ORIGINAL ARTICLE

Efficacy and safety of an oral device to reduce food intake and promote weight loss

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Summary

Objective

Minimal risk weight loss tools are needed. This study's objective was to confirm Food and Drug Administration submissions of the SmartByte™ System's safety and efficacy.

Methods

This 16-week, prospective, single-arm, four-centre, observational study assessed the oral device in combination with a video-delivered lifestyle programme in adults aged 18–49 years with body mass index 27 to <35 kg m^{-2}.

Results

Seventy-six subjects received the device and video lifestyle instruction. The prespecified per protocol (PP) population ($N = 40$) required sensor-verified use of the device ≥7 times per week for 14 of 16 weeks, overall device usage rate of ≥33% and study completion. At week 16, 12 (30%) achieved ≥5% weight loss, 16 (40%) achieved ≥4% and 21 (52.5%) achieved ≥3%. Week 16 mean loss for the PP population was 2.93%, and among 36 participants who did not meet PP criteria, it was 1.45%. Among 76 intent-to-treat subjects, two subjects reported three mild to moderate device-related adverse events, resolving spontaneously (one hard palate abrasion and two tongue lacerations).

Conclusion

The System, a minimal risk tool, can help individuals achieve meaningful weight loss, when used with a lifestyle video. More frequent device use was associated with more weight loss, on average, and greater chance of achieving ≥4% or ≥5% weight loss.

Keywords: SmartByte device, weight loss device.

Introduction

The epidemic of obesity and its health consequences (1–3) and the difficulty of achieving and sustaining weight loss (4,5) mandate a need for effective, low risk, low cost tools that can be applied in primary care settings to help patients safely achieve meaningful weight loss. A new device takes advantage of the physiologic and biologic changes that occur when the oral cavity is limited in size, resulting in smaller bites, more oral processing and slower rate of food intake. As evidenced in the literature, individuals who eat their meals quickly tend to consume larger meals (6,7), which can disassociate satiety from the amount of food consumed (8,9), which often leads to over-eating (10) and higher body mass index (BMI) (11,12). Conversely, slowing food consumption has been shown to reduce food intake, hasten satiety and support weight loss in individuals with overweight and obesity (9,13,14).

The SmartByte™ system (Scientific Intake, Inc., Atlanta, GA [Lawrence, MA], USA) is a non-invasive, clinically validated, removable medical device (only placed when eating) designed to slow the eating rate by reducing the volume of the oral cavity and support mindful eating, with the goal of reducing calorie intake to achieve sustained weight loss. It is fitted to each individual and worn in the upper palate while eating. The device is derived from an earlier prototype, Sensor

Monitored Alimentary Restriction Therapy (SMART). The device contains an embedded heat sensor chip that provides downloadable data to confirm use and time of use.

Earlier studies including a food intake laboratory study and a clinical observational study have shown that use of the SMART™ device reduces acute food intake (15) and can produce total body-weight loss (TBL) (16). In the study of acute food intake (15), after a habituation day and baseline day, subjects randomized to the device consumed significantly fewer calories over three test meals compared with control subjects (daily caloric reduction of 22.9%, on average, for device using participants vs. 5.1%, on average, for control condition, $p < 0.05$). For individuals who used the device, there were no changes in hunger or satiety measures, despite reduction in energy intake (15). Another study with the device observed weight loss over 16 weeks in 20 adults with BMI 27.0–33 kg m^{-2} (16). For the 16 participants who completed 16 weeks, mean weight loss was 5.9 ± 0.9 kg (6.4% ± 1.0%, $p < 0.001$). Subjects reported that, over time, they made conscious efforts to slow their eating rate, regardless of device use.

