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Effects of a Viscous-Fibre Supplemented Evening Meal and the Following Un-Supplemented Breakfast on Post-Prandial Satiety Responses in Healthy Women

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Abstract: The post-prandial satiety response and “second-meal effect” of a viscous fibre supplement PolyGlycopleX[®] (PGX[®]) was evaluated in a single-blind, randomised controlled crossover study of 14 healthy adult women. The two hour post-prandial satiety response, expressed as the area under the curve (AUC) of perceived hunger/fullness score versus post-prandial time, of a standardised evening meal with concurrent intake of either PGX softgel or rice flour softgel (control) was determined. On the following morning, after an overnight fast, the four hour satiety response to a standardised breakfast with no softgel supplementation was assessed. A significantly higher satiety response (AUC) to the standard dinner for the PGX-supplemented dinner compared with the control dinner ($p = 0.001$) was found. No significant difference ($p = 0.09$) was observed in the satiety response (AUC) of the breakfast regardless of which supplemented-dinner had been consumed prior, however the p value indicated a trend towards a higher response to the breakfast following the PGX-supplemented dinner. The fullness scores of the breakfast following the PGX-supplemented dinner at 15, 30, 90, 120, 150, 180, 210 and 240 minutes post-prandial were significantly higher than those for the breakfast following the control dinner ($p = <0.001, 0.007, 0.009, 0.009, 0.049, 0.03, 0.003$ and <0.001 respectively). PGX supplementation at dinner increased the satiety effects of both the dinner itself and the subsequent un-supplemented breakfast; a “second meal effect” indicating the potential for this fibre supplement to induce extended satiety.

Keywords: fibre, satiety, meal, appetite, hunger

Abbreviations: PGX; PolyGlycopleX; AUC; area under the curve; LMS; labelled magnitude scale; MCT; medium chain triglycerides; VAS; visual analogue scale

Highlights

- We examine the satiety effect of viscous fibre on initial and subsequent meals.
- We examined the fullness score at post prandial time points.
- The “second-meal effect” was investigated.

1. Introduction

The consumption of meals high in dietary fibre, especially soluble viscous fibres such as alginate and guar has been demonstrated to induce long lasting perceptions of post-prandial fullness known as satiety [1, 2, 3] . This post-prandial effect of viscous fibres may be one reason why increased dietary fibre intake in the diet can increase satiety levels over a longer term and reduce hunger and energy intake, effects that may ultimately reduce risk of obesity [4].

Intake of food containing viscous dietary fibres can result in gel formation in the stomach and increased viscosity of the upper gastrointestinal tract contents [5, 6]. These physicochemical changes may delay gastric emptying and slow the rate of absorption of nutrients from the small intestine resulting in lowered but sustained postprandial blood glucose levels [7, 8, 9, 10, 11] lowering the glycaemic index (GI) of available carbohydrate-containing foods to which the fibre has been added [12, 13] . The release of gut hormones such as cholecystokinin (CCK) in the duodenum and peptide YY (PYY) and glucagon-like-peptide (GLP-1) in the ileum/colon are involved in suppressing food intake [14]. In contrast, the release of ghrelin in the stomach stimulates appetite and food intake [15]. These changes to the gastrointestinal processing of food, as a consequence of the inclusion of viscous fibres in the diet, can promote satiety through modulating the release of these gastrointestinal hormones [7, 16, 17, 18, 19].

Increased intake of dietary fibre through increased consumption of wholegrains, vegetables and fruit is recommended in the Australian Dietary Guidelines [20]. Fibre intake by American adults is approximately half the recommended level [21]. Australian adults eat 24g of dietary fibre, 6 g less than the 30g recommended level [22]. The use of fibre supplements may be an effective way to boost fibre consumption to the recommended levels [23]. Combinations of viscous fibres have been used in the development of fibre supplements with elevated viscosity, specifically aimed at providing high satiety effects when taken in conjunction with a meal. One such supplement is PolyGlycopleX[®] (PGX[®]) which is a commercially manufactured soluble viscous fibre complex of konjac glucomannan, sodium alginate and xanthan gum with a higher viscosity than currently known single dietary fibre sources and with gel-forming properties [16,10].

