

Dose-Dependent Suppression of Hunger by a Specific Alginate in a Low-Viscosity Drink Formulation

Harry P.F. Peters¹, Remco J. Koppert¹, Hanny M. Boers¹, Anna Ström¹, Sergey M. Melnikov¹, Edward Haddeman¹, Ewoud A.H. Schuring¹, David J. Mela¹ and Sheila A. Wiseman¹

Addition of specific types of alginates to drinks can enhance postmeal suppression of hunger, by forming strong gastric gels in the presence of calcium. However, some recent studies have not demonstrated an effect of alginate/calcium on appetite, perhaps because the selected alginates do not produce sufficiently strong gels or because the alginates were not sufficiently hydrated when consumed. Therefore, the objective of the study was to test effects on appetite of a strongly gelling and fully hydrated alginate in an acceptable, low-viscosity drink formulation. In a balanced order crossover design, 23 volunteers consumed a meal replacement drink containing protein and calcium and either 0 (control), 0.6, or 0.8% of a specific high-guluronate alginate. Appetite (six self-report scales) was measured for 5 h postconsumption. Relevant physicochemical properties of the drinks were measured, i.e., product viscosity and strength of gel formed under simulated gastric conditions. Hunger was robustly reduced (20–30% lower area under the curve) with 0.8% alginate ($P < 0.001$, analysis of covariance), an effect consistent across all appetite scales. Most effects were also significant with 0.6% alginate, and a clear dose–response observed. Gastric gel strength was 1.8 and 3.8 N for the 0.6 and 0.8% alginate drinks, respectively, while product viscosity was acceptable ($<0.5 \text{ Pa}\cdot\text{s}$ at 10 s^{-1}). We conclude that strongly gastric-gelling alginates at relatively low concentrations in a low-viscosity drink formulation produced a robust reduction in hunger responses. This and other related studies indicate that the specific alginate source and product matrix critically impacts upon apparent efficacy.

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INTRODUCTION

Many different diets and diet programs can be effective in reducing body weight in people following the overall diet plan (1–4). However, many subjects fail to adhere to these diets and the reduction in weight is therefore not achieved or maintained (2–5). Perceived hunger has been shown to be a significant predictor of failure to lose weight in clinical trials (6). Delaying the return of hunger after consumption can potentially increase consumer satisfaction with weight control programs and reduced-energy food products, and encourage long-term compliance with a reduced-energy diet.

Satiety feelings on a meal-to-meal basis are partly determined by gastrointestinal (GI) stimuli (7–9). One proposed route toward enhancing satiety is the use of selected fibers to prolong gastric emptying or increase distension (10–12). It has previously been shown that this can be accomplished by increasing the viscosity of meals, but also by formation of gels within the stomach (13,14). However, the viscosity of drinks needs to be high to increase satiety, and this may reduce

consumer acceptance for many (e.g., fluid) types of products. Producing a palatable drink based on postconsumption gelation stimulated by gastric conditions might therefore be a preferred option (14,15).

Alginates are a large class of gelling fibers. The formation of alginate gels can be triggered by low pH and the presence of divalent cations, which also influence the strength of gels formed. However, recent literature with regard to the effects of gelling fibers, in particular alginates, on satiety and energy intake is inconsistent (16–19). These inconsistencies are most probably explained by differences in the amount and type of alginate used and the food format in which the fiber is given, the latter affecting the hydration of the incorporated fiber (15). We have previously shown (14) that a specific, strongly gelling alginate in the presence of Ca^{2+} increased satiety more than an alginate forming a weak gel. The amount of alginate, which also determines gel strength (15), also appears to determine effects on satiety, although it is unknown what minimum level of alginate is needed. Levels as low as 0.8% of a strongly gelling

¹Unilever Research & Development, Vlaardingen, The Netherlands. Correspondence: Harry P.F. Peters (harry.peters@unilever.com)

