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Investigating acute satiation and meal termination effects of a commercial lipid emulsion: A breakfast meal study

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HIGHLIGHTS

- We investigate whether the commercial lipid emulsion Fabuless™ elicits short-term satiation.
- Cross-over intervention of 4 lipid preloads, tested for short-term effects.
- Within-meal energy intake, meal termination time and appetite scores were measured.
- No evidence of Fabuless™ promoting acute satiation in lean men.

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ABSTRACT

Background: Early clinical studies showed the commercial lipid emulsion Fabuless™ to decrease energy intake (EI) and prevent weight regain, but later studies have failed to confirm this finding. Where appetite suppression has been observed it is commonly attributed to the ileal brake, where emulsified fats pass undigested to the distal small intestine and promote later satiety, but satiety profiles suggest possible transient effects within 15 min. The aim of this study was to determine whether this emulsion promotes short-term satiation and meal termination.
Methods: In a randomised cross-over intervention 18 lean men were given 4 lipid preloads immediately prior to a breakfast meal, during which *ad libitum* food consumption, time to meal termination and VAS-rated appetite scores were measured. Preloads were given as lipid emulsion and lipid control, both alone as a 'shot' and combined with a dairy yoghurt: (i) lipid emulsion alone (LE, Fabuless™ 4.2g lipid, 0.2 MJ), (ii) lipid control alone (LC, 4 .2g lipid, 0.2 MJ), (iii) LE + yoghurt (1.2 MJ), (iv) LC + yoghurt (1.2 MJ).
Results: Whilst both yoghurt preloads suppressed EI at breakfast relative to the 'shots', as expected, neither lipid emulsion suppressed EI or triggered more rapid meal termination when compared to energy matched lipid controls ($P > 0.05$). There was also no difference in VAS-assessed appetite scores between emulsion and control, for either preload.
Conclusions: When consumed with a meal there was no evidence in lean men that this commercial lipid emulsion promotes satiation or suppresses short-term food intake.

1. Introduction

The global prevalence of obesity has raised great interest in functional foods targeted to promote satiety and suppression of food intake. Although when matched for energy content lipids are generally considered the least satiating of the macronutrients, studies have shown that various emulsions of lipid and water may enhance these poor satiety effects [1–4], and may even be useful for weight management [4]. These findings are by no means universal however and several studies including from our laboratory have failed to observe suppression of appetite and food intake [5–11]. Lipid emulsions certainly appear vulnerable to loss of function when structure is altered. Processing, temperature and even some dispersion techniques may disrupt the efficacy of the emulsion [7,9], as well as adverse interactions with other fats and salts which may breakdown the integrity of the structure [7].

Fabuless™ is a well-known commercial emulsion, containing fractionated palm and oat oils dispersed in water, which has had mixed success with recent clinical studies [5,6,8–10] failing to confirm early findings of Burns and colleagues of suppressed food intake [1–3]. It had been hypothesised to alter intake through activation of the ileal brake. Delivery of nutrients usually absorbed at more proximal sites in the small intestine into the distal ileum initiates a feedback loop of

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slowed gastric emptying, slowed gut motility and enhanced secretion of peptides such as GLP-1 and PYY, that in turn may put a 'brake' on eating. Certainly direct infusion of lipids into the distal ileum has been shown to subdue appetite and eating behaviour [12–21] but whether this can be mimicked by orally delivered lipid emulsions has not been well demonstrated. Fabuless has a lipid particle coat which has been proposed to protect against absorption in the proximal duodenum [22]. It is thought that the hydrophilic galactolipids from the oat fraction delay digestion of the emulsion and delivers undigested triglyceride into the distal ileum. One study reported that Fabuless can slow gastrointestinal transit speed thereby increasing transit time by 45 min [23], an effect not to our knowledge as yet substantiated. Certainly, however, there is evidence that lipid in water emulsions can slow gastric emptying, with factors such as acid stability and particle size important since they effect delivery of energy to the duodenum [24].