Solah *et al.* [10, 24] reported that PGX significantly improved post-prandial fullness and satiety when compared to an inulin control, with 7.5 g supplementation of the breakfast bread meal having the greatest effects. Brand-Miller *et al.* [25] demonstrated that PGX supplementation also reduces post-prandial glycaemia, when a 7.5g supplementation to a white bread meal containing 50g available carbohydrate reduced the incremental area under the 120 minute post-prandial blood glucose curve by 50% compared to that of the un-supplemented bread meal.

The satiety response to a meal is commonly determined for a post-prandial period of several hours, during which time no food and beverages (except limited amounts of water) are consumed. However the post-prandial physiological response to one meal (e.g. dinner) may delay the absorption rate of nutrients, resulting in changes in hormonal signals in the gut and effects on colonic fermentation [26, 27, 28, 29] and thus affect the satiety response to the following meal (e.g. breakfast the following morning). This phenomenon is known as the “second-meal effect”. Brand-Miller *et al.* [25] found that softgels containing PGX gave a

second-meal effect on post-prandial glycaemia as a dose related response by improving glucose tolerance at breakfast time when consumed with the previous evening meal. Chen *et al.* [30] found a second-meal effect where postprandial glucose was reduced in people with type 2 diabetes as a result of soy yoghurt consumption with the previous meal. In a study by Isaksson *et al.* [31] a rye breakfast resulted in higher satiety ratings in the morning and afternoon, compared with the isocaloric control breakfast of wheat bread, and reduced *ad libitum* energy intake at lunch on the subsequent day. Despite the lack of overall effect on appetite sensation, Ibrügger *et al.* [32] observed an effect of wholegrain rye consumption on *ad libitum* energy intake at a third meal. Reichert *et al.* [33] found fullness scores increased over a 10 week period with PGX softgel supplementation of meals, indicating a carry-over effect, but found no effect on fullness in the three hours after PGX softgel supplementation with a meal or a second meal effect. There is limited published research investigating second meal effects on postprandial satiety. Further research is important since fibre supplements demonstrating a second-meal effect on satiety, compared to those providing only short term effects, may through inducing a longer lasting reduction in appetite be more effective in reducing overall dietary energy intake.

The objective of this study was to determine the effect of:

- a) a standardised dinner with concurrent intake of either a PGX softgel supplement or a rice flour softgel (control) supplement by healthy women on the post-prandial satiety response.
- b) the PGX softgel supplement or control supplemented dinner on the post-prandial satiety response an un-supplemented standardised breakfast the following morning.

2. Materials and Methods

2.1. Participants

Healthy adult female participants were recruited from the population of students at Curtin University (Bentley, WA, Australia) through approved flyers and emails. All participants attended a short interview session prior to the study to explain the procedures. Volunteers were assessed for eligibility to ensure recruitment of regular breakfast eaters. Exclusion criteria were those with food allergies, smoking, pregnancy, more than three alcoholic drinks per day, type 2 diabetes, cardiovascular diseases or being on a weight loss diet. A written informed consent was signed by each participant prior to commencing the study and participants had the option to withdraw at any point in time.

Curtin University approved this research and ethical approval was obtained for this study from the Human Research Ethics Committee of Curtin University (HR03/2014). Seventeen participants were recruited for the study and 14 completed the entire study. Two participants withdrew due to personal reasons and one due to time constraints.

2.2 Test Meals and Supplements

Dinner consisted of a pre-packed frozen meal (Lean Cuisine, Simplot Australia, Mentone, Victoria, Australia) which was supplied to the participants who prepared the meal according to manufacturer's instructions at home. These dinners provided a standardised energy intake (1,520kJ) and food volume (380g) for each participant. Bottled water (600 mL) was also provided for consumption as part of the dinner (see Table 1 for detailed nutritional composition). As part of the total dinner meal, six softgel supplements were provided. Each softgel contained either 0.75g of the PGX[®] (Inovobiologic Inc., Calgary, Canada) or 0.75g raw rice flour (supplied by Inovobiologic Inc., Calgary, Canada). An evening snack was also provided to participants in the form of a 32g muesli bar (Uncle Tobys[®], Nestle Australia, Rutherglen, Victoria, Australia). The total dinner meal design met the needs of the participant

