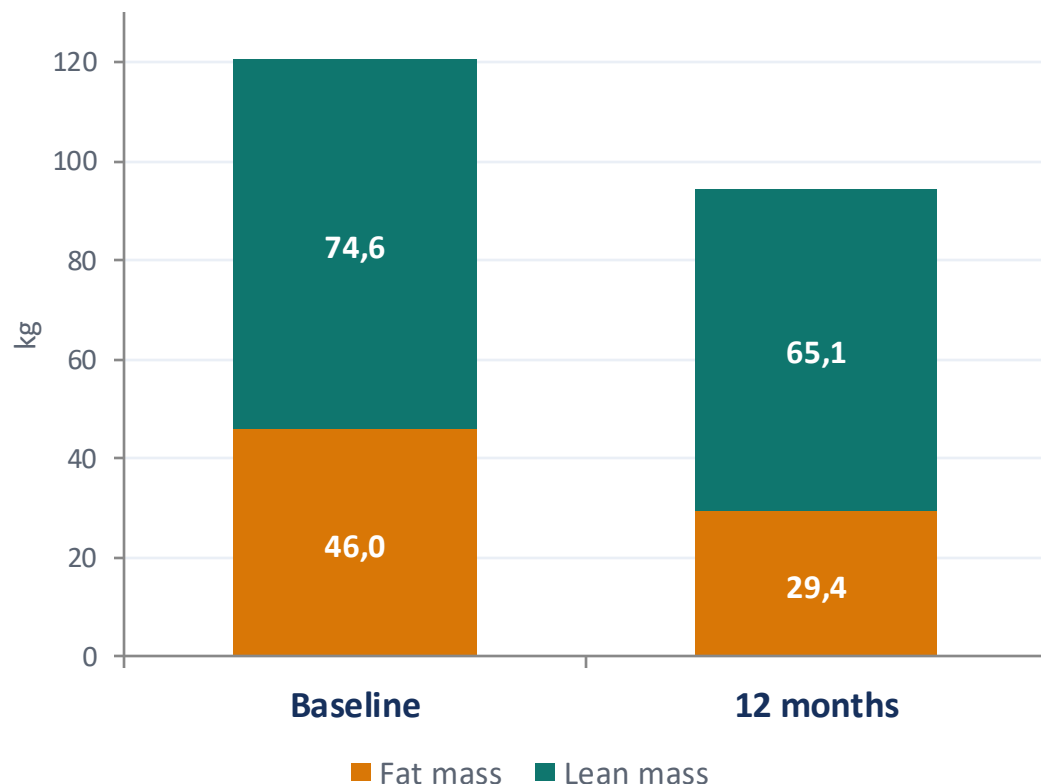
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BODY COMPOSITION

Fat mass fell by a third; lean mass by an eighth



	Baseline	12 mo	Δ	Δ relative
Fat mass, kg	45.95	29.38	-16.6	-36.1 %
Lean mass, kg	74.58	65.14	-9.44	-12.7 %
Fat mass, %	37.4	30.5	-6.97 pp	
Lean mass, %	62.4	69.4	+6.94 pp	

Read the last column, not the percentages

Lean mass as a share of body weight rose by 6.9 points.

That is arithmetic, not anabolism: the denominator shrank.
In absolute terms lean mass fell 9.4 kg.