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Table 1 Nutrition composition of drinks containing no (control), 0.6%, or 0.8% alginate

	Energy (kcal)	Fat (g)	Protein (g)	Carbohydrate		
				Total ^a (g)	Of which sugars (g)	Of which fibers (g)
Control	190	6.7	10.2	24.6	16.7	5.1 ^b
0.6% Alginate	191	6.7	10.2	24.0	16.7	4.7 ^c
0.8% Alginate	194	6.7	10.2	24.3	16.7	5.2 ^d

^aTotal carbohydrates, including sugars (lactose, sucrose, fructose) and fibers. ^bIncludes 0.3 g carrageenan, 2.1 g cellulose, and 1.9 g resistant maltodextrin. ^cIncludes 2.0 g alginate and 1.9 g resistant maltodextrin. ^dIncludes 2.7 g alginate and 1.9 g resistant maltodextrin.

alginate have been shown to significantly increase satiety (14,20,21), whereas 0.4% did not (21).

Liquids would be a useful delivery vehicle for alginates as an appetite control agent, because this ensures that the fibers are consumed in a fully hydrated form. However, where calcium or other divalent cations are needed for the formation of strong gels, the presence of available Ca²⁺ together with alginates in a liquid product would make it prone to unwanted, spontaneous gelation, leading to reduced product quality and poor consumer acceptance. Therefore, most alginates have previously either been separately added to drinks immediately before consumption (14,19,21), or the Ca²⁺ source was consumed separately from the alginate (17), or the alginates were provided in a solid product format (16) or pill (18).

The aim of the present study was therefore to test the effect on satiety of two levels of a strongly gelling alginate (0.6 and 0.8%) in an acceptable (stable, low viscosity) drink formulation. This drink was designed in such a way that it only gels under gastric conditions and not in the product before consumption. We hypothesized that an alginate of sufficient gel strength in this format would dose-dependently decrease hunger responses at relatively low alginate levels.

METHODS AND PROCEDURES

Subjects

The volunteers were recruited from local area of the research site in Vlaardingen, the Netherlands. Initial recruitment started in October 2007. During recruitment the subjects received an information brochure and attended an information session in which it was explained that satiety would be measured. Selection criteria were: age 18–60 years, BMI (kg/m²) ≥21 and ≤32.0, apparent health (measured by questionnaire) and no use of medicines judged likely to influence the study results. In order to focus on potential responsiveness to physiological signals only normal and low-restraint eaters were included (22). Any subject with a tendency toward diagnosable eating disorders (anorexia nervosa or bulimia) was also excluded (23).

Due to dropout of one subject for reasons unrelated to the test products, 23 volunteers (16 women, 5 men) completed the study. Their mean age was 52.8 years (range 36–60) and mean BMI was 25.9 (range 21.7–30.3).

Study design

The study protocol was approved by the Wageningen Dutch Ethical Committee in the Netherlands. The study used a balanced treatment order, random allocation, double-blind, and three-way complete cross-over design. For 3 weeks each volunteer visited the test facility on the same weekday. During these days, subjects consumed a meal replacement shake with 0, 0.6, or 0.8% alginate for breakfast at 08:00. Subjects' self-assessments of feelings of hunger/satiety and GI complaints were

measured using electronic line scales, described below, every half hour from 08:00 until 13:00.

Test foods

Subjects consumed a breakfast consisting of prototype ready-to-drink meal replacement shake (Optima Milk Chocolate RTD, 325 ml, 190 kcal; Slim-Fast, Unilever, Englewood Cliffs, NJ) containing 0, 0.6, or 0.8% added alginate (see Table 1 for composition). These levels were chosen based on previous studies where 0.8% of a strongly gelling alginate had been shown to significantly increase satiety (14,20,21), whereas 0.4% did not (21).