Table 1. Nutrient composition of food and supplement items

	Individual dinner items				Total PGX [®]	Individual breakfast items				Total
	Standardised dinner	PGX [®] (six)	Rice flour (control) (six)	Drinking water	supplemented dinner meal	Special K Original [®]	Cornflakes	Full cream milk	Drinking water	breakfast meal
Mass of serve (g)	380	4.5	4.5	600	990	22.5	22.5	175	200	420
Protein (g/serve)	17.9	0	0	0	17.9	4.4	1.7	5.6	0	117
Fat (g/serve)	7.6	8.3	8.8	0	24.7	0.2	0.6	6.3	0	7.1
Available Carbohydrates (g/serve)	53.2	0	0	0	53.2	15	18.1	8.3	0	41.4
Total dietary fibre (g/serve)	NA	3.8	4.0*	0	3.8	2.6	1.2	0	0	3.8
Energy (kJ)	1520	204	203	0	1724	350	347	508	0	1205

*resistant starch

as a typical/ healthy “dinner” containing cooked rice, water, vegetables, cooked marinated chicken and differed only in curry flavour. A standard breakfast of 1261 kJ was previously determined to provide a meal that would induce immediate post-meal satiety of at least “Moderately full” using the LMS in a previously fasted panellists [24]. The standard breakfast (total weight 220g) (see Table 1 for composition) used in this research was similar to the previous breakfast [24] and contained cereal flakes (45g) (Cornflakes and Special K[®], Kellogg’s, Ferntree Gulley, Vic, Australia), whole cow’s milk (175g) and water (200 mL).

2.3. Study Design and Procedure

This was a blind, randomised controlled crossover study, designed to assess the participants’ self-perception of satiety of (a) the standardised dinner supplemented with either the PGX or the rice flour control softgels and (b) the standardised (un-supplemented) breakfast the morning following the supplemented dinner.

Participants were screened for individual precision and trained using the method described by Solah et.al.[24]. The participants who met the individual precision criteria were allocated a random three digit code and randomised into two groups. Group 1 commenced with the meal combination of the rice flour (control) supplemented dinner meal and the un-supplemented breakfast the following day. This meal combination was repeated four times with a washout period between each session of three days, before participants assessed four sessions of the PGX supplemented dinner meal and un-supplemented breakfast combination. Group 2 commenced with four sessions of the PGX supplemented dinner meal and un-supplemented breakfast meal combination and then moved onto the combination of the rice flour (control) supplemented dinner meal and the un-supplemented breakfast. Fourteen participants completed the study, eight from group 1 and six from group 2. There were no significant differences between groups 1 and 2 (independent sample t-test, $P > 0.05$) in the mean baseline

age, weight or BMI between those participants completing the study. The characteristics (mean \pm standard error of mean) of the 14 female participants completing the study were: Age, 23.3 ± 2.7 y; Body weight, 59.1 ± 15 kg and BMI, 23.4 ± 5.4 kg/m².

On the afternoon of each dinner session, participants were provided with all dinner meal items, the evening snack and bottled water (Table 1). Participants were requested to consume the dinner meal at 7pm. Within their own homes, participants were requested to rate their self-perception of hunger/fullness on a satiety line scale (see section 2.4 for details) before commencing the meal (time 0), then to consume the entire dinner meal, including supplement softgels and water within 15 minutes. They were then asked to record their hunger/fullness at 15, 30, 45, 60, 90, 120, 150, 180 minutes after commencement of the dinner on the satiety line scale.

After the final (180 minutes) post-prandial hunger/fullness rating, participants were permitted to drink additional water *ad libitum* but consume no food other than the evening snack provided. Participants were requested to consume this snack two hours after the final (180 minutes) dinner meal hunger/fullness rating. Following consumption of the snack, participants were asked to fast overnight for a minimum of 10 hours before attending the Sensory Evaluation Facility in the School of Public Health, Curtin University between 8 and 9am the following morning for baseline anthropometric measurements (first visit only) and at 8am for evaluation of the breakfast meal. Anthropometric measurements were made in light clothing and without shoes. A portable stadiometer was used to measure height to the nearest 0.1 cm and weight was measured to the nearest 0.1 kg using a pre-calibrated scale.

After anthropometric measurements, participants rated their fasting self-perception of hunger/fullness on the satiety line scale (time 0) (see section 2.4 for details) then consumed the standardised breakfast meal (Table 1) within 12 minutes. Participants then re-rated their hunger/fullness on a satiety line scale at 15, 30, 45, 60, 90, 120, 150, 180, 210 and 240

minutes after meal consumption. During this time participants were not permitted to perform any vigorous physical activities or consume any food or drinks (except *ad libitum* water). Upon completion of the study, participants were given a \$20 gift voucher for their participation.

