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Liver fibrosis after Duodenoileal Diversion with self-assembling Magnets Results @ 12 & 24 months

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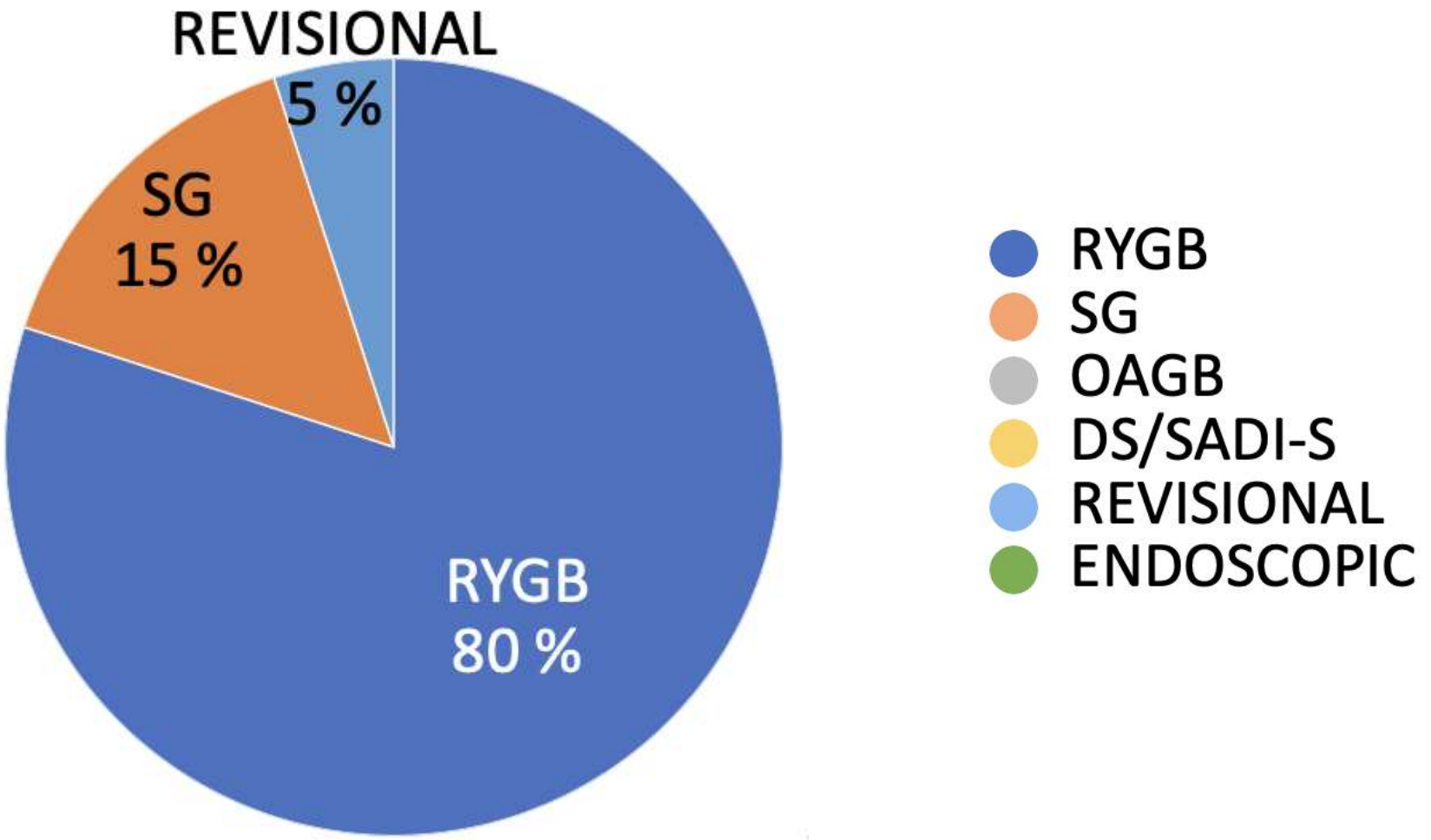
JOINT COMMISSION
INTERNATIONAL

DISCLOSURE

Consultant & Principal Investigator - GI Windows Surgical

CASE MIX DISCLOSURE



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PRINCIPAL INVESTIGATOR:

Procedure for Duodenum to Ileal Diversion to Treat Type 2 Diabetes

Randomized, Single-Center, Parallel-group, Open-label Pilot Study to Evaluate the Safety and Effectiveness of the GI Windows Magnet Anastomosis System (MAS) When Used to Create a Dual-path Enteral Diversion To Effect Glycemic Control in Obese Patients with Type 2 Diabetes Mellitus (T2DM)

NIH U.S. National Library of Medicine

ClinicalTrials.gov

NCT03130244

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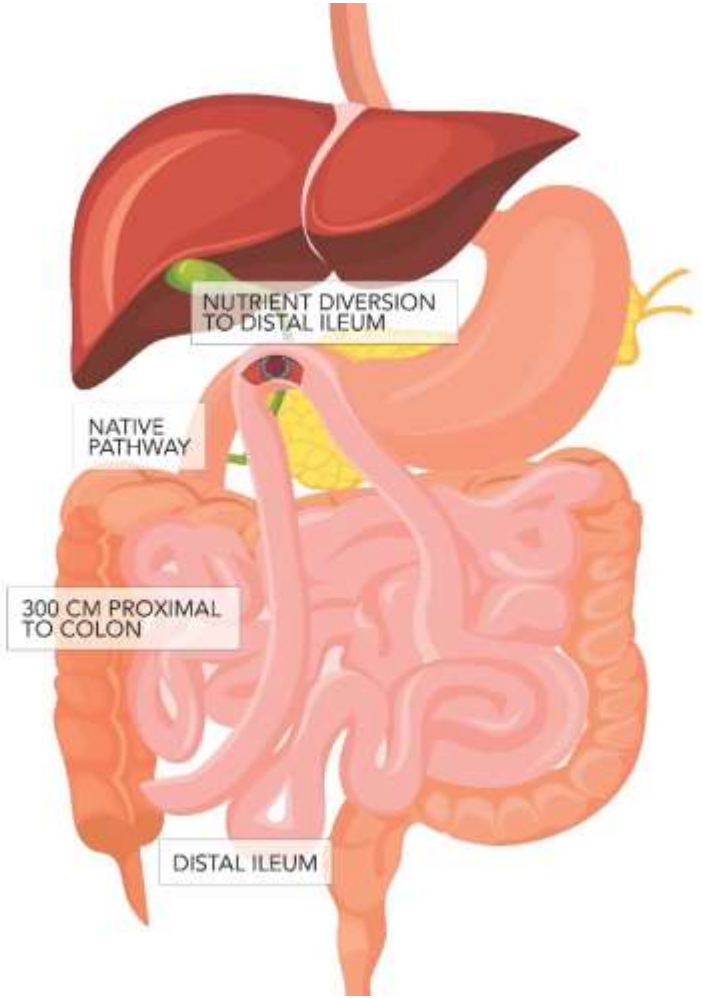
STUDY OBJECTIVE



We aimed to assess metabolic results after surgery with duodenal-ileal anastomosis without stomach restriction through self-assembling laparo-endoscopic magnets with Fibroscan results after 12 and 24 months of the procedure.

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INCLUSION CRITERIA

Age: 18-65

BMI 30-45

T2DM >6m &<10y

HBA1C 6,5 - 10 %

>1 Oral antidiabetic drug (no insuline)