It is notable that in some studies Fabuless significantly modulated the reporting of some, albeit not all, aspects of appetite-related feelings soon after it was consumed [1,2] and far earlier than could be induced by nutrient sensing within the ileum. A previous study conducted by our laboratory which showed that a dairy yoghurt supplemented with the Fabuless emulsion altered subjective ratings of appetite, although not food intake, recorded satiety effects as early as 15 min after the lipid was consumed [6]. In light of our previous findings and those of the earlier researchers, we were interested to determine whether Fabuless could influence within-meal satiation, shorten the time to meal termination and in turn suppress food intake during the meal. To do this we gave the Fabuless emulsion and matched lipid control with a breakfast meal in 2 formats, (i) alone as a 'shot', with 185 mL water (0.2 MJ), and (ii) stirred into a dairy yoghurt (1.2 MJ).

2. Participants and methods

2.1. Participants

Participants were recruited by poster, newspaper and electronic advertisement within the wider Auckland area. Eighteen lean (BMI 18-25 kg/m^2), healthy male participants aged between 18 and 55 years were enrolled into the study. Body weight, height and blood pressure were measured during a screening visit to the Human Nutrition Unit (HNU) appetite research centre. Participants also completed the three factor eating questionnaire (TFEQ) to determine restraint associated with eating behaviours [25], confirmed that they were habitual breakfast consumers, and that the foods presented during the intervention were acceptable choices. Exclusion criteria included self-reported history of overweight and obesity or eating disorders, current energy restricted diet, current or recent smoker, or any significant disease. None of the participants were taking medications known to affect appetite or weight regulation. Ethical approval for the study was obtained from the Northern Region X, Health and Disabilities Ethics Committee, Auckland, New Zealand and written consent was obtained from each of the participants. The international trial registration number was ACTRN12609000852257.

2.2. Study design

This was a 4 treatment, randomised, cross-over study. Participants attended the HNU on 4 occasions, each separated by a minimum washout of 2 days during which they returned home and were free to resume their usual diet and exercise patterns. Participants were asked to abstain from alcohol and strenuous physical activity for 24 h prior to each of the study days, to fast from 2000 h the previous evening, and to avoid morning exercise on the day of the study. On the day prior to each treatment energy intake (EI) was recorded and physical activity level assessed as time spent on mild–moderate and vigorous–strenuous activity, hours standing and hours sitting, watching TV/computer tasks. Each 3 h study period began at 9 am and finished at 12 noon. The study protocol is shown in Fig. 1. On each of the study days, lipid preload treatments were randomly allocated to each participant and served immediately prior to an *ad libitum* breakfast meal. The treatments comprised either a lipid emulsion (LE, Fabuless) or a matched non-emulsified lipid control (LC). They were administered in 2 ways, (i) alone as a 'shot', with a glass of water, or (ii) stirred by hand into a dairy yoghurt. *Ad lib* EI, which was the primary outcome for this trial, was measured at the breakfast meal and appetite sensations were assessed for the following 2 h using visual analogue scales (VAS).

2.3. Daily protocol

Upon arrival at 0900 h participants were given 150 mL of water to drink and instruction on the morning's events. Participants were escorted to individual sensory booths where they completed baseline VAS rating subjective feelings of hunger, fullness, satisfaction and prospective food consumption (thoughts of food, TOF), following the methods of Blundell and colleagues [26]. At 0925 h (t − 5 min) the lipid preload was served which was consumed in full within 5 min, after which preload palatability and VAS appetite ratings were completed. At 0930 (t0 min) the breakfast meal was served and participants instructed to 'eat until comfortably full'. A period of 30 min was given for the meal, where external distractions were minimised with no access to phones or laptop/tablet technologies, and no interaction with other participants. When participants had completed their meal they were requested to raise a sign which stated "I am full", which was recorded as the time of meal termination. They remained in the breakfast booth until the 30 min had been completed, when palatability ratings and VAS appetite ratings were again recorded (t30 min). Once the *ad lib* breakfast had been completed, the participants were given a second 150 mL glass of water or a decaffeinated, black tea or coffee which they consumed in full. No more food or liquids were allowed throughout the morning, and participants remained at the HNU where they were allowed to undertake sedentary activities but were not allowed to sleep. VAS appetite ratings were recorded at half hourly intervals from 1000 h throughout the morning until the end of the study at 12 noon.

