

Duodenal Mucosal Resurfacing For Type 2 Diabetes Mellitus – An Overview And A New Way Forward.

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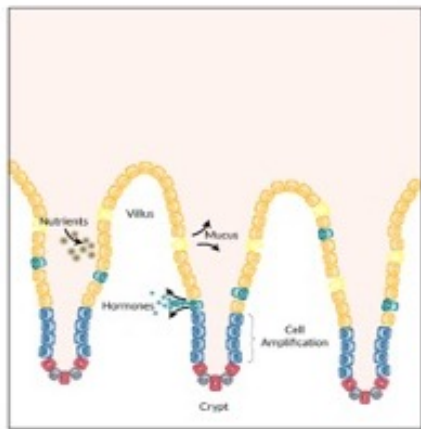


Duodenal Mucosal Resurfacing

- Novel treatment for T2DM – first in human study
- Three research groups worldwide
- Endoscopic day procedure – “Gastroscopy +”
- Modified scope to second part of the duodenum
- Energy applied to superficial layer of mucosa – ablation
- Scope removed
- Modified diet afterwards
- Proton pump inhibitor for 7 days

Role of Duodenal Mucosal Hyperplasia in Metabolic Disease

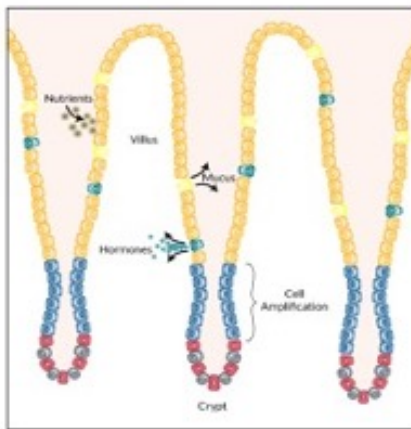
Normal duodenal lining



Epithelial proliferation due to high fat & high sugar diets^{1,4}



Duodenal lining overgrowth²⁻⁴



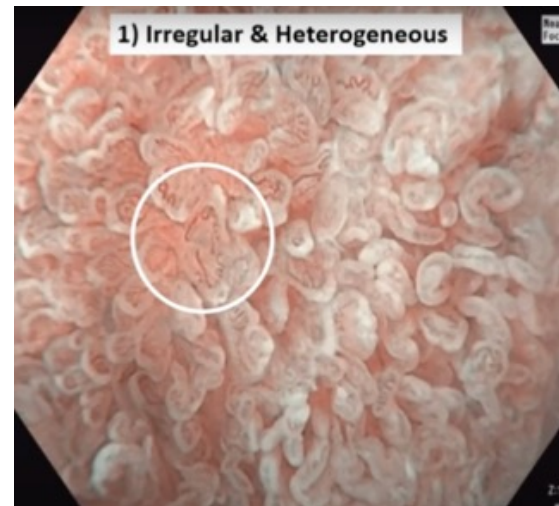
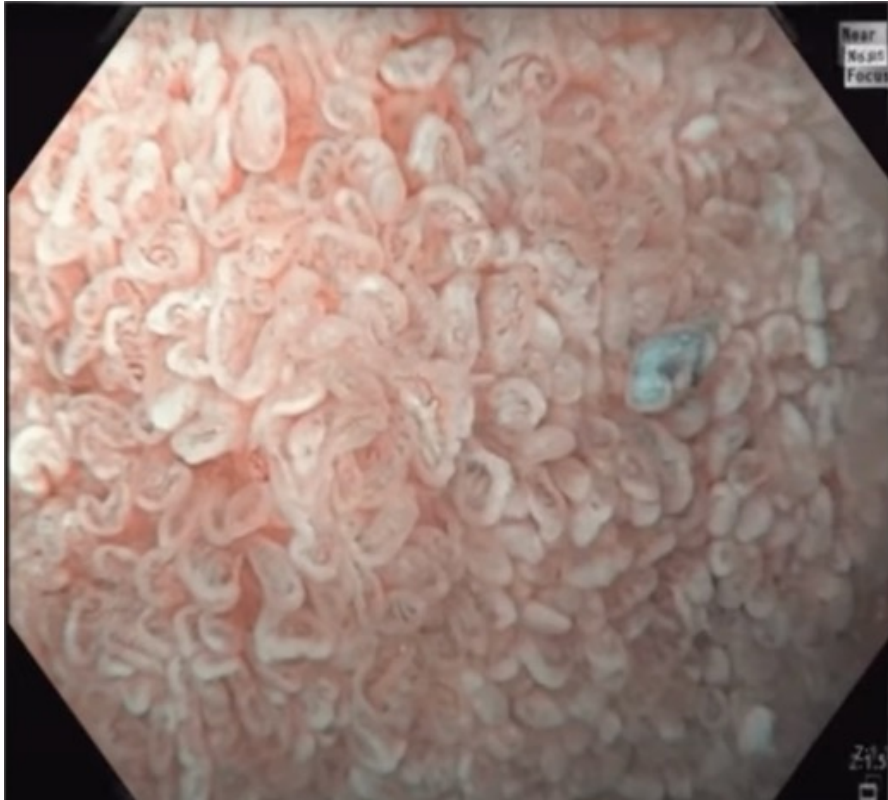
Duodenal hormone hyperactivity^{2,5}