LIVER FIBROSIS AFTER DUODENOILEAL DIVERSION WITH SELF-ASSEMBLING MAGNETS RESULTS AT 12 & 24 MONTHS

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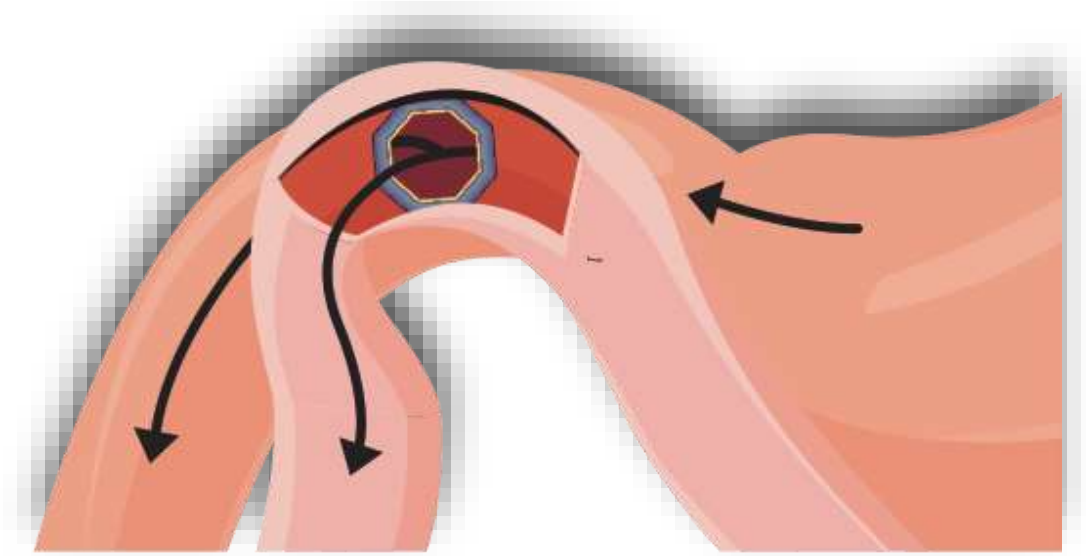
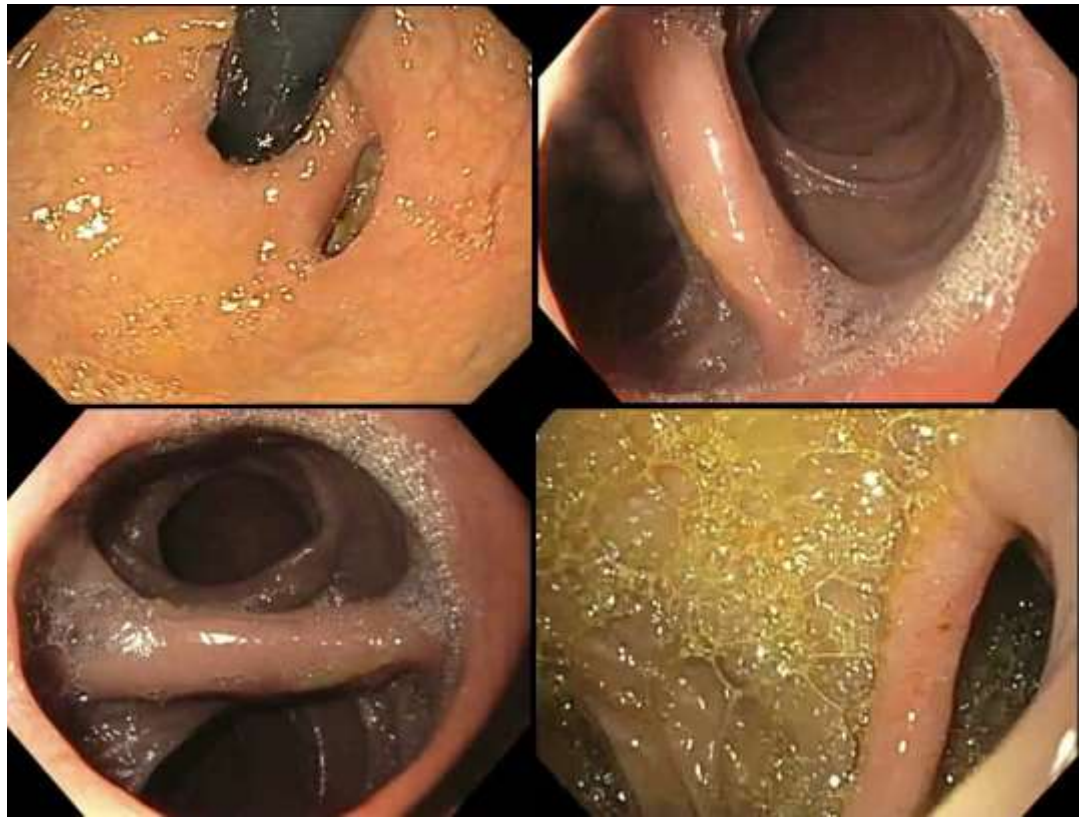
DUODENAL to ILEAL DIVERSION





Potential Benefits of Magnets

Self forming – regular lap instruments
Elimination of Permanent Foreign Material
Reduction in Bleeding
Reduction of Leaks

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RESULTS

- 13 patients
- 53.3% were Males
- Mean age was 47.3 (34-65),
- Mean BMI was 39.6 (35-47.9) kg/m2

- Mean baseline Fibroscan 9.57 kPa (F2-F3)
- No intraoperative complications were recorded
- The protocol required an overnight stay

- Magnets were expelled at a median of 26 days (no associated complications)

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FIBROSCAN CUTOFF FOR NAFLD

Non-alcoholic Fatty Liver Disease (NAFLD or NASH)	2 to 7 kPa	F0 to F1	Is normal.
	7.5 to 10 kPa	F2	Has moderate scarring.
	10 to 14 kPa	F3	Has severe scarring.
	14 kPa or higher	F4	Has cirrhosis.