2.4 Satiety Rating Tool

The 19.0 cm labelled magnitude scale (LMS) (Figure 1) was used as the satiety measurement tool. The LMS was considered to provide better discrimination of satiety sensations compared to a VAS for the trained panel and panellists were reminded that hunger involves “desire to eat or anticipation” or “craving and fullness involves feelings of being replete physical stretch” [24]. In addition the LMS may be more suitable for participants from different cultural backgrounds [34], such as the student population at Curtin University from which the participants were recruited. The LMS was labelled with word anchors to describe the feeling of hunger and fullness, with “Greatest Imaginable Hunger” at the far left, “Neither Hungry nor Full” at the centre-point and “Greatest Imaginable Fullness” at the far right. Participants were asked to mark a line anywhere on the line scale that matched their perception of hunger/fullness. The line scale marks made by the participants were enumerated by measuring their distance (to nearest 0.1cm) from the centre-point (considered as a rating of 0.0 cm); therefore a maximum positive score of 9.5cm equated to “Greatest Imaginable Fullness” and a maximum negative score of -9.5cm to “Greatest Imaginable Hunger”.

Food : *Breakfast Cereal*
Record : *Prior to eating breakfast*
Record No : *0*
Time :

Instructions: Please mark your feelings of hunger or fullness right now by placing a vertical dash on the line below

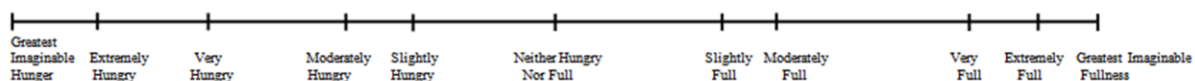


Figure 1. Labelled magnitude scale used to assess satiety

2.5 Statistics

Results are reported as means \pm standard deviation (SD) or 95% confidence intervals. Within each dinner or breakfast component of the two supplemented dinner/ un-supplemented breakfast combinations, the satiety rating at each individual post-prandial time point was determined and the AUC of the post-prandial satiety response of hunger/fullness rating (cm) vs time (minutes) was calculated using the trapezoidal rule.

The treatment effect at each test occasion was assessed by using mixed linear regression with robust error estimations. The between group difference at each time point was adjusted by the Bonferroni method for multiple comparisons. The results from regressions were presented as coefficient along with 95% confidence interval and *p* values. The overall treatment effect of PGX was assessed by comparing AUC (combined data of eight tests) using a multilevel mixed effect model. All analyses were performed using Stata statistical software (MP 13.1, StataCorp, College Station, TX, USA) and values of $p < 0.05$ were considered as significant.

3. Results and Discussion

3.1. Composition of meals

The test dinner and breakfast meals (Table 1) were identical in their composition and mass except for the PGX softgel or the rice flour softgel control. The soluble dietary fibre, PGX and the rice flour control softgels were close to isocaloric (Table 1). The PGX softgel contained medium chain triglycerides (MCT) and the rice flour control contained cotton seed oil, both of which contributed to the energy intake. There may be a satiety effect of MCT [35] and as the rice flour is uncooked, it consists primarily of resistant starch [9]. The test breakfasts following each of the supplemented dinners were identical in their composition and mass.

3.2 Post-prandial satiety effects of supplemented dinners

The post-prandial satiety effects of the PGX supplemented dinner meal were different than that of the rice flour (control). Figure 2 presents the satiety response of the two supplemented dinner meals. There was no difference ($p=1.00$) in the hunger/fullness score before the consumption (time 0 minutes) of the two supplemented dinners. The individual scores, before dinner, were in the negative range corresponding to the anchors on the LMS, confirming that the participants perceived that they were hungry before consumption of the dinner.