To maintain an acceptable product viscosity and prevent spontaneous gelation within the product, the proteins usually contained in the meal replacer (skim milk powder and caseinate) were replaced by a whey protein source low in freely available calcium (3% wt/wt whey protein isolate; BiPro, Davisco Food International, Eden Prairie, MN). A calcium source (0.26% wt/wt Ca₃(PO₄)₂; CFT, Budenheim, Germany) was added that was insoluble at product pH of 7, but soluble at gastric pH.

The sodium alginate (Manugel DMB; FMC Biopolymers, Cork, Ireland) had a 70:30 guluronate:mannuronate ratio, and thus can be considered a "high G" alginate. To confirm that the alginate drinks produced physiologically relevant gel strength, this was tested under simulated gastric conditions (see below).

In order to keep the total fiber content of the three drinks identical, alginate was exchanged for carrageenan and cellulose as indicated in Table 1. The drinks were sterilized, filled in aluminum cans and stored ambient. They were chilled (refrigerated) 24 h before use in the trial.

Physicochemical properties of test foods

The viscosity of the drinks was measured using an TA-AR 1000 Rheometer (TA Instruments, Leatherhead, UK). The geometry used was a cone ($\phi = 40$ mm, truncation = 71 μ m, angle = 1.59°) and plate. The viscosity was recorded at 20 °C between shear rates of 0.03–1,000/s.

For the large deformation rheology, samples were prepared by dispersing glucono-delta-lactone (Sigma, St Louis, MO) in water and subsequently adding this dispersion to the alginate solution under mixing. The liquid solution was thereafter poured into cylindrical (12 mm × 12 mm) Teflon moulds before the onset of gelation. The samples were then incubated at 37 °C for 2 h to reach an approximate pH of 2.6. The gels were carefully removed from the moulds and flat plate compression tests were performed using a Texture Analyzer (Stable Micro Systems; TA.XT Plus, Godalming, UK) at 20 °C with a crosshead speed of 5 mm/s. Five repetitions were performed on each sample. The force to fracture was also measured 1 day, 1 week, and 3 months later.

The pH of the solutions was measured using a Seven Multi meter (Mettler, Toledo OH) with a combined temperature and pH electrode (Mettler inlab 413) calibrated between pH 7 and 4.

Subjective feelings of hunger, satiety, and palatability

Volunteers arrived at the test facility at 07:45 in the morning and at 08:00 received the test products. They were given a maximum of 15 min to consume the test products.

Subjects' self-assessments of feelings of hunger/satiety were measured by means of marks on 60-mm line scales using EVAS (Electronic Visual

Analogue Scale) (24) on a hand-held device (iPAQ) every half hour from 08:00 until 13:00 on each test day. The scale items were “appetite for a meal,” “appetite for a snack,” “hunger,” “how much do you want to eat?,” “satiety,” and “fullness.” These were anchored at the low end with the most negative or lowest intensity feelings (e.g., “not at all”), and with opposing terms at the high end (e.g., “very high”), as described by Flint *et al.* (25).

Immediately after consumption of the test food the overall liking, and specifically liking of the mouth feel and taste, was also recorded by the volunteers using EVAS. Liking scores were anchored at the low end with the most negative or lowest intensity feelings (“extremely unpleasant”), and with opposing terms at the high end (“extremely pleasant”).

GI disturbances

GI disturbances (nausea, heartburn, belching, stomach discomfort, abdominal bloating, GI cramps, flatulence, diarrhea, and urge to defecate) and general bodily symptoms (headache, dizziness, and fatigue) were also scored electronically every hour, on 4-point scales (0 = not, 1 = mild, 2 = moderate, and 3 = severe). The questions were phrased to refer to symptoms that the volunteers might possibly have experienced during the preceding hour.

