

A single endoscopic duodenal mucosal resurfacing procedure exerts a sustained an improvement in hepatic transaminase levels in a cohort of type 2 diabetes patients

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Background

Duodenal mucosal resurfacing (DMR) is an endoscopic intervention that elicits metabolic improvement in type 2 diabetes (T2D), likely through an insulin sensitizing mechanism. A first-in-human single center study has reported robust improvements in glycemic control after DMR.¹ A lowering of hepatic transaminase levels has also been observed after DMR.

Objective

To report the hepatic transaminase levels in T2D patients 6 months post-DMR.

Methods

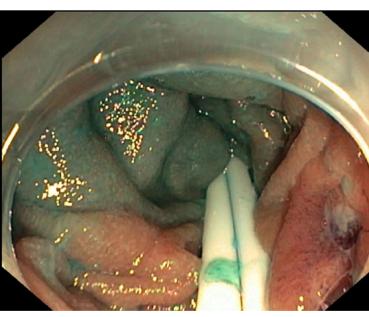
Patients Composite of 2 clinical studies in subjects with T2D with a minimum follow-up of 6 months: a single-site first-in-human (FIH) study and the subsequent multicenter Revita-1 (R1) study.

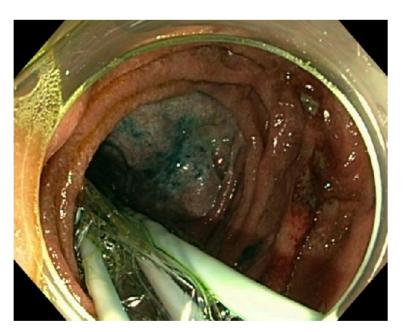
Duodenal Mucosal Resurfacing

Step 1. Duodenal lumen sizing and lifting.

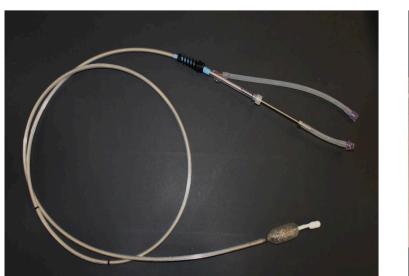


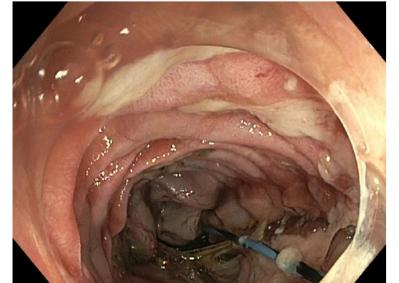




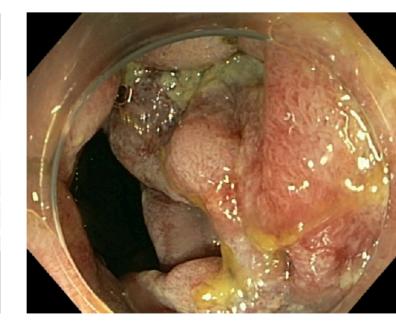


Step 2. Mucosal thermal ablation (length 9 cm).









Medication & diet

Sulfonylurea (SU): Stopped 4 weeks before DMR to mitigate hypoglycemia risk.

Proton pump inhibitor: 1 week before until 4 weeks after DMR. Diet: Graduated diet for 2 weeks post DMR.

Results

• Baseline characteristics from FIH and R1 subjects are shown in Table 1.

- In 23 FIH subjects who showed preprocedural ultrasound (US) findings compatible with steatosis, hepatic transaminase levels decreased significantly (Figure 1, below).
- Hepatic transaminase levels decreased or remained low after DMR across all baseline levels (Figure 2, middle).
- Metabolic indices improved after DMR (Figure 3, right).

