

ONE YEAR RESULTS OF AN ENDOSCOPIC, DUODENAL-JEJUNAL EXCLUSION DEVICE FOR WEIGHT LOSS AND CONTROL OF TYPE 2 DIABETES

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Background: The duodenal-jejunal bypass liner (DJBL, GI Dynamics, Inc., Lexington, MA) is an endoscopic implant that mimics the intestinal bypass component of the Roux-en-Y gastric bypass. Previously reported studies have shown promising improvements in type 2 diabetes (T2D) and weight loss for up to 6 months. This report describes improvements in T2D and metabolic changes in subjects with T2D who were implanted with the DJBL for one year. **Methods:** This is a prospective, non-randomized, open label study with 22 patients enrolled. **Inclusion criteria:** Age higher 18 years and less 65 years, BMI higher 35 kg/m²; and type 2 diabetes with or without other co-morbidities, unsuccessful history with nonsurgical weight reduction methods, candidates to bariatric surgery. There were 9 early endoscopic removals due to device movement (3), nausea/vomiting (1), abdominal pain (1), GI hemorrhage (1), non-device related abdominal neoplasm (1) and Principal Investigator request (2). **Results:** At one year (n=13 patients), observed absolute weight loss of 20.4 kg (p less 0.0001), excess weight percentage loss of 35.3% (p less 0.0001), body mass index of 7.4 kg/m² (p less 0.0001) and waist circumference of 10.1cm (p=0.0001) was observed. Likewise, glucose levels decreased from 175.6 to 126.7 mg/dL (p less 0.0001) and glycosylated hemoglobin from 8.8 to 6.4% (p less 0.0001). The use of diabetic medications, except metformin was reduced and 19.2% of patients no longer required any anti-diabetic drugs. Insulin (p=0.02) and C-peptide (p=0.015), cholesterol (p=0.001), LDL (p=0.01), and triglycerides (p=0.006) levels were normalized at 1 year. **Conclusions:** The endoscopic DJBL has a durable effect on glucose control, weight loss and metabolic function for one year, suggesting this new device is a suitable option for the treatment of T2D and obesity.