Background diet, physical activities, and other measurements

On the day before each test day, volunteers were asked to avoid alcohol and playing sports in the evening. Each subject's evening meal and all other food and beverage consumption up to 22:00 before the first test day had to be recorded, and that same evening meal and other consumption had to be repeated on the evening before all other test days. Eating and drinking after 22:00 on the evening before each test day was not allowed except for noncaloric drinks. This was done to minimize variation in glycogen stores in the test days (25). The time and amount of noncaloric drink consumption before the first test day was recorded and the same noncaloric drink (time and amount) had to be consumed during the evening before the other test days.

Subjects were asked not to change their style of living (including mode of transportation) during the study, so that energy expenditure would also be roughly the same during the several study days. Sleeping time, mode of transportation, menstrual cycle, and incidental lifestyle changes were also recorded. Body weight was assessed during each visit before the test meal was given.

On each test day volunteers were asked to arrive fasted at the Uni-lever Test Center at 07:45. During the test days only coffee/tea, water, and noncaloric soft drinks (max. 150 ml) were allowed each hour, and only immediately after filling in the satiety and other questionnaires. The amounts consumed on the first day were recorded and repeated on the other test days, to minimize within-subject variation. Added sugar or milk was not allowed, only a noncaloric sweetener.

After receiving their test drinks at 08:00 volunteers were instructed not to eat until the test phase (5 h) was completed. Subjects were then allowed to leave the test center if they wished, and instructed to return to the unit by 12:30. After returning to the test facility, subjects were asked if they had consumed anything that morning. All subjects indicated their compliance with the instructions.

Statistical analyses

The data were analyzed using analysis of covariance with baseline measurement as covariate. This model takes into account the possible baseline influences using the correlation of the baseline with the score on each subsequent time point. Sources of variation taken into account were subject (as a random factor), treatment, period and period \times treatment interaction. The difference of each treatment vs. control was estimated using the Dunnett difference test (two-sided). The analysis was performed per time point and also for area under the curve (AUC), using SAS (version 9.3, PROC MIXED; SAS Institute, Cary, NC).

Results are presented as least squares means with s.e., unless otherwise specified. Feelings of hunger/satiety and liking were measured by means of a mark on electronic 60-mm line scales, and scores were converted to

100 mm for analysis. The 64 mm appetite EVAS scores were transformed and expressed on a 100-mm basis, and as incremental cumulative AUC, using the values at $t = 0$ min (just before consumption of the drink) as a covariate. The AUC was calculated using the trapezoid rule.

Earlier studies from our research centre using closely similar protocols produced a within-subject variance of about 85 mm·min for AUC. Based on this variance, a confidence limit of 0.05 and a power of 0.8, 18 subjects were required for this experiment. Six other subjects were included to allow for dropouts. To exclude period \times treatment effects, and to control for possible period effects, the experimental design was completely balanced and subjects randomly allocated using a Williams design, which balances the treatments and treatment orders over the periods and subjects.

GI disturbances and general bodily symptoms were analyzed using frequency of occurrence per time point and a standard ANOVA with the personal scores corrected for each subject's overall mean score.

RESULTS

Physicochemical properties of test foods

Product viscosities measured at a shear rate relevant to oral conditions (~ 10 /s) were 0.08, 0.13, and 0.36 Pa·s for the drinks containing 0, 0.6%, or 0.8% alginate, respectively (viscosities for the full range of shear rates 0.03–1,000/s can be found in Ström *et al.* (15)). For comparison, viscosity at this shear rate is about 0.001 Pa·s for water, ~ 0.003 –0.03 Pa·s for different milk products, about 0.5–5 Pa·s for different (drink) yoghurts and about 2–10 Pa·s for honey.

Forces to fracture under simulated gastric conditions (i.e., gelation at low pH) were 0.39, 1.77, and 3.83 N for the drinks containing 0, 0.6%, or 0.8% alginate, respectively. This did not change significantly over time when measured 1 day, 1 week, and 3 months after manufacture (data not shown). Visual inspection of the drinks also showed that the drinks were stable (e.g., no phase separation occurred). The pH of all drinks was ~ 6.9 .