The device was further modified and, as the SmartByte system, was tested in a controlled, randomized, prospective, open-label, 16-week study in 173 individuals with BMI 26–36 kg m^{-2} (17). There were 102 individuals randomized to the device and a lifestyle intervention instructional video and 71 received the video instruction alone. Mean weight loss was 1.65% in the device users and 0.36% in the control condition ($p = 0.025$) (17). However, overall adherence was poor. As shown in Figure S1, there was a direct relationship between device usage and weight loss. This indicates that mean weight loss was affected by adherence. A *post hoc* analysis of per protocol (PP) device use (attendance at four of seven study visits and use of the device for at least 33% of eating episodes) showed that for 41 participants in the device group meeting requirements, mean weight loss was 4.39% and among 67 in the control group was −0.29% ($p < 0.0001$). The profile of device-related adverse events showed two reports of gum irritation, two reports of transient choking, one activation of gag reflex and one gum irritation, all of which resolved spontaneously (17). Because of the favourable safety profile and evidence that the device could produce weight loss, if used as directed, the Food and Drug Administration (FDA) requested further observational evidence of device efficacy and safety, and the study reported here was undertaken. This paper describes a confirmatory study required by the FDA to further assess the impact of device use over 16 weeks in adults with overweight and obesity in the USA. The device received FDA clearance in September 2016 (18).

Materials and methods

Study design

This 16-week, prospective, single-arm, four-centre, observational study assessed the impact of the device as a tool used in combination with a lifestyle programme delivered by video among a population aged 18–49 years with overweight and less severe obesity (class 1). The objective was to enrol an additional 70 or more participants (as recommended by the FDA) to confirm the efficacy and safety of the device. The study was performed in accordance with the Declaration of Helsinki and approved by a central institutional review board, Quorum Review. Start date: March 2014. Study completion: January 2015.

Subjects

Seventy-six subjects were enrolled in the study. Inclusion criteria were as follows: age 18–49 years; BMI 27–35 kg m^{-2}; self-reported stable weight during the previous 3 months (no fluctuation of 3% or more); dental check-up within previous 12 months; normal condition, anatomy and function of the oral cavity as confirmed by trained healthcare provider; no functional problems when swallowing solids or liquids; and agreement to fully follow the study protocol. Exclusion criteria were as follows: concomitant participation in formal weight loss programme; clinically significant disease; history of bariatric surgery; type 1 or type 2 diabetes treated with insulinotropic medication; tobacco or nicotine gum u; or any of conditions in the oral cavity that would preclude fitting and wearing the device. Written and verbal informed consent was obtained from all subjects. All subjects received financial compensation for their participation and completion of the study.

Study device

The removable device (placed only when eating) is depicted in Figure 1. The device is composed of biocompatible materials that are moulded to fit an individual's palatal contour; soft edges facilitate a comfortable fit. A small, proprietary sensor is embedded within the device to precisely measure the times, frequency and duration of device use at 5-min intervals. Data are downloaded for review.

Figure 1 The SmartByte™ System. The system includes a device made of biocompatible materials that are moulded to fit an individual's palatal contour; soft edges facilitate a comfortable fit. A small, proprietary sensor is embedded within the device to precisely measure the times, frequency and duration of device use at 5-min intervals.

Procedures

The study included two screening visits, a run-in visit, run-in/pre-baseline visit, baseline visit and study visits every 2 weeks for up to 16 weeks, including the end-of-study visit scheduled for week 16 (visit 13).

At screening visit 1 (−28 d), a trained clinician (MD, DO, NP or PA) collected a medical history, performed a physical evaluation (including weight measurement) and conducted an oral evaluation of each subject to determine compatibility with the device. The clinician first confirmed that each subject was under the regular care of a dentist and did not have dentures, braces, a removable appliance (e.g. bridge or partial), a known allergy to the mould material or any condition that would make placement and removal of the device difficult. Clinicians were trained according to a robust in-house protocol that included detailed instruction regarding oral health assessment and mould forming and inspection. At the second screening visit, eligibility was reconfirmed, physical measurements (height, weight, etc.) were taken and a palatal mould used for device fabrication was created for each eligible subject. At the second screening visit, of 130 participants, 94 were deemed eligible for device usage.