Mean Baseline 9,57 kPa (3,3-18,2) in 13 patients

LIVER FIBROSIS AFTER DUODENOILEAL DIVERSION WITH SELF-ASSEMBLING MAGNETS RESULTS AT 12 & 24 MONTHS

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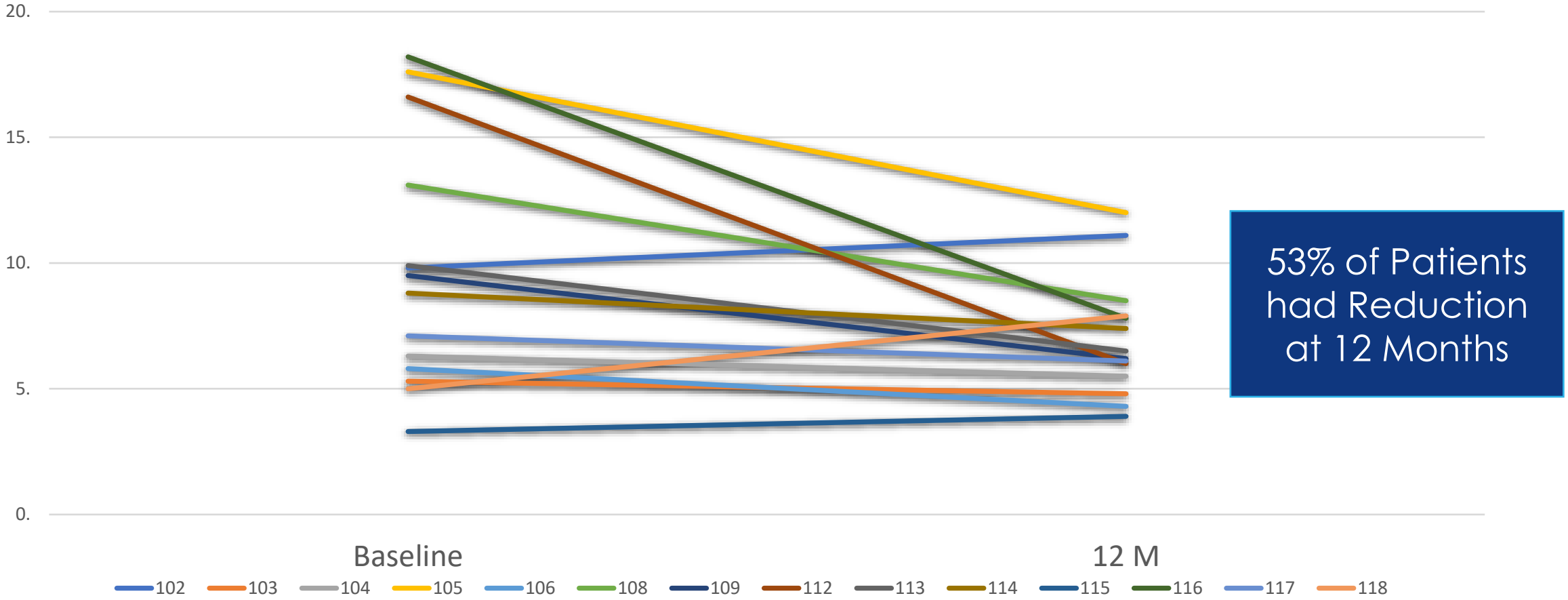
Fibroscan Liver Stiffness Measurement (kPa) Change Over 12 M (N=13)



53% of Patients had Reduction at 12 Months

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LIVER FIBROSIS AFTER DUODENOILEAL DIVERSION WITH SELF-ASSEMBLING MAGNETS RESULTS AT 12 & 24 MONTHS