2.4. Lipid preloads

The Fabuless emulsion was purchased from a retail outlet as individually packaged serves. The emulsion and pair-matched lipid control (matched for energy and macronutrient content) was served either alone with water or hand stirred into a 1 MJ semi-liquid dairy yoghurt immediately prior to presentation to the participants. The 4 preloads were (i) 15 g lipid emulsion, LE (Fabuless, containing 4.2 g lipid, 0.2 MJ) + 185 mL water (ii) 15 g lipid control, LC (non-emulsified, containing 4.2 g lipid, 0.2 MJ) + 85 mL water, (iii) 15 g lipid emulsion + yoghurt, LE + Y (1.2 MJ), (iv) 15 g lipid control + yoghurt, LC + Y (1.2 MJ). All treatments were matched for weight, with a total weight of 200 g (see Table 1). The fatty acid (f.a.) composition of the emulsified (Fabuless: 42% C16:0; 40% C18:1; 10% C18:2; 8% other f.a.s) and control (palm olein: 40% C16:0; 43% C18:1; 12% C18:2; 5% other f.a.s) lipids were matched as closely as possible. The energy and macronutrient composition of the 4 lipid preloads was calculated using the dietary programme FoodWorks™ (Professional Edition, Version 5, 1998–2007; Xyris Software, Australia).

2.5. Visual analogue scales (VAS)

Subjective feelings of hunger, fullness, satisfaction and TOF were recorded on paper by placing a vertical line across 100 mm VAS scales. The questions asked were "How hungry do you feel?", "How full do you feel?", "How satisfied do you feel?" and "How much do you think you can eat now?" [26]. The scales were anchored at either end by statements; "I am not hungry at all/I am not full at all/I am completely

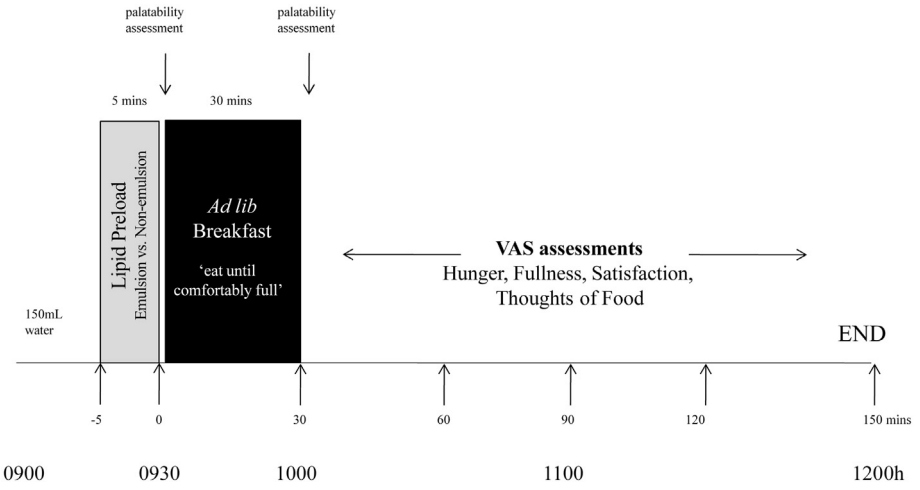

Fig. 1. Daily protocol.

empty/nothing at all" on the left and "I am as hungry I have ever been/I am totally full/I cannot eat another bite/a large amount" on the right. As a distraction from the main outcome VAS rating how thirsty, energetic and relaxed the participants felt were included. Nausea was also rated. VAS were completed prior to the lipid preload (t − 5 min), prior to the *ad lib* breakfast (t0 min), immediately following the breakfast (t30 min), and at 30 min intervals over the following 2 h (t60, 90, 120, 150 min). Immediately after the preload lipid and also following the *ad lib* breakfast participants rated pleasantness, visual appeal, smell, taste, aftertaste and overall palatability on separate 100-mm VAS. The questions asked were "How pleasant was the meal?", "How did the meal look/smell/taste?", "How much aftertaste was there?" and "How appealing was the meal?" Each question was anchored on the left hand side with the statements not at all pleasant/bad/none/bad.