Insulin Resistance Syndrome

Excessive duodenal hormone signaling leads to insulin resistance

Unhealthy Duodenum

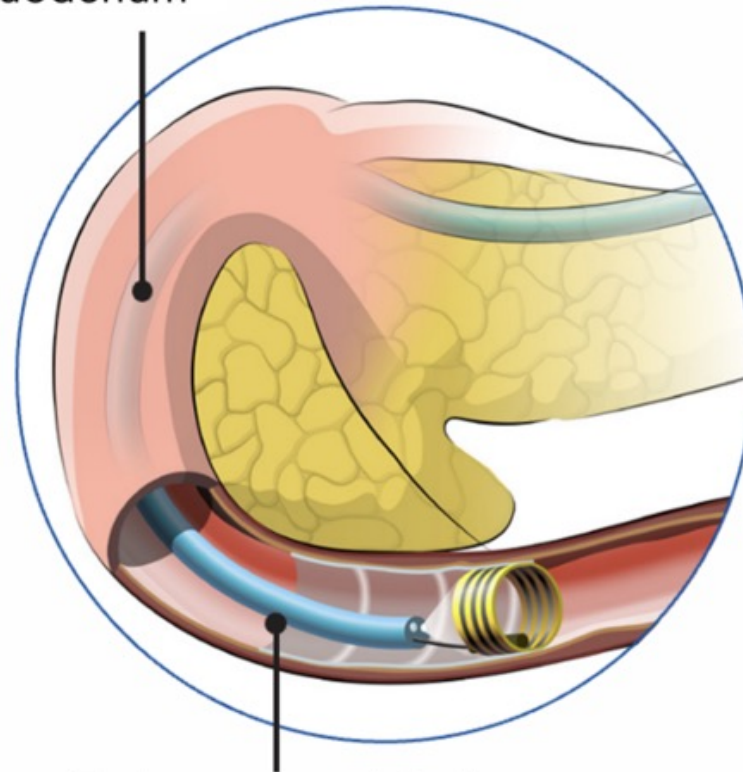


Duodenal Mucosal Resurfacing Procedure

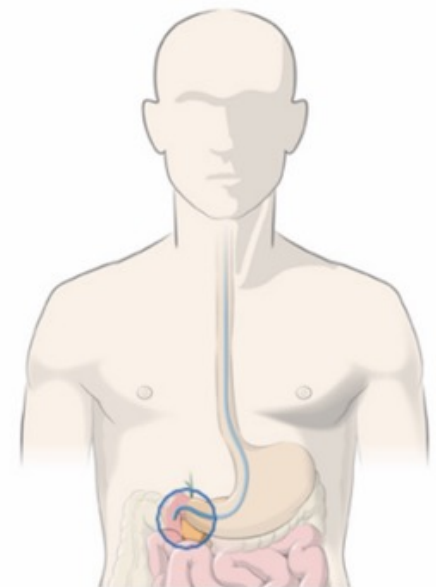
- Duodenal Mucosal Resurfacing – An Endoscopic Approach to Treating Type 2 Diabetes