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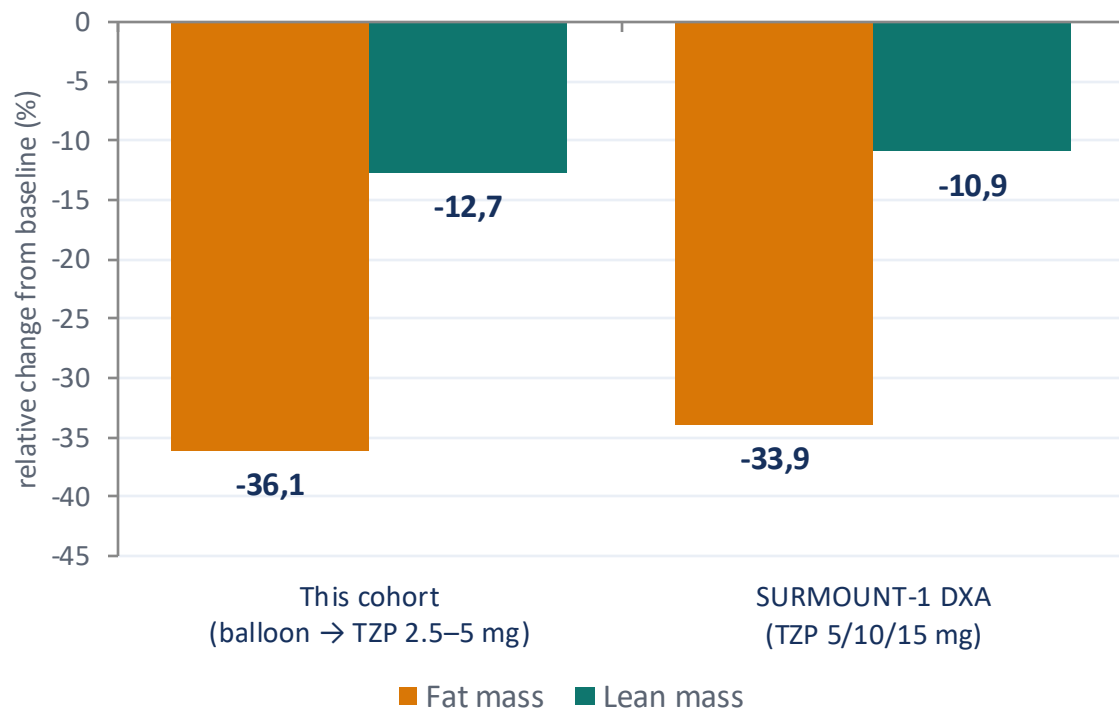
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Where did the 27 kg come from?



The claim we can make

A 36 % reduction in fat mass — matching pooled tirzepatide 5/10/15 mg — obtained at 2.5–5.0 mg, with the balloon carrying the first four months, and with 2 months free of therapy.