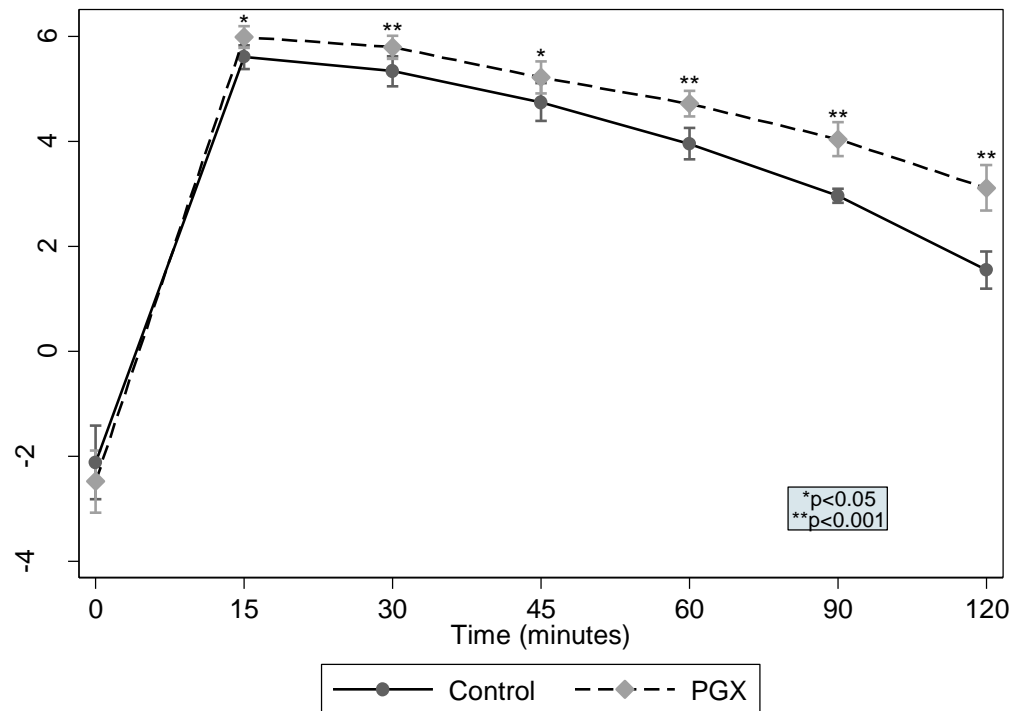


Figure 2. Hunger/fullness scores from labelled magnitude scale (LMS) over time after dinner by group.

Data are presented as marginal means \pm 95% confidence intervals derived from a mixed effect model with robust standard error estimations and Bonferroni adjustment for multiple comparisons, based on 14 participants. A significant difference between groups at each time point is signified as: * $p < 0.05$; ** $p < 0.001$. Control: rice flour supplemented dinner; PGX supplemented dinner.

A significantly higher satiety score ($p = 0.01$) was found at 15 minutes for the PGX-supplemented dinner compared to the control supplemented dinner. These 15 minute scores corresponded to “Moderately Full” to “Very Full” on the LMS. The PGX-supplemented dinner continued to give a significantly higher score than the control-supplemented dinner for the remaining post prandial time points (15 mins, $p = 0.01$; 30 mins, $p < 0.001$; 45 mins, $p = 0.02$; 60 minutes, $p < 0.001$; 90 min, $p < 0.001$; 120 mins $p < 0.001$).

The AUC of the postprandial satiety response to the PGX-supplemented dinner (mean \pm SD, 507 ± 243 cm x min) was greater (mean difference=90, 95% CI of difference [36, 144], $p<0.001$) than that of the control supplemented dinner (417 ± 201 cm x min).

The finding of the present study that PGX-supplementation increased the satiety response of a meal is in agreement with previous reports on this viscous dietary fibre supplement, where 5 g of PGX with meals increased the feelings of satiety during afternoon and evening [9]. Reichert *et al.* [33], using a visual analogue scale (VAS) measured subjective appetite at baseline, day 4, week 6 and week 14 and reported that fullness scores increased over a 10 week period. However they did not find a significant result for fullness in the three hours after softgel supplementation with meals but only measured three time post-prandial points (at 5 minutes before, 30 minutes after and 2.5 hours after breakfast, lunch and dinner) [33]. In contrast the results of the present study found a significant 2 hour post-prandial effect on satiety of PGX when supplemented in a softgel form with dinner.

3.3 Postprandial satiety effects of un-supplemented breakfast following supplemented dinners

Differences in the satiety response to the standard un-supplemented breakfast were observed, depending on whether the PGX supplemented dinner or the rice flour (control)-supplemented dinner was consumed on the evening before. The satiety response to the standard breakfast as consumed on the morning after each of the supplemented dinner meals is presented in Figure 3.