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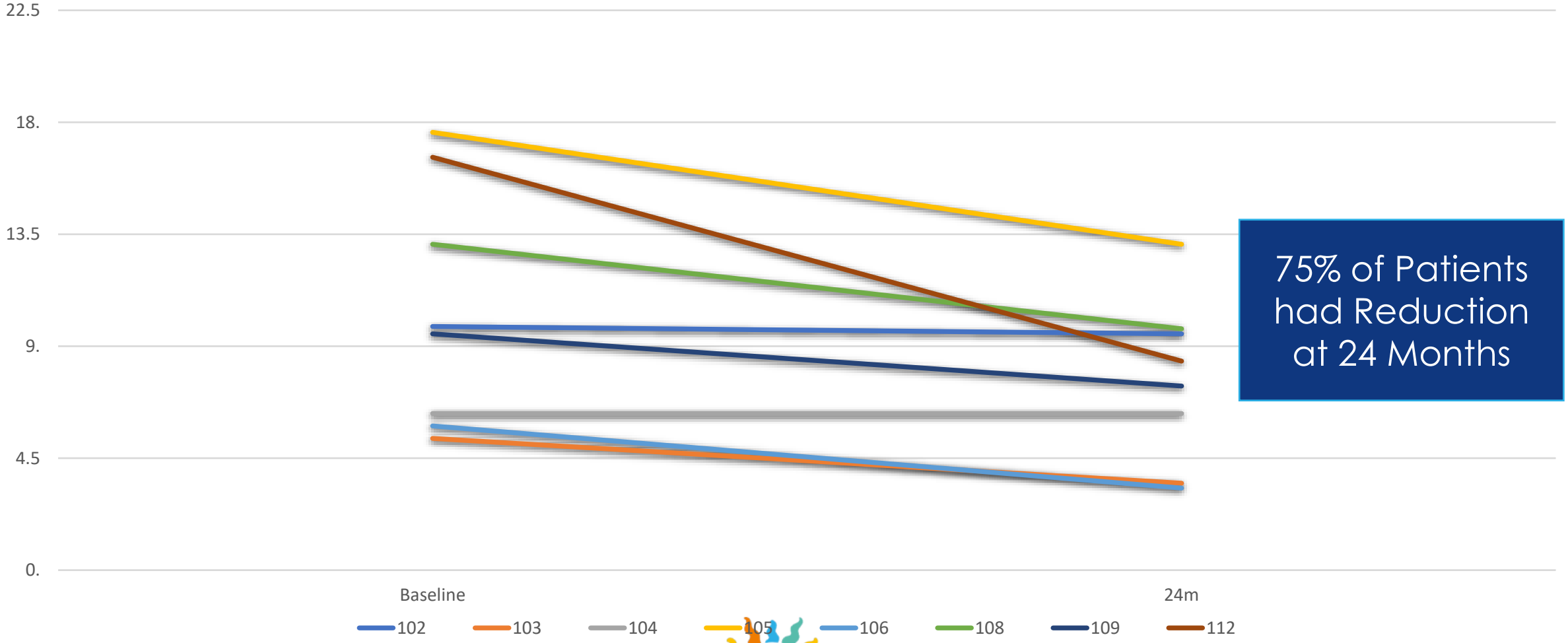
Fibroscan Liver Stiffness Measurement (kPa) Change Over 24 M (N=8)