Palatability and satiety ratings and GI symptoms

Palatability scores of the drinks did not differ significantly between treatments. For the control, 0.6%, and 0.8% alginate drink, respectively, mean overall palatability scores were 64, 66, and 62 mm (s.e. = 4.4, $P = 0.65$); mean mouth feel scores were 66, 63, and 58 mm (s.e. = 4.1, $P = 0.15$).

Results for “hunger” and “fullness” are shown in **Figures 1 and 2** (other appetite curves showed similar changes, data not shown). “Hunger” and “fullness” were reduced robustly (20 and 34% lower AUC, respectively) with 0.8% alginate (both $P < 0.001$), an effect consistent across all appetite scales. Effects were also significant with 0.6% alginate for most scales (except for “hunger,” $P = 0.07$, and “desire for a snack,” $P = 0.33$). A clear dose–response effect was observed for all line scales: for example the “hunger” AUC (mean \pm s.e.) was 53 (± 3.7), 47 (± 3.7), and 42 (± 3.7) mm·min ($P < 0.001$) for the control, 0.6%, and 0.8% alginate drink, respectively. The “fullness” AUC was 36 (± 3.8), 44 (± 3.9), and 48 (± 3.8) mm·min ($P < 0.001$) for the control, 0.6%, and 0.8% alginate drink, respectively. The biggest difference vs. the control is apparent soon after consumption. However, both for fullness and hunger, the difference as compared to the control remained more or less constant over the recording time for the 0.8% alginate intervention, whereas

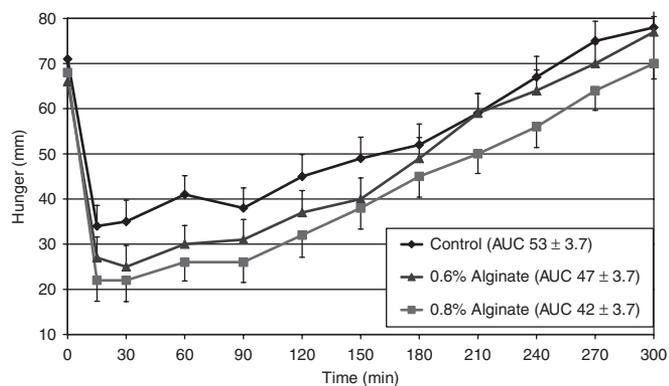


Figure 1 Hunger ratings (least square (LS) means, $n = 23$) after consumption of control drink or drink with addition of 0.6% or 0.8% alginate. Area under the curve of 0.8% alginate significantly different from control ($P < 0.001$). AUC (LS mean \pm s.e.) is shown as an insert in the legend.

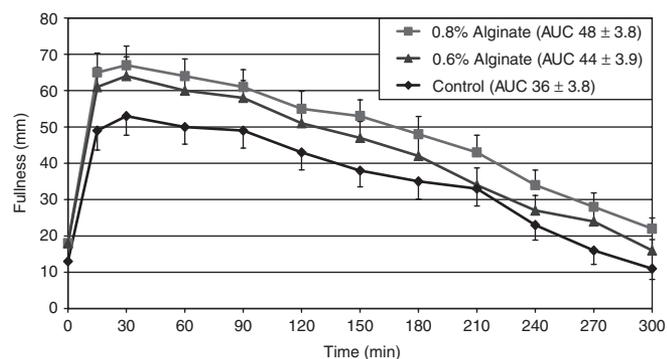


Figure 2 Fullness ratings (least square (LS) means, $n = 23$) after consumption of control drink or drink with addition of 0.6% or 0.8% alginate. Area under the curve of 0.6% alginate and 0.8% alginate significantly different from control ($P < 0.05$ and $P < 0.0001$, respectively). AUC (LS mean \pm s.e.) is shown as an insert in the legend.

the difference vs. the control for the 0.6% alginate appears to diminish this same period.