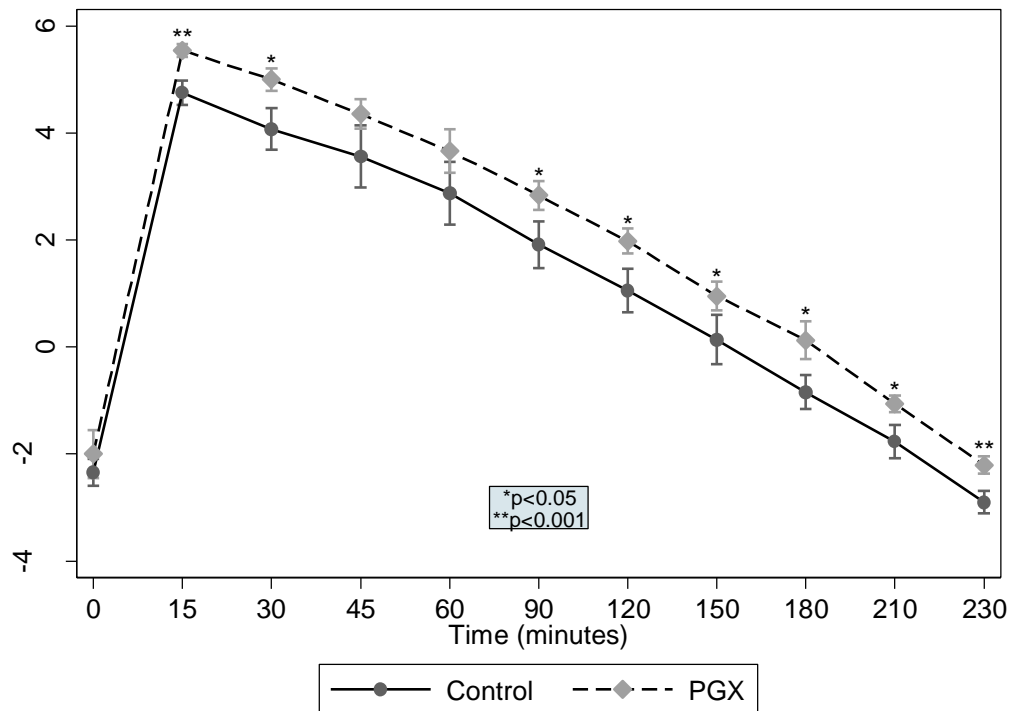


Figure 3. Hunger/fullness scores labelled magnitude scale (LMS) over time after breakfast by group.

Data are presented as marginal means \pm 95% confidence intervals derived from a mixed effect model with robust standard error estimations and Bonferroni adjustment for multiple comparisons, based on 14 participants. A significant difference between groups at each time point is signified as: * $p < 0.05$; ** $p < 0.001$. Control: standardised (un-supplemented) breakfast on morning after rice flour supplemented dinner; PGX: standardised (un-supplemented) breakfast on morning after PolyGlycopleX[®]-supplemented dinner.

There was no significant difference in hunger/fullness score before the consumption (time: 0 minutes) of the standardised breakfast following each of the two supplemented dinners. The mean scores at 0 minutes were in the same range to those before the dinner meals. The expected satiety difference in time 0 (fasting score prior breakfast) as a result of different supplemented dinners did not occur. A possible reason for this is 8am time as student participants reported 8am was too early to eat and this may explain why they were only

slightly hungry. During training participants also reported difficulty in determining the difference between slightly hungry, “planning to eat” and moderately hungry, “needing food” whereas slightly full, “starting to feel full” and moderately full. “feeling full” were easier to discriminate [24]. While most satiety studies adjust for baseline, this data was used as presented by participants and not adjusted for baseline because of the expectation of previous meal effect. At 15 and 30 minutes post-prandial the mean hunger/fullness scores were significantly higher for breakfast following of the PGX-supplemented dinner than that following the control-supplemented dinner (15 min, $p < 0.001$; 30 min, $p = 0.007$ respectively). The scores at these time points corresponded to between the LMS scale anchors of “Moderately Full” and “Very Full”. At 90 minutes, the breakfast following the PGX-supplemented dinner gave a mean score in the vicinity of the LMS anchor “Slightly Full”, which was significant higher ($p = 0.009$) than that for the breakfast following the control-supplemented dinner. Breakfast following the PGX-supplemented dinner also gave higher hunger/fullness scores than that following the control-supplemented dinner at 120 minutes ($p = 0.009$), 150 minutes ($p = 0.049$), 180 minutes ($p = 0.03$), 210 minutes ($p = 0.003$) and 240 minutes ($p < 0.001$).