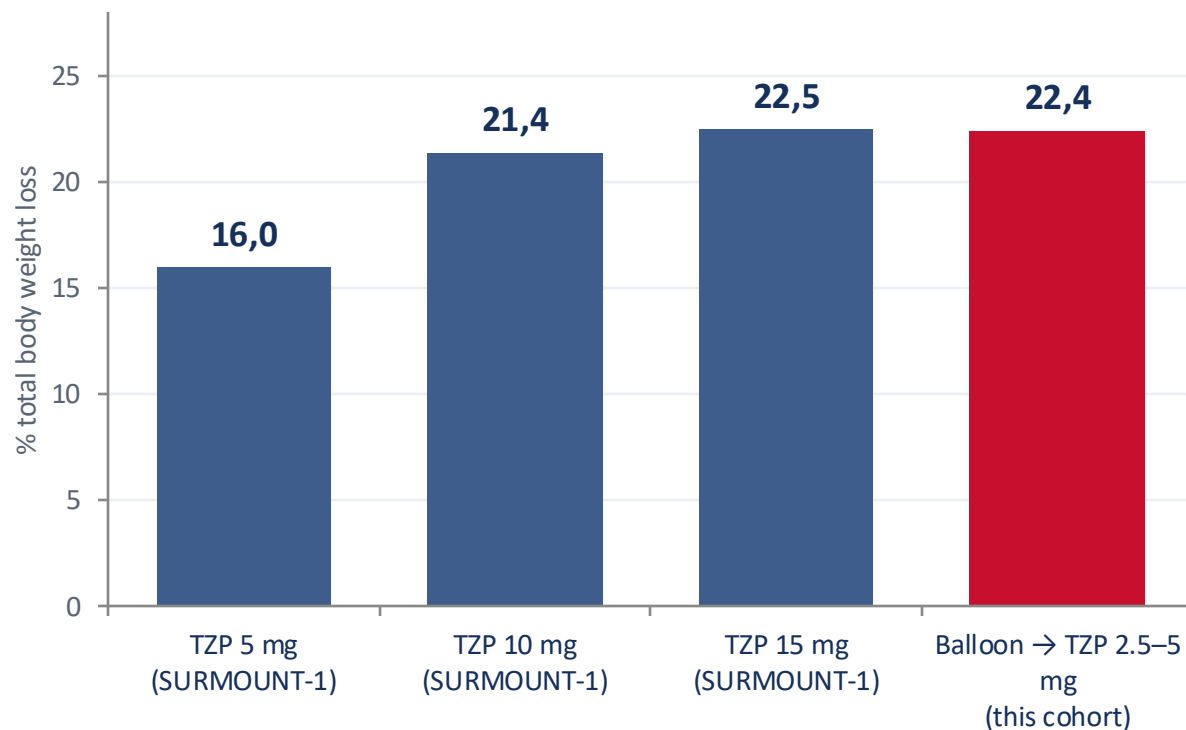
The claim we cannot make

Of the tissue lost, our sequence did not spare lean mass better than the drug alone.

Two caveats: our body composition is bioimpedance, not DXA; and our absolute weight loss was larger, which itself drives lean loss.



The same weight loss, at the starting dose



Cost

The 2.5–5 mg pens are the cheapest in the range — and the ones that stay available when supply tightens.

Tolerability

No escalation beyond 5 mg means no patient ever met the doses where GI intolerance drives discontinuation.

Headroom

If weight is regained, there are still three dose steps left. Patients started on 15 mg have none.

Non-randomised, single-centre, indirect comparison across different populations and time horizons (52 vs 72 weeks).



Zero serious events, zero attrition

0

serious adverse events

0

discontinuations for intolerance

0

drop-outs from follow-up

What did happen

1 patient

Balloon hyperinflation at day 68

Removed; no sequelae. The only device-related event in 79 patients.

3 patients

Transient diarrhoea during dose escalation

Resolved within 48 hours. No dose reduction, no discontinuation.



ONGOING · PROTOCOL TRL-2025-01

From one centre to many

Prospective multicentre study

Protocol TRL-2025-01 · currently enrolling

- Balloon plus low-dose GLP-1 and dual GIP/GLP-1 receptor agonists
- Multiple centres — removes the single-operator confound
- Body composition on a harmonised protocol across sites
- Powered to test whether the sequence drives the fat-mass effect

Enrolment closes
**December
2026**

Results at IFSO Paris 2027

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Allurion

CLINICAL PROTOCOL V.1

A Prospective Evaluation of the Allurion Balloon Combined with Low-Dose Semaglutide, Integrated with a Digital Health Platform, for Medication Adherence, Weight Loss, and Fat-Free Mass Preservation in Adults with Obesity

Study No.: TRL-2025-01

Protocol Revision Date: 30-APR-2025

Sponsor: Allurion Technologies, Inc.
11 Huron Dr.
Natick, MA 01760
USA

Principal Investigator: Luigi Flagiello, MD
Italy

This clinical investigation is performed in accordance with applicable guidelines, standards and regulations based on ISO 14155:2020 Clinical Investigation Plan (Annex's A and A1).




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~25

new patients / month with
Allurion + tirzepatide protocol

Enrolment has continued since the abstract was submitted — each new patient, at their own timepoint, is tracking the same trajectory as the first 79.

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 **FMG**


Ruesch
1919

From one centre to many And maybe in the future ...



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Conclusions

1 A sequence, not a combination

Four months of balloon followed by low-dose tirzepatide produced 22.4 % TBWL at twelve months, measured two months after the last dose.

2 Dose, not intensity, is the finding

The result matches tirzepatide 15 mg in SURMOUNT-1, obtained at 2.5–5 mg — leaving cost, tolerability and dose headroom on the table.

3 Fat mass drove it — lean mass fell too but is “banally” normal

Fat mass –36 %, lean mass –12.7 %. We report both in kilograms, and we do not claim lean preservation beyond what the drug alone achieves.

4 Tolerability was the strongest signal

Zero serious events, zero intolerance discontinuations, zero attrition across 79 patients and twelve months.



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"Advancing Multimodal Obesity Care"

24-27 August 2027

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PARIS 2027

See you in

PARIS