GI symptoms and general bodily symptoms were rarely reported, and none differed significantly between treatments and control. Headache was the most prevalent symptom recorded, but was already apparent before the intervention started (four times rated “mild” in the control group) and diminished during the day. The second most prevalent symptom was bloating. Three out of twenty-three subjects reported “mild” bloating 60 min after consumption of the 0.8% alginate (as opposed to 1 in the control group and none in the 0.6% alginate group) and this disappeared during the day. All other symptoms were reported by two or fewer subjects.

DISCUSSION

This study clearly indicates the potential for a specific high-guluronate alginate at relatively low levels (0.6–0.8%) to significantly reduce hunger and increase fullness responses to a drink specifically designed to generate a sufficiently strong gel in the stomach, whereas remaining acceptable as a product for frequent consumption.

The purpose of our study was threefold. First, we wanted to confirm our hypothesis that an alginate producing a sufficiently strong gel in the stomach would increase satiety. Second, building on our previous research, we wanted to clarify the likely minimum level of such a strongly gelling alginate required for satiety. Lastly, we wanted to test efficacy of alginate within a drink formulation that gelled in the stomach, but not in the product, in order to have a product vehicle that was both palatable (low viscosity) and ensured the alginate was sufficiently hydrated.

Alginates are linear copolymers composed of two monomeric units; β -1-4-linked D-mannuronic acid (M) and α -1-4-linked guluronic acid (G). Alginates are extracted from the cell walls of various brown seaweeds and the ratio between M and G depends on the type of seaweed. The formation of alginate gels can be triggered by low pH, but in the presence of divalent ions such as Ca^{2+} , alginates form stronger gels. The strength of this gel depends on the content of G, with those alginates rich in G (“high G”) forming stronger gels. Both the concentration and chemical structure (e.g., G/M ratio) of the specific alginate source material affect the strength of gel formed, under acid conditions, or in presence of calcium (26,27). Accordingly, the effects of specific alginates on gastric and satiety responses may also be determined by these same factors (14,21). The format of an alginate-containing product may further affect the *in vivo* physicochemical properties, as the kinetics and outcome of hydration (and solubility) of alginates in tablets or a bar may differ from a solution, where (pre-)hydration and solubility are optimal (27–29).

By combining insights from *in vitro* (25) and *in vivo* experiments (14,20) we were able to show that a minimum gel strength is required for inducing greater satiety. A weak high-M alginate did not produce satiety, whereas strong gelling alginates (high G, either Protonal (20) or Manugel DMB (14,21)) did. Furthermore, Marciani *et al.* (13) used agar beads differing in strength and showed that a minimal bead strength (0.6 N) was needed to resist antral grinding forces and to produce satiety. The present study suggests that a minimum of 1.8 N, but preferably somewhat higher (e.g., around 2 N) gel strength under gastric conditions is a likely prerequisite for a meaningful satiety effect.

These differences in properties between the different alginates affecting their gel strength might also explain the variable results of other studies. Pelkman *et al.* (17) tested the effect of ingestion of 2.8 g of an alginate (Manugel LBA and GHB)-pectin blend in a drink twice per day for 7 days, but found no meaningful change in subjective measures of appetite (though effects on food intake in a subgroup). The gel strength was however not reported. Paxman *et al.* (19) showed that 1.5 g of an alginate that forms a very strong gel under acid conditions (Protonal, gel strength 30 N) reduced reported daily energy intake when consumed for 7 days, although satiety data were not reported. Mattes (16) found no effect of a combination of an alginate (2.0% wt/wt) and guar gum (7.0% wt/wt) on satiety when given twice per day for 5 days. However, the amount of alginate in the 55 g bar used was relatively low (1.1 g) and the

type of alginate was not specified. Therefore, its gelling potential cannot be verified. In addition, the bar format might have decreased the availability of the fibers for gelation due to uncertain hydration rates or solubility of the fibers. Very recently, Odunsi *et al.* (18) showed that 10 days treatment with a commercial product containing alginate among its ingredients had no effects on appetite, and on this basis they questioned the utility of alginates in general for weight management. Again, however, the type of alginate (as well as quantity) was not specified and thus its gelling potential could not be verified (30).