2.6. Ad libitum breakfast meal

The breakfast meal consisted of toast bread, margarine-like spread, jam and marmalade, plus cereal and milk. When participants had finished eating they raised an 'I am full' sign. The meal termination signal for each individual was unable to be seen by other participants and observed only by the research staff. The items presented at the *ad lib* breakfast are shown in Table 2. Discrete items such as toast bread were served in small bite size pieces (4 per slice) to minimise possible confounding effects that presentation of fixed, large portion sizes may have on EI. Toast was prepared within the HNU kitchen and presented to the participant whilst warm. Marmalade, jam, margarine spread, breakfast cereal and milk were all self-served by the participants from their respective packaging. All items were presented in moderate excess with the intent that participants would not consume the entirety of any single item, and were able to be consumed in any order. Each item was weighed before and after the meal to the nearest 0.5 g (Sartorius AG, Gottingen, Germany). Energy and macronutrient content of the breakfast foods was also calculated using the dietary programme FoodWorks™.

2.7. Statistical analysis

Participant information at baseline is presented as mean and standard deviation (SD). Efficacy outcomes for EI, time to meal termination and VAS appetite ratings are presented as mean and standard error of the mean (SEM). EI was the primary outcome, with sample size estimates based upon a 10% difference between treatments at the breakfast meal detected as significant. EI and time to meal termination were analysed using one-way ANOVA, with Tukey's post hoc pairwise comparison test if significance was observed. Repeated measures VAS were analysed using linear mixed model ANOVA including baseline as a covariate, and Tukey's post hoc multiple comparison test if significance in main treatment or interaction was observed. Statistical significance was based on 95% limits ($P < 0.05$). Analyses were conducted using SAS: PROC MIXED, SAS version 9.2, SAS Institute Inc., Cary, NC, USA, 243 2002–2008).

3. Results

3.1. Participants

Eighteen male participants completed this 4 treatment study. No participants withdrew or were excluded for non-compliance. The participants had a mean age of 27 (14, sd) years and were lean (BMI 22.5 kg/m^2, 1.7 sd), healthy, and unrestrained relative to eating behaviours (mean 4.9, 4.6 sd, units). On the day prior to intervention there was no significant difference between visits for reported EI ($P > 0.05$) or reported level of physical activity ($P > 0.05$).

3.2. Energy intake

Ad lib EI at the breakfast meal on each of the 4 study days is shown in Fig. 2a. Mean EI was 3859 kJ (279 sem) and 4272 kJ (382 sem) following LE and LC 'shot' treatments and 3541 kJ (340 sem) and 3265 kJ (284

Table 1
Energy and macronutrient composition of the 4 lipid preloads.

Breakfast	Emulsion lipid/water (g)	Control lipid/water (g)	Yoghurt (g)	Water to drink (g)	Total weight (g)	Energy (kJ)	ED (kJ/g)	Fat (g)	Fat (%en)	CHO (g)	CHO (%en)	Prot (g)	Prot (%en)
LE*	15	0	0	185	200	155	0.8	4.2	100	0	0	0	0
LC*	0	15	0	185	200	156	0.8	4.2	100	0	0	0	0
LE + yoghurt$	15	0	185	0	200	1200	6.0	15.9	50	29	38	7	10
LC + yoghurt$	0	15	185	0	200	1200	6.0	15.9	50	29	38	7	10

Lipid emulsion (LE; 4.2 g lipid + 10.8 g water; Fabuless) and matched non-emulsified lipid control (LC; 4.2 g lipid + 10.8 g water) were co-presented alone as a 'shot' with a 185 mL glass of water* or stirred into a semi-liquid yoghurt$, ED, energy density; CHO, carbohydrate; Prot, protein; %en, percentage of energy.

Table 2
Energy and macronutrient composition of foods offered at the *ad lib* breakfast meal.

Breakfast menu items	Total weight (g)	Energy (kJ)	ED (kJ/g)	Fat (g)	Fat (%en)	CHO (g)	CHO (en%)	Protein (g)	Protein (%en)
Bread, light rye, sliced, 10 rounds served as 1/4 slices	559	5953	10.7	11	7	274	78	45	13
Marmalade with peel, orange, 1 jar	270	3051	11.3	3	3	176	98	3	1
Jam, raspberry, 1 jar	270	3456	12.8	0	0	203	100	0	0
Margarine, spread, 1 tub	250	6050	24.2	163	99	0	0	0	0
Cornflakes™,1 box	500	7650	15.3	0	0	405	90	30	7
Milk, reduced fat, 1 L	1000	2450	2.5	30	45	50	34	30	21

ED, energy density; %en, percentage of energy; CHO, carbohydrate.