- Screening upper GI endoscopy
- Major papilla identified and marked
- Catheter inserted into scope and extends from tip of endoscope
- Endoscope and catheter passed into D2
- Sequential ablations are completed to ablate the mucosal surface of the duodenum distal to the papilla until the end of D4
- Ablations performed under direct endoscopic vision
- Does NOT require radiation
- Does NOT require guidewire

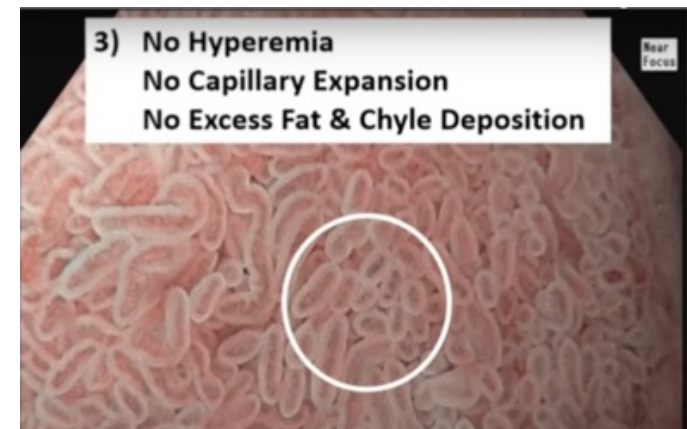
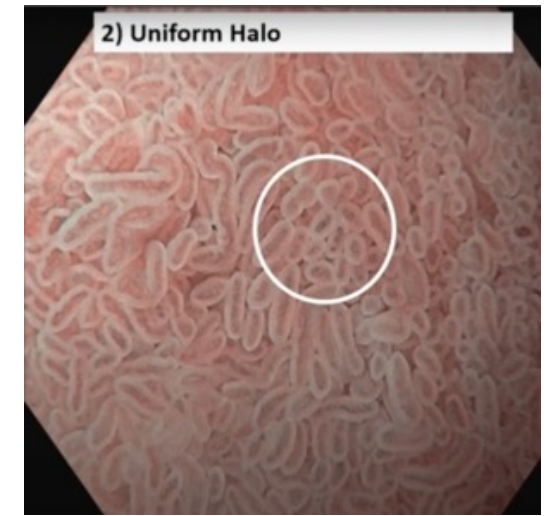
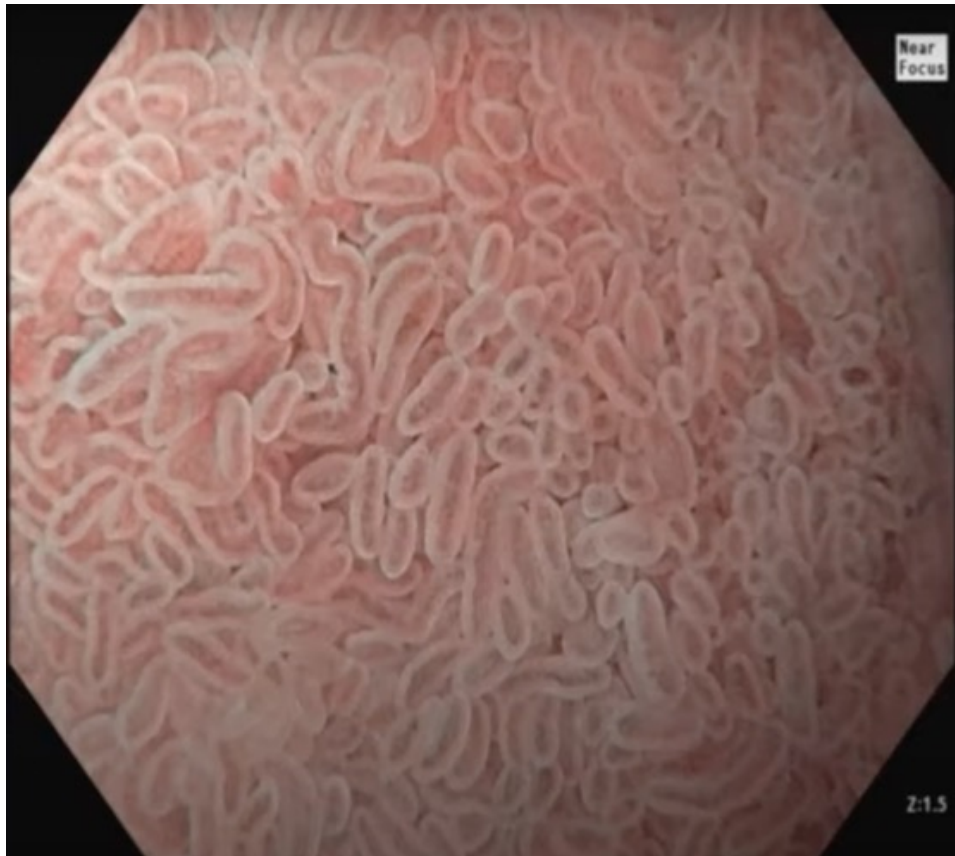
Duodenum