Figure 1. Hepatic transaminase levels in patients with US proved steatosis

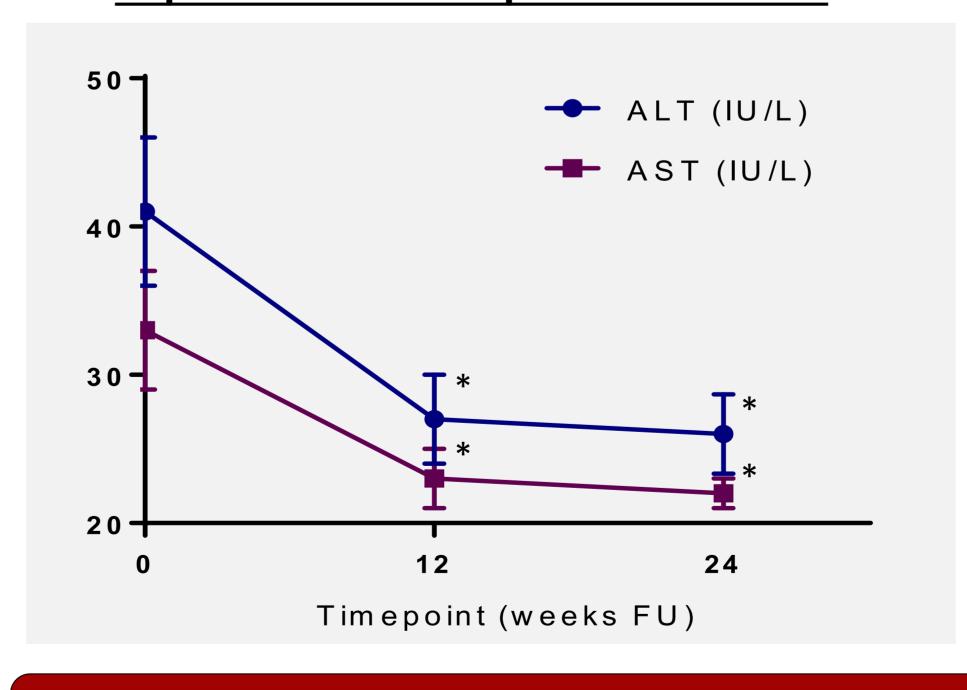


Table 1. Baseline characteristics

	FIH (n=30)	R1 (n=22)	Significance
Age (years)	52±1.4	56±1.8	p = 0.075
Duration of T2D (years)	5.6±0.5	6.4±0.5	p = 0.877
BMI (kg/m2)	32±0.9	32±0.7	p = 0.340
HbA1c (%)	9.7±0.3	8.4±0.2	p = 0.009
HOMA-IR	5.9±0.8	8.0±1.4	p = 0.163