sem) following LE + Y and LC + Y yoghurt treatments respectively. There was a significant difference in EI between the 4 lipid preloads ($P = 0.0017$), as a result of the lower intake following the higher energy 1.2 MJ yoghurt preloads compared to the 0.2 MJ 'shots', when analysed independent of lipid structure (pair-wise comparison, yoghurt: 3404 kJ vs 'shot': 4065 kJ; $P = 0.002$). There was 66% compensation at the breakfast for the additional 1 MJ energy content of the yoghurt treatments. There was however no evidence that emulsification of the lipid in either test vehicle ('shot' or yoghurt) provided significant physiological suppression of EI during the meal (emulsion vs control: delta 'shot', −413 kJ; delta yoghurt, +276 kJ, both, ns). When macronutrient intake was compared between diets, there was no significant difference in fat, protein or carbohydrate intake during the free choice breakfast meal ($P > 0.05$).

3.3. Time to meal termination

Fig. 2b shows the time to meal termination following each of the lipid preloads. The average time taken for the meal, independent of treatment allocation, was 16.9 (0.5, SEM; range 8–28) min. No individual required longer than the allocated 30 min on any treatment. There was no significant difference between preloads in the time to completion of the breakfast meal when participants were instructed to 'eat until comfortably full' (LE: 16.9, 1.0 min; LC: 17.3, 1.0 min; LE + Y: 17.2, 1.1 min; LC + Y: 16.1, 1.1, min; $P > 0.05$). Notably, the observed increase in EI at breakfast following the low energy 0.2 MJ 'shots' (LE, LC) compared with the 1.2 MJ yoghurt preloads (LE + Y, LC + Y), reported above, were not a consequence of a longer meal time.

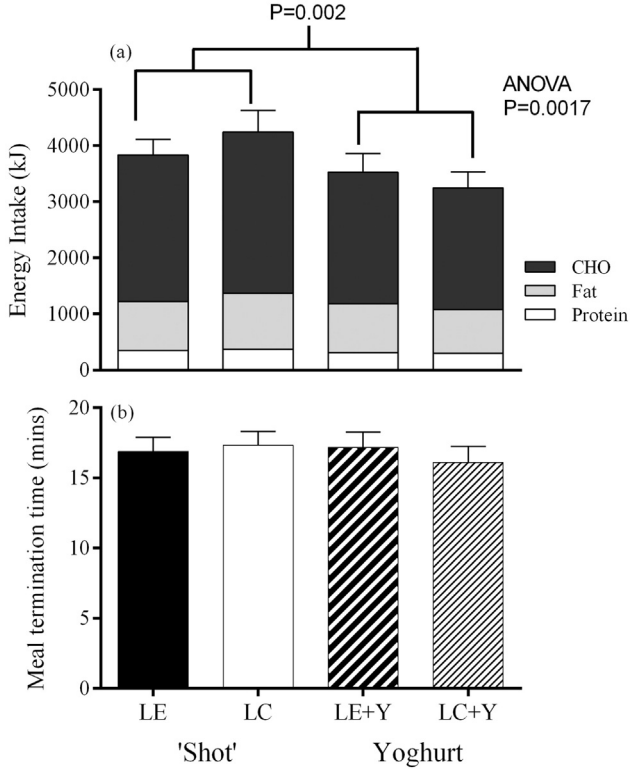

Fig. 2. Mean (SEM) (a) *ad libitum* energy (EI) and macronutrient intake and (b) time to termination of the breakfast meal. Differences in EI observed between the 4 preloads ($P = 0.0017$) was a consequence of the food format ('shot' vs yoghurt, $P = 0.002$ *post hoc*) and not the emulsion ($P > 0.05$ *post hoc*). LE, lipid emulsion; LC, lipid control; LE + Y, lipid emulsion + yoghurt; LC + Y, lipid control + yoghurt.

3.4. Visual analogue scales (VAS)

3.4.1. Palatability

As expected, all VAS-assessed ratings of pleasantness, visual appeal, smell, taste and palatability were significantly greater when emulsion and control lipids were stirred into the dairy yoghurt (LE + Y, LC + Y) than when given as a 'shot' with water alone (LE, LC; $P < 0.05$, Fig. 3a). When comparing between pair-matched emulsion and control preloads ('shot': LE vs LC; yoghurt: LE + Y vs LC + Y;) there was little difference in ratings ($P > 0.05$), other than for aftertaste which rated significantly worse (ie. higher) for LE than for LC when 'shots' were administered ($P < 0.05$). Participants reported an 'oaty' aftertaste. Nausea did not significantly change following any of the 4 preloads (data not shown, $P > 0.05$). There was no evidence that palatability of the fixed item *ad lib* breakfast changed through the 4 visits of the intervention despite the repeated measure design (Fig. 3b).