75% of Patients had Reduction at 24 Months

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LIVER FIBROSIS 12M RESULTS

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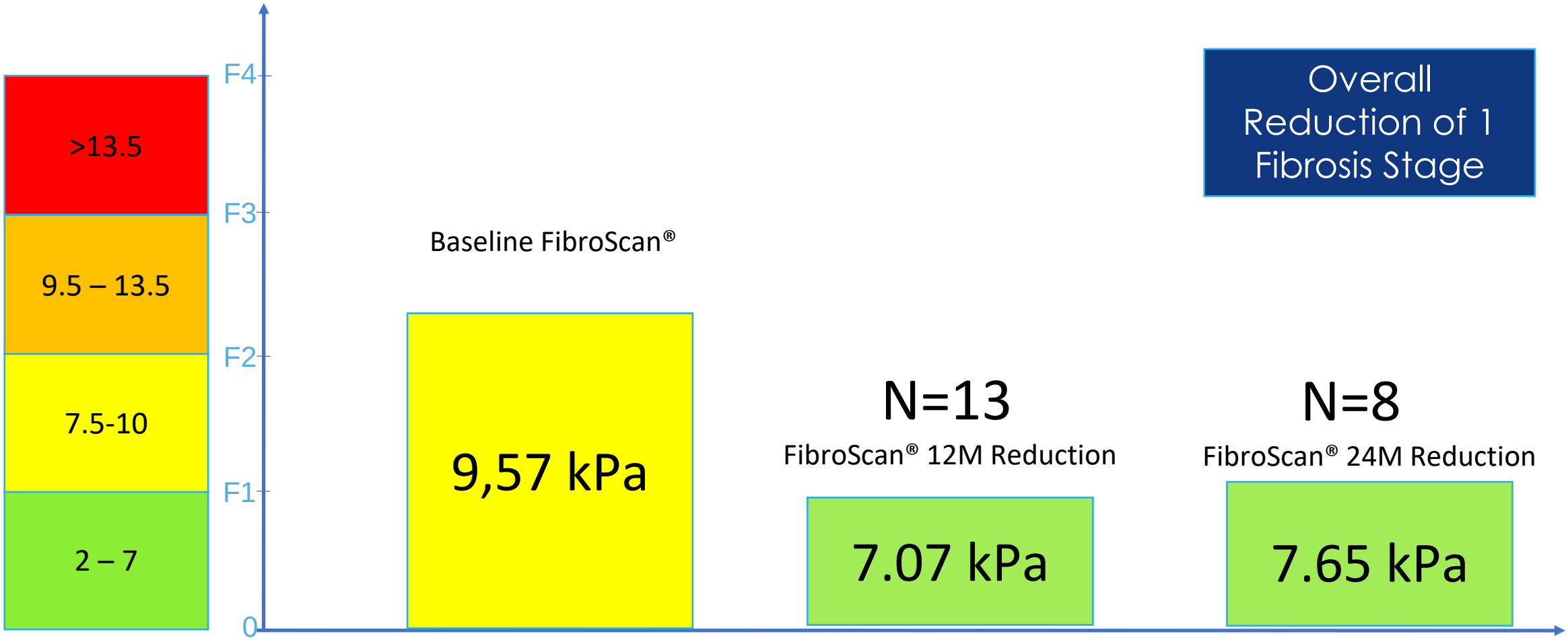

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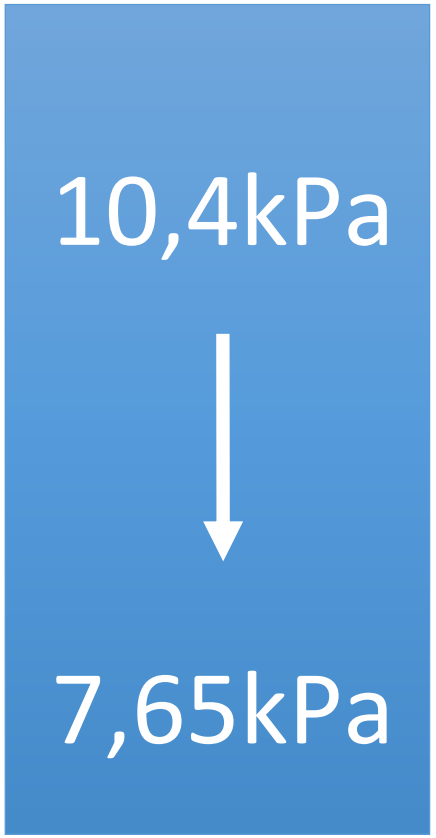
WEIGHT LOSS & FIBROSCAN SCORE IMPROVEMENT

TWL%

N=8@24m



Avg Liver Improvement

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REDUCTION IN FIBROSIS - NO WEIGHT LOSS

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POSSIBLE MECHANISMS OF ACTION

- Weight loss with less amount of liver fat
- Decrease insulin resistance through increased secretion of GLP1
- Decrease in pro-inflammatory cytokinases
- Fibrogenesis is slowed by increased action of the FXR receptor (farnesoid X receptor - role in regulating bile acid)
- Modification of the microbiota with decrease in systemic inflammation
- Modification occurs at the level of bile salts that decreases lipotoxic precursors

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CONCLUSIONS

- Duodenal-ileal anastomosis with self-assembling magnets in obese patients with T2DM is associated with **positive metabolic outcomes**
- Fibroscan measurements showed a **reduction in fibrosis** staging at 12 & 24 months
- In patients with **minimal to no W-L** show a reduction in Fibrosis
- Early results are encouraging, but longer-term follow-up and larger patient populations are required

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THANK YOU!

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