The run-in period began at visit 3 (day −12) at which time subjects received their device. The clinician examined and confirmed the fit of the device in the oral cavity. Subjects were instructed to use the device during every meal and every snack as well as during the consumption of sugar-sweetened beverages during the run-in period. Subjects were instructed to remove and store the device in the provided protective case when not in use. Subjects returned to the clinic at visit 4 (day −6), sensor data were downloaded and subjects reported the number of meals consumed. Patients with confirmed use of the device during at least one eating episode per day (from sensor data) and 66% of eating episodes (sensor data for numerator and self-reported number of meals for denominator) during the run-in period were then eligible for enrolment in the study. Of 94 participants, 76 met run-in use criteria and continued in the trial.

At visit 5 (day 0), subjects returned to the clinic, viewed an educational DVD video (healthy eating) and were enrolled in the study. Subjects viewed the video, had download of sensor usage and were weighed and assessed medically every 2 weeks for the duration of the 16-week study period.

Predefined outcome measures

Co-primary endpoints were (1) the proportion of subjects achieving ≥5% TBL at week 16 and (2) mean %TBL at week 16 weeks compared with visit 5 (day 0). Exploratory endpoints included the relationship of device usage to weight loss. As required by the FDA, the investigators obtained data on percentage excess weight loss, calculated as weight lost (numerator) divided by a denominator composed of the weight at study start minus the weight projected at BMI 25 kg m^{-2} and then multiplied by 100.

Safety

Adverse events (any untoward medical occurrence regardless of a causal relationship with the study treatment) were assessed for the intent-to-treat (ITT) population and recorded at each visit.

Statistical methods

The initial sample size calculation deemed that 70 subjects who completed the run-in period and baseline visit would be adequate to evaluate the two co-primary endpoints. This sample size determination was based on the preliminary studies submitted to the FDA (19). See Appendix S1 for additional discussion.

Two populations were predefined: ITT and PP. The ITT population included all subjects who completed the run-in period, met run-period adherence criteria and completed the baseline visit. The predefined PP population included subjects whose device sensor weekly downloads demonstrated use of the device seven or more times during that week and that this occurred for

14 of 16 weeks. Subjects also reported the number of meals per week, and the sensor verified usage rate had to be at least 33% of self-reported eating episodes. The final PP criterion was completion of the study through week 16. Efficacy assessments of the co-primary and secondary endpoints were analysed in the PP population. Safety analyses were based on the ITT population.

Study data are summarized with descriptive statistics. Means, standard deviations and 95% confidence intervals are reported for continuous variables. Counts, proportions and 95% confidence intervals for proportions are reported for categorical variables.

Results

Baseline characteristics, adherence and retention

The baseline characteristics of the 76 subjects who were enrolled (comprising the ITT population) and 40 subjects who met PP criteria are presented in Table 1. Sixty-seven subjects completed the last study visit (88%). Seven subjects withdrew consent, one was lost to follow-up and one became pregnant. Subject disposition from screening to conclusion is presented in Figure 2.

Table 1 Baseline characteristics

Baseline characteristics	ITT population (n = 76)	PP population (N = 40)
Gender, *n* (%)		
Male	9 (11.8)	3 (7.5)
Female	67 (88.2)	37 (92.5)
Ethnicity, *n* (%)		
Hispanic or Latino	27 (35.5)	14 (35.0)
Not Hispanic or Latino	49 (64.5)	28 (65.0)
Race* *n*, (%)		
Asian	5 (6.6)	2 (5.0)
Black or African–American	18 (23.7)	9 (22.5)
White	55 (72.4)	29 (72.5)
Mean age,[†] years (SD)	34.8 (7.9)	36.4 (8.1)
Mean weight, lbs (SD)	188.2 (22.38)	187.6 (19.9)
Mean body mass index,[‡] kg m^{-2} (SD)	31.7 (2.4)	31.6 (2.4)
Mean eating episodes per day, N (SD)	3.6 (1.1)	3.9 (1.0)