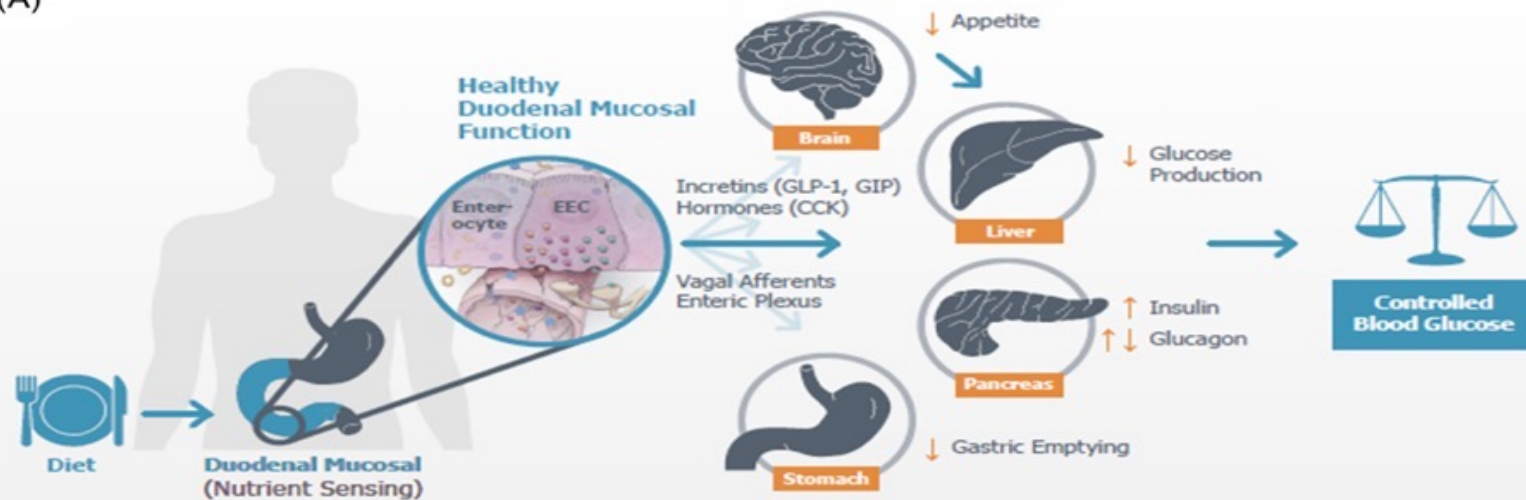
Endoscope and Catheter



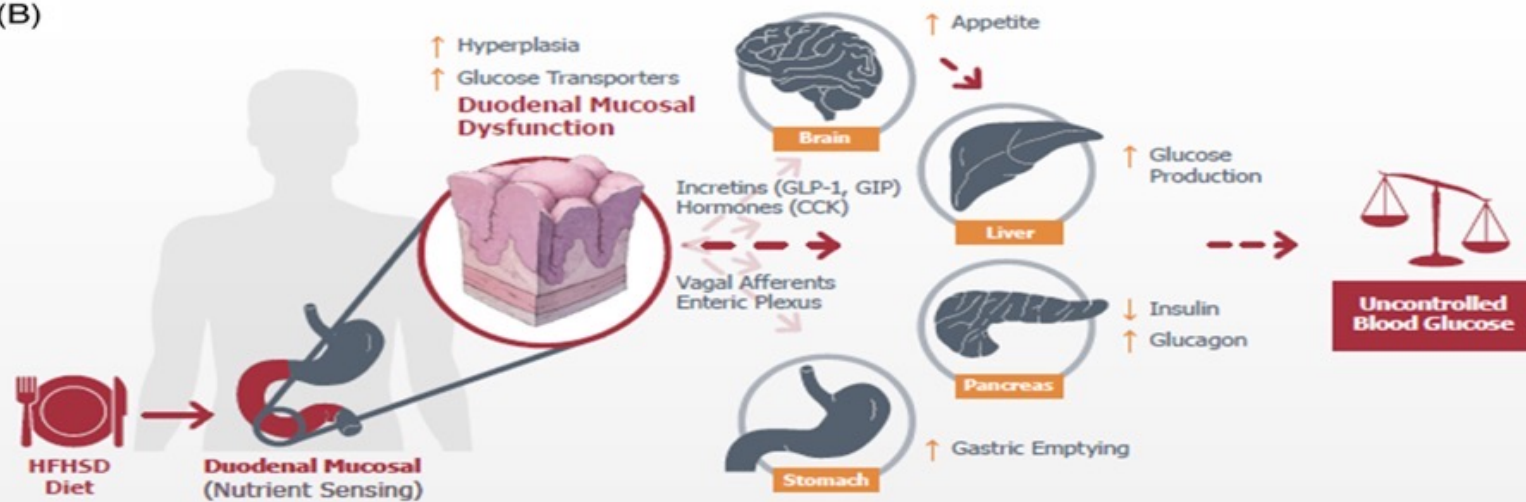
Healthy Duodenum



(A)



(B)



DMR Clinical Outcomes

- DMR with hydrothermal ablation showed significant HbA1c reductions (~1.2% at 6 months) and fasting glucose improvements, but early studies reported duodenal stenosis as a complication. (Rajagopalan et al., 2016)
- Procedure modifications in a multicenter study (Van Baar et al.) improved safety, leading to sustained metabolic benefits (HbA1c, fasting glucose, insulin resistance) at 24 months, with only one mild SAE reported.
- A randomized, sham-controlled trial found HbA1c and liver fat reductions, but overall results were not statistically significant, though subgroups with high fasting plasma glucose showed improvements.
- A systematic review/meta-analysis (Lin et al.) confirmed DMR significantly improves metabolic parameters, independent of weight loss
- The first human study using non-thermal ablation demonstrated promising glycemic improvements, a 100% technical success rate, and no severe complications, with complete mucosal healing in 4 weeks.

Duodenal Musosal Resurfacing – RESTORE

- Age 22-70
- BMI 22-40 (45)
- T2DM <10 years
- HbA1c 7.1-10%
- 2 or more non-insulin medicine (eg OHG, GLP1)
- No history of gastric surgery or coeliac disease

Patients looked after by Western Health diabetes team (Endo, DNE, dietician) for 12 months after procedure. Car parking paid and gift cards \$150 after each visit.

Pts undergo: blood tests, DEXA scans, blinded CGM, procedure and two follow up scopes



Restore Study Team

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