

Effect of the Epitomee Capsule for weight loss on gastric emptying

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Background:

The Epitomee Capsule for weight loss is based on absorbent pharmaceuticals polymers and bonding materials that self-expand in the stomach to create a pH-sensitive super-absorbent gel structure which promotes early satiety signaling. We hypothesized that the effect is mediated by delaying gastric emptying (Fig. 1).

Methods:

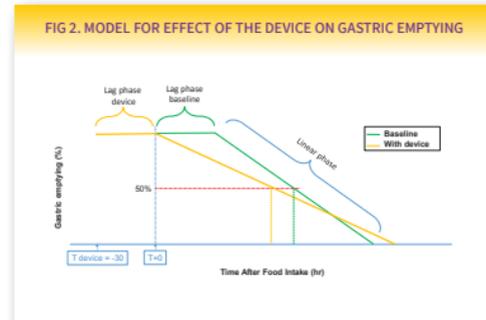
Gastric emptying of solid test meal was monitored in healthy volunteers before and after 10 days intake of the capsule (2 capsules per day) using Tc-99m imaging obtained at 60 minutes intervals, from test meal uptake up to 210 minutes following the meal. The capsule is used 30 minutes before meal, mimicking solid food digestion pattern known as the gastric emptying lag phase such that the gastric emptying linear phase being in closer proximity to the test meal consumption (Fig. 2). Accordingly, calculated baseline $t_{1/2}$ includes both the lag and linear phases of gastric emptying while post treatment values include only the linear phase. To allow true comparison between pre and post treatment, we therefore calculated the emptying rate during the linear phase by a linear fit to the data from 60 to 180 minutes post meal consumption.

Results:

Subjects (6 females, 4 males) with BMI range of 24-35 kg/m² were included. $t_{1/2}$ at baseline and after capsule ingestion was 90 minutes and 75 minutes, respectively. The linear emptying rate for baseline and after capsule ingestion was 35%/hour and 28%/hour, respectively (Fig. 3) (Table 1.). This corresponds to a 40% decrease in gastric linear phase emptying rate following capsule intake ($p=0.03$).

Conclusions:

Epitomee Capsule intake resulted in a significant decrease in the rate of gastric emptying linear phase. The decreased gastric emptying linear rate was masked by the relatively shorter $t_{1/2}$ due to the absence of normal gastric emptying pattern known as the lag phase, when the capsule is used. Additional studies are required to verify the mechanism in obese subjects.



Key words: Obesity, weight loss, medical device

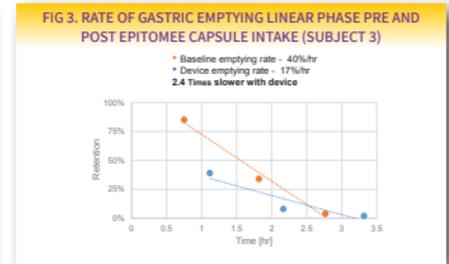


TABLE 1. RATE OF GASTRIC EMPTYING LINEAR PHASE PRE AND POST EPITOMEE CAPSULE INTAKE

Subject #	Emptying Rate (%/hr)		Ratio
	Baseline	Device	
1	25%	15%	1.7
2	32%	21%	1.6
3	40%	17%	2.4
4	30%	22%	1.4
5	36%	18%	2.0
6	39%	48%	0.8
7	38%	28%	1.4
8	40%	37%	1.1
9	33%	33%	1.0
10	37%	40%	0.9
Average	35%	28%	1.4