*Subjects may be counted in more than one category.
[†]Age is derived from the date of informed consent and subject-reported date of birth. For more detail, please see the Statistical Analysis Plan.
[‡]BMI is calculated as (weight in kg)/((height in meters)^2). Four ITT subjects having BMI $\leq$ 35 kg m^2 at visit 1 had BMI > 35.0 kg m^2 (<36 kg m^2) at visit 5.
BMI, body mass index; ITT, intent-to-treat; PP, per protocol; SD, standard deviation.

Weight change from screening to study start

Mean weight change from screening visit 1 to baseline visit for the ITT population was a gain of 0.23 kg (standard deviation 1.26 kg).

Co-primary endpoint analysis, per protocol population

The mean %TBL at week 16 weeks for the PP population was 2.93% (confidence interval 1.80, 4.06). Twelve of the 40 subjects in the PP population achieved $\geq$5% TBL at week 16 (range weight loss 5.1–9.1%), representing 30% of the population. The 95% two-sided exact binomial confidence interval calculated by the Clopper–Pearson method was 0.17–0.47. The trajectory of mean weight loss over the course of the study for the PP population is depicted in Figure 3. The categorical weight losses for the PP population are depicted in Figure 4.

Additional analyses were performed in the PP population. For those achieving 4% or more weight loss, mean weight loss was 6.3% ± 1.0% (range 4.3–9.1%). At 16 weeks, there was mean excess weight loss of 18.76% in the PP population.

Co-primary endpoint analysis, intent-to-treat population

The mean %TBL at week 16 weeks for the ITT population, using last observation carried forward, was 2.05%. For the ITT population, 15 of 76 (19.7%) participants achieved $\geq$5% TBL at week 16. For the 36 ITT participants who were *not* in the PP population, mean weight loss at 16 weeks was 1.45%; 6 (16.6%) achieved $\geq$4% weight loss (range 4.2–8.4%); 3 (8.3%) achieved $\geq$5% weight loss.

Figure 5 depicts a waterfall plot describing the weight loss (%TBL) for individual subjects, PP and ITT populations. Among the 40 subjects in the PP population at 16 weeks, 12 subjects (30%) achieved $\geq$5 %TBL, 16 (40%) achieved $\geq$4 %TBL and 21 (52.5%) achieved $\geq$3 %TBL. Data for 7/76 drop outs (ITT) are shown as last observation carried forward. Although PP was intended to identify device use and, thus, weight loss success, Figure 5 demonstrates that even without device use defined by PP criteria, some participants were successful with weight loss.