3.4.2. Hunger, fullness, satisfaction, TOF

Fig. 4 shows VAS-rated hunger and fullness throughout the study morning. Satisfaction and TOF were also assessed (data not shown). There was no difference in baseline fasted (t − 5 min) ratings for any VAS-assessed measure ($P > 0.05$), confirming similar levels of appetitive response prior to administration of the lipid preloads. None of the 4 treatments had a significant effect on any VAS ratings immediately after consumption (t0 min). Perhaps surprisingly the 2 yoghurt treatments (1.2 MJ: LE + Y, LC + Y) did not immediately suppress hunger or promote fullness to any greater extent than the lipid 'shots' + water (0.2 MJ: LE, LC) despite their greater energy content. The fact that they were weight matched and also the short 5 min time period may explain this. Consumption of the breakfast meal had a significant effect on all VAS-assessed outcomes (all, $P < 0.05$), and confirmed that participants did follow the instructions to 'eat until comfortably full'. After breakfast there was a predictable, slow enhancement of hunger and TOF over the 60, 90, 120 and 150 min time points and, conversely, a decline in fullness and satisfaction over the same period.

4. Discussion

In this study we found no significant acute effects of the commercial lipid emulsion Fabuless when given as a preload either in 'shot' format or when incorporated by hand into a dairy yoghurt. This was despite evidence from our previous study [6] and that of others [1,2] that this lipid

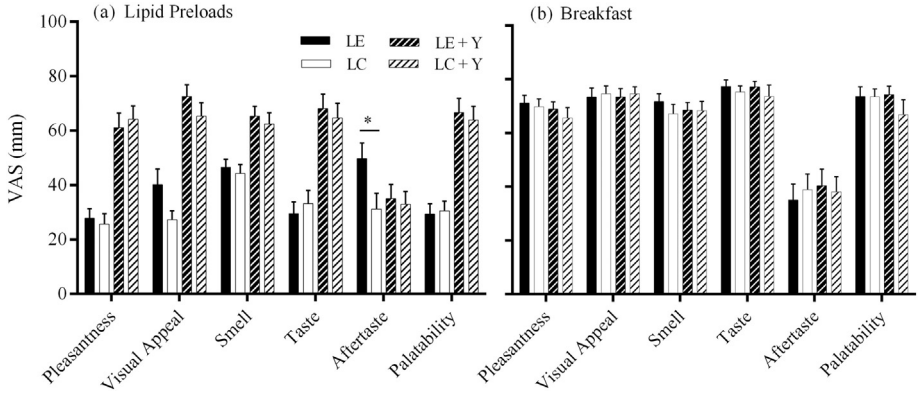

Fig. 3. Mean (SEM) visual analogue scales (VAS) showing scores for pleasantness, visual appeal, smell, taste, after-taste and palatability of (a) the 4 lipid preloads, (b) the *ad libitum* breakfast meal.

emulsion can induce rapid postprandial changes in some markers of VAS-assessed appetite. We hypothesised that the emulsion may alter satiation, acting through early cognitive and/or physiological processes within the satiety cascade [26], which may have led to early meal termination and/or decreased food intake. Satiation is heavily influenced by palatability, which was reasonably matched between the emulsions and control lipids in our trial, although it is not possible to determine whether other orosensory cues which we were unable to measure may have played a part in the absence of response. Clearly this would have been more likely had either of the emulsions led to a significant change in endpoint measures. Poor design is unlikely to account for lack of effect since the trial adhered to preset international guidelines [26]. This small sample trial was adequately powered to detect a clinically significant difference at the breakfast meal of >400 kJ (~10% of total meal intake in our current trial) as shown in similar prior studies from our own laboratory [27], amongst many others. Smaller changes in EI were not identified as statistically or clinically significant in this study.