Another research question considered here was the level of alginate needed for a satiety effect. In previous experiments using a liquid meal replacer of similar composition, we also had observed that 1% (14) and 0.8% (21) Manugel DMB alginate increased satiety, whereas 0.4% did not (21). We now show that levels as low as 0.6% Manugel DMB in a 325-ml meal replacer increases satiety. However, the effects were not significant in all scales and clearly less effective than 0.8%. This suggests that levels <0.6% of a strongly gelling alginate may not give consistently robust benefits for appetite control in this product format.

This study used a shelf-stable product containing the alginate together with significant amounts of calcium. This contrasts with previous studies where alginate has been either added to a calcium-containing drink prior consumption (14,19–21), or pregelation of the product was avoided by the use of a two-component system (17) where the alginate and calcium source were only mixed together at the time of consumption. When alginates have been provided in a bar (16) or pill (18) format, appetite was not affected (though in both cases the form of alginate was not described). To prevent in-product gelation in this study we used a protein source very low in calcium together with an insoluble calcium source.

The effects observed here cannot be attributed to the differences in product viscosity. Data from Marciani *et al.* (13,31) suggest that an 80–100-fold higher viscosity may be needed for a significant effect on satiety or fullness. The effects can also not be attributed to differences in palatability, as these were not substantially different between drinks.

In many appetite studies, satiety ratings are measured in combination with a measure of food intake. We deliberately chose not to measure food intake, as the intervention was performed within the context of a meal replacer. Meal replacer programs by themselves induce a reduced-energy intake, and there is already extensive clinical evidence for their efficacy (1,3). However, feelings of hunger during the reduced-energy intake are a concern expressed by consumers, and may adversely affect their ability to tolerate and maintain compliance to weight loss programs such as those using meal replacers. Our main intention was to enhance the ability of products to reduce perceived hunger, thereby enhancing the consumer experience (and hopefully sustained compliance) in such a meal replacer weight loss plan. Delaying the return of hunger after consumption should increase consumer satisfaction with and perhaps also compliance to these diets. As such, our main interest was to test the extent to which addition of specific alginates to a

meal replacer could additionally suppress the return of hunger after consumption (and at least for 4 h it did). Measuring food intake would have interfered with the measurement of this delay in hunger over the 5 h timeframe.

There is little prior research that allows for quantitative extrapolation from these differences in self-reported satiety to potential implications, for example diet adherence. A 10% difference in scores (which was exceeded in all cases by the 0.8% alginate) in this type of design has been described as “a reasonable and realistic difference” (25). Differences in “hunger” scores in this range have also been associated with significantly increased reported “ease” of following a diet programme (32), although this does not prove a causal link between these outcomes. Others such as Womble *et al.* (6) and Drapeau *et al.* (33) have reported significant correlations between measures of hunger or fullness and improved outcomes for weight loss. However, this does not allow any statement of the value of discrete changes in scores, nor whether there is a threshold effect for these relationships.

In conclusion, we have shown that strongly gelling alginates at a concentration of at least 0.6% had a robust effect on enhancing satiety in a liquid formulation. This is consistent with other research using these types of strongly gelling alginates (14,19–21). However, other studies using different (or unspecified) types of alginates do not report consistent effects on appetite. We therefore urge caution in extrapolating results from any specific product to “alginates” in general, especially without explicit characterization and specification of the tested material. Similar caution also applies to studies of other fiber types. Detailed specifications of the study materials are clearly needed to replicate and compare this and other studies using alginates and other fibers, and to better understand the underlying reason for potential efficacy (or ineffectiveness) of fiber-containing pills or products.

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DISCLOSURE

The authors declared no conflict of interest.

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