Adherence to device use

The mean percentage of device compliance within the PP population was 69%, based upon the reported eating episodes and sensor monitored use throughout
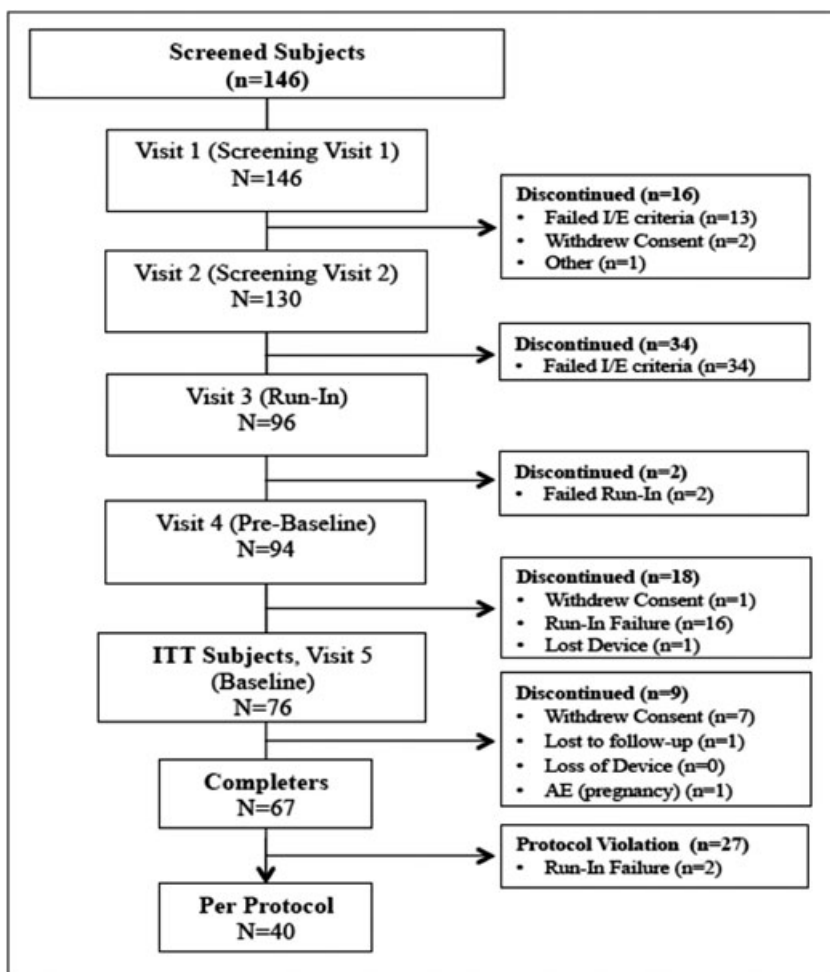
Figure 2 Subject disposition. Screening visit 1 evaluated suitability for device usage. At screening visit 2, a palatal mould was taken, and subjects could fail to be included because oral conditions were not acceptable. At visit 3, the device was provided, and subjects were instructed in its use during the trial run-in. Subjects who could not tolerate the device could be excluded. At visit 4, the device was retrieved, and sensor data confirmed continued eligibility. Subjects who did not meet sensor-verified usage criteria were excluded. At visit 5 (day 0, baseline visit), the device was reissued to subjects, and lifestyle modification video was viewed. At each study visit subsequently, download of sensor usage, medical assessment and instructional video were completed by participants. ITT, intent-to-treat.
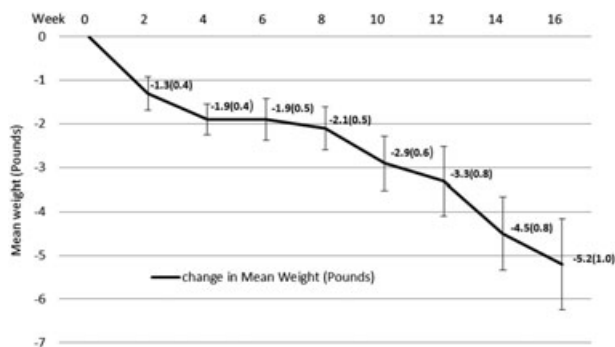
Figure 3 Trajectory of mean weight loss over the course of the study for the per protocol population.

the 16-week study duration. The usage of the device over time in PP participants and ITT participants who did not meet PP criteria is depicted in Figure 6. Greater proportional device use in the PP population was observed.