The AUCs of the postprandial satiety response to the standardised breakfast following each type of supplemented dinner were not significantly different (breakfast following PGX-supplemented dinner, mean \pm SD, 404 ± 419 cm x min; breakfast following control-supplemented dinner, mean \pm SD, 205 ± 494 cm x min; mean difference = 198, 95% CI of difference [-29, 426], $p = 0.09$). However the p value suggests a trend towards a higher AUC for the breakfast following the PGX-supplemented dinner.

Results from the present study suggest that there is a second meal effect of PGX[®] consumption on appetite, based on the significantly higher fullness scores at most postprandial time points after breakfast following the PGX-supplemented dinner. Brand-

Miller *et al.* [25] previously reported a second meal effect on postprandial glycaemia from PGX consumption, when PGX consumed as softgels with the previous evening meal improved glucose tolerance at breakfast time. The mechanism involved in the PGX second meal effect needs further investigation. Isaksson *et al.* [31] suggested it could be fibre fermentation or structure that contributes to increased satiety. In an *in vitro* model, Reimer *et al.* [36] found that PGX was fermented by colonic microbiota. Ramnani *et al.* [37] reported that polysaccharides such as agar and alginate increased total SCFA production, indicating that they are fermented. Given its soluble fibre composition, it is likely that PGX is also highly fermentable. Chen *et al.* [30] reported that soya protein resulted in a second meal effect on postprandial glycaemia and suggested that this may be an effect of increased viscosity. Such viscosity effects might also explain the second meal effect of PGX observed in the present study. Isaksson *et al.* [38] found the satiating effect of high fibre rye porridge breakfast did not last to the afternoon. It was suggested that dietary fibre provides nutrients in the lower part of the small intestine which may lead to satiety signals as well as slow passage time [38]. Brand Miller *et al.* [25] reported PGX softgels (capsule form) did not significantly reduce glycaemia relative to placebo in the two hours after consumption but found a “second meal” effect, which indicates slower digestion of PGX. The combination of fermentation, increased total SCFA production and slower passage through the gastrointestinal tract may explain the “second meal” effect. The previously reported ability of PGX to increase postprandial satiety and reduce postprandial glycaemia [25] combined with the present finding of a second-meal effect on satiety, suggests a potential role for this fibre supplement in reducing energy intake and therefore, possibly weight control.

The limitation of the present study was the low number of participants that reduced the ability of the study to detect a significant difference in the AUC of the breakfasts following the two supplemented dinners. While there may be an advantage if the a participant can recall the

actual physical feeling of “moderately full” or “very full” from previous eating occasions a limitation could be that by training participants, they may lose individual sensitivity and record feelings of fullness in a memorised way that does not relate to real satiety. Since the present study involved a cohort of healthy female participants, further studies are now required in other types of participants including men and those overweight or obese, to ascertain if the second-meal effect observed in healthy women in the present study can be translated to the wider population.

4. Conclusion

This study evaluated the post-prandial satiety response to a dinner supplemented with PGX, a soluble viscous fibre supplement in a softgel form and the second-meal effect of this supplemented dinner as the satiety response to an un-supplemented breakfast the following morning. Supplementation with the PGX increased the satiety response of the dinner meal. In addition an increased fullness score at most post prandial time points after consumption of the standardised breakfast following the PGX- supplemented dinner were observed, indicating a second-meal effect on satiety of PGX-softgel supplementation.

PGX, consumed at dinner, increased feelings of fullness at breakfast time, a finding suggesting the potential for PGX softgels to be effective at providing extended satiety effects which could lead to reduced overall dietary energy intake.

However post-prandial satiety studies of the second-meal effect of PGX-supplementation in a larger, at risk cohort such as those overweight and obese that include also includes outcome measures of short-term food intake and appetite hormone levels are required to substantiate our findings. In addition longer term studies of the effect of PGX softgel supplementation on energy intake and body weight are also required.

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Competing Interests: SW receives consulting fees from InovoBiologic Inc. and RJG is the owner of the Factors Group that retains an interest in PGX. PGX is a trademark of InovoBiologic, Inc. All other Trade Marks are the property of their respective owners.

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Highlights

- We examine the satiety effect of viscous fibre on initial and subsequent meals.
- We examined the fullness score at post prandial time points.
- The “second-meal effect” was investigated.

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