Figure 2. Hepatic transaminase levels

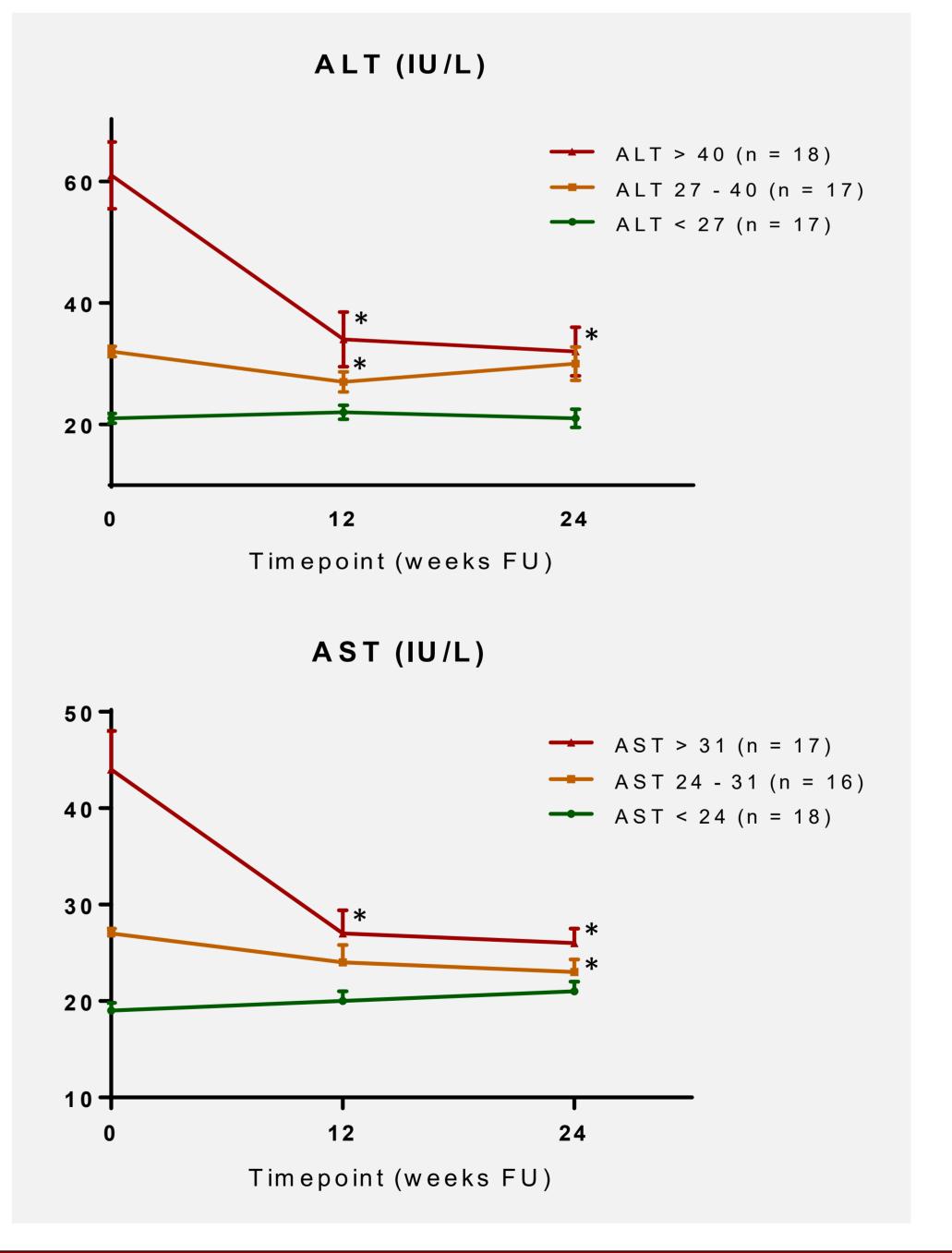
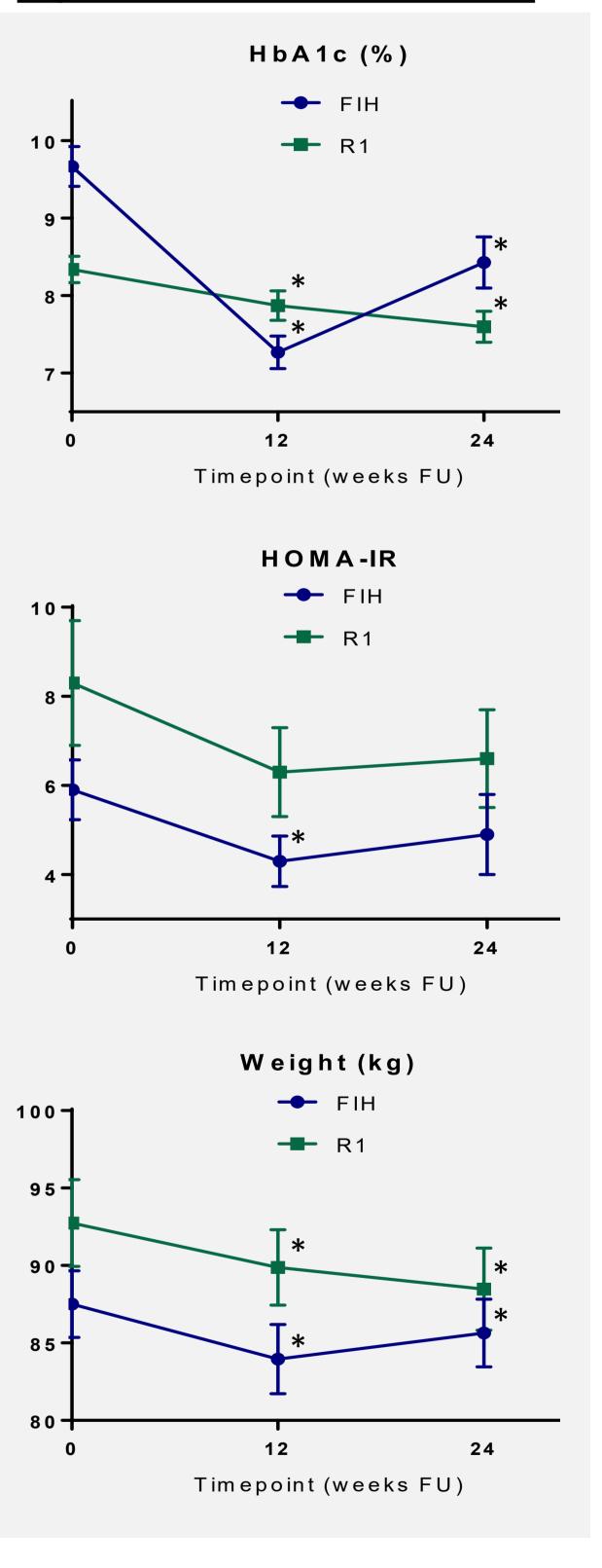


Figure 3. Metabolic indices



Data are presented as mean ± SEM. *p < 0.05 compared to baseline. HbA1c: glycated hemoglobin. HOMA-IR: homeostasis model assessment of insulin resistance.

Conclusion

DMR is a minimally invasive procedure that improves both glycemic markers and markers of fatty liver disease in subjects with T2D. A single duodenal mucosal resurfacing procedure resulted in a decrease of liver transaminases. This unique endoscopic intervention deserves further study to ascertain its potential efficacy as a treatment for fatty liver disease.