Mean weight loss by study site

Mean weight loss at each research site for the ITT and PP populations was assessed. For each site, mean weight losses at 16 weeks in the PP population were 1.4%, 3.6%, 4.8% and 1.75% among 9, 9, 11 and 11 participants, respectively. Among those in the ITT population, weight losses at each site were 1.59%,

Proportion of Participants Who Achieve >3%, >4% and >5% Weight Loss at Week 16

Figure 4 Categorical weight losses for the per protocol population. TBL, total body-weight loss.
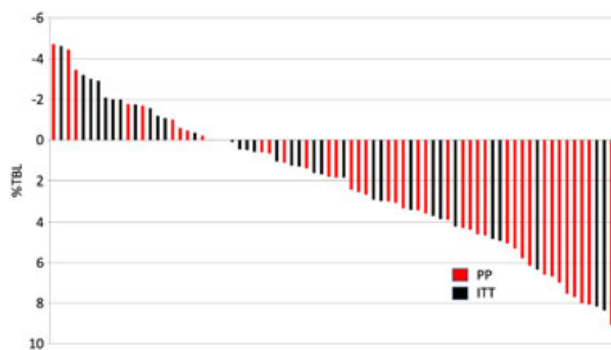
Figure 5 Individual percentage weight loss (%TBL) at week 16 for PP and ITT subjects. The individual weight losses are plotted for those who met PP criteria and those who did not (black). Participants were more likely to lose ≥3%, ≥4% or ≥5% criteria if they met PP criteria. Still, some participants who did not meet the usage criteria, still lose weight at those criteria. ITT, intent-to-treat; PP, per protocol; TBL, total body-weight loss.

2.49%, 3.41% and 0.87% among 19, 19, 18 and 20 participants, respectively. The finding of greater mean weight loss at two sites may suggest a site effect, but the numbers are small.

Safety assessment

During the study, among the 76 subjects, one serious adverse event (pregnancy) was reported, but was deemed not device related. There were 12 participants who reported 24 non-serious adverse events. Three events (one hard palate abrasion and two tongue lacerations) were device related. The hard palate abrasion event was considered non-serious and moderate in severity. The event was initiated by food becoming caught in the device. The subject experienced soreness, but no bleeding. The subject did not use the device for 11 d, but the event resolved

without medical intervention, and the subject resumed use of the device. There was no recurrence of this event, and the subject continued to use the device uneventfully through the end of the study. There were no negative sequelae from the event, and total weight loss for this subject was 4.9 %TBL at 16 weeks. Two tongue lacerations were reported by one subject. Both events were considered non-serious and mild in severity, and they also resulted from food becoming caught in the device. The subject attempted to move the food with her tongue, and her tongue sustained minor scrapes without bleeding on both occasions. Both events resolved on the same day without any intervention, and the usage record indicated that there was no interruption in device usage in either event. The subject was instructed to remove the device and wash it should food become caught and not attempt to manoeuvre the food with her tongue. There were no recurrences of this event. The subject continued to use the device regularly, averaging 11.5 uses per week after the reported events, and the subject also completed the study achieving weight loss of 3.9 %TBL at 16 weeks.

Discussion

In 2013, an expert panel formed by the National Institutes of Health addressed five critical questions (20) in obesity, one of which was, 'How much weight loss is needed to produce health benefits?' The graded evidence statements that resulted from the analyses showed the strongest support for weight loss beginning at 3% (for glycaemic measures and triglycerides) and 5% (for blood pressure, HDL and LDL cholesterol) to be considered clinically meaningful (20). Thus, it is not necessary to achieve a BMI <25 or even <30 kg m^{-2} for patients to
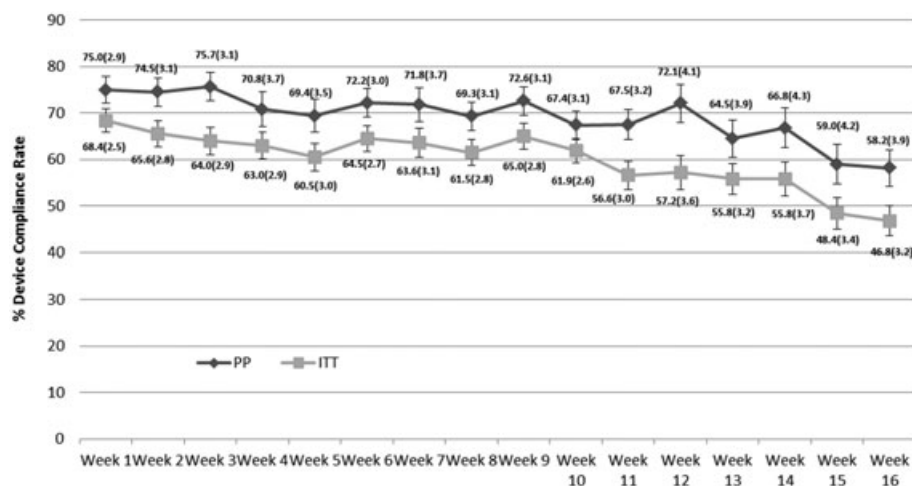
Figure 6 Mean percentage of daily device use based on daily meal episodes: per protocol (PP) and intent-to-treat (ITT). The device sensor was monitored and compared with the meal diary. The proportion of device use (%) is shown in the figure. The PP definition required sensor-verified use of the device >7 times per week for 14 of 16 weeks, overall device usage rate of at least 33% of self-reported eating episodes and study completion.