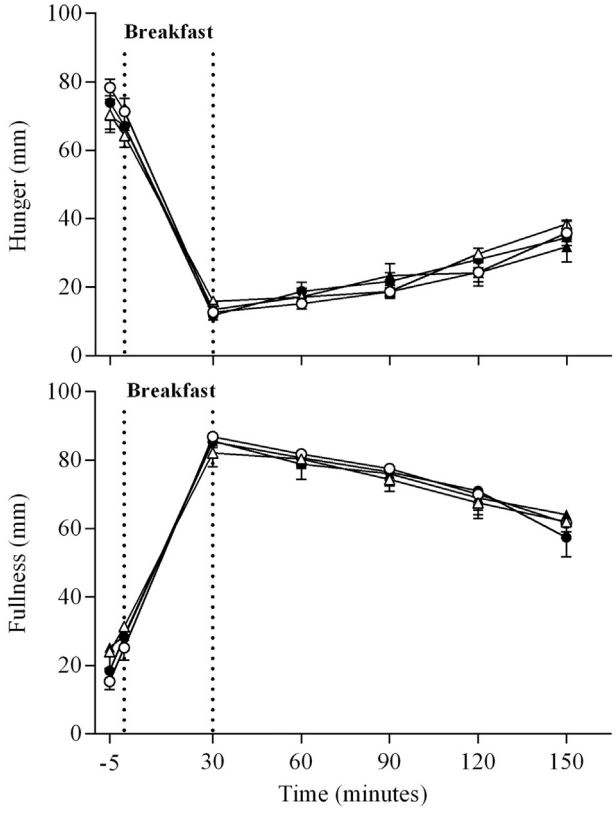

Fig. 4. Mean (SEM) visual analogue scales (VAS) showing scores for hunger and fullness. The lipid preload was consumed in full at t = −5 min, and the breakfast meal was served immediately afterwards. A maximum of 30 min was allowed for the breakfast meal. LE, lipid emulsion (●); LC, lipid control (○); LE + Y, lipid emulsion + yoghurt (▲); LC + Y, lipid control + yoghurt (Δ).

We assessed two delivery methods in this trial, since this commercial emulsion has previously been shown to have variable efficacy depending on the format by which it is delivered [6,7]. Factors such as acid stability and particle size have long been known to be important in controlling rate of gastric emptying and delivery of nutrients to the proximal small intestine [24]. The majority of trials which have observed significant changes in hunger, satiety and/or eating behaviour have provided the emulsion within a minimally processed semi-liquid dairy yoghurt format [1–4,11,28]. Yoghurt is a product of the acidic fermentation of milk lactose to lactic acid and, whilst pH can clearly alter significantly during commercial processing, represents a highly specific medium within which to incorporate lipid emulsions.

The mechanism by which Fabuless has previously been hypothesised to suppress appetite is essentially untested. Whether orally delivered 'protected' lipids are able to reach the distal small intestine and induce the ileal brake is not known, and there is yet to be convincing data in support of this effect other than by carefully controlled tube feeding studies [16–19,21] where sensory effects, oral processing and proximal GI effects are of course bypassed as nutrients are delivered directly into the GI tract.

In order to assess satiation in this trial we used 2 end points to investigate the effect of the emulsions on eating behaviour. Firstly the energy consumed at the meal, and secondly the time to meal termination. As expected we showed that, independent of treatment, there was a positive correlation between time taken to complete the breakfast meal and total energy consumed at that meal. Also that energy content of the preload was a significant driver of total energy consumed at the outcome meal, with the additional 1 MJ consumed within both yoghurt preloads compensated for in large part by a reduction in breakfast EI. This was despite VAS-assessed feelings of hunger and fullness changing very little following both the low and high energy preloads when measured immediately after the products were consumed. There was energy compensation of 66% at the breakfast for the additional (+1 MJ) energy content of the 2 yoghurt preloads, higher than often reported in many preload satiety studies when the outcome meal is served 3–4 h later [27]. Again, this was as expected in a trial assessing satiation (within-meal termination) rather than satiety (intake at a subsequent meal).

In conclusion, despite administering this commercial lipid in a dairy yoghurt format previously shown to alter satiety within 15 min of consumption [6], there was no evidence in our current trial of lean men that

this emulsion promotes satiation through early termination of a concurrent meal, or the suppression of food intake at that meal.

Disclosures

SDP holds the Fonterra Chair of Human Nutrition at the University of Auckland.

There are no conflicts of interest declared by the other authors.

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