

## Intragastric Balloon: 342 Patients Treated at a Multicenter Bariatric Practice

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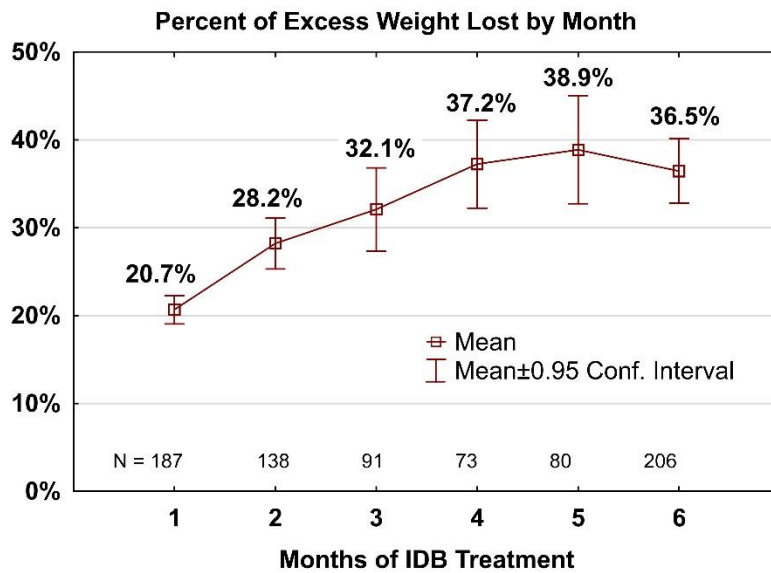
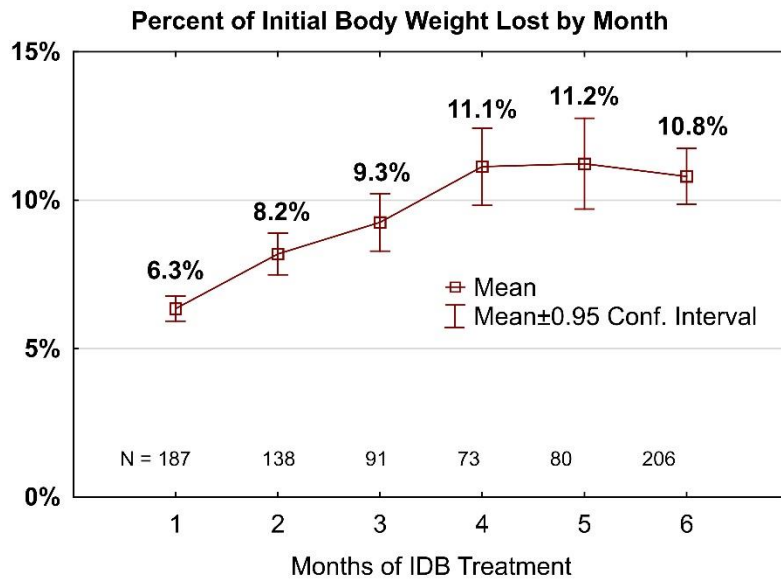
**BACKGROUND:** The ReShape™ Integrated Dual Balloon (IDB) is a nonsurgical treatment for obesity recently introduced in the United States. We report on our continuing experience in a large multicenter bariatric practice.

**METHODS:** Following appropriate workup, the IDB was placed endoscopically in an outpatient setting. Patients were scheduled for monthly follow up visits. The balloon was scheduled for endoscopic removal at 6 months. All subjects successfully implanted with the IDB were analyzed for baseline demographics, available weight loss data and safety profile.

**RESULTS:** Implanted subjects (n=342) were 76% female with the following mean baseline values: age 45 (range 18-72), weight 231 lbs (range 152-450) and BMI 37.5 (range 27.8-65.7). The mean treatment duration for retrieved patients was 166 days (range 3-246) with 276 IDBs retrieved and 66 still implanted. All attempted implantations were successful without complications. Mean weight loss for 240 subjects with 120 days or more of treatment was 24.3 lbs (-8.5, 93), 10.5% of initial body weight (-3.2, 44.5%) and 36.2% of excess body weight (-14, 171%). 81% of patients lost  $\geq$  5% initial body weight and 49% more than 10% of initial body weight. For the 300 subjects with at least one weight value, last observation carried forward weight loss values were 23.0 lbs, 10.0% of initial weight and 34.2% of excess weight. Multivariable analysis demonstrated that greater weight loss was associated with older patients ( $p=0.004$ ), longer periods of IDB treatment ( $p=0.02$ ) and larger numbers of in-person and virtual follow-up visits ( $p=0.001$ ). Greater fill volume was also associated with greater weight loss ( $p=0.07$ ).

Seven of 276 retrieved patients (2.5%) had gastric ulcer and all resolved with PPI treatment. Twenty-two of 342 (6.4%) were retrieved before 120 days due to intolerance; these patients had an average weight loss at retrieval of 7.7% of initial body weight. Seven of 342 (2.0%) had balloon deflation; two of these were dual balloon deflations with uneventful rectal passage. Three patients had gastric outlet obstruction requiring retrieval; one of these patients had gastric perforation requiring operative repair. Three patients had pancreatitis requiring hospitalization for resolution; two IDB's were retrieved and one patient refused retrieval.

**CONCLUSION:** The ReShape IDB is a safe and effective endoscopic intervention for weight loss in appropriate patients. 49% of our assessed patients lost at least 10% of initial body weight. Gastric ulceration, deflations, pancreatitis and early retrievals for intolerance occur infrequently and have no long term sequelae if treated promptly.



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