achieve clinically significant health benefits and to improve health risk (20).

Analysis of subjects in the Diabetes Prevention Program showed a 16% reduction in risk for progression to diabetes with every kilogram of weight loss (21). Another study found that achieving 3% TBL produced a 37% reduction in progression to type 2 diabetes over 4 years (22). More recently, investigators from the Look AHEAD study showed that improvement in triglycerides and systolic blood pressure begins with 2% to 5% TBL (23).

It is difficult to achieve weight loss in routine medical practice. Brief interventions produce on average 2% weight loss (24). Still, it is possible to achieve more weight loss with more intensive approaches. Comprehensive lifestyle intervention delivered face-to-face in at least 14 group or individual sessions over 6 months, with follow-up for 1 year, has been endorsed in the Obesity Guidelines as effective in producing moderate (5% to 10%) weight loss (20). This degree of contact can be costly, however. Similarly, pharmacologic treatments such as orlistat, lorcaserin, phentermine/topiramate, naltrexone/bupropion and liraglutide when added to lifestyle intervention may produce more weight loss than lifestyle intervention alone, but all add to costs and may add adverse events (24). Of course bariatric surgery produces significant and durable weight loss but is reserved for more severe and complicated obesity. (20,25,26) Recently, two new devices, intragastric balloons, have been approved and marketed in the USA. This minimally invasive approach uses endoscopic procedures to place one or more balloons into the stomach,

which distends the stomach, resulting in an early feeling of satiety when meals are consumed. However, these devices must be removed after 6 months and adverse events occurred, and complications have been reported (19,27–29). These approaches should be viewed as tools in a toolbox. There is a need for multiple approaches to help in manage this complex, chronic disease.

In this prospective single-arm study, the investigators assessed the efficacy and safety of the device in reducing weight among adults with overweight and obesity. This study followed on to two prior studies (15,16) and a randomized trial (17) submitted to the FDA, and the results of the current study confirm prior experience (16,17). Importantly, the results confirm early safety data (16,17). Given that there is a great need for safe approaches to treatment of patients who would benefit from weight loss, but whose health risk status does not justify approaches that come with some risk, such as medications or surgery, lower risk approaches to weight management are very much needed. Indeed, this minimal risk approach may be appropriate for patients with BMI ≥25 but no risk factors, to promote healthy eating behaviours as recommended by the Guidelines (20).

For a treatment to work, it must be used. In this study, the investigators sought to replicate the earlier observation (17) that the amount of device use was associated with weight loss success in defining a PP population. Our efficacy data did support that individuals who met the PP criteria had a greater chance of achieving weight loss than those who did not meet device use criteria. However, there were some patients who did not

meet PP criteria, who lost significant weight. This may have been the effect of the lifestyle intervention delivered by video that all participants viewed, or, perhaps, for some people, minimal use, or use only in situations where patients are likely to over-eat, may have an effect.

What is the significance of the weight loss observed? In the PP population, over 50% achieved reductions in total body weight (≥ 3 %TBL) in 16 weeks. This amount of weight loss has been confirmed in the AHA/ACC/TOS Obesity Guidelines to be clinically significant and associated with health risk improvement (20).

The study analysis demonstrates a gradual decrease in device use over our 16-week study; however, weight loss became more robust, starting at 8 weeks. Our findings are similar to the decline in device use seen in an earlier study by McGee and colleagues (16), which showed the highest usage during the first 4 weeks (mean 14 uses per week) and then steadily declined to seven uses per week by week 16. Importantly, in that study, subjects reported greater awareness of food choices, portion sizes and eating rate, and they were less likely to engage in habitual, emotional or opportunistic eating (16). Several subjects reported that they would likely resume intensive device use when needed (16). These data, and ours, suggest that frequent use of the device may not be necessary for all individuals. Whereas some individuals may require more frequent and/or continuous device use, others may 'learn' new eating behaviours that can be sustained without frequent use of the device. These findings are concordant with the behavioural therapies that incorporate mindfulness approaches to food ingestion (19). Mindfulness describes a diverse range of practices that emphasize focused attention on present moment experience without judgement; the use of the device helps to focus the user on the present moment process of eating. Slowing the rate of food intake and longer oral processing are ways for individuals to savour foods more and potentially eat less. Thus, the SmartByte device could be a tool to entrain mindful eating.

Several limitations of the study are notable. The chief limitation is lack of a control group. In the prior randomized study of the device submitted to the FDA (17), the control group viewed a lifestyle video and did not use a device. In that study, the mean weight loss in the control group viewing the lifestyle video was only 0.29%. Another limitation is the definition of adherence used herein. The analysis of the ITT population found six individuals who showed significant weight reduction, ranging from 4.2% TBL to 8.4% TBL, but who did not meet the PP criteria. In addition, there were variations in weight loss success by study site. Additionally, studies

longer than 16 weeks are needed to evaluate this promising device.

Despite these limitations, the findings demonstrate the safety and acceptability of the SmartByte device use. For patients who use of the device at most meals, there may be clinically significant weight loss and thus health benefits. Importantly, as discussed, initial use of the device may help individuals learn to modify their eating habits, making continuing use less necessary.

Longer duration studies are needed to further elucidate the sustainability of the weight demonstrated in this study and explore the behavioural aspects of device use on eating habits and dietary modification. In the future, the authors would like to see studies of the device incorporated in behavioural programmes targeting mindfulness and in long-term studies of continuous or intermittent device usage.

Conflict of Interest Statement

No conflict of interest was declared.

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Trial Registration

NCT02119299 (www:clinicaltrials.gov)

Disclosure statement

D. R. reports personal fees and other from Scientific Intake during the conduct of the study; and personal fees from Baro Nova, personal fees from Eisai, personal fees and other from Novo Nordisk, personal fees from OREXIGEN, personal fees from Merck, personal fees from Janssen, personal fees from Kwang Dong, personal fees from Gila Therapeutics and personal fees from Real Appeal outside the submitted work. C. G. P. reports consulting fees from Scientific Intake. W. L. is an employee of

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Supporting Information

Additional Supporting Information may be found online in the supporting information tab for this article.

Supplemental Figure 1. Adherence of participants to device use. Among 102 subjects who were randomized to device and lifestyle video, mean weight loss at 16 weeks is displayed by percentage of device use at meals. Percentage of device use is calculated by comparing sensor monitoring and meal diary with calculation of percentage of meals used by each individual. Mean Percent weight change data shown are last observation carried forward.
Table 1. Summary of Site Poolability by 5% TBL (PP) [a]
Table 2. Summary of Site Poolability by 4% TBL (